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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2738; Airspace Docket No. 24–AAL–99]

RIN 2120–AA66

Amendment of Alaskan Very High Frequency Omnidirectional Range Federal Airways V–444 and V–504 in Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Alaskan Very High Frequency Omnidirectional Range (VOR) Federal Airways V–444 and V–504. The FAA is taking this action due to the pending decommissioning of the Evansville, AK, Nondirectional Radio Beacon (NDB).

DATES: Effective date 0901 UTC, October 2, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published an NPRM for Docket No. FAA–2024–2738 in the **Federal Register** (89 FR 106375; December 30, 2024), proposing to amend Alaskan VOR Federal Airways V–444 and V–504 in Alaska. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Two comments were received with one being in favor of the action and the other being outside the scope of this airspace action.

Incorporation by Reference

Alaskan VOR Federal Airways are published in paragraph 6010 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These amendments will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending to 14 CFR part 71 by modifying Alaskan VOR Federal Airways V–444 and V–504 in Alaska. The FAA is taking these actions due to the pending decommissioning of the Evansville, AK, NDB.

V–444: Prior to this rule, V–444 in Alaska extended between the Barrow, AK, VOR/DME and the intersection of the Northway, AK, VOR/Tactical Air Navigation (VORTAC) 120° (M), 138° (T), and the Gulkana, AK, VOR/DME 062° (M), 079° (T) radials. As amended, V–444 extends between the Bettles, AK, VOR/DME and the intersection of the Northway, AK, VORTAC 120° (M), 138° (T), and the Gulkana, AK, VOR/DME 062° (M), 079° (T) radials.

V–504: Prior to this rule, V–504 extended between the Nenana, AK, VORTAC and the Deadhorse, AK, VOR/DME. As amended, V–504 extends between the Neana VORTAC and the Bettles, AK, VOR/DME.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of amending Alaskan VOR Federal Airways V–444 and V–504 in Alaska qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) paragraph 5–6.5.a of FAA's NEPA implementation policy and procedures which categorically

excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5k, which categorically excludes from further environmental impact review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with the FAA's NEPA implementation policy and procedures regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p.389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6010(b) Alaskan VOR Federal Airways.

* * * * *

V–444 [Amended]

From Bettles, AK; Fairbanks, AK; Big Delta, AK; Northway, AK; intersection of the Northway 138° and Gulkana 079° radials.

* * * * *

V–504 [Amended]

From Nenana, AK; to Bettles, AK.

* * * * *

Issued in Washington, DC, on July 11, 2025.

Brian Eric Konie,

Manager (A), Rules and Regulations Group.

[FR Doc. 2025–13296 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2025–1714; Airspace Docket No. 25–ASO–8]

RIN 2120–AA66

Renaming of Restricted Areas R–5311A, R–5311B, and R–5311C; Fort Liberty, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action is an administrative change to rename restricted areas R–5311A, R–5311B, and R–5311C, Fort Liberty, NC, and to update the using agency description to reflect the change. This action does not alter airspace boundaries or impose additional operating requirements on users of the affected airspace.

DATES: Effective date 0901 UTC, October 2, 2025.

ADDRESSES: A copy of this final rule and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FOR FURTHER INFORMATION CONTACT: Brian Vidis, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it updates the information in the airspace descriptions of restricted areas R–5311A, R–5311B, and R–5311C.

History

On February 10, 2025, the Secretary of Defense directed the U.S. Army to change the name of ''Fort Liberty, NC'' by reverting to its previous name, ''Fort Bragg, NC.'' [1] Consequently, this rulemaking action implements the requisite changes to part 73 by updating the airspace descriptions of restricted areas R–5311A, R–5311B, and R–5311C to reflect the new name.

The Rule

This action amends 14 CFR part 73 by updating the airspace titles and using agency descriptions for restricted areas R–5311A, R–5311B, and R–5311C by removing the name ''Fort Liberty, NC'' and replacing it with ''Fort Bragg, NC.''

Additionally, the FAA makes a minor technical amendment to a geographic coordinate in the description of restricted area R–5311A. This amendment to the geographic coordinate corrects a typographical error in the description of restricted area R–5311A and does not change the boundary of the restricted area. The point listed as ''lat. °79°02′29″ W'' is changed to ''lat. 35°07′01″ N, long. 79°02′29″ W'' as intended.

Good Cause for Bypassing Notice and Comment

Under 5 U.S.C. 553, federal agencies engaged in informal rulemaking must provide the public with a notice of proposed rulemaking and an opportunity for public participation. However, 5 U.S.C. 553(b)(B) exempts a rule from these requirements ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' Courts have construed these exceptions narrowly, but have nonetheless accepted determinations of good cause that notice and comment is unnecessary in ''those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *See*

[1] *See https://www.defense.gov/News/Releases/Release/Article/4062245/secretary-of-defense-pete-hegseth-renames-fort-liberty-to-fort-bragg/.*

Mack Trucks, Inc. v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012). This action consists of administrative name changes and minor technical amendments only. It does not affect the boundaries, altitudes, time of designation, operating requirements, or activities conducted in the restricted areas. Therefore, FAA has determined that good cause exists for why notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of making administrative name changes to the geographic location and using agency information of restricted areas R–5311A, R–5311B, and R–5311C qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and in accordance with FAA Order 1050.1G, *FAA National Environmental Policy Act Implementing Procedures,* paragraph B–2.5(a), which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph B–2.5(d)—Modification of the technical description of special use airspace (SUA) that does not alter the dimensions, altitudes, or times of designation of the airspace (such as changes in designation of the controlling or using agency, or correction of typographical errors). In accordance with FAA's NEPA implementation procedures regarding extraordinary circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact statement.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for 14 CFR part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p.389.

§ 73.53 North Carolina (NC) [Amended]

■ 2. Section 73.53 is amended as follows:

* * * * *

R–5311A Fort Liberty, NC [Removed]

R–5311B Fort Liberty, NC [Removed]

R–5311C Fort Liberty, NC [Removed]

R–5311A Fort Bragg, NC [New]

Boundaries. Beginning at lat. 35°10′40″ N, long. 79°01′56″ W; to lat. 35°08′48″ N, long. 79°01′59″ W; to lat. 35°07′01″ N, long. 79°02′29″ W; to lat. 35°05′36″ N, long. 79°01′49″ W; to lat. 35°02′56″ N, long. 79°05′39″ W; to lat. 35°02′46″ N, long. 79°20′09″ W; to lat. 35°07′06″ N, long. 79°22′49″ W; to lat. 35°09′43″ N, long. 79°20′07″ W; thence along Little River to the point of beginning.

Designated altitudes. Surface to but not including 7,000 feet MSL.

Time of designation. Continuous.

Controlling agency. FAA, Washington ARTCC.

Using agency. U.S. Army, Commanding General, Fort Bragg, NC.

R–5311B Fort Bragg, NC [New]

Boundaries. Beginning at lat. 35°10′40″ N, long. 79°01′56″ W; to lat. 35°08′48″ N, long. 79°01′59″ W; to lat. 35°07′01″ N, long. 79°02′29″ W; to lat. 35°05′36″ N, long. 79°01′49″ W; to lat. 35°02′56″ N, long. 79°05′39″ W; to lat. 35°02′46″ N, long. 79°20′09″ W; to lat. 35°07′06″W; to lat. 35°09′43″ N, long. 79°20′07″ W; thence along Little River to the point of beginning.

Designated altitudes. From 7,000 feet MSL to but not including 12,000 feet MSL.

Time of designation. Continuous.

Controlling agency. FAA, Washington ARTCC.

Using agency. U.S. Army, Commanding General, Fort Bragg, NC.

R–5311C Fort Bragg, NC [New]

Boundaries. Beginning at lat. 35°10′40″ N, long. 79°01′56″ W; to lat. 35°08′48″ N, long. 79°01′59″ W; to lat. 35°07′01″ N, long. 79°02′29″ W; to lat. 35°05′36″ N, long. 79°01′49″ W; to lat. 35°02′56″ N, long. 79°05′39″ W; to lat. 35°02′46″ N, long. 79°20′09″ W; to lat. 35°07′06″ N, long. 79°22′49″ W; to lat. 35°09′43″ N, long. 79°20′07″ W; thence along Little River to the point of beginning.

Designated altitudes. From 12,000 feet MSL to but not including FL 290.

Time of designation. Continuous.

Controlling agency. FAA Washington ARTCC.

Using agency. U.S. Army, Commanding General, Fort Bragg, NC.

* * * * *

Issued in Washington, DC, on July 11, 2025.

Brian Eric Konie,

Manager (A), Rules and Regulations Group.

[FR Doc. 2025–13282 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31615; Amdt. No. 586]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: Effective 0901 UTC, August 07, 2025.

FOR FURTHER INFORMATION CONTACT: Romana B. Wolf, Manager, Flight

Procedures and Airspace Group, Flight Technologies and Procedures Division, Office of Safety Standards, Flight Standards Service, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on July 7, 2024.

Romana B. Wolf,

Manager, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Office of Safety Standards, Flight Standards Service, Aviation Safety, Federal Aviation Administration.

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows:

PART 95—IFR ALTITUDES

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113 and 14 CFR 11.49(b)(2).

■ 2. Part 95 is amended as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 586 effective date August 07, 2025]

From	To	MEA
§ 95.0040 Colored Federal Airways		
§ 95.5 Green Federal Airway G10 Is Amended To Delete		
WOODY ISLAND, AK NDB	KACHEMAK, AK NDB	6000 MAA–17500
§ 95.5 Green Federal Airway G12 Is Amended To Delete		
PORT HEIDEN, AK NDB/DME	CHINOOK, AK NDB	2500 MAA–17500
§ 95.4 Green Federal Airway G8 Is Amended To Delete		
ELFEE, AK NDB	CRACK, AK FIX	*5000
*4100–MOCA		MAA–17500
CRACK, AK FIX	CHINOOK, AK NDB	*3000
*2300–MOCA		MAA–17500
CHINOOK, AK NDB	NOSKY, AK FIX	*6000
*4900–MOCA		MAA–17500
NOSKY, AK FIX	KACHEMAK, AK NDB	6100 MAA–17500
§ 95.11 Amber Federal Airway A16 Is Amended To Delete		
ACTIVE PASS, CA NDB	WHITE ROCK, CA NDB	*3000
*2100–MOCA		MAA–17500
*FOR THAT AIRSPACE OVER U.S. TERRITORY		
§ 95.2 Red Federal Airway R99 Is Amended by Adding		
DUTCH HARBOR, AK NDB/DME	ST PAUL ISLAND, AK NDB/DME	*4800 MAA–17500

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT—Continued

[Amendment 586 effective date August 07, 2025]

From	To	MEA
*HF COMMS REQUIRED BELOW 8000 MSL		
Is Amended To Delete		
ST PAUL ISLAND, AK NDB	DUTCH HARBOR, AK NDB	*4800 MAA–17500
*HF COMMS REQUIRED BELOW 8000 MSL		
DUTCH HARBOR, AK NDB	CHINOOK, AK NDB	*9000
*6300–MOCA		MAA–17500
CHINOOK, AK NDB	ILIAMNA, AK NDB/DME	*5000
*4400–MOCA		MAA–17500
ILIAMNA, AK NDB/DME	KACHEMAK, AK NDB	6100 MAA–17500
§ 95.6 Blue Federal Airway B27 Is Amended To Delete		
WOODY ISLAND, AK NDB	CHINOOK, AK NDB	10000 MAA–17500
CHINOOK, AK NDB	WANIX, AK FIX	*8000
*7500–MOCA		MAA–17500
WANIX, AK FIX	OSCARVILLE, AK NDB	
	NW BND	4000
	SE BND	8000 MAA–17500
OSCARVILLE, AK NDB	ST MARYS, AK NDB	3000 MAA–17500
ST MARYS, AK NDB	FORT DAVIS, AK NDB	3000 MAA–17500
FORT DAVIS, AK NDB	HOTHAM, AK NDB	6000 MAA–17500

From	To	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes **§ 95.3220 RNAV Route T220 Is Amended by Adding**			
MARCS, TX FIX	CRAYS, TX WP	2400	17500
CRAYS, TX WP	MEESO, TX WP	2600	17500
MEESO, TX WP	MNURE, TX WP	2300	17500
MNURE, TX WP	SEALY, TX WP	2100	17500
Is Amended To Delete			
INDUSTRY, TX VORTAC	SEALY, TX FIX	2100	17500
§ 95.3248 RNAV Route T248 Is Amended To Read in Part			
GAMBELL, AK DME	QAYAQ, AK WP	3600	17500
§ 95.3250 RNAV Route T250 Is Amended by Adding			
GAMBELL, AK DME	KUKULIAK, AK VOR/DME	3000	17500
KUKULIAK, AK VOR/DME	QAYAQ, AK WP	3700	17500
QAYAQ, AK WP	BANAT, AK WP	3000	17500
BANAT, AK WP	AKELT, AK FIX	3000	17500
AKELT, AK FIX	BETHEL, AK VORTAC	3800	17500
Is Amended To Delete			
BETHEL, AK VORTAC	AKELT, AK FIX	3800	17500
AKELT, AK FIX	QAYAQ, AK WP	3000	17500
QAYAQ, AK WP	KUKULIAK, AK VOR/DME	3700	17500
§ 95.3492 RNAV Route T492 Is Added To Read			
FIINN, FL WP	PMPNO, FL WP	3000	10000
PMPNO, FL WP	WEZER, FL WP	3000	10000
WEZER, FL WP	YOJIX, FL FIX	3000	10000
YOJIX, FL FIX	YONMA, FL FIX	2200	17500
YONMA, FL FIX	*ODDEL, FL FIX	1800	17500
*2700–MCA ODDEL, FL FIX , E BND			

From	To	MEA	MAA
ODDEL, FL FIX	DEARY, FL FIX	2700	17500
§ 95.3494 RNAV Route T494 Is Added To Read			
SKWAD, FL WP *1700–MOCA	TWOON, FL WP	*3000	16000
§ 95.3545 RNAV Route T545 Is Added To Read			
BROWNSVILLE, TX VORTAC	MANNY, TX FIX	2000	17500
MANNY, TX FIX *1300–MOCA	OPULL, TX FIX	*2000	17500
OPULL, TX FIX *1500–MOCA	ASCOT, TX FIX	*2000	17500
ASCOT, TX FIX	CORPUS CHRISTI, TX VORTAC	2000	17500
CORPUS CHRISTI, TX VORTAC	SLENA, TX FIX	2000	17500
SLENA, TX FIX	YENNS, TX FIX	2000	17500
YENNS, TX FIX	EMBOW, TX FIX	2400	17500
EMBOW, TX FIX	SAN ANTONIO, TX VORTAC	2900	17500
SAN ANTONIO, TX VORTAC *3000–MOCA	GOBBY, TX FIX	*3500	17500
GOBBY, TX FIX	AMUSE, TX FIX	3500	17500
AMUSE, TX FIX	BASIS, TX FIX	3000	17500
BASIS, TX FIX	GOOCH SPRINGS, TX VORTAC	3300	17500
§ 95.3797 RNAV Route T797 Is Added To Read			
INTERNATIONAL FALLS, MN VOR/DME	U.S. CANADIAN BORDER	2900	17500
§ 95.4000 High Altitude RNAV Routes **§ 95.4182 RNAV Route Q182 Is Added To Read**			
ST PAUL ISLAND, AK NDB/DME *GNSS REQUIRED	GARRS, AK WP	*18000	45000
GARRS, AK WP *GNSS REQUIRED	KING SALMON, AK VORTAC	*18000	45000
§ 95.4436 RNAV Route Q436 Is Amended To Read in Part			
KAYYS, MI WP *18000–GNSS MEA *DME/DME/IRU MEA	DIXSN, MI WP	*18000	45000
§ 95.4828 RNAV Route Q828 Is Added To Read			
U.S. CANADIAN BORDER *GNSS REQUIRED	DULUTH, MN VORTAC	*18000	45000
§ 95.4945 RNAV Route Q945 Is Added To Read			
DICKINSON, ND VORTAC *18000–GNSS MEA *DME/DME/IRU MEA	U.S. CANADIAN BORDER	*18000	45000
§ 95.4971 RNAV Route Q971 Is Added To Read			
MINOT, ND VOR/DME *GNSS REQUIRED	U.S. CANADIAN BORDER	*18000	45000

From	To	MEA
§ 95.6001 Victor Routes—U.S. **§ 95.6001 VOR Federal Airway V1 Is Amended To Delete**		
NORFOLK, VA VORTAC	CAPE CHARLES, VA VORTAC	*2500
*1800–MOCA		MAA–17500
CAPE CHARLES, VA VORTAC	SALISBURY, MD VORTAC	2000
		MAA–17500
SALISBURY, MD VORTAC	WATERLOO, DE VOR/DME	*2000
*1500–MOCA		MAA–17500
*SALISBURY R–039 UNUSABLE BELOW 5000 MSL		
§ 95.6007 VOR Federal Airway V7 Is Amended To Delete		
LAKELAND, FL VORTAC	*DADES, FL FIX	**2300

From	To	MEA
*5000–MRA		MAA–17500
**1800–MOCA		
DADES, FL FIX	NITTS, FL FIX	*2300
*1800–MOCA		MAA–17500
NITTS, FL FIX	*ORATE, FL FIX	**3000
*3000–MRA		MAA–17500
**1700–MOCA		
ORATE, FL FIX	CROSS CITY, FL VORTAC	*2000
*1500–MOCA		MAA–17500
CROSS CITY, FL VORTAC	SEMINOLE, FL VORTAC	2000
		MAA–17500
§ 95.6010 VOR Federal Airway V10 Is Amended To Delete		
BURLINGTON, IA VOR/DME	BRADFORD, IL VORTAC	2600
		MAA–17500
BRADFORD, IL VORTAC	PLANO, IL FIX	3000
		MAA–17500
§ 95.6017 VOR Federal Airway V17 Is Amended To Read in Part		
COTULLA, TX VORTAC	MILET, TX FIX.	
	SW BND	2500
	NE BND	4000
		MAA–17500
SOMER, TX FIX	SAN ANTONIO, TX VORTAC.	
	N BND	3000
	S BND	4000
		MAA–17500
§ 95.6029 VOR Federal Airway V29 Is Amended To Delete		
SNOW HILL, MD VORTAC	*SALISBURY, MD VORTAC	**2000
*5000–MCA SALISBURY, MD VORTAC , N BND		
**1500–MOCA		MAA–17500
SALISBURY, MD VORTAC	*EZIZI, DE FIX	5000
*7000–MCA EZIZI, DE WP, N BND		
		MAA–17500
EZIZI, DE FIX	*LAFLN, DE FIX	**7000
*7000–MCA LAFLN, DE WP, S BND		
		MAA–17500
**5000–GNSS MEA		
LAFLN, DE FIX	SMYRNA, DE VORTAC	1800
		MAA–17500
§ 95.6030 VOR Federal Airway V30 Is Amended To Read in Part		
SQUIB, MI FIX	PULLMAN, MI VOR/DME	UNUSABLE
§ 95.6035 VOR Federal Airway V35 Is Amended To Delete		
ST PETERSBURG, FL VORTAC	ENDED, FL FIX	2500
		MAA–17500
ENDED, FL FIX	CROSS CITY, FL VORTAC	*3000
*1500–MOCA		MAA–17500
CROSS CITY, FL VORTAC	GREENVILLE, FL VORTAC	2000
		MAA–17500
GREENVILLE, FL VORTAC	*SALER, GA FIX	UNUSABLE
*3000–MRA		
SALER, GA FIX	PECAN, GA VOR/DME	*2000
*1700–MOCA		MAA–17500
§ 95.6037 VOR Federal Airway V37 Is Amended To Read in Part		
CRAIG, FL VORTAC	BRUNSWICK, GA VORTAC	2000
		MAA–17500
§ 95.6038 VOR Federal Airway V38 Is Amended by Adding		
HARCUM, VA VORTAC	LNSKY, VA FIX	2000
		MAA–17500

From	To	MEA
Is Amended To Delete		
HARCUM, VA VORTAC	CAPE CHARLES, VA VORTAC	2000 MAA–17500
§ 95.6045 VOR Federal Airway V45 Is Amended To Read in Part		
PULASKI, VA VORTAC	BLUEFIELD, WV VOR/DME	6300 MAA–17500
§ 95.6068 VOR Federal Airway V68 Is Amended To Delete		
SAN ANTONIO, TX VORTAC	*BRAUN, TX FIX	3100
*5500–MRA		MAA–17500
BRAUN, TX FIX	MARCS, TX FIX	3100
		MAA–17500
MARCS, TX FIX	CRAYS, TX WP	*2900
*2000–MOCA		MAA–17500
CRAYS, TX FIX	INDUSTRY, TX VORTAC	2600
		MAA–17500
§ 95.6084 VOR Federal Airway V84 Is Amended To Read in Part		
PIVOT, IL FIX	JYBEE, MI FIX	UNUSABLE
JYBEE, MI FIX	PULLMAN, MI VOR/DME	UNUSABLE
§ 95.6129 VOR Federal Airway V129 Is Amended To Delete		
INTERNATIONAL FALLS, MN VOR/DME	U.S. CANADIAN BORDER	2500 MAA–17500
§ 95.6137 VOR Federal Airway V137 Is Amended To Read in Part		
PALMDALE, CA VORTAC	VICKY, CA FIX	*8000
*6500–MOCA		MAA–17500
§ 95.6139 VOR Federal Airway V139 Is Amended by Adding		
PEARS, NC FIX	BERTI, NC FIX	*6000
*2100–GNSS MEA		MAA–17500
BERTI, NC FIX	WINAL, NC FIX.	
	NE BND	*4000
	SW BND	*6000
*1700–MOCA		MAA–17500
WINAL, NC FIX	NPTUN, NC FIX	*4000
*1700–MOCA		MAA–17500
NPTUN, NC FIX	NORFOLK, VA VORTAC	2100
		MAA–17500
NORFOLK, VA VORTAC	LNSKY, VA FIX	*3000
*1800–MOCA		MAA–17500
LNSKY, VA FIX	BEEEG, MD FIX	*4000
*1600–MOCA		MAA–17500
BEEEG, MD FIX	RADDS, DE FIX.	
	NE BND	*3000
	SW BND	*4000
*1700–MOCA		MAA–17500
RADDS, DE FIX	SEA ISLE, NJ VORTAC	*3000
*1700–MOCA		MAA–17500
Is Amended To Delete		
PEARS, NC FIX	SUNNS, NC FIX	*6000
*2100–MOCA		MAA–17500
*2100–GNSS MEA		
SUNNS, NC FIX	NORFOLK, VA VORTAC.	
	NE BND	*2500
	SW BND	*4800
*1600–MOCA		MAA–17500
*2000–GNSS MEA		
NORFOLK, VA VORTAC	CAPE CHARLES, VA VORTAC	*2500
*1800–MOCA		MAA–17500
CAPE CHARLES, VA VORTAC	DUNFE, VA FIX.	
	NE BND	*4000
	SW BND	*2000
*1600–MOCA		MAA–17500

From	To	MEA
DUNFE, VA FIX	SNOW HILL, MD VORTAC	*4000
*1600–MOCA		MAA–17500
SNOW HILL, MD VORTAC	CBEAV, MD FIX	2000
		MAA–17500
CBEAV, MD FIX	SEA ISLE, NJ VORTAC	*2500
*1700–MOCA		MAA–17500
Is Amended To Read in Part		
PROVIDENCE, RI VOR/DME	*INNDY, MA FIX	**5500
*5500–MRA		
**1700–MOCA		MAA–17500
**2000–GNSS MEA		
§ 95.6156 VOR Federal Airway V156 Is Amended To Delete		
MOLINE, IL VOR/DME	BRADFORD, IL VORTAC	2800
		MAA–17500
BRADFORD, IL VORTAC	PEOTONE, IL VORTAC	2700
		MAA–17500
§ 95.6157 VOR Federal Airway V157 Is Amended by Adding		
OCALA, FL VORTAC	*LEJKO, FL FIX	2000
*3000—MRA		MAA–17500
LEJKO, FL FIX	GATORS, FL VORTAC	2000
		MAA–17500
GATORS, FL VORTAC	*TAALR, FL FIX	**3000
*3000–MCA TAALR, FL FIX , S BND		
**1600–MOCA		MAA–17500
TAALR, FL FIX	WAYCROSS, GA VORTAC	2300
		MAA–17500
WAYCROSS, GA VORTAC	DUBLIN, GA VORTAC	2000
		MAA–17500
Is Amended To Delete		
OCALA, FL VORTAC	TAYLOR, FL VORTAC	2000
		MAA–17500
TAYLOR, FL VORTAC	WAYCROSS, GA VORTAC	2300
		MAA–17500
§ 95.6159 VOR Federal Airway V159 Is Amended To Delete		
OCALA, FL VORTAC	*PERSE, FL FIX	2000
*3000–MRA		MAA–17500
PERSE, FL FIX	*WILON, FL WP	2000
*3000–MRA		MAA–17500
WILON, FL WP	CROSS CITY, FL VORTAC	2000
		MAA–17500
CROSS CITY, FL VORTAC	GREENVILLE, FL VORTAC	2000
		MAA–17500
§ 95.6161 VOR Federal Airway V161 Is Amended To Delete		
THREE RIVERS, TX VORTAC	LEMIG, TX FIX	2000
		MAA–17500
LEMIG, TX FIX	CENTER POINT, TX VORTAC	4100
		MAA–17500
§ 95.6163 VOR Federal Airway V163 Is Amended by Adding		
CORPUS CHRISTI, TX VORTAC	SKIDS, TX FIX	1900
		MAA–17500
SKIDS, TX FIX	SLENA, TX FIX	*3000
*1900–MOCA		MAA–17500
SLENA, TX FIX	SAN ANTONIO, TX VORTAC	3000
		MAA–17500
Is Amended To Delete		
CORPUS CHRISTI, TX VORTAC	SINTO, TX FIX	1800
		MAA–17500
SINTO, TX FIX	THREE RIVERS, TX VORTAC	2000
		MAA–17500

From	To	MEA
THREE RIVERS, TX VORTAC	YENNS, TX FIX.	
	S BND	2000
	N BND	3000
		MAA–17500
YENNS, TX FIX	SAN ANTONIO, TX VORTAC	*3000
*2500–MOCA		MAA–17500
§ 95.6198 VOR Federal Airway V198 Is Amended by Adding		
GREENVILLE, FL VORTAC	HADDE, FL FIX	2000
		MAA–17500
HADDE, FL FIX	TAALR, FL FIX	*3000
*1600–MOCA		MAA–17500
TAALR, FL FIX	*MONIA, GA FIX	**7000
*7000–MRA		
*7000–MCA MONIA, GA FIX, W BND		
**1600–MOCA		MAA–17500
MONIA, GA FIX	CRAIG, FL VORTAC	*3000
*2100–MOCA		MAA–17500
Is Amended To Delete		
GREENVILLE, FL VORTAC	TAYLOR, FL VORTAC	2000
		MAA–17500
TAYLOR, FL VORTAC	CRAIG, FL VORTAC	*3000
*2100–MOCA		MAA–17500
§ 95.6212 VOR Federal Airway V212 Is Amended To Delete		
INDUSTRY, TX VORTAC	NAVASOTA, TX VOR/DME	2200
		MAA–17500
§ 95.6222 VOR Federal Airway V222 Is Amended To Delete		
STONEWALL, TX VORTAC	MARCS, TX FIX	4500
		MAA–17500
MARCS, TX FIX	CRAYS, TX FIX	*2900
*2000–MOCA		MAA–17500
CRAYS, TX FIX	INDUSTRY, TX VORTAC	2600
		MAA–17500
INDUSTRY, TX VORTAC	SEALY, TX FIX	2100
		MAA–17500
SEALY, TX FIX	HUMBLE, TX VORTAC	2000
		MAA–17500
§ 95.6262 VOR Federal Airway V262 Is Amended To Delete		
PEORIA, IL VORTAC	BRADFORD, IL VORTAC	2700
		MAA–17500
BRADFORD, IL VORTAC	MOTIF, IL FIX	2700
		MAA–17500
MOTIF, IL FIX	JOLIET, IL VOR/DME	*3000
*2300–MOCA		MAA–17500
§ 95.6268 VOR Federal Airway V268 Is Amended To Read in Part		
SANDY POINT, RI VOR/DME	*INNDY, MA FIX	2100
*5500–MRA		
		MAA–17500
§ 95.6274 VOR Federal Airway V274 Is Amended To Read in Part		
PULLMAN, MI VOR/DME	VICTORY, MI VOR/DME	UNUSABLE
§ 95.6286 VOR Federal Airway V286 Is Amended To Delete		
BROOKE, VA VORTAC	*ZUNAR, VA FIX	**3000
*5000–MCA ZUNAR, VA WP, SE BND		
		MAA–17500
**2000–GNSS MEA		
ZUNAR, VA FIX	FAGED, VA FIX	*5000
		MAA–17500
*2000–GNSS MEA		
FAGED, VA FIX	GWYNN, VA FIX	2000
		MAA–17500

From	To	MEA
GWYNN, VA FIX	CAPE CHARLES, VA VORTAC	*2000
*1500–MOCA		MAA–17500
§ 95.6303 VOR Federal Airway V303 Is Amended To Read in Part		
HOT SPRINGS, AR VOR/DME	BLURB, AR FIX.	
	NW BND	*5000
	SE BND	*3500
*3100–MOCA		MAA–17500
BLURB, AR FIX	BLIMP, AR FIX.	
	NW BND	*4100
	SE BND	*5000
*3700–MOCA		MAA–17500
§ 95.6466 VOR Federal Airway V466 Is Amended To Read in Part		
VOLUNTEER, TN VORTAC	TAMPI, TN FIX	3600
		MAA–17500
TAMPI, TN FIX	FARLI, TN FIX	4500
		MAA–17500
FARLI, TN FIX	YUMMY, VA FIX	UNUSABLE
YUMMY, VA FIX	GLADE SPRING, VA VOR/DME	6400
		MAA–17500
GLADE SPRING, VA VOR/DME	*DORFF, VA FIX	*6900
*7000–MRA		
		MAA–17500
*GLADE SPRING R-078 UNUSABLE USE PULASKI R-263		
DORFF, VA FIX	PULASKI, VA VORTAC	6200
		MAA–17500
§ 95.6472 VOR Federal Airway V472 Is Amended To Read in Part		
ELIZABETH CITY, NC VOR/DME	WINAL, NC FIX	*4000
*1600–MOCA		MAA–17500
WINAL, NC FIX	BERTI, NC FIX.	
	NE BND	*4000
	SW BND	*6000
*1700–MOCA		MAA–17500
BERTI, NC FIX	*ZAGGY, NC FIX	**6000
*6000–MCA ZAGGY, NC FIX , NE BND		
		MAA–17500
**2100–GNSS MEA		
§ 95.6519 VOR Federal Airway V519 Is Amended To Read in Part		
VOLUNTEER, TN VORTAC	TAMPI, TN FIX	3600
		MAA–17500
TAMPI, TN FIX	FARLI, TN FIX	4500
		MAA–17500
FARLI, TN FIX	YUMMY, VA FIX	UNUSABLE
YUMMY, VA FIX	GLADE SPRING, VA VOR/DME	6400
		MAA–17500
GLADE SPRING, VA VOR/DME	*TELOC, VA FIX	**9900
*13000–MRA		
**6900–MOCA		MAA–17500
**GLADE SPRING R-058 UNUSABLE USE BLUEFIELD R-239		
TELOC, VA FIX	BLUEFIELD, WV VOR/DME.	
	NE BND	6600
	SW BND	9900
		MAA–17500
§ 95.6532 VOR Federal Airway V532 Is Amended To Read in Part		
BLURB, AR FIX	BLIMP, AR FIX.	
	NW BND	*4100
	SE BND	*5000
*3700–MOCA		MAA–17500
§ 95.6550 VOR Federal Airway V550 Is Amended To Read in Part		
COTULLA, TX VORTAC	MILET, TX FIX.	
	SW BND	2500

From	To	MEA
	NE BND	4000 MAA–17500
MILET, TX FIX	SAN ANTONIO, TX VORTAC	3000 MAA–17500
§ 95.6558 VOR Federal Airway V558 Is Amended To Delete		
CENTEX, TX VORTAC	MOUZE, TX FIX	2200 MAA–17500
MOUZE, TX FIX	INDUSTRY, TX VORTAC	2100 MAA–17500
§ 95.6568 VOR Federal Airway V568 Is Amended To Delete		
CORPUS CHRISTI, TX VORTAC	THREE RIVERS, TX VORTAC	2000 MAA–17500
THREE RIVERS, TX VORTAC	LEMIG, TX FIX	2000 MAA–17500
LEMIG, TX FIX	SAN ANTONIO, TX VORTAC	3000 MAA–17500
§ 95.6574 VOR Federal Airway V574 Is Amended To Read in Part		
CENTEX, TX VORTAC	NAVASOTA, TX VOR/DME	2400 MAA–17500
§ 95.6414 Alaska VOR Federal Airway V414 Is Amended To Delete		
GAMBELL, AK NDB/DME	KUKULIAK, AK VOR/DME	3000 MAA–17500
§ 95.6619 Alaska VOR Federal Airway V619 Is Amended To Delete		
PORT HEIDEN, AK NDB/DME	CHINOOK, AK NDB	4000 MAA–17500
CHINOOK, AK NDB	DILLINGHAM, AK VOR/DME	3000 MAA–17500

From	To	MEA	MAA
§ 95.7001 Jet Routes **§ 95.7026 Jet Route J26 Is Amended To Delete**			
KIRKSVILLE, MO VORTAC	BRADFORD, IL VORTAC	18000	45000
BRADFORD, IL VORTAC	JOLIET, IL VOR/DME	18000	45000
§ 95.7064 Jet Route J64 Is Amended To Delete			
LAMONI, IA VOR/DME	BRADFORD, IL VORTAC	18000	45000
BRADFORD, IL VORTAC	FORT WAYNE, IN VORTAC	18000	45000
§ 95.7181 Jet Route J181 Is Amended To Delete			
HALLSVILLE, MO VORTAC	BAYLI, IL FIX	18000	23000
BAYLI, IL FIX	BRADFORD, IL VORTAC	18000	45000
§ 95.7483 Jet Route J483 Is Amended To Delete			
MINOT, ND VOR/DME	U.S. CANADIAN BORDER	18000	45000
§ 95.7538 Jet Route J538 Is Amended To Delete			
U.S. CANADIAN BORDER	DULUTH, MN VORTAC	18000	45000
§ 95.7562 Jet Route J562 Is Amended To Delete			
DICKINSON, ND VORTAC	U.S. CANADIAN BORDER	18000	45000
§ 95.7606 Jet Route J606 Is Amended To Delete			
ST PAUL ISLAND, AK NDB/DME	CHINOOK, AK NDB	18000	45000

Airway Segment		Changeover Points	
From	To	Distance	From
§ 95.8003 VOR Federal Airway Changeover Point V139 Is Amended To Delete Changeover Point			
CAPE CHARLES, VA VORTAC	SNOW HILL, MD VORTAC	38	CAPE CHARLES
SNOW HILL, MD VORTAC	SEA ISLE, NJ VORTAC	25	SNOW HILL
V159 Is Amended To Delete Changeover Point			
OCALA, FL VORTAC	CROSS CITY, FL VORTAC	28	OCALA
V286 Is Amended To Delete Changeover Point			
BROOKE, VA VORTAC	CAPE CHARLES, VA VORTAC	22	BROOKE

[FR Doc. 2025–13281 Filed 7–15–25; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31613; Amdt. No. 4173]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 16, 2025. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 16, 2025.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.
2. The FAA Air Traffic Organization Service Area in which the affected airport is located;
3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,
4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Romana B. Wolf, Manager, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Office of Safety Standards, Flight Standards Service, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms are 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and

ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on July 4, 2025.

Romana B. Wolf,

Manager, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Office of Safety Standards, Flight Standards Service, Aviation Safety, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 7 August 2025

King Salmon, AK, AKN/PAKN, ILS Y OR LOC Y RWY 12, Amdt 19A
King Salmon, AK, AKN/PAKN, LOC BC RWY 30, Amdt 6A
King Salmon, AK, AKN/PAKN, VOR Y OR TACAN Y RWY 30, Amdt 12B
Chicago, IL, MDW, RNAV (GPS) RWY 4L, Amdt 1B
Bethel, ME, 0B1, RNAV (GPS) Z RWY 32, Amdt 1
Minneapolis, MN, MIC, RNAV (GPS) RWY 14, Orig-A
Lebanon, MO, LBO, RNAV (GPS) RWY 18, Amdt 1
Lebanon, MO, LBO, RNAV (GPS) RWY 36, Amdt 1
Springfield, MO, SGF, VOR OR TACAN RWY 20, Amdt 19
Endicott, NY, CZG, Takeoff Minimums and Obstacle DP, Amdt 4A
New York, NY, JFK, RNAV (RNP) Z RWY 22L, Amdt 1C, CANCELED
New York, NY, JFK, RNAV (RNP) Z RWY 31L, Amdt 1A, CANCELED
New York, NY, JFK, RNAV (RNP) Z RWY 31R, Amdt 1B, CANCELED
George West, TX, 8T6, RNAV (GPS) RWY 13, Amdt 1
George West, TX, 8T6, Takeoff Minimums and Obstacle DP, Amdt 1
George West, TX, 8T6, VOR/DME–A, Amdt 2B, CANCELED
Clarksville, VA, W63, RNAV (GPS) RWY 4, Orig
Clarksville, VA, W63, RNAV (GPS)-A, Orig, CANCELED
Clarksville, VA, W63, RNAV (GPS)-B, Orig-A, CANCELED
Staunton/Waynesboro/Harrisonburg, VA, SHD, NDB RWY 5, Amdt 10A, CANCELED
Madison, WI, MSN, Takeoff Minimums and Obstacle DP, Amdt 9

[FR Doc. 2025–13278 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31614; Amdt. No. 4174]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 16, 2025. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 16, 2025.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The Office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Romana B. Wolf, Manager, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Office of Safety Standards, Flight Standards Service, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on July 4, 2025.

Romana B. Wolf,

Manager, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Office of Safety Standards, Flight Standards Service, Aviation Safety, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Procedure name
7–Aug–25	FL	Pompano Beach	Pompano Beach Airpark	5/0702	6/13/2025	RNAV (GPS) RWY 15, Amdt 1A.
7–Aug–25	TX	Galveston	Scholes Intl At Galveston	5/0770	6/9/2025	ILS OR LOC RWY 14, Amdt 13A.
7–Aug–25	NM	Raton	Raton Muni/Crews Fld	5/3629	6/13/2025	RNAV (GPS) RWY 25, Orig-C.
7–Aug–25	KY	Covington	Cincinnati/Northern Kentucky Intl.	5/3911	6/16/2025	ILS OR LOC RWY 36L, ILS RWY 36L (CAT II), Amdt 2.
7–Aug–25	UT	Ogden	Ogden-Hinckley	5/4962	6/16/2025	VOR–A, Orig-A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Procedure name
7–Aug–25	AK	Kodiak	Kodiak	5/6589	6/24/2025	RNAV (GPS) RWY 26, Amdt 3A.

[FR Doc. 2025–13279 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0647]

Special Local Regulation; Charlevoix Venetian Night Boat Parade; Charlevoix, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Charlevoix Venetian Night Boat Parade; Charlevoix, MI special local regulation on the U.S. navigable waters of Round Lake, Charlevoix, MI on July 26, 2025. Enforcement of this regulation is necessary to protect the safety of life and property on these navigable waters prior to, during, and immediately after the Charlevoix Venetian Night Boat Parade. During the enforcement period listed below, entry into, transiting, or anchoring within the regulated area is prohibited unless authorized by the Captain of the Port Northern Great Lakes or a designated representative.

DATES: The regulations in 33 CFR 100.908 will be enforced from 9:30 p.m. to 11 p.m. on July 26, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LT Rebecca Simpson, Chief of Waterways Management, division, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the established special local regulation in 33 CFR 100.908 for the Charlevoix Venetian Night Boat Parade; Charlevoix, MI from 9:30 p.m. to 11 p.m. on July 26, 2025.

In accordance with the requirements in § 100.908, entry into, transiting, or anchoring within the regulated area is prohibited unless authorized by the Captain of the Port (COTP) Northern Great Lakes or a designated representative. Those seeking permission to enter the regulated area may request permission from the COTP Northern Great Lakes or a designated representative. Vessels and persons granted permission to enter the regulated area must obey all lawful orders or directions of the Captain of the Port Northern Great Lakes or a designated representative. While within the regulated area, all vessels must operate at the minimum speed necessary to maintain a safe course.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the COTP Northern Great Lakes determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may suspend such enforcement and notify the public of the suspension via Broadcast Notice to Mariners and grant general permission to enter the regulated area.

Dated: July 11, 2025.

J.R. Bendle,

Captain, U.S. Coast Guard, Captain of the Port Northern Great Lakes.

[FR Doc. 2025–13292 Filed 7–15–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0657]

RIN 1625–AA00

Safety Zone; Little Potato Slough, Stockton, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 100-yard radius of the vessels and machinery conducting operations at the site of the vessel CHALEUR in Little Potato Slough near Stockton, CA. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by salvage operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector San Francisco.

DATES: This rule is effective without actual notice from July 16, 2025 through 11 p.m. August 14, 2025. For the purposes of enforcement, actual notice will be used from 1 a.m. July 14, 2025 until July 16, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2025–0657 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Ensign Saralyn Young, U.S. Coast Guard Sector San Francisco, Waterways Management; telephone 415–399–7443, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the vessel CHALEUR is submerged within Little Potato Slough and the Coast Guard, which must oversee salvage operations, did not receive final details of the plan until July 8, 2025. It is impracticable to publish an NPRM because we must establish this safety zone by July 14, 2025.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is impracticable because prompt action is needed to respond to the potential safety hazards associated with the salvage operations to begin on July 14, 2025.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port (COTP) San Francisco has determined that potential hazards associated with the salvage operations of the vessel CHALEUR beginning July 14, 2025, will be a safety concern for anyone within a 100-yard radius of the barges and vessels in Little Potato Slough. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during salvage operations.

IV. Discussion of the Rule

This rule establishes a safety zone from 1 a.m. on July 14, 2025, until 11 p.m. on August 14, 2025. The safety zone will cover all navigable waters within 100 yards of vessels and machinery being used in the salvage operations of the vessel CHALEUR. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the salvage operations are taking place. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it.

This regulatory action determination is based on the size, location, and duration of the safety zone. The amount of vessel traffic through Little Potato Slough during the duration of the zone is not anticipated to interfere with salvage operations. The Coast Guard will issue a Broadcast Notice to Mariners about the safety zone to inform the public.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit entry within 100 yards of vessels and barges being used in the salvage operations of the vessel CHALEUR. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping

requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T11–210 to read as follows:

§ 165.T11–210 Safety Zone; Little Potato Slough, Stockton, CA.

(a) *Location.* The following area is a safety zone: All waters of Little Potato Slough, from surface to bottom, within 100 yards of the vessels involved in the salvage operations of the vessel CHALEUR at coordinates 38°3′29″ N, 121°30′3″ W.

(b) *Definitions.* As used in the section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the Captain of the Port (COTP) San Francisco in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request to enter the safety zone through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced from 1 a.m. on July 14, 2025, through 11 p.m. on August 14, 2025.

Dated: July 11, 2025.

Jarod S. Toczko,

Captain, U.S. Coast Guard, Acting Captain of the Port Sector San Francisco.

[FR Doc. 2025–13293 Filed 7–15–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0221]

RIN 1625–AA00

Safety Zone; Rainy Lake, City of Ranier, MN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of Rainy Lake. This action is necessary to protect personnel, vessels, and the marine environment from potential hazards on these navigable waters near Ranier Beach Park, Ranier, MN, during a fireworks display on August 9, 2025. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Duluth or a designated representative.

DATES: This rule is effective from 8 p.m. through 11 p.m. on August 9, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2025–0221 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LT Zachary Fedak, Waterways Management, Marine Safety Unit Duluth, U.S. Coast Guard; telephone 218–522–0708, email *Zachary.A.Fedak@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On January 6, 2025, an organization notified the Coast Guard that from 10 p.m. to 10:30 p.m. on August 9, 2025, it will be conducting a fireworks display launched from a barge in Rainy Lake approximately 250 yards northwest of Ranier Beach Park in Ranier, MN. In response, on June 4, 2025, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Rainy Lake, City of Ranier, MN (90 FR 23651). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended July 7, 2025, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is impracticable and contrary to the public interest; this regulatory action is necessary to ensure the safety of participants, spectators, and waterway users during the scheduled fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with the fireworks to be used in this August 9, 2025, display will be a safety concern for anyone within a 200-yard radius of the barge. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published June 4, 2025. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 8 p.m. through 11 p.m. on August 9, 2025. The safety zone will cover all navigable waters within 200 yards of a barge in Rainy Lake located approximately 250 yards northwest of Ranier Beach Park in Ranier, MN. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 10 p.m. to 10:30 p.m. fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory

Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it.

This regulatory action determination is based on the size, location, duration and time of day of the regulated area. Vessel traffic would be able to safely transit around this safety zone which would impact a small, designated area of Ranier Lake for 3 hours during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 3 hours that would prohibit entry within 200 yards of a fireworks barge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 165

Harbors; Marine safety; Navigation (water); Reporting and recordkeeping requirements; Security measures; Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T09–0221 to read as follows:

§ 165.T09–0221 Safety Zone; Rainy Lake, City of Ranier, MN.

(a) *Location.* The following area is a safety zone: All navigable waters of Rainy Lake, from surface to bottom, within a 200-yard radius of the firework barge to be positioned at 48°37′04″ N, 093°20′52″ W. These coordinates are based on World Geodetic System 84.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Duluth (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this

section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 8 p.m. to 11 p.m. on August 9, 2025.

John P. Botti,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Duluth.

[FR Doc. 2025–13290 Filed 7–15–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2025–0589]

Safety Zone; Fireworks Displays Within the East Coast Guard District; The Wharf, Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display at ''The Wharf DC,'' in Washington, DC, to provide for the safety of life on navigable waterways during this event. Our regulation, ''Safety Zones; Fireworks Displays within the East Coast Guard District,'' identifies the precise location. During the enforcement period, vessels may not enter, remain in, or transit through the safety zone unless authorized to do so by the COTP or his representative, and vessels in the vicinity must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 165.506 will be enforced for the location identified in line no. 1 of table 2 to 33 CFR 165.506(h)(2) from 8:00 p.m. until 10 p.m., on July 20, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email *MDNCRMarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone regulation for a fireworks display at The Wharf DC from 8 p.m. to 10 p.m. on July 20, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation, ''Safety Zones; Fireworks Displays within the East Coast Guard District,'' § 165.506, specifies the location of the safety zone for the fireworks show, which encompasses portions of the Washington Channel in the Upper Potomac River. As reflected in 33 CFR 165.23, vessels in the vicinity of the safety zone may not enter, remain in, or transit through the safety zone during the enforcement period unless authorized to do so by the COTP or his representative, and they must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: July 10, 2025.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2025–13284 Filed 7–15–25; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2024–0542; FRL–12793–03–R5]

Air Plan Approval; Ohio; Second Maintenance Plan for the Ohio Portion of the Campbell-Clermont, KY-OH SO_2 Maintenance Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving, under the Clean Air Act (CAA), the second 10-year maintenance plan submitted to EPA on November 7, 2024, by the Ohio Environmental Protection Agency (Ohio EPA) for the Ohio portion of the Campbell-Clermont Counties, Kentucky-Ohio maintenance area. The Ohio portion of this area consists of Pierce Township in Clermont County, Ohio. The plan addresses the second 10-year maintenance period for the 2010 sulfur dioxide (SO_2) National Ambient Air Quality Standards (NAAQS). EPA is approving Ohio EPA's submittal for the area because it provides for the continued maintenance of the 2010 SO_2 NAAQS through the end of the second 10-year portion of the maintenance period.

DATES: This direct final rule will be effective September 15, 2025, unless EPA receives adverse comments by August 15, 2025. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2024–0542 at *https://www.regulations.gov,* or via email to *arra.sarah@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Cecilia Magos, Air and Radiation Division (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7336, *magos.cecilia@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background

On June 22, 2010 (75 FR 35520), EPA promulgated a new 1-hour primary SO_2 NAAQS of 75 parts per billion (ppb). EPA promulgated designations for this standard in four rounds. On August 5, 2013 (78 FR 47191), EPA designated the Campbell-Clermont Counties, KY-OH area as nonattainment due to the measured violations of the 2010 SO_2 NAAQS. The Ohio portion of the nonattainment area consists of Pierce Township in Clermont County, Ohio. EPA conducted designations for the 2010 SO_2 NAAQS based on monitoring data from the years 2009 to 2011 from the nearby SO_2 monitor in Highland Heights, Campbell County, Kentucky (AQS Site ID: 21–037–3002, coordinates 39.021881, −84.474450).

By April 5, 2015, Ohio and Kentucky were both required to submit a nonattainment State Implementation Plan (SIP) that met the requirements of CAA sections 172(c) and 191–192, and provided for attainment of the 2010 primary SO_2 NAAQS as expeditiously as practicable, but no later than October 4, 2018. Air analysis conducted by Ohio EPA in Clermont County, Ohio found one source, the Walter C. Beckjord plant (Beckjord plant), to be the main contributor of SO_2 monitored violations in the nonattainment area. The 2014 shutdown and later demolition of the Beckjord plant resulted in a significant, permanent, and enforceable reduction in SO_2 emissions affecting the nonattainment area. The monitored SO_2 design value at the nearby Highland Heights monitor for 2012 to 2014 was 72 parts per billion (ppb), below the 2010 SO_2 NAAQS. As a result, Ohio EPA chose to submit a redesignation and maintenance plan request for the Pierce Township, Ohio portion of the Campbell-Clermont, KY-OH nonattainment area to EPA on August 11, 2015. The submission included a plan to provide for maintenance of the 2010 SO_2 NAAQS in the area for the first 10-year period.

On November 21, 2016 (81 FR 83158), EPA redesignated the Ohio portion of the Campbell-Clermont, KY-OH 2010 SO_2 nonattainment area to attainment and approved the associated maintenance plan into the Ohio SIP. The purpose of Ohio EPA's November 7, 2024, submittal is to fulfill the second 10-year planning requirement of CAA section 175A(b) to ensure compliance with the 2010 SO_2 NAAQS through 2036.

II. EPA's Evaluation of the Second Maintenance Plan

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, a State must submit a revision to the SIP that demonstrates the applicable NAAQS will continue to attain for at least 10 years after an area is redesignated to attainment. Section 175A also requires that eight years after the redesignation, the State must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the 10 years following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain contingency measures deemed necessary to ensure prompt corrections of any future NAAQS violations.

EPA's 1992 Calcagni Memo provides further guidance on the content and requirements of an approvable maintenance plan.[1] Specifically, the maintenance plan should address five requirements: (1) an attainment emissions inventory, (2) a maintenance demonstration, (3) continued air quality monitoring, (4) verification of continued attainment, and (5) contingency measures.

Ohio EPA's November 7, 2024, second 10-year maintenance plan request outlines a plan for continued maintenance of the 2010 SO_2 NAAQS for the Pierce Township, Ohio portion of the Campbell-Clermont, KY-OH maintenance area through 2036. EPA is approving Ohio EPA's November 7, 2024, submittal, which contains Ohio EPA's maintenance plan and all the necessary components, as a revision to the Ohio SIP.

A. Attainment Emissions Inventory

For maintenance plans, a State should develop a comprehensive and accurate inventory of actual emissions for an attainment year that identifies the level of emissions in an area sufficient to maintain the NAAQS. Ohio EPA submitted an attainment emission inventory which addresses the Campbell-Clermont, KY-OH maintenance area's base year emissions and projections of future emissions for point, mobile sources, and other area sources.

Ohio EPA is designating 2016 as its base year inventory for the second 10-year maintenance period. The base year inventory of 2016 represents a comprehensive, accurate, and current inventory of actual emissions that satisfies section 172(c)(3), due to the permanent shutdown of the Beckjord plant in 2014, which led to significant, permanent and enforceable SO_2 emissions reductions in the area. EPA also approved Ohio EPA's redesignation and first maintenance plan in 2016 (81 FR 83158, November 21, 2016). EPA finds using 2016 as the base year to be appropriate for the second 10-year period of the second maintenance plan submittal. The total SO_2 emissions for the Ohio portion of the Campbell-Clermont, KY-OH maintenance area for the 2014 attainment year were 32,610.56 tons per year (tpy). The total SO_2 emissions in the Campbell-Clermont, KY-OH maintenance area for the 2016 base year were 33.08 tpy, with 10.18 tpy from Ohio sources as shown in Table 1 below.

TABLE 1—2016 BASE YEAR SO_2 EMISSIONS FROM THE CAMPBELL-CLERMONT, KY-OH AREA

[tpy]

	EGU point	Non-EGU	Non-road	Other	On-road	Total
Ohio	0.00	0.10	2.83	6.31	0.94	10.18
Kentucky	0.00	2.06	0.85	15.46	4.53	22.90
Area Total	0.00	2.16	3.68	21.77	5.47	33.08

[1] Calcagni, John, Director, Air Quality Management Division, EPA Office of Air Quality Planning and Standards, ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' September 4, 1992. (Calcagni Memo)

B. Maintenance Demonstration

Ohio EPA is demonstrating maintenance through 2036 by showing that future emissions of SO_2 for the Campbell-Clermont, KY-OH area remain at or below attainment year emission levels. For the second maintenance period, 2036 is an appropriate year because it is 10 years beyond the first 10-year maintenance period. Ohio EPA projected the 2036 emissions inventory for the Campbell-Clermont, KY-OH on-road, non-road, and other source SO_2 emissions to 2036 (using 2032 as a surrogate) from the EPA's 2016 version 2 emissions modeling platform (2016 v2 EMP).[2] As emissions have been shown to be decreasing over time, the emissions for 2036 were assumed to be the same as 2032, which is a conservative assumption. Annual emissions data are derived from the 2017 National Emissions Inventory (NEI). EPA recognizes that the 2016v2 EMP was the most recently available emissions modeling platform available at the time of Ohio EPA's SIP development that included projected SO_2 emissions.[3] Consistent with the first 10-year maintenance plan, biogenic emissions are negligible and not included in the inventory summaries.

The first maintenance plan for the area did not establish emission budgets, since the area was first designated nonattainment based on emissions from nearby sources that have since shutdown.[4] Additionally, Ohio EPA conducted a review of U.S. census data to indicate the stagnant population growth in the Pierce Township area and project the 2036 population size. The area saw a decrease in population growth from 14.5% in 2000 to 2010 to 4.7% in 2010 to 2020. Further, according to Ohio EPA, the calculated expected population growth in the first 10-year maintenance plan submittal for the year 2020 was 15,146 for the Pierce Township area.[5] The 2020 U.S. Census data confirmed the actual 2020 population size to be 15,096.[6] Based on limited population growth and the permanent shutdown of sources that had contributed to the nonattainment status of the area, EPA did not consider an updated emissions budget to be necessary as part of the second maintenance plan submittal for the Campbell-Clermont, KY-OH area.

The 2036 second 10-year maintenance period emissions inventory for the Campbell-Clermont, KY-OH maintenance area is summarized in Table 2 below. The maintenance demonstration for the Campbell-Clermont, KY-OH area shows maintenance of the 2010 SO_2 NAAQS by providing emissions information to support the demonstration that future emissions of SO_2 will remain at or below the 2016 base year levels and 2014 attainment year levels, taking into account future source growth and implementation of future controls. Table 2 shows total SO_2 emissions in the Campbell-Clermont, KY-OH area are expected to decrease by 4.31 tpy between 2016 and 2036.

TABLE 2—2016 AND 2036 SECOND MAINTENANCE PERIOD COMBINED CAMPBELL-CLERMONT, KY-OH AREA SO_2 EMISSION INVENTORIES

[tpy]

Source category	2016 Base year	2036 Future year	Net-change (2016–2036)
Ohio:			
EGU Point	0.0	0.0	0.0
Non-EGU	0.10	0.14	0.04
Non-Road	2.83	1.38	−1.45
Other	6.31	6.26	−0.05
On-Road	0.94	0.36	−0.58
Total	10.18	8.14	−2.04
Kentucky:			
EGU Point	0.0	0.0	0.0
Non-EGU	2.06	2.07	0.01
Non-Road	0.85	0.43	−0.42
Other	15.46	15.46	0.0
On-Road	4.53	2.67	−1.86
Total	22.90	20.63	-2.27
Area Total	33.08	28.77	−4.31

C. Monitoring Network

The monitoring data for the Campbell-Clermont, KY-OH area is based on air quality data collected from the monitor located in Highland Heights, Campbell County, Kentucky. Monitoring data for the area from the Highland Heights monitor for the Campbell-Clermont, KY-OH area has been certified and recorded in EPA's Air Quality System database. Ohio EPA and Kentucky Division of Air Quality (DAQ) have committed to continue monitoring for SO_2 in the Campbell-Clermont, KY-OH area. Table 3 shows the 99th percentile results of the Campbell-Clermont area Highland Heights monitor, complete, quality-assured data. The overall 2021–2023 design value for the Campbell-Clermont, KY-OH area is 8 ppb, remaining well below the 2010 SO_2 NAAQS level of 75 ppb. For every 3-year period since the 2012–2014 design value period, the Highland Heights monitor has had a design value below the 2010 SO_2 NAAQS.

[2] The inventory documentation for the modeling platform can be found here: *https://www.epa.gov/air-emissions-modeling/2016v2-platform.*

[3] EPA released the 2022v1 Emissions Modeling Platform on October 21, 2024, which included analytic year SO_2 emissions inventories for the years 2026, 2032, and 2038. *See https://www.epa.gov/air-emissions-modeling/2022v1-emissions-modeling-platform.*

[4] *See* EPA Round 1 Ohio State Recommendation TSD: *https://www.epa.gov/sites/default/files/2016-03/documents/oh-epa-tsd.pdf.*

[5] *See* 81 FR 83158 (November 21, 2016), Campbell-Clermont KY-OH Area 2010 SO_2 Redesignation and Maintenance Plan submittal, Appendix C.

[6] *See https://data.census.gov/all?q=pierce+township,+ohio.*

TABLE 3—MONITORING DATA FOR THE CAMPBELL-CLERMONT, KY-OH MAINTENANCE AREA

AQS site	Location	Year (ppb)							
		2016	2017	2018	2019	2020	2021	2022	2023
21–037–3002	Campbell County, KY	12	16	9	8	10	9	9.9	4.8

Ohio EPA has committed to consult with Kentucky DAQ to continue the operation of an appropriate monitoring network. Kentucky DAQ is committed to monitoring SO_2 levels according to an EPA approved monitoring plan, as required to ensure maintenance of the 2010 SO_2 NAAQS. Should changes in the location of an SO_2 monitor become necessary, Kentucky DAQ has assured Ohio that it will consult with EPA prior to making changes to ensure the adequacy of the monitoring network and ensure compliance with 40 CFR part 58 and all other federal requirements. Kentucky DAQ has also assured Ohio EPA it will remain obligated to meet monitoring requirements and continue to qualify and assure monitoring data in accordance with 40 CFR part 58, and to enter all data into the Air Quality System (AQS) in accordance with Federal guidelines.

D. Verification of Continued Attainment

The 2014 SO_2 Guidance states each air agency should ensure that it has the legal authority to implement and enforce all measures necessary to attain and maintain the 2010 SO_2 NAAQS. The air agency's submittal should include how it will track progress of the maintenance plan for the area either through air quality monitoring or modeling.

Ohio EPA has the legal authority to enforce and implement the requirements of the maintenance plan for the Ohio portion of the Campbell-Clermont, KY-OH area. This includes the authority to adopt, implement, and enforce any subsequent emission control measures determined to be necessary to correct future SO_2 attainment problems. Also, Ohio EPA will continue to operate an approved SO_2 monitoring network in the Campbell-Clermont, KY-OH area. There are no plans to discontinue operation, relocate, or otherwise change the existing SO_2 monitoring network other than through revisions in the network approved by EPA.

To track future levels of emissions, Ohio EPA will continue to submit air emissions information annually in accordance with EPA's Air Emissions Reporting Rule (AERR) and submit to EPA updated emission inventories for all source categories at least once every three years, consistent with the requirements of 40 CFR part 51, subpart A, and in 40 CFR 51.122.

E. Contingency Plan

Section 175A of the CAA requires that the State adopt a maintenance plan, as a SIP revision, that includes such contingency measures as EPA deems necessary to ensure that the State will promptly correct a violation of the NAAQS that occurs after redesignation of the area to attainment of the NAAQS. The maintenance plan must identify: the contingency measures to be considered and, if needed for maintenance, adopted and implemented; a schedule and procedure for adoption and implementation; and, a timeframe for action by the State. The State should also identify specific indicators to be used to determine when the contingency measures need to be considered, adopted, and implemented. The maintenance plan must include a commitment that the State will implement all measures with respect to the control of the pollutant that were contained in the SIP before redesignation of the area to attainment in accordance with section 175A(d) of the CAA.

Ohio EPA has an active enforcement program to address any future violations and commits to continue operating a comprehensive program to identify violations of the 2010 SO_2 NAAQS. This includes aggressive follow-up for compliance and enforcement, and a commitment to implement necessary corrective actions in the event of a violation. Furthermore, if a new measure or control is already promulgated and scheduled to be implemented at the Federal or State level, and Ohio EPA determines it to be sufficient to address a 2010 SO_2 violation, local measures may be unnecessary. Ohio EPA will submit to EPA an analysis demonstrating the proposed measures are adequate to return the area to attainment.

Fully validated and quality assured SO_2 monitoring data will serve as the primary trigger for any responses to prevent or correct a NAAQS violation in the area. Ohio EPA has established both warning and action level responses, each with specific triggering indicators.

A warning level response will occur when the annual average 99th percentile daily maximum 1-hour SO_2 concentration of 79 ppb occurs in the area in a single calendar year. A warning level response will prompt a study to determine if the trigger indicates a trend toward increasing SO_2 concentrations in the Campbell-Clermont, KY-OH area. The study will help examine if there is a trend towards higher SO_2 values or emissions appear to be increasing and determine the control measures needed to reverse the trend. The implementation of controls will take place as expeditiously as possible but no later than 12 months from the conclusion of the most recent calendar year.

An action level response will occur when the two-year average of the 99th percentile daily maximum 1-hour SO_2 concentration of 76 ppb or greater occurs in the area. Additionally, a violation of the standard, where the three-year average of the 99th percentile daily maximum 1-hour value of SO_2 concentration is 75 ppb or higher, will also prompt an action level response. This response will require Ohio EPA, in conjunction with the metropolitan planning organization or regional council of governments, to determine additional control measures needed to ensure future attainment of the 2010 SO_2 NAAQS. Ohio will select measures that can be implemented within 18 months from the close of the calendar year that prompted an action level response. Ohio may also determine that significant new regulations not currently included as part of the maintenance provisions will be implemented in a timely manner and constitute an action level response.

Ohio EPA has specified the selected contingency measures will be adopted from a comprehensive list of measures deemed appropriate and effective at the time the selection is made. This list of measures will be based on cost-effectiveness, emission reduction potential, economic and social considerations or other factors deemed appropriate by Ohio EPA.

III. What action is EPA taking?

EPA is approving the second 10-year period SO_2 maintenance plan for the Pierce Township, Ohio portion of the

Campbell-Clermont counties, KY-OH 2010 SO_2 NAAQS maintenance area, submitted by Ohio EPA on November 7, 2024. EPA's review of the air quality for the maintenance area indicates continued attainment well below the level of the 2010 SO_2 NAAQS through 2036. EPA's approval of the maintenance plan will satisfy CAA section 175A requirements for the second 10-year maintenance period for the Ohio portion of the Campbell-Clermont, KY-OH area.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective September 15, 2025 without further notice unless we receive relevant adverse written comments by August 15, 2025. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective September 15, 2025.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rulemaking does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: July 1, 2025.

Cheryl Newton,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, title 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.1870, the table in paragraph (e) is amended under ''Summary of Criteria Pollutant Maintenance Plan'' by revising the entry for ''SO_2 (2010)'' to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED OHIO NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Title	Applicable geographical or non-attainment area	State date	EPA approval	Comments
*	*	*	*	*
Summary of Criteria Pollutant Maintenance Plan				
*	*	*	*	*
SO_2 (2010)	Campbell-Clermont (Pierce Township in Clermont County).	11/07/2024	7/16/2025, 90 FR [insert **Federal Register** page where the document begins].	2nd Maintenance Plan.
*	*	*	*	*

* * * * *

[FR Doc. 2025–13344 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2025–0268; FRL–12868–02–R9]

Air Plan Approval; Guam; Base Year Emissions Inventory for the 2010 1-Hour Sulfur Dioxide National Ambient Air Quality Standard for the Piti-Cabras Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to Guam's State Implementation Plan (SIP) under section 110(k)(3) of the Clean Air Act (CAA or ''the Act''). This revision concerns the base year emissions inventory for the Piti-Cabras, Guam sulfur dioxide (SO_2) nonattainment area (''Piti-Cabras area'' or NAA) for the 2010 1-hour SO_2 National Ambient Air Quality Standard (NAAQS, ''standard,'' or ''2010 SO_2 NAAQS'').

DATES: This rule is effective October 14, 2025 without further notice, unless the EPA receives adverse comments by August 15, 2025. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2025–0268 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Khoi Nguyen, Geographic Strategies and Modeling Section, Planning & Analysis Branch, Air & Radiation Division, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; telephone number: 415–947–4120; email address: *Nguyen.Khoi@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Background
II. Guam EPA's Base Year Emissions Inventory for the Piti-Cabras Nonattainment Area
III. The EPA's Evaluation
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I. Background

On June 22, 2010, the EPA published in the **Federal Register** a strengthened, primary 1-hour SO_2 NAAQS, establishing a new standard at a level of 75 parts per billion (ppb), based on the 3-year average of the annual 99th percentile of daily maximum 1-hour average concentrations of SO_2.[1] Following promulgation of a new or revised NAAQS, the EPA is required to designate all areas of the country as either ''attainment,'' ''nonattainment,'' or ''unclassifiable.'' [2] On December 21, 2017, the EPA signed a notice designating six areas in three States and two territories as nonattainment in the third round of SO_2 designations, effective April 9, 2018.[3] With that action, the EPA designated as nonattainment the portion of Guam within a 6.074-km radius centered on UTM Easting 249,601.60 m, and UTM Northing 1,489,602.00 m (UTM Zone 55N).[4]

The Piti-Cabras area is located on the western side of the island of Guam, centered on the Piti and Cabras power plants, which are both owned by Guam Power Authority (GPA). The Piti facility (also referred to as Marianas Energy Company (MEC) by Guam) consists of two baseload electric generating units (8 and 9). Piti 8 and 9 are two 45.2 megawatt (MW) diesel engines. The Cabras facility consists of two baseload electric generating units (1 and 2) that

[1] On June 2, 2010, the EPA signed the final rule titled, ''Primary National Ambient Air Quality Standard for Sulfur Dioxide,'' 75 FR 35520 (June 22, 2010), codified at 40 CFR part 50.

[2] CAA section 107(d)(1).

[3] 83 FR 1098 (January 9, 2018).

[4] For designations technical discussions, see the Technical Support Document, Chapter 11: Intended Round 3 Area Designations for the 2010 1-Hour SO_2 Primary National Ambient Air Quality Standard for Guam. EPA Office of Air and Radiation, December 2017, Section 3, 6–26, available in the docket for this action.

are 66 MW units. These facilities are the primary emitters of SO_2 in the area. Nearby, the Taiwan Electrical and Mechanical Engineering Services (TEMES) power plant (also referred to as ''Piti 7''),[5] and commercial and United States Navy (''Navy'') marine vessel ports are also significant emitters of SO_2. No other sources on or beyond the island were determined to have the potential to cause or contribute to significant impacts within the area of analysis. The Modeling Technical Support Document (TSD) included in the docket for this action accompanied a recent proposed Clean Data Determination for Piti-Cabras and contains more information on the facilities and emissions.[6]

Section 191 of the CAA directs states containing an area designated nonattainment for the 2010 SO_2 NAAQS to develop and submit a nonattainment area SIP to the EPA within 18 months of the effective date of an area's designation as nonattainment. The nonattainment area SIP revision (also referred to as an attainment plan) must meet the requirements of subparts l and 5 of part D, of Title 1 of the CAA, 42 U.S.C. 7401 *et seq.,* and provide for attainment of the NAAQS by the applicable statutory attainment date.[7] To be approved by the EPA, under section 192(a), these nonattainment area SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than five years from the effective date of designation.

The Guam Environmental Protection Agency (Guam EPA) was required to prepare and submit to the EPA a nonattainment area SIP by October 9, 2019, to bring the area into attainment by the attainment date of April 9, 2023. However, Guam EPA failed to submit a complete attainment plan for the area by the October 9, 2019 deadline. On November 3, 2020, the EPA issued a finding that Guam EPA failed to submit the required attainment plan for the Piti-Cabras area.[8] Pursuant to section 179 of the CAA and 40 CFR 52.31, the November 3, 2020 finding triggered sanctions clocks. More specifically, under 40 CFR 52.31, the offset sanction in CAA section 179(b)(2) would be imposed 18 months after December 3, 2020 effective date of the finding, and the highway funding sanction in CAA section 179(b)(1) would be imposed six months after the offset sanction was imposed, unless the EPA determined that a subsequent SIP submission corrected the identified deficiencies before the applicable deadlines.[9]

The finding also started a two-year clock by which the EPA is required under CAA section 110(c) to promulgate a Federal Implementation Plan (FIP) for the area, unless Guam EPA submits, and the EPA approves, a SIP for the area before December 3, 2022.

On December 19, 2024, the EPA issued a finding that the Piti-Cabras nonattainment area failed to attain the 2010 SO_2 NAAQS by the statutory attainment date of April 9, 2023.[10] This finding triggered a requirement for Guam EPA to submit a plan demonstrating attainment of the 2010 SO_2 NAAQS as expeditiously as practicable, but no later than December 19, 2029.[11] In that action, the EPA noted that the Guam's submission of a complete SO_2 attainment plan for the new attainment date in response to this finding of failure to attain would also address the Territory's existing obligations to submit an attainment plan for the 2010 SO_2 NAAQS.

On June 20, 2025, the EPA proposed to determine that the Piti-Cabras area is attaining the 2010 SO_2 NAAQS and qualifies for a Clean Data Determination (CDD) under the EPA's Clean Data Policy.[12] If the EPA finalizes the CDD, it would suspend the requirements for the Piti-Cabras area to submit an attainment demonstration and certain other associated nonattainment planning requirements for so long as the Piti-Cabras area continues to attain the 2010 SO_2 NAAQS. A final CDD would also suspend the EPA's obligation to promulgate a FIP and the sanctions clocks associated with the finding of failure to submit issued on November 3, 2020,[13] with regard to the attainment demonstration, demonstrations for reasonably available control measures and reasonably available control technology (RACM/RACT), reasonable further progress (RFP), emissions limitations and control measures as necessary to provide for attainment, and contingency measures. Guam EPA would still be required to submit an emissions inventory required by CAA section 172(c)(3) and a nonattainment new source review (NNSR) program required by CAA section 172(c)(5).[14]

II. Guam EPA's Base Year Emissions Inventory for the Piti-Cabras Nonattainment Area

Guam EPA submitted the emissions inventory element to the EPA on June 6, 2025.[15] The submittal is titled ''Guam Environmental Protection Agency Piti-Cabras SO_2 State Implementation Plan Emission Inventory Technical Support Document'' (''EI submittal''). In the EI submittal, Guam EPA reviewed and compiled actual emissions from sources of SO_2 in the Piti-Cabras area for the base year emissions inventory requirement. Guam's 2020 base year SO_2 emissions inventory for the Piti-Cabras area, by emission source category, is contained in Table 1 in this document.

Guam EPA estimated SO_2 emissions for point and non-point sources. The point source category was the largest SO_2 emissions source category. In 2020, GPA operated six energy generation units (EGUs) in the NAA, which contributed the majority of point source emissions. Additional point sources consisted of generators and boilers operated by the Department of Defense (DoD)/United States Navy (US Navy). SO_2 emissions from back-up generators operated by other commercial entities were assumed to be negligible due to their likely limited run hours and because, since 2011, Guam territorial law has required all diesel imported for distribution and sale to be ultra low sulfur diesel.[16] In the non-point source categories, port emissions were a significant contributor. The port of Guam receives vessel calls from both commercial and US Navy ships. Accordingly, Guam EPA estimated marine SO_2 emissions from commercial and U.S. Navy ships hoteling in the port. Guam EPA was unable to estimate emissions from other activities at the port, other non-point sources, and on-road and non-road mobile sources due to lack of data. However, we find that the emissions from these sources would have a negligible impact on the total SO_2 emissions in the NAA because of the ultra low sulfur diesel requirement. While exceptions were provided for certain EGUs and U.S. Navy sources, these sources are already reflected in the emissions inventory. In particular, the GPA EGUs are the largest emissions

[5] Piti/TEMES 7 is a 40 MW combustion turbine and is also owned by GPA.

[6] ''Technical Support Document (TSD) for the Piti-Cabras, Guam 2010 1-Hour SO_2 Nonattainment Area Clean Data Determination Modeling Analysis,'' EPA Region 9, June 2025.

[7] See sections 172 and 191–192 of the CAA.

[8] 85 FR 69504 (November 3, 2020).

[9] See 40 CFR 52.31(d)(5).

[10] 89 FR 103819.

[11] Id. at 103822.

[12] 90 FR 26235 (June 20, 2025).

[13] 85 FR 69504.

[14] Guam EPA submitted a SIP revision addressing NNSR on March 13, 2025. The EPA found this submittal complete and proposed to approve it into the SIP on June 18, 2025, 90 FR 25984.

[15] Letter dated June 6, 2025, from Michelle C. R. Lastimoza, Administrator, Guam EPA, to Josh F. W. Cook, Regional Administrator, U.S. Environmental Protection Agency Region 9 (submitted electronically June 6, 2025).

[16] 10 GCA section 49119.

source in the NAA, contributing 98 percent of the estimated annual total SO_2 emissions in 2020.

TABLE 1—ANNUAL SO_2 EMISSIONS IN THE PITI-CABRAS AREA IN 2020

Source category	Source description	Estimated SO_2 emissions 2020 (tons/year)
Point Sources	GPA EGUs	12,274.54
	DoD EGUs	0.0264
	DoD Boilers	9.04
Non-point Sources	Marine Sources	234.31
	Total	12,517.92

Source: EI submittal, Table 8.

All point source emissions were calculated using the EPA's AP–42 emissions factors [17] together with the sulfur content of the fuel, as determined by shipment records, and 2020 annual fuel consumption records (Table 2). For non-point sources, marine emissions from hoteling vessels were estimated using port of Guam annual vessel call reports and EPA emissions factors.[18]

TABLE 2—ANNUAL SO_2 EMISSIONS INVENTORY FOR GPA POWER PLANTS IN THE PITI-CABRAS AREA IN 2020

Guam power authority plant	Nominal power (megawatts)	Fuel sulfur content ($\%_{weight/weight}$)	SO_2 emissions 2020 (tons/year)
Piti 8	44.2	1.74 or 0.99	2791.74
Piti 9	44.2	1.74 or 0.99	2666.84
Cabras 1	66	1.74 or 0.99	3389.2
Cabras 2	66	1.74 or 0.99	3426.55
(TEMES) Piti 7	40	0.001	0.11
Tenjo Vista	26.4	0.001	0.1036
Total	286.80		12,274.54

Source: EI submittal, Table 1.

III. The EPA's Evaluation

We have reviewed Guam EPA's public notice and comment procedures in the EI submittal and find that Guam EPA's EI submittal meets the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

The EPA's 2014 SO_2 Nonattainment Guidance further describes the statutory elements comprising an SO_2 attainment plan. These requirements include submission of a comprehensive, accurate and current base year emissions inventory of all sources of SO_2 within the nonattainment area, per CAA section 172(c)(3).[19]

Guam EPA selected 2020 for the base year emissions inventory for the Piti-Cabras area, which is appropriate because it is a recent year that is representative of conditions leading to nonattainment. In particular, it is part of the three-year design value period for which the EPA determined that the Piti-Cabras area failed to attain the 2010 SO_2 NAAQS by its original attainment date.[20]

We find the emissions estimation methodologies employed in the EI submittal appropriate as they relied on the EPA's AP–42 and other recommended emissions factors and EPA emissions estimation guidance. All emission calculations, source data, and supporting documentations were included in the EI submittal.

In conclusion, the EPA has evaluated Guam EPA's EI submittal for the Piti-Cabras area and has determined that it was developed in a manner consistent with CAA section 172(c)(3) and with applicable EPA guidance.

IV. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, the EPA is fully approving the submitted base year emissions inventory based on our determination that it fulfills all relevant requirements. The EPA is approving Guam EPA's EI submittal as meeting the requirements of CAA section 172(c)(3). Specifically, we are finding that the submittal satisfies the base year emissions inventory requirement triggered by the December 19, 2024 finding of failure to attain, as well as the Territory's obligation to submit a base year inventory for the 2010 SO_2 NAAQS stemming from the EPA's designation of the area as nonattainment in 2017. With this final action, the emissions inventory element of the EPA's obligation as to this nonattainment area under the consent decree in *Center for Biological Diversity et al.* v. *Regan,* No. 4:24–cv–01900 (N.D. Cal.), doc. 28, paragraphs 1.c–d, 2, will also be met.

We do not anticipate that anyone will object to this approval, therefore, we are finalizing approval without first

[17] AP–42 is the primary compilation of the EPA's emissions factor information. See *https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors-stationary-sources.*

[18] Ports Emissions Inventory Guidance: Methodologies for Estimating Port-Related and Goods Movement Mobile Source Emissions. Office of Transportation and Air Quality, US EPA (April 2022).

[19] See ''Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions'' (April 23, 2014).

[20] 89 FR 103819, 103821–89 FR 103822 (December 19, 2024) (''the relevant three-year DV period for the April 9, 2023 attainment date was from 2020–2022'').

proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same emissions inventory submittal. If we receive adverse comments by August 15, 2025, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective October 14, 2025 without further notice. This will incorporate the submittal into the federally enforceable SIP.

Please note that if the EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, the EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 15, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Sulfur oxides.

Dated: July 7, 2025.

Joshua F.W. Cook,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AAA—Guam

■ 2. Section 52.2670 is amended by adding in paragraph (e), under the table heading ''EPA Approved Guam Nonregulatory Provisions and Quasi-Regulatory Measures'' an entry for ''Guam Environmental Protection Agency Piti-Cabras SO_2 State Implementation Plan Emission Inventory Technical Support Document'' after the entry for ''Appendix K: Inventory data for 1973.''

§ 52.2670 Identification of plan.

* * * * *

(e) * * *

EPA Approved Guam Nonregulatory Provisions and Quasi-Regulatory Measures

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
Implementation Plan for Compliance With the Ambient Air Quality Standards For Territory of Guam				
*	*	*	*	*
Guam Environmental Protection Agency Piti-Cabras SO_2 State Implementation Plan Emission Inventory Technical Support Document.	Piti-Cabras Nonattainment Area.	June 6, 2025	7/16/2025, 90 FR [Insert **Federal Register** page where the document begins].	Submitted on June 6, 2025 as an attachment to a letter dated June 6, 2025.

[FR Doc. 2025–13328 Filed 7–15–25; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2025–0076; FRL–12691–02–R1]

Air Plan Approval; Connecticut; 2017 Base Year Emissions Inventory for the 2015 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted by the State of Connecticut that relate to the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS). The SIP revisions are for the Greater Connecticut and the Connecticut portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT ozone nonattainment areas. This action will approve submittals which include the 2017 base year emissions inventories for these two nonattainment areas for the 2015 Ozone National Ambient Air Quality Standard. This action is being taken under the Clean Air Act (CAA).

DATES: This rule is effective on August 15, 2025.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R01–OAR–2025–0076. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection.

FOR FURTHER INFORMATION CONTACT: Patrick Lillis, Air and Radiation Division (Mail Code 5–MI), U.S. Environmental Protection Agency—Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts, 02109–3912; telephone number: (617) 918–1067, email address: *lillis.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. Background
II. Response to Comments
III. Final Action
IV. Statutory and Executive Order Reviews

I. Background

The Notice of Proposed Rulemaking (NPRM) proposed approval of SIP revisions submitted by the State of Connecticut that relate to the 2015 Ozone National Ambient Air Quality Standards. The SIP revisions included the 2017 base year emissions inventories for the Greater Connecticut and the Connecticut portion of the New York–Northern New Jersey–Long Island, NY–NJ–CT ozone nonattainment areas. We proposed to find that the emissions inventories were prepared in accordance with the requirements of CAA sections 172(c)(3) and 182(a)(1). The EPA is now finalizing the proposed approval of Connecticut's 2017 base year emissions inventories for the 2015 Ozone NAAQS.

II. Response to Comments

EPA received four comments during the comment period, all of which are available in the docket for this rulemaking action. Three of the comments urge EPA to take the action proposed: to approve Connecticut's base year emissions inventories. One of these three also raises additional topics outside the scope of the current action. That comment includes recommendations to ''enhance the effectiveness'' of the base year emission inventory. However, those recommendations are not within the scope of EPA's approval. For example, one recommendation is to ensure regular updates to emission inventories. This EPA action concerns a base year inventory submitted in accordance with CAA sections 172(c)(3) and 182(a)(1). The requirement to submit a revised inventory is separate from the base year inventory. See CAA section 182(a)(3)(A). Since this action does not entail any revised inventory, this recommendation is out of scope. Similarly, the other recommendations concerning stronger enforcement mechanism and public awareness campaigns are unrelated to the base year inventory. The fourth comment focuses mainly on a recommendation for reducing ozone levels with catalytic converters that is outside the scope of the current action. In addition, the comments do not assert, or explain how, EPA approval of this action would be erroneous or otherwise inconsistent with the CAA, applicable regulations, or other authorities. As such, the comments require no further response to finalize the action as proposed.

III. Final Action

For the reasons described in our April 7, 2025, notice of proposed rulemaking,[1] EPA is taking final action to approve Connecticut's 2017 base year emissions inventories for the 2015 ozone NAAQS as a revision to the Connecticut SIP.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

[1] 90 FR 14935.

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 15, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 30, 2025.

Mark Sanborn,

Regional Administrator, EPA Region 1.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52 of chapter I, title 40 of the Code of Federal Regulations to read as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart H-Connecticut

■ 2. Section 52.370 is amended by adding paragraph (c)(137) to read as follows:

§ 52.370 Identification of plan.

* * * * *

(c) * * *

(137) Revisions to the State Implementation Plan submitted by the Connecticut Department of Energy and Environmental Protection on May 3, 2024

(i) [Reserved]

(ii) *Additional materials.*

(A) Letter from the Connecticut Department of Energy and Environmental Protection, dated May 3, 2024, submitting revision to the Connecticut State Implementation Plan.

(B) [Reserved]

■ 3. Section 52.384 is amended by adding paragraph (f) to read as follows:

§ 52.384 Emission inventories.

* * * * *

(f) The State of Connecticut submitted base year emission inventories representing emissions for calendar year 2017 from the Connecticut portion of the NY–NJ–CT moderate 8-hour ozone nonattainment area and the Greater Connecticut marginal 8-hour ozone nonattainment area on May 3, 2024, as revisions to the State's SIP. The 2017 base year emission inventory requirement of section 182(a)(1) of the Clean Air Act, as amended in 1990, has been satisfied for these areas. The inventories consist of emission estimates of volatile organic compounds and nitrogen oxides, and cover point, area, non-road mobile, on-road mobile and biogenic sources. The inventories were submitted as revisions to the SIP in partial fulfillment of obligations for nonattainment areas under EPA's 2015 8-hour ozone standard.

[FR Doc. 2025–13331 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2024–0256; FRL–12021–01–R2]

Air Plan Approval; New Jersey; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: The Environmental Protection Agency (EPA) is updating the regulatory materials incorporated by reference into the New Jersey State Implementation Plan (SIP). The regulations affected by this action have been previously submitted by the New Jersey Department of Environmental Protection (NJDEP) and approved by the EPA in prior rulemakings. The EPA is also notifying the public of corrections to the Code of Federal Regulations (CFR) tables that identify material incorporated by reference into the New Jersey SIP. This update affects the materials that are available for public inspection at the EPA Regional Office.

DATES: This action is effective July 16, 2025.

ADDRESSES: SIP materials whose incorporated by reference into 40 CFR part 52 is finalized through this action are available for inspection at the following locations: online at *https://www.regulations.gov* in the docket for this action, by appointment at the Environmental Protection Agency, Region 2, 290 Broadway, New York, New York 10007–1866. For information on the availability of this material at the EPA Regional Office, please contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Linda Longo, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866, telephone number: (212) 637–3565, email address: *longo.linda@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Each state has a SIP containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS). The SIP is extensive, containing such elements as air pollution control regulations, emission inventories, monitoring networks, attainment

demonstrations, and enforcement mechanisms.

Each state must formally adopt the control measures and strategies in the SIP after the public has had an opportunity to comment on them and then submit the proposed SIP revisions to the EPA. Once these control measures and strategies are approved by the EPA, and after notice and comment, they are incorporated into the federally approved SIP and are identified in part 55, ''Approval and Promulgation of Implementation Plans,'' Title 40 of the Code of Federal Regulations (40 CFR part 52). The full text of the state regulation approved by the EPA is not reproduced in its entirety in 40 CFR part 52 but is ''incorporated by reference.'' This means that EPA has approved a given state regulation or specified changes to a given regulation with a specific effective date. The public is referred to the location of the full text version should they want to know which measures are contained in each SIP. The information provided allows the EPA and the public to monitor the extent to which a state implements a SIP to attain and maintain the NAAQS and to take enforcement action for violations of the SIP.

The SIP is a living document which the state can revise as necessary to address the unique air pollution problems in the state. Therefore, the EPA from time to time must take action on proposed revisions containing new and/or revised regulations. A submission from a state can revise one or more rules in their entirety or portions of rules. The state indicates the changes in the submission (such as by using redline/strikethrough text) and the EPA then takes action on the requested changes. The EPA establishes a docket for its actions using a unique Docket Identification Number, which is listed in each action. These dockets and the complete submission are available for viewing on *https://www.regulations.gov.*

On May 22, 1997 (62 FR 27968), the EPA revised the procedures for incorporating by reference, into the CFR, materials approved by the EPA into each state SIP. These changes revised the format for the identification of the SIP in 40 CFR part 52, streamlined the mechanisms for announcing the EPA approval of revisions to a SIP, and streamlined the mechanisms for the EPA's updating of the IBR information contained for each SIP in 40 CFR part 52. The revised procedures also called for the EPA to maintain ''SIP Compilations'' that contain the federally approved regulations and source-specific permits submitted by each state agency. The EPA generally updates these SIP Compilations on an annual basis. Under the revised procedures, the EPA must periodically publish an informational document in the rules section of the **Federal Register** notifying the public that updates have been made to a SIP Compilation for a particular state. The EPA began applying the 1997 revised procedures to New Jersey on July 3, 2017, and is providing this notice in accordance with such procedures. *See* 82 FR 30758 (July 3, 2017).

II. EPA Action

In this action, the EPA is providing notice of an update to the materials incorporated by reference into the New Jersey SIP as of March 31, 2025, and identified in 40 CFR 52.1570(c) and (d). This update includes SIP materials approved by the EPA since the last IBR update. *See,* 82 FR 30758 (July 3, 2017). The EPA is providing notice of the following corrections to 40 CFR 52.1570(c) and (d):

Changes Applicable to Paragraph (c), EPA-Approved New Jersey State Regulations and Laws

A. Revising the following:

(a) Title 7, Chapter 27, Subchapter 7, Sulfur
(b) Title 7, Chapter 27, Subchapter 7.2(k), Commercial fuel exemption
(c) Title 7, Chapter 27, Subchapter 8, Permits and Certificates for minor facilities (and major facilities without an operating permit)
(d) Title 7, Chapter 27, Subchapter 12, Prevention and Control of Air Pollution Emergencies
(e) Title 7, Chapter 27, Subchapter 14, section 14.1, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Definitions
(f) Title 7, Chapter 27, Subchapter 14, section 14.2, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Applicability
(g) Title 7, Chapter 27, Subchapter 14, section 14.3, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/General prohibitions
(h) Title 7, Chapter 27, Subchapter 14, section 14.4, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/General public highway standards
(i) Title 7, Chapter 27, Subchapter 14, section 14.5, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Motor vehicle inspections
(j) Title 7, Chapter 27, Subchapter 14, section 14.6, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Motor vehicle standards
(k) Title 7, Chapter 27, Subchapter 14, section 14.7, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Licensed emissions inspectors
(l) Title 7, Chapter 27, Subchapter 14, section 14.10, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Penalties
(m) Title 7, Chapter 27, Subchapter 14, appendix, Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/appendix
(n) Title 7, Chapter 27, Subchapter 15, Control and Prohibition of Air Pollution from Gasoline-Fueled Motor Vehicles/Definition
(o) Title 7, Chapter 27, Subchapter 16, Control and Prohibition of Air Pollution by Volatile Organic Compounds
(p) Title 7, Chapter 27, Subchapter 17, Control and Prohibition of Air Pollution by Toxic Substances
(q) Title 7, Chapter 27, Subchapter 18, Control and Prohibition of Air Pollution from New or Altered Sources Affecting Ambient Air Quality (Emission Offset Rules)
(r) Title 7, Chapter 27, Subchapter 19 Control and Prohibition of Air Pollution from Oxides of Nitrogen
(s) Title 7, Chapter 27, Subchapter 21, Emission Statements
(t) Title 7, Chapter 27A, Subchapter 3, section 3.10, Civil Administrative Penalties for Violations of Rules Adopted Pursuant to the Act
(u) Title 7, Chapter 27B, Subchapter 4, sections 4.1–4.3 and sections 4.6–4.8, Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles
(v) Title 7, Chapter 27B, Subchapter 5, Air Test Method 5: Testing Procedures for Gasoline-Fueled Motor Vehicles
(w) Title 13, Chapter 20, Subchapters 7.1–7.6, Vehicle Inspections
(x) Title 13, Chapter 20, Subchapter 26, sections 26.2 and 26.11–12 and 26.16–17, Compliance with Diesel Emission Standards and Equipment, Periodic Inspection Program for Diesel Emissions, and Self-Inspection of Certain Classes of Motor Vehicles
(y) Title 13, Chapter 20, Subchapter 32, Inspection Standards and Test Procedures to be Used by Official Inspection Facilities
(z) Title 13, Chapter 20, Subchapter 33, Inspection Standards and Test Procedures to be Used by Licensed Private Inspection Facilities
(aa) Title 13, Chapter 20, Subchapter 43, Enhanced Motor Vehicle Inspection and Maintenance Program
(ab) Title 13, Chapter 20, Subchapter 44, Private Inspection Facility Licensing

(ac) N.J.S.A. 52:13D–14, New Jersey's Conflict of Interest Law
(ad) N.J.S.A. 52:13D–16(a)-(b), New Jersey's Conflict of Interest Law
(ae) N.J.S.A. 52:13D–21(n), New Jersey's Conflict of Interest Law

B. Removing the following:
(a) Title 7, Chapter 27, Subchapter 8, Permits and Certificates, Hearings, and Confidentiality
(b) Title 7, Chapter 27, section 8.1, Definitions
(c) Title 7, Chapter 27, section 8.2, Applicability
(d) Title 7, Chapter 27, section 8.11, Permits and Certificates, Hearings, and Confidentiality
(e) Title 7, Chapter 27, Subchapter 30, Clean Air Interstate Rule (CAIR) NOx Trading Program
(f) Title 7, Chapter 27, Subchapter 31, NOx Budget Program
(g) Title 7, Chapter 27, Subchapter 34, TBAC Emissions Reporting

C. No changes to the following:
(a) Title 7, Chapter 26, Subchapter 2A
(b) Title 7, Chapter 27, Subchapter 1
(c) Title 7, Chapter 27, Subchapter 2
(d) Title 7, Chapter 27, Subchapter 3
(e) Title 7, Chapter 27, Subchapter 4
(f) Title 7, Chapter 27, Subchapter 5
(g) Title 7, Chapter 27, Subchapter 6
(h) Title 7, Chapter 27, Subchapter 9
(i) Title 7, Chapter 27, Subchapter 10
(j) Title 7, Chapter 27, Subchapter 11
(k) Title 7, Chapter 27, Subchapter 13
(l) Title 7, Chapter 27, Subchapter 23
(m) Title 7, Chapter 27, Subchapter 24
(n) Title 7, Chapter 27, Subchapter 25
(o) Title 7, Chapter 27, Subchapter 26
(p) Title 7, Chapter 27, Subchapter 29
(q) Title 7, Chapter 27B, Subchapter 3
(r) Title 13, Chapter 20, Subchapter 24, section 20
(s) Title 13, Chapter 20, Subchapter 28, sections 28.3, 28.4 and 28.6
(t) Title 13, Chapter 20, Subchapter 29, sections 29.1, 29.2 and 29.3
(u) Title 13, Chapter 20, Subchapter 45
(v) Title 13, Chapter 21, Subchapter 5, section 5.12
(w) Title 13, Chapter 21, Subchapter 15, sections 15.8 and 15.12
(x) Title 16, Chapter 53
(y) Title 39, Chapter 8, Subchapter 1
(z) Title 39, Chapter 8, Subchapter 2
(aa) Title 39, Chapter 8, Subchapter 3

Changes Applicable to Paragraph (d), EPA-Approved New Jersey Source-Specific Provisions

A. Adding the following:
(a) Transcontinental Gas Pipelines Corp., LNG Station 240, PI 02626
(b) Joint Base McGuire-Dix-Lakehurst (Lakehurst, NJ), BOP 15001
(c) Gerdau Ameristeel Sayreville, PI 18052, BOP 150001, U2, 2
(d) CMC Steel New Jersey, PI 18052, BOP 180001, U2, 2
(e) Paulsboro Refinery, PI 55829, BOP 180002, U900
(f) Buckeye Port Reading Terminal, PI 17996, BOP 160001, U8
(g) Buckeye Pennsauken Terminal, PI 51606, BOP 130002, U1
(h) Phillips 66 Company Linden, PI 41805, BOP 170004, U16
(i) CMC Steel, PI 18052, BOP 150002, U1

B. No changes to the following:
(a) Johnson Matthey
(b) Sandoz Pharmaceuticals Corporation
(c) PSEG Fossil Hudson Generation Station
(d) Conoco Phillips (Facility is now Phillips 66.)
(e) Vineland Municipal Electric Utility—Howard M. Down
(f) BL England Generating Station (Facility is now RC Cape May.)
(g) Atlantic States Cast Iron Pipe Company
(h) Trigen-Trenton Energy Co
(i) PSE&G Nuclear Hope Creek and Salem Generating Stations Cooling Tower
(j) Co-Steel Corp of Sayreville (Formerly New Jersey Steel Corporation)

III. Good Cause Exemption

The EPA has determined that this action falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make an action effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). This administrative action simply codifies provisions which are already in effect as a matter of law in Federal and approved state programs, makes typographical/ministerial revisions to the tables in the CFR, and makes ministerial changes to the prefatory heading to the tables in the CFR. Under section 553(b)(3)(B) of the APA, an agency may find good cause where procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Public comment for this administrative action is ''unnecessary'' and ''contrary to the public interest'' since the codification (and corrections) only reflect existing law. Immediate notice of this action in the **Federal Register** benefits the public by providing the public notice of the updated New Jersey SIP Compilation and notice of corrections to the New Jersey ''Identification of Plan'' portion of the CFR. Further, pursuant to section 553(d)(3), making this action immediately effective benefits the public by immediately updating both the SIP Compilation and the CFR ''Identification of plan'' section (which includes table entry corrections).

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of regulations promulgated by New Jersey, previously approved by the EPA and federally effective as of March 31, 2025, contained in New Jersey SIP Compilation. The EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 2 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Review

Under the Clean Air Act (CAA), the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this final rule and notification of administrative change does not impose additional requirements beyond those imposed by the State law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866:
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications, and it will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

This action is subject to the Congressional Review Act (CRA), and the EPA will submit a rule report to each House of the Congress and the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 15, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference.

Authority: 42 U.S.C. 7401 *et seq.*

Michael Martucci,

Regional Administrator, Region 2.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart FF—New Jersey

■ 2. In § 52.1570, revise paragraphs (b)(1) and (3), (c), and (d) to read as follows:

§ 52.1570 Identification of plan.

* * * * *

(b) * * *

(1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date as of March 31, 2025, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval and notification of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with the EPA approval dates after March 31, 2025, have been approved by EPA for inclusion in the State implementation plan and for incorporation by reference into the plan as it is contained in this section, and will be considered by the Director of the Federal Register for approval in the next update to the SIP compilation.

* * * * *

(3) Copies of the materials incorporated by reference into the state implementation plan may be inspected at the Environmental Protection Agency, Region 2, Air Programs Branch, 290 Broadway, New York, New York 10007. To obtain the material, please call the Regional Office at 212–637–3322. You may view material with an approval date as of March 31, 2025, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *https://www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

(c) *EPA approved regulations.*

EPA-APPROVED NEW JERSEY STATE REGULATIONS AND LAWS

State citation	Title/subject	State effective date	EPA approval date	Comments
Title 7, Chapter 26, Subchapter 2A.	Additional, Specific Disposal Regulations for Sanitary Landfills.	June 1, 1987	June 29, 1990, 55 FR 26687.	
Title 7, Chapter 27, Subchapter 1.	General Provisions	May 1, 1956	May 31, 1972, 37 FR 10880.	
Title 7, Chapter 27, Subchapter 2.	Control and Prohibition of Open Burning.	June 8, 1981	September 30, 1981, 46 FR 47779.	
Title 7, Chapter 27, Subchapter 3.	Control and Prohibition of Smoke from Combustion of Fuel.	October 12, 1977	January 27, 1984, 49 FR 3463.	
Title 7, Chapter 27, Subchapter 4.	Control and Prohibition of Particles from Combustion of Fuel.	April 20, 2009	August 3, 2010, 75 FR 45483.	
Title 7, Chapter 27, Subchapter 5.	Prohibition of Air Pollution	October 12, 1977	January 27, 1984, 49 FR 3463.	
Title 7, Chapter 27, Subchapter 6.	Control and Prohibition of Particles from Manufacturing Processes (except section 6.5).	May 23, 1977	January 26, 1979, 44 FR 5425.	Section 6.5, ''Variances,'' is not approved (40 CFR 52. 52.1587(c)(20) and 52.1604(a)). Any State-issued variances must be formally incorporated as SIP revisions if EPA is to be bound to their provisions (40 CFR 52.1604(a)).
Title 7, Chapter 27, Subchapter 7.	Sulfur	March 1, 1967	May 31, 1972, 37 FR 10880.	Subchapter 7.2(k) is no longer approved due to EPA action on August 1, 2022, 87 FR 46890.
Title 7, Chapter 27, Subchapter 7.2(k).	Commercial fuel exemption.	November 6, 2017	August 1, 2022, 87 FR 46890.	
Title 7, Chapter 27, Subchapter 8.	Permits and Certificates for minor facilities (and major facilities without an operating permit).	August 23, 2018	February 28, 2025, 90 FR 10872.	• Section 8.1 was previously approved into the State's Federally approved SIP on November 28, 2023 (88 FR 83036). • The following provisions are not approved: (1) five odor provisions at 8.2(d)(3)(ii)(2), 8.2(e)(2)(ii), 8.3(j), 8.4(k)(2), and 8.4(q); as well as (2) an affirmative defense provision at 8.3(n).

EPA-APPROVED NEW JERSEY STATE REGULATIONS AND LAWS—Continued

State citation	Title/subject	State effective date	EPA approval date	Comments
Title 7, Chapter 27, Subchapter 9.	Sulfur in Fuels	September 20, 2010 ..	January 3, 2012, 77 FR 19.	Sulfur dioxide ''bubble'' permits issued by the State pursuant to section 9.2 and not waived under the provisions of section 9.4 become applicable parts of the SIP only after receiving EPA approval as a SIP revision.
Title 7, Chapter 27, Subchapter 10.	Sulfur in Solid Fuels	April 20, 2009	August 3, 2010, 75 FR 45483.	Notification of ''large zone 3 coal conversions'' must be provided to EPA (40 CFR 52.1601(b)).
Title 7, Chapter 27, Subchapter 11.	Incinerators	August 15, 1968	May 31, 1972, 37 FR 10880.	
Title 7, Chapter 27, Subchapter 12.	Prevention and Control of Air Pollution Emergencies.	May 20, 1974	May 30, 2018, 83 FR 24661.	
Title 7, Chapter 27, Subchapter 13.	Ambient Air Quality Standards.	June 25, 1985	November 25, 1986, 51 FR 42565.	
Title 7, Chapter 27, Subchapter 14, section 14.1.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Definitions.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.2.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Applicability.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.3.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/General prohibitions.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.4.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/General public highway standards.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.5.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Motor vehicle inspections.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.6.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Motor vehicle standards.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.7.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Licensed emissions inspectors.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, section 14.10.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/Penalties.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 14, appendix.	Control and Prohibition of Air Pollution from Diesel-Powered Motor Vehicles/appendix.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 15.	Control and Prohibition of Air Pollution from Gasoline-Fueled Motor Vehicles/Definition.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27, Subchapter 16.	Control and Prohibition of Air Pollution by Volatile Organic Compounds.	January 16, 2018	November 28, 2023, 88 FR 83036.	
Title 7, Chapter 27, Subchapter 17.	Control and Prohibition of Air Pollution by Toxic Substances.	January 16, 2018	November 28, 2023, 88 FR 83036.	
Title 7, Chapter 27, Subchapter 18.	Control and Prohibition of Air Pollution from New or Altered Sources Affecting Ambient Air Quality (Emission Offset Rules).	November 6, 2017	November 28, 2023, 88 FR 83036.	
Title 7, Chapter 27, Subchapter 19.	Control and Prohibition of Air Pollution by Oxides of Nitrogen.	January 16, 2018	November 28, 2023, 88 FR 83036.	Subchapter 19 is approved into the SIP except for the following provisions: (1) Phased compliance plan through repowering in section 19.21 that allows for implementation beyond May 1, 1999; and (2) phased compliance plan through the use of innovative control technology in section 19.23 that allows for implementation beyond May 1, 1999.

EPA-APPROVED NEW JERSEY STATE REGULATIONS AND LAWS—Continued

State citation	Title/subject	State effective date	EPA approval date	Comments
Title 7, Chapter 27, Subchapter 21.	Emission Statements	January 16, 2018	November 28, 2023, 88 FR 83036.	Section 7:27–21.3(b)(1) and 7:27–21.3(b)(2) of New Jersey's Emission Statement rule requires facilities to report on the following pollutants to assist the State in air quality planning needs: Hydrochloric acid, hydrazine, methylene chloride, tetrachloroethylene, 1, 1, 1 trichloroethane, carbon dioxide and methane. EPA will not take SIP-related enforcement action on these pollutants.
Title 7, Chapter 27, Subchapter 23.	Prevention of Air Pollution from Architectural Coatings.	December 29, 2008 ...	December 22, 2010, 75 FR 80340.	
Title 7, Chapter 27, Subchapter 24.	Prevention of Air Pollution from Consumer Products.	December 29, 2008 ...	December 22, 2010, 75 FR 80340.	
Title 7, Chapter 27, Subchapter 25.	Control and Prohibition of Air Pollution by Vehicular Fuels.	December 29, 2008 ...	December 22, 2010, 75 FR 80340.	
Title 7, Chapter 27, Subchapter 26.	Prevention of Air Pollution from Adhesives, Sealants, Adhesive Primers and Sealant Primers.	December 29, 2008 ...	December 22, 2010, 75 FR 80340.	
Title 7, Chapter 27, Subchapter 29.	Low Emission Vehicle (LEV) Program.	January 17, 2006	February 13, 2008, 73 FR 8200.	In section 29.13(g), Title 13, Chapter 1, Article 2, section 1961.1 of the California Code of Regulations relating to greenhouse gas emission standards, is not incorporated into the SIP.
Title 7, Chapter 27A, Subchapter 3, section 3.10.	Civil Administrative Penalties for Violations of Rules Adopted Pursuant to the Act.	January 16, 2018	November 28, 2023, 88 FR 83036.	
Title 7, Chapter 27B, Subchapter 3.	Air Test Method 3: Sampling and Analytic Procedures for the Determination of Volatile Organic Compounds from Source Operations.	June 20, 1994	August 7, 1997, 62 FR 42412.	
Title 7, Chapter 27B, Subchapter 4, section 4.1.	Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27B, Subchapter 4, section 4.2.	Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27B, Subchapter 4, section 4.3.	Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27B, Subchapter 4, section 4.6.	Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27B, Subchapter 4, section 4.7.	Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27B, Subchapter 4, section 4.8.	Air Test Method 4: Testing Procedures for Diesel-Powered Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 7, Chapter 27B, Subchapter 5.	Air Test Method 5: Testing Procedures for Gasoline-Fueled Motor Vehicles.	October 3, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 7.1.	Vehicle Inspections	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 7.2.	Vehicle Inspections	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 7.3.	Vehicle Inspections	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 7.4.	Vehicle Inspections	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 7.5.	Vehicle Inspections	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 7.6.	Vehicle Inspections	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 24, section 20.	Motorcycles	October 19, 2009	March 15, 2012, 77 FR 15263.	

EPA-APPROVED NEW JERSEY STATE REGULATIONS AND LAWS—Continued

State citation	Title/subject	State effective date	EPA approval date	Comments
Title 13, Chapter 20, Subchapter 26, section 26.2.	Compliance with Diesel Emission Standards and Equipment, Periodic Inspection Program for Diesel Emissions, and Self-Inspection of Certain Classes of Motor Vehicles.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 26, section 26.11.	Compliance with Diesel Emission Standards and Equipment, Periodic Inspection Program for Diesel Emissions, and Self-Inspection of Certain Classes of Motor Vehicles.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 26, section 26.12.	Compliance with Diesel Emission Standards and Equipment, Periodic Inspection Program for Diesel Emissions, and Self-Inspection of Certain Classes of Motor Vehicles.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 26, section 26.16.	Compliance with Diesel Emission Standards and Equipment, Periodic Inspection Program for Diesel Emissions, and Self-Inspection of Certain Classes of Motor Vehicles.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 26, section 26.17.	Compliance with Diesel Emission Standards and Equipment, Periodic Inspection Program for Diesel Emissions, and Self-Inspection of Certain Classes of Motor Vehicles.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 28, sections 28.3, 28.4 and 28.6.	Inspection of New Motor Vehicles.	October 19, 2009	March 15, 2012, 77 FR 15263.	
Title 13, Chapter 20, Subchapter 29, sections 29.1, 29.2 and 29.3.	Mobile Inspection Unit	October 19, 2009	March 15, 2012, 77 FR 15263.	
Title 13, Chapter 20, Subchapter 32.	Inspection Standards and Test Procedures to be Used by Official Inspection Facilities.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 33.	Inspection Standards and Test Procedures to be Used by Licensed Private Inspection Facilities.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 43.	Enhanced Motor Vehicle Inspection and Maintenance Program.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 44.	Private Inspection Facility Licensing.	April 26, 2016	May 9, 2018, EPA approval finalized at 83 FR 21174.	
Title 13, Chapter 20, Subchapter 45.	Motor Vehicle Emission Repair Facility Registration.	October 19, 2009	March 15, 2012, 77 FR 15263.	
Title 13, Chapter 21, Subchapter 5, section 5.12.	Registration Plate Decals	December 6, 1999	January 22, 2002, 67 FR 2811.	
Title 13, Chapter 21, Subchapter 15, sections 15.8 and 15.12.	New Jersey Licensed Motor Vehicle Dealers.	October 19, 2009	March 15, 2012, 77 FR 15263.	
Title 16, Chapter 53	Autobus Specifications	September 26, 1983 ..	June 13, 1986, 51 FR 21549.	Only sections 3.23, 3.24, 3.27, 6.15, 6.21, 6.30, 7.14, 7.17, 7.23, 8.15, 8.22, 8.25 are approved.
Title 39, Chapter 8, Subchapter 1.	Motor Vehicle Inspections Exceptions.	July 1, 2010	March 15, 2012, 77 FR 15263.	
Title 39, Chapter 8, Subchapter 2.	Inspection of Motor Vehicles; Rules, Regulations.	July 1, 2010	March 15, 2012, 77 FR 15263.	
Title 39, Chapter 8, Subchapter 3.	Certificate of Approval, Issuance; Owner's Obligation for Safety.	July 1, 2010	March 15, 2012, 77 FR 15263.	
N.J.S.A. 52:13D–14	New Jersey's Conflict of Interest Law.	January 11, 1972	May 30, 2018, 83 FR 24661.	
N.J.S.A.52:13D–16(a)–(b)	New Jersey's Conflict of Interest Law.	September 16, 1996 ..	May 30, 2018, 83 FR 24661.	

EPA-APPROVED NEW JERSEY STATE REGULATIONS AND LAWS—Continued

State citation	Title/subject	State effective date	EPA approval date	Comments
N.J.S.A. 52:13D–21(n)	New Jersey's Conflict of Interest Law.	March 15, 2006	May 30, 2018, 83 FR 24661.	

(d) *EPA approved State source-specific requirements.*

EPA-APPROVED NEW JERSEY SOURCE-SPECIFIC PROVISIONS

Name of source	Identifier No.	State effective date	EPA approval date	Comments
Johnson Matthey	55270	June 13, 1995	January 17, 1997, 62 FR 2581.	NO_X RACT Facility Specific NO_X Emission Limits NJAC 7:27–9.13. Multi-chamber metals recovery furnace, installation of low NO_X burner.
Sandoz Pharmaceuticals Corporation.	104855	March 23, 1995	January 17, 1997, 62 FR 2581.	NO_X RACT Facility Specific NO_X Emission Limits NJAC 7:27–9.13. Controlled air combustion small trash from fired boiler energy recovery system.
PSEG Fossil Hudson Generation Station.	BOP110001	March 8, 2011	January 3, 2012, 77 FR 19.	NO_X, SO_2, PM_{10} BART source specific control units: U1–OS1 (cyclone boiler (shutdown)), U1–OS2 (dry bottom wall-fired boiler), U15–OS(coal receiving system), U16–OS (coal reclaim system).
Conoco Phillips (Facility is now Phillips 66.).	BOP110001	September 21, 2011	January 3, 2012, 77 FR 19.	NO_X, SO_2 and PM_{10} BART source specific control units: OS1–E241, OS2–E243, OS3–E245, OS4–E246, OS5–E247, OS6–E248, OS7–E249, OS8–E250, OS11–E242, OS13–E253, and OS15–E258 (process heaters).
Vineland Municipal Electric Utility—Howard M. Down.	BOP110001	September 26, 2011	January 3, 2012, 77 FR 19.	NO_X, SO_2 and PM_{10} BART source specific control units: U10–OS2(fuel oil boiler retired September 1, 2012), U10–OS3 (turbine (shutdown)), and U22–OS (emergency generator).
BL England Generating Station (Facility is now RC Cape May.).	BOP100003	December 16, 2010 ..	January 3, 2012, 77 FR 19.	NO_X, SO_2 and PM_{10} BART source specific control units: U1–OS1(wet bottom coal-fired boiler (shutdown)), U2–OS1 (cyclone wet bottom coal fired boiler), U3–OS1 (oil-fired tangential boiler), U6–OS1 (emergency fire water pump engine), U7–OS1, U7–OS2, U7–OS4, U7–OS5, U7–OS6, U7–OS7,U7–OS10, U7–OS11, U7–OS12 (coal handling systems) and U8–OS1 (cooling tower).
Atlantic States Cast Iron Pipe Company.	85004	November 22, 1994 ..	October 20, 1998, 63 FR 55949.	Approving NO_X RACT Source Specific regulations NJAC 7:27–19.13 Cupola and Annealing Oven processes. Effective date 12/21/98.
Trigen-Trenton Energy Co	61015	January 11, 2007	July 16, 2008, 73 FR 40752.	Alternative NO_X Emission Limit pursuant to NJAC 7:27–19.13 For 2 Cooper Bessemer Distillate Oil or Dual Fired 4 stroke Diesel Internal Combustion Engines.
PSE&G Nuclear Hope Creek and Salem Generating Stations Cooling Tower.	BOP050003	August 7, 2007 Significant Modification Approval.	April 1, 2009, 74 FR 14734.	TSP/PM 10 Source Specific Variance to SIP NJAC 7:27–6.5 Cooling Tower Unit 24, OS1 Effective Date 5/1/2009.
Co-Steel Corp of Sayreville (Formerly New Jersey Steel Corporation).	15076	September 3, 1997 ...	November 12, 2003, 68 FR 63991.	NO_X Source specific emission limit under NJAC 7:27–19.13 for Electric arc furnace, melt shop metallurgy and billet reheat furnace sources. Effective date 12/13/2003.
Transcontinental Gas Pipelines Corp., LNG Station 240.	02626	June 12, 2014	August 10, 2017, 82 FR 37308.	Alternate NO_X Emission Limit and other requirements pursuant to NJAC 7:27–19.13 for four natural gas-fired water bath heaters ((U7–U10).
Joint Base McGuire-Dix-Lakehurst (Lakehurst, NJ).	BOP15001	August 26, 2016	August 10, 2017, 82 FR 37308.	Alternate NO_X Emission Limit and other requirements pursuant to NJAC 7:27–19.13 for two natural gas-fired boilers (Nos 2 and 3).
Gerdau Ameristeel Sayreville.	Program Interest 18052; Activity Number BOP 150001; Emission Unit U2; Operating Scenario OS301; Ref #2.	March 26, 2018	May 30, 2019, 84 FR 24980.	None.
CMC Steel New Jersey	Program Interest 18052; Activity Number BOP 180001; Emission Unit U2; Operating Scenario OS301; Ref #2.	December 5, 2018	May 30, 2019, 84 FR 24980.	New ownership from Gerdau Ameristeel Sayreville to Commercial Metal Company (CMC).
Paulsboro Refinery	PI 55829; BOP 180002 U900.	6/26/2018	10/11/2019, 84 FR 54785	The External floating roof tanks (EFRTs) that are not being domed include tank numbers 725, 802, 1023, 1027, 2869, 2940, 2941, 3174, S8O, S8I, and S82. The EFRTs that may complete doming after the regulatory deadline include tank numbers 1063, 1116, 1320, 1065, and 1066.
Buckeye Port Reading Terminal.	PI 17996, BOP 160001 U8.	6/13/2018	10/11/2019, 84 FR 54785	The EFRTs that are not being domed include tank numbers 7930, 7934, 7937, and 7945. The EFRTs that may complete doming after the regulatory deadline include tank numbers 1219 and 1178.

EPA-APPROVED NEW JERSEY SOURCE-SPECIFIC PROVISIONS—Continued

Name of source	Identifier No.	State effective date	EPA approval date	Comments
Buckeye Pennsauken Terminal.	PI 51606, BOP 130002 U1.	8/21/2014	10/11/2019, 84 FR 54785	The EFRT that are not being domed include tank number 2018.
Phillips 66 Company Linden.	PI 41805, BOP 170004 U16.	1/26/2018	10/11/2019, 84 FR 54785	The EFRTs that are not being domed include tank numbers T52, T105, T119, T134, T244, T349, T350, T354, T355, and T356. The EFRT that may complete doming after the regulatory deadline include tank number T234.
CMC Steel New Jersey	BOP 150002; PI 18052; Emission Unit U1.	5/1/2019	2/17/2021	None.

* * * * *

[FR Doc. 2025–13333 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0331; FRL–12856–01–OCSPP]

Triclopyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triclopyr, including its metabolites and degradates, in or on orange subgroup 10–10A. UPL Chile S.A. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 16, 2025. Objections and requests for hearings must be received on or before September 15, 2025, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2024–0331, is available online at *https://www.regulations.gov* or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' FFDCA section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. FFDCA section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .''

C. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

D. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2024–0331 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before September 15, 2025. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2024–0331, by one of the following methods:

•*Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments.

Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

•*Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

•*Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Petitioned-For Tolerance

In the **Federal Register** of January 13, 2025 (90 FR 2661) (FRL–11682–11–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP4E9105) by UPL Chile S.A. (El Rosal 4610, Huechuraba Santiago, Chile, Postal Code: 8590724). The petition requests that EPA amend 40 CFR 180.417 by establishing a tolerance for residues of triclopyr, [(3,5,6-trichloro-2- pyridinyl)oxy]acetic acid, including its metabolites and degradates, in or on imported commodities in orange subgroup 10–10A at 0.07 parts per million (ppm). That document referenced a summary of the petition prepared by Exponent, Inc. on behalf of UPL Chile S.A., the petitioner, which is available in docket ID number EPA–HQ–OPP–2024–0331 at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing a tolerance at a different level than petitioned for. The reason for this change is explained in Unit IV.C.

III. Final Tolerance Action

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for triclopyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with triclopyr follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for triclopyr in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to triclopyr and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

A. *Aggregate Risk and Determination of Safety.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate PODs to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 88% of the aPAD for females 13–49 years old and 15% of the aPAD for all infants, the most highly exposed population subgroup. No acute residential or recreational exposures are expected, so the acute aggregate risk is equivalent to the acute dietary risk and is not of concern. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 63% of the cPAD for all infants <1 year old, the most highly exposed population subgroup. No long-term residential exposures are expected, so the chronic aggregate risk is equivalent to the chronic dietary risk and is not of concern.

For the short-term aggregate risk assessment, potential residential exposures were combined with food and drinking water exposures. Specifically, the short-term aggregate assessment for adults combines dietary (food + drinking water) exposures with handler inhalation exposures resulting from the registered turf use and the MOE is 420. For children 1 to <2 years old, the short-term aggregate assessment combines dietary (food + drinking water) exposure with potential post-application incidental oral exposure resulting from the registered turf use and the MOE is 125. For children 3 to <6 years old, the short-term aggregate assessment combines dietary (food + drinking water) exposure with potential post-application inhalation and incidental oral swimmer exposure resulting from the registered aquatic use and the MOE is 380. As the short-term aggregate MOEs are greater than 100, the risks are not of concern.

Although there are intermediate-term residential exposures, intermediate-term aggregate risk was not separately assessed since (1) the short- and intermediate-term points of departure are the same and (2) the short-term aggregate risk assessment provides a worst-case estimate of residential exposure. For these reasons, the short-term aggregate risk assessment is protective of intermediate-term exposures.

As stated in Unit III.A. of the February 25, 2016, final rule, EPA has determined that an aggregate exposure risk assessment for cancer risk is not required based on weight-of-evidence conclusions on the marginal evidence of carcinogenicity in two adequate rodent carcinogenicity studies and the use of the chronic RfD which will adequately account for any potential carcinogenic effects.

B. *Toxicological Profile.* For a discussion of the Toxicological Profile of triclopyr, see Unit III.A. of the final rule published in the **Federal Register** of February 25, 2016 (81 FR 9353) (FRL–9941–87).

C. *Toxicological Points of Departure/Levels of Concern.* Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD), and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability

of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints and points of departure for triclopyr used for human risk assessment can be found in the document, ''Triclopyr: Section 3 Human Health Risk Assessment for Tolerances without U.S. Registration on Orange Subgroup 10–10A'' in docket ID number EPA–HQ–OPP–2024–0331.

D. *Exposure Assessment.* For a summary of the assumptions used in EPA's exposure assessments for triclopyr, see Unit III.C. of the February 25, 2016, final rule and the updates described below.

EPA's dietary exposure assessments have been updated to include the additional exposures from the petitioned-for tolerance. Acute and chronic dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 food consumption data from the USDA's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment was unrefined, using tolerance-level residues for all registered and proposed commodities. The chronic dietary exposure assessment was slightly refined, using tolerance-level residues for all commodities except milk. An anticipated residue (AR) calculated from a livestock feeding study was used for milk. Default processing factors were used to estimate residues in processed commodities. Drinking water was incorporated directly into the dietary assessment. The acute and chronic dietary exposure assessments assumed 100% crop treated for all registered and proposed commodities.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

EPA revised the triclopyr drinking water assessment since the February 25, 2016, final rule using current models, newly submitted studies, and changes in labels. The estimated drinking water concentrations (EDWCs) were higher for surface water sources than for ground water sources. The acute dietary exposure assessment used the highest 1-in-10-year acute EDWC of 758 parts per billion (ppb) of triclopyr and the chronic dietary exposure assessment incorporated the highest 1-in-10-year chronic EDWC of 396 ppb of triclopyr. As the current action is for a tolerance without a corresponding U.S. registration (*i.e.,* an import tolerance), there will be no effect on the EDWCs, and the previously provided EDWCs are still adequate for use. The drinking water models and their descriptions are available at the EPA internet site: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment.*

The residential exposure assessment used the same assumptions as described in the February 25, 2016, final rule. As this action is for an import tolerance, it does not impact the domestic use pattern and does not involve applications by homeowners or commercial applicators in residential settings. Therefore, no new residential exposure is expected.

Cumulative exposures. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to triclopyr and any other substances. 3,5,6-trichloro-2-pyridinol, commonly known as TCP, is a metabolite of triclopyr, chlorpyrifos, and chlorpyrifos-methyl. Risk assessment of TCP was conducted in 2002, which concluded that the acute and chronic dietary aggregate exposure estimates are below EPA's level of concern. As TCP is not a residue of concern in plants and this action is for an import tolerance with no impact on the domestic use pattern, this action will not result in any additional exposure to TCP. The results of the 2002 TCP assessment are still considered valid. For the purposes of this action, EPA has not assumed that triclopyr has a common mechanism of toxicity with other substances.

E. *Safety Factor for Infants and Children.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III. of the final rule published in the **Federal Register** of February 28, 2024 (89 FR 14591) (FRL–11763–01).

Therefore, based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to triclopyr residues. More detailed information on this action can be found in the document titled ''Triclopyr: Section 3 Human Health Risk Assessment for Tolerances without U.S. Registration on Orange Subgroup 10–10A'' in docket ID number EPA–HQ–OPP–2024–0331.

IV. Other Considerations

A. Analytical Enforcement Methodology

For information about the analytical enforcement methodology, see Unit IV.A. of the February 25, 2016, final rule.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex has not established any MRLs for triclopyr.

C. Revisions to Petitioned-For Tolerance

EPA is establishing the tolerance for residues of triclopyr in or on orange subgroup 10–10A at 0.1 ppm instead of the petitioned-for 0.07 ppm in order to

harmonize with the existing European Union (EU) MRLs for triclopyr in oranges and mandarins. The petition requested that EPA establish the tolerance at 0.07 ppm consistent with the European Food Safety Authority (EFSA) Reasoned Opinion ''Modification of the existing maximum residue levels for triclopyr in oranges, lemons and mandarins,'' dated July 27, 2022. The EFSA Reasoned Opinion concluded that the submitted data were sufficient to derive MRLs of 0.07 mg/kg for oranges and mandarins, but it did not determine whether the existing MRLs of 0.1 mg/kg for these commodities should be maintained or lowered. The EU subsequently maintained the existing MRLs of 0.1 mg/kg in Commission Regulation (EU) 2023/679, dated March 23, 2023. There are no Codex, Canadian, or Mexican MRLs for triclopyr. Thus, to harmonize with the EU MRLs, EPA is establishing the tolerance at 0.1 ppm, which is sufficient to cover the residues expected on the imported commodities in orange subgroup 10–10A and which EPA has determined is safe. A revised petition was submitted by UPL Chile S.A. to support this change to the petitioned-for tolerance.

V. Conclusion

Therefore, a tolerance is established for residues of triclopyr, [(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid, including its metabolites and degradates, in or on orange subgroup 10–10A at 0.1 ppm.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

Since tolerance actions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the RFA, 5 U.S.C. 601 *et seq.,* do not apply to this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .'' (FFDCA 408(b)(2)(C)). The Agency's consideration is summarized in Unit III.E.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 14, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.417, amend the table in paragraph (a)(1) by adding in alphabetical order the entry ''Orange subgroup 10–10A [1]'' and adding footnote 1 to read as follows:

§ 180.417 Triclopyr; tolerance for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Orange subgroup 10–10A [1]	0.1
* * * * *	

[1] There are no U.S. registrations for these commodities as of July 16, 2025.

* * * * *

[FR Doc. 2025–13317 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0217; 12852–01–OCSPP]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamiprid in or on multiple spice commodities that are identified and discussed in this document. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the American Spice Trade Association submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on these commodities.

DATES: This rule is effective on July 16, 2025. Objections and requests for hearings must be received on or before September 15, 2025 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2024–0217, is available at *https://www.regulations.gov.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2427; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document might apply to them:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' FFDCA section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. FFDCA section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . .''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2024–0217 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before September 15, 2025.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See ''Revised Order Urging Electronic Filing and Service,'' dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf.* Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.*

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-For Tolerance

In the **Federal Register** of July 1, 2024 (89 FR 54398 (FRL–11682–05–OCSPP)), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F9085) by the American Spice Trade Association. The petition requested that 40 CFR part 180 be amended by establishing tolerances

for residues of the insecticide acetamiprid in or on pepper, black at 0.1 parts per million (ppm) and the following spices at 2.0 ppm: ambrette, seed; angelica, seed; angelica, dahurian, seed; anise, seed; annatto, seed; candlebush; caraway, black, seed; caraway, seed; celery, seed; chervil, seed; chinese nutmeg tree; coriander, seed; cubeb, seed; culantro, seed; cumin, seed; dill, seed; fennel, seed; fennel flower, seed; fenugreek, seed; grains of paradise, seed; guarana; honewort, seed; lovage, seed; mahaleb; malabar tamarind; milk thistle; mustard, black, seed; mustard, brown, seed; mustard, white, seed; nutmeg; poppy seed; sesame seed; and wattle seed. That document referenced a summary of the petition that was prepared by the petitioner and included in the docket. No comments were received in response to that notice of filing.

III. Final Tolerance Action

A. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances that vary from what the petitioner sought. Specifically, EPA is establishing tolerance values that are consistent with Organization for Economic Cooperation and Development (OECD) rounding class practice. EPA is also correcting commodity definitions for several commodities. The reasons for these changes are explained in Unit IV.C.

EPA has determined that it has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetamiprid, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetamiprid is summarized in this unit.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting discussions that previously published in other tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for this new rulemaking.

For acetamiprid, EPA previously published a tolerance rulemaking in the **Federal Register** of February 14, 2020 (85 FR 8433 (FRL–10004–12)), in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to acetamiprid and established tolerances for residues of that chemical. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they remain unchanged. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by acetamiprid, can be found in the document titled ''Acetamiprid. Human Health Risk Assessment for Proposed Tolerances for Residues, Without U.S. Registrations on Pepper, Black and Spices in Crop Group 26 that Overlap with the Codex Crop Subgroup of Spices, Seed'' (hereinafter ''Acetamiprid Human Health Risk Assessment''), which is available in the docket for this action.

B. Toxicological Profile

For a discussion of the toxicological profile of acetamiprid, see Unit III.A. in the final rule of February 14, 2020.

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOCs) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD), and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

More detailed information on the toxicological endpoints for acetamiprid used for human health risk assessment can be found in the Acetamiprid Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in 40 CFR 180.578. EPA assessed dietary exposures from acetamiprid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified in the toxicological studies for acetamiprid. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute dietary exposure assessment used tolerance-level residues, 100 percent crop treated (PCT), and empirical and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA likewise used DEEM–FCID, Version 4.02, which incorporates 2005–2010 consumption data from USDA's NHANES/WWEIA. As to residue levels in food, the chronic dietary exposure assessment used tolerance-level residues except for milk and apple juice, for which EPA used Pesticide Data Program monitoring data; 100 PCT; and empirical and default processing factors. The chronic assessment also accounted for potential residues from the food handling establishment (FHE) use of acetamiprid. For commodities that would only have residues resulting from the FHE use, EPA used a residue value of one-half of the existing FHE tolerance and a PCT estimate of 4.65%.

iii. *Cancer.* EPA has concluded that acetamiprid is not likely to be carcinogenic to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* FFDCA section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

FFDCA section 408(b)(2)(F) states that EPA may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, EPA must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The acute and chronic assessments assumed 100 PCT for agricultural uses and the PCT estimate of 4.65% for the FHE use.

EPA estimates the percent of commodities treated in FHEs for uses of active ingredients based on the best available information. This includes survey information on pesticide usage related to the number of facilities being treated, product forms used (*e.g.,* liquids and aerosols), and treatment schedule by FHE segments (*e.g.,* warehouse, food processor, distributor, and restaurant). EPA also incorporated the best available information related to the transfer of commodities between various segments of FHEs and the percent of food consumed by location, either in the home or outside the home.

All information currently available has been considered and EPA has concluded that for any active ingredient, including acetamiprid, there is at most a 4.65% likelihood that a food commodity could contain potential residues resulting from one or more treatments while in the FHE channel of trade. Similar to estimates of agricultural use, this estimate should be reconsidered in 5 years.

EPA believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which acetamiprid may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetamiprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetamiprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment.*

Based on the Pesticide in Water Calculator and Provisional Cranberry Model, the estimated drinking water concentrations of acetamiprid for acute exposures are 88.1 parts per billion (ppb) in surface water and 211 ppb in ground water, and for chronic exposures are 12.7 ppb in surface water and 175 ppb in ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 211 ppb was used to assess the contribution from drinking water. For the chronic dietary risk assessment, the water concentration of value 175 ppb was used to assess the contribution from drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). There are no new proposed residential uses for acetamiprid at this time. However, acetamiprid is currently registered for uses that could result in residential handler and post-application exposures, including gardens and trees, spot-on pet treatment, fly control, indoor crack/crevice, mattresses for bed bug control, and animal barns. For a summary of these exposures, see Unit III.C.3. in the final rule of February 14, 2020.

4. *Cumulative effects from substances with a common mechanism of toxicity.* FFDCA section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found acetamiprid to share a common mechanism of toxicity with any other substances, and acetamiprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetamiprid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to

EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Evidence of qualitative susceptibility was observed in the 2-generation reproductive toxicity study, with the offspring effects (reductions in pup weights, reduction in litter size and viability, delays in weaning indices and the age to attain vaginal opening and preputial separation) considered more severe than the observed decrease in parental body weights. Qualitative susceptibility was also seen in the developmental neurotoxicity study with offspring effects (decreased pup weight, pre-weaning survival, and decreased startle response) occurring in the presence of marginal parental body weight decreases.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all scenarios, with the exception of the assessment of inhalation exposure. The default FQPA 10X SF remains in place for assessing inhalation exposure due to the lack of a subchronic inhalation study. That decision is based on the following findings:

i. The toxicity database for acetamiprid is complete with the exception of a subchronic inhalation study.

ii. Acetamiprid produced signs of neurotoxicity in the high dose groups of the acute and developmental neurotoxicity studies in rats and the subchronic toxicity study in mice. However, no neurotoxic findings were reported in the subchronic neurotoxicity study in rats. Additionally, there are clear NOAELs identified for the neurotoxicity effects observed in the guideline studies. The doses and endpoints selected for risk assessment are protective and account for all adverse toxicological effects observed in the database.

iii. No quantitative or qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetamiprid was observed in the developmental toxicity study in either rats or rabbits. Although increased qualitative susceptibility was seen in the reproduction toxicity and the DNT study, the degree of concern for the effects is low. There are clear NOAELs for the offspring effect and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified with respect to susceptibility. The endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues, and the chronic dietary exposure assessment was slightly refined using 100 PCT and tolerance-level residues for most agricultural commodities, with a PCT estimate of 4.65% used for commodities that would only have residues resulting from the FHE use. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetamiprid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by acetamiprid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute Population Adjusted Dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate margin of exposure (MOE) exists. Where different routes of exposure have different levels of concern, the Agency uses the aggregate risk index (ARI) approach for calculating short-, intermediate-, and long-term aggregate risk estimates.

1. *Acute dietary risk.* The acute dietary risk estimates for acetamiprid are not of concern. Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that acute exposure to acetamiprid from food and water is 75% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic dietary risk.* The chronic dietary risk estimates for acetamiprid are not of concern. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water is 31% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Acetamiprid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to acetamiprid.

Using the exposure assumptions described in this unit for short-term exposures, EPA used the ARI approach for calculating the exposure estimates. Estimates greater than or equal to 1.0 are not of concern. For all lifestages, the ARIs are greater than the target ARI of 1.0, and are not of concern. The ARIs ranged from 1.4 to 5.3. Children 1 to < 2 years old exposed to bed bug treatments indoors resulted in the lowest aggregate ARI of 1.4.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified, and intermediate-term exposure is expected; however, since the same endpoint and POD were selected for short- and intermediate term durations, short-term exposure and risk estimates are considered protective of potential intermediate-term exposure and risk.

5. *Long-term risk.* For both adults and children, worst-case long-term scenarios reflect post-application exposure to pets treated with spot-on products. The long-term aggregate risk estimates are not of concern.

6. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acetamiprid is not likely to be carcinogenic to humans.

7. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Approved tolerance enforcement methods for acetamiprid residues in crops are available, including methods using gas chromatography with electron capture detection (GC/ECD) analysis for vegetables and non-citrus fruits, high-performance liquid chromatography with ultraviolet detection (HPLC/UV) analysis for citrus fruits only, and HPLC with tandem mass spectrometric

detection (LC/MS/MS) analysis for vegetables and non-citrus fruits. An approved HPLC/UV tolerance enforcement method for livestock matrices is available.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The tolerance levels established in this action are harmonized with the established Codex MRLs for all commodities.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested. Specifically, EPA is correcting commodity definitions for the following commodities: ''caraway, black, seed'' and ''caraway, seed'' to ''caraway, black''; ''cumin, seed'' to ''cumin''; ''fennel, seed'' to ''fennel, common, seed''; ''grains of paradise, seed'' to ''grains of paradise''; ''malabar tamarind'' to ''tamarind, seed''; ''mustard, black, seed'', ''mustard, brown, seed'', and ''mustard, white, seed'' to ''mustard, seed''; and ''wattle seed'' to ''wattleseed''.

EPA is also establishing tolerance values that are consistent with OECD rounding class practice by dropping trailing zeroes. EPA is establishing tolerances at 2 ppm, rather than the requested 2.0 ppm, for the following spices: ambrette, seed; angelica, seed; angelica, dahurian, seed; anise, seed; annatto, seed; candlebush; caraway, black; celery, seed; chervil, seed; chinese nutmeg tree; coriander, seed; cubeb, seed; culantro, seed; cumin; dill, seed; fennel, common, seed; fennel flower, seed; fenugreek, seed; grains of paradise; guarana; honewort, seed; lovage, seed; mahaleb; tamarind, seed; milk thistle; mustard, seed; and wattleseed.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid, in or on pepper, black at 0.1 ppm and the following spices at 2 ppm: ambrette, seed; angelica, seed; angelica, dahurian, seed; anise, seed; annatto, seed; candlebush; caraway, black; celery, seed; chervil, seed; chinese nutmeg tree; coriander, seed; cubeb, seed; culantro, seed; cumin; dill, seed; fennel, common, seed; fennel flower, seed; fenugreek, seed; grains of paradise; guarana; honewort, seed; lovage, seed; mahaleb; milk thistle; mustard, seed; nutmeg; poppy seed; sesame, seed; tamarind, seed and wattleseed.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

Since tolerance actions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the RFA, 5 U.S.C. 601 *et seq.,* do not apply to this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or on the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 Policy on Children's Health applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . '' (FFDCA 408(b)(2)(C)). The Agency's consideration is summarized in Unit III.D.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 2, 2025.

Charles Smith,

Director, Registration Division Office of Pesticide Programs.

For the reasons set forth in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Amend § 180.578, by:

■ a. Adding the heading ''Table 1 to Paragraph (a)(1)'' to the table in paragraph (a)(1);

■ b. Adding the following commodities in alphabetical order to the table in paragraph (a)(1): ''ambrette, seed''; ''angelica, seed''; ''angelica, dahurian, seed''; ''anise, seed''; ''annatto, seed''; ''candlebush''; ''caraway, black''; ''celery, seed''; ''chervil, seed''; ''chinese nutmeg tree''; ''coriander, seed''; ''cubeb, seed''; ''culantro, seed''; ''cumin''; ''dill, seed''; ''fennel, common, seed''; ''fennel flower, seed''; ''fenugreek, seed''; ''grains of paradise''; ''guarana''; ''honewort, seed''; ''lovage, seed''; ''mahaleb''; ''milk thistle''; ''mustard, seed''; ''nutmeg''; ''pepper, black''; ''poppy seed''; ''sesame, seed''; ''tamarind, seed''; ''wattleseed''; and

■ c. Adding an end note 2 to the table in paragraph (a)(1).

The additions read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Ambrette, seed[2]	2
Angelica, seed[2]	2
Angelica, dahurian, seed[2]	2
Anise, seed[2]	2
Annatto, seed[2]	2
* * * * *	
Candlebush[2]	2
* * * * *	
Caraway, black[2]	2
Celery, seed[2]	2
* * * * *	
Chervil, seed[2]	2
Chinese nutmeg tree[2]	2
* * * * *	
Coriander, seed[2]	2
* * * * *	
Cubeb, seed[2]	2
Culantro, seed[2]	2
Cumin[2]	2
Dill, seed[2]	2
* * * * *	
Fennel flower, seed[2]	2
Fennel, common, seed[2]	2
Fenugreek, seed[2]	2
* * * * *	
Grains of paradise[2]	2
* * * * *	
Honeywort, seed[2]	2
* * * * *	
Lovage, seed[2]	2
Mahaleb[2]	2
Milk, thistle[2]	2
Mustard, seed[2]	2
Nutmeg[2]	2
* * * * *	
Pepper, black[2]	0.1
Poppy, seed[2]	2
* * * * *	
Sesame, seed[2]	2
* * * * *	
Tamarind, seed[2]	2
* * * * *	
Wattleseed[2]	2

[1] There are no U.S. registrations as of February 10, 2010, for the use of acetamiprid on dried tea.

[2] There are no U.S. registrations for these commodities as of July 16, 2025.

* * * * *

[FR Doc. 2025–13289 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[RTID 0648–XF039; Docket No. 250312–0037]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher/Processors Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary because the 2025 total allowable catch of Pacific cod allocated to catcher/processors using trawl gear in the Central Regulatory Area of the GOA has been or will be reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), July 14, 2025, through 2400 hours, A.l.t., December 31, 2025.

FOR FURTHER INFORMATION CONTACT: Abby Jahn, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the GOA (FMP) prepared and recommended by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2025 total allowable catch (TAC) of Pacific cod allocated to catcher/processors using trawl gear in the Central Regulatory Area of the GOA is 626 metric tons as established by the final 2025 and 2026 harvest specifications for groundfish of the GOA (90 FR 12468, March 18, 2025).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS

(Regional Administrator), has determined that the 2025 TAC of Pacific cod allocated to catcher/processors using trawl gear in the Central Regulatory Area of the GOA has been or will be reached. Therefore, NMFS is prohibiting retention of Pacific cod caught by catcher/processors using trawl gear in the Central Regulatory Area of the GOA and requiring that Pacific cod caught by catcher/processors using trawl gear in the Central Regulatory Area of the GOA be treated in the same manner as prohibited species in accordance with § 679.21(a)(2) for the remainder of the year. This action is necessary to prevent exceeding the 2025 TAC of Pacific cod allocated to catcher/processors using trawl gear in the Central Regulatory Area of the GOA.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b) of the Magnuson-Steven Act, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data on Pacific cod harvest by catcher/processors in the Central Regulatory Area of the GOA only became available as of July 11, 2025.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 14, 2025.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2025–13303 Filed 7–14–25; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 90, No. 134
Wednesday, July 16, 2025

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2020–0098; FRL–12594–01–R8]

Air Plan Approval; State of Utah; Utah $PM_{2.5}$ State Implementation Plan Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve, through parallel processing, a State Implementation Plan (SIP) submission from the State of Utah with revisions to Utah Administrative Code (UAC), Utah State SIP, and the best available control measures/best available control technologies (BACM/BACT) determinations for five facilities found in the Salt Lake City, Utah nonattainment area (NAA) for the 2006 24-hour fine particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 microns ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) (State of Utah draft dated May 20, 2025). The EPA is taking this action pursuant to the Clean Air Act (CAA or the Act).

DATES: Written comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2020–0098, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *https://www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *https://www.regulations.gov.* Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

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SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

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I. Background

A. Statutory and Regulatory Background for EPA's Regulation of $PM_{2.5}$

Under section 109 of the Act, the EPA has promulgated NAAQS for certain pollutants, including $PM_{2.5}$ (40 CFR 50.2(b)). Once the EPA promulgates a NAAQS, section 107 of the Act specifies a process for the designation of each area within a state, generally as either an attainment area (an area attaining the NAAQS) or as a NAA (an area not attaining the NAAQS, or that contributes to nonattainment of the NAAQS in a nearby area). For $PM_{2.5}$, certain areas have also been designated ''unclassifiable.'' These various designations, in turn, trigger certain state planning requirements.

For all areas, regardless of designation, section 110 of the Act requires that each state adopt and submit for EPA approval, a plan to provide for implementation, maintenance, and enforcement of the NAAQS. This plan is commonly referred to as a SIP. CAA section 110 contains requirements that a SIP must meet to gain EPA approval.[1] For NAAs, SIPs must meet additional requirements in part D of title I of the Act.

On October 17, 2006 (71 FR 61144), the EPA revised the level of the 24-hour $PM_{2.5}$ NAAQS, lowering the primary and secondary standards from the 1997 standard of 65 micrograms per cubic meter ($\mu g/m^3$) to 35 $\mu g/m^3$. On November 13, 2009 (74 FR 58688), the EPA designated three NAAs in Utah for the 2006 24-hour $PM_{2.5}$ NAAQS of 35 $\mu g/m^3$. These are the Salt Lake City; Provo; and Logan, Utah-Idaho [2] NAAs.

The EPA originally issued a rule in 2007 [3] regarding implementation of the 2006 24-hour $PM_{2.5}$ NAAQS for the NAA plan requirements specified in CAA title I, part D, subpart 1. Under subpart 1, Utah was required to submit an attainment plan for each area no later than three years from the date of nonattainment designation. These plans needed to provide for the attainment of the $PM_{2.5}$ standards as expeditiously as practicable, but no later than five years from the date the areas were designated nonattainment.

In 2013, the U.S. Court of Appeals for the District of Columbia held that the EPA should have implemented the 2006

[1] EPA's approval of a SIP has several consequences. For example, after the EPA approves a SIP, the EPA and citizens may enforce the SIP's requirements in federal court under section 113 and section 304 of the Act; in other words, the EPA's approval of a SIP makes the SIP ''federally enforceable.'' Also, once the EPA has approved a SIP, a state cannot unilaterally change the federally enforceable version of the SIP. Instead, the state must first submit a SIP revision to the EPA and gain EPA's approval of that revision.

[2] The Logan, Utah-Idaho NAA was redesignated to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS on May 19, 2021 (86 FR 27035).

[3] 72 FR 20586 (Apr. 25, 2007).

$PM_{2.5}$ 24-hour standards, as well as the other $PM_{2.5}$ NAAQS, based on both subpart 1 and subpart 4 of CAA title I, part D.[4] Under subpart 4, all NAAs are initially classified as Moderate, and Moderate area attainment plans must address the requirements of subpart 4 as well as subpart 1. Additionally, subpart 4 sets a different SIP submittal due date and attainment year. For a Moderate area, the attainment SIP is due 18 months after designation and the attainment year is as expeditiously as practicable, but no later than the end of the sixth calendar year after designation.

On June 2, 2014 (79 FR 31566), the EPA finalized the Identification of Nonattainment Classification and Deadlines for Submission of State Implementation Plan (SIP) Provisions for the 1997 Fine Particulate ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) and 2006 24-hour $PM_{2.5}$ NAAQS. This rule classified the areas that were designated as Moderate in 2009 as nonattainment and set the attainment SIP submittal due date for those areas to December 31, 2014. Additionally, this rule established the Moderate area attainment date of December 31, 2015.

On August 24, 2016 (81 FR 58010), the EPA finalized the Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements (''$PM_{2.5}$ Requirements Rule''), which partially addressed the 2013 National Resources Defense Council (*NRDC)* decision. The final $PM_{2.5}$ Requirements Rule details how air agencies can meet the SIP requirements under subparts 1 and 4 that apply to areas designated nonattainment for any $PM_{2.5}$ NAAQS, such as: general requirements for attainment plan due dates and attainment demonstrations; provisions for demonstrating reasonable further progress (RFP); quantitative milestones; contingency measures; nonattainment new source review (NNSR) permitting programs; and reasonable available control measures (RACM) (including reasonably available control technologies (RACT)). The statutory attainment planning requirements of subparts 1 and 4 were established to ensure that the following goals of the CAA are met: (i) that states implement measures that provide for attainment of the $PM_{2.5}$ NAAQS as expeditiously as practicable; and (ii) that states adopt emissions reduction strategies that will be the most effective at reducing $PM_{2.5}$ levels in NAAs.

If an area is reclassified from Moderate to Serious, the area will then be subject to Serious $PM_{2.5}$ CAA requirements under subpart 1 and subpart 4, and the CAA requires the state to submit the following Serious area SIP elements: (1) CAA section 172(c)(3); (2) CAA sections 172(c)(1) and 189(b)(1)(B); (3) CAA section 188(c)(2); (4) CAA section 172(c)(2); (5) CAA section 189(c); (6) CAA section 189(e); (7) CAA section 172(c)(9); and (8) CAA section 302(j) and CAA section 189(b)(3).

Serious area 2006 24-hour $PM_{2.5}$ plans must also satisfy the general requirements applicable to all SIP submissions under section 110 of the CAA, including the requirement to provide necessary assurances that the implementing agencies have adequate personnel, funding, and authority under CAA section 110(a)(2)(E), and the requirements concerning enforcement in CAA section 110(a)(2)(C).

B. Utah's PM2.5 Attainment Status and SIP Development

After the November 13, 2009 designation of nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS, Utah developed draft $PM_{2.5}$ attainment plans intended to meet the requirements of subpart 1. Utah submitted these revised 2006 24-hour $PM_{2.5}$ attainment plans for the Salt Lake City and Provo NAAs on December 14, 2012.

After the court's 2013 decision, Utah amended its attainment plans to address the requirements of subpart 4. On December 16, 2014, Utah Division of Air Quality (UDAQ) withdrew all prior Salt Lake City and Provo 2006 24-hour $PM_{2.5}$ Moderate SIP attainment plan submissions and submitted a subpart 1 and subpart 4 Salt Lake City and Provo 2006 24-hour $PM_{2.5}$ Moderate SIP. Additionally, the State of Utah submitted various revisions to the UAC Title R307 (Environmental Quality) area source rules in multiple submissions: February 2, 2012; May 9, 2013; June 8, 2013; February 18, 2014; April 17, 2014; May 20, 2014; July 10, 2014; and August 6, 2014. These area source rules were either new or revised to meet RACM/RACT for the Salt Lake City and Provo 2006 24-hour $PM_{2.5}$ SIPs. The EPA acted on these submittals, along with the area source rule revisions in the December 16, 2014, submission, on February 25, 2016 (81 FR 9343), October 19, 2016 (81 FR 71988), October 2, 2019 (84 FR 52368), and February 26, 2020 (85 FR 10989).

On January 19, 2017, the State of Utah submitted revisions to their Part H.11, 12, and 13 emission limits section of the Utah 2006 24-hour $PM_{2.5}$ SIP and revised R307–110–17. R307–110–17 incorporation by reference (IBR) section IX., Control Measures for Area and Point Sources, Part H, Emission Limits; which formally incorporates the Salt Lake City and Provo 2006 24-hour $PM_{2.5}$ Part H.11, 12, and 13 emission limits into Utah's State regulations. This was undertaken by UDAQ to correlate any overlapping limits between the 2006 24-hour $PM_{2.5}$ Part H.11, 12, and 13, to the coarse particulate matter (PM_{10}) Part H.1, 2, 3, and 4.

On May 10, 2017 (82 FR 21711), the EPA published a final rule reclassifying the Salt Lake City and Provo areas to ''Serious'' nonattainment status, based on the EPA's determination that the areas could not practicably attain the 2006 24-hour $PM_{2.5}$ standards by the December 31, 2015 attainment date. This reclassification became effective on June 9, 2017. The reclassification was based on the EPA's evaluation of ambient air quality data from the 2013–2015 period, indicating that it was not practicable for some of the monitoring sites in the Salt Lake City and Provo areas to show $PM_{2.5}$ design values at or below the level of the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2015.

On March 23, 2018, the State of Utah submitted quantitative milestone reports for the Salt Lake City and Provo 2006 24-hour $PM_{2.5}$ NAAs, meeting its due date of no later than 90 days after the December 31, 2017, milestone date. On October 24, 2018, the EPA determined that the 2017 quantitative milestone reports for the Salt Lake City and Provo 2006 24-hour $PM_{2.5}$ NAAs were adequate.[5]

After the Serious reclassification, UDAQ revised certain area source rules in UAC section R307–200 and R307–300 Series and submitted these revisions on April 19, 2018, May 21, 2020, and July 21, 2020. On February 4, 2019, the State of Utah submitted the Serious 2006 24-hour $PM_{2.5}$ SIP for the Salt Lake City NAA which included the BACM/BACT analysis for the Provo Serious 2006 $PM_{2.5}$ NAA. The analysis was based on the emission limits submitted on January 19, 2017, for only Part H.13. On February 15, 2019, Utah submitted the Serious 2006 24-hour $PM_{2.5}$ SIP for the Salt Lake City NAA, which included revisions to Utah SIP Part H.11 and 12, and the accompanying BACM/BACT analysis. The February 4, 2019 and February 15, 2019, submission included BACM/BACT analyses for on-road, off-road, and area source rules; some of

[4] *Nat. Res. Def. Council* v. *EPA,* 706 F.3d 428, 437 (D.C. Cir. 2013) (*NRDC*) or 2013 National Resources Defense Council (NRDC) decision.

[5] The state's quantitative milestone reports and the adequacy determination letter from the EPA Administrator to the Governor of Utah are in the docket for this action.

these area source rules were revised and others were deemed BACM/BACT without revising.[6]

Applying the Clean Data Policy,[7] on April 10, 2019 (84 FR 14267) and September 27, 2019 (84 FR 51055), the EPA finalized a determination that the obligation to submit any remaining attainment-related SIP revisions arising from classification of the Provo and Salt Lake City area, as Moderate NAAs and the subsequent reclassification as Serious NAAs for the 2006 24-hour $PM_{2.5}$ NAAQS does not apply for so long as the area continues to attain the 2006 24-hour $PM_{2.5}$ NAAQS.[8] The attainment-related SIP revisions that were suspended include: an attainment demonstration (Moderate and Serious), provisions demonstrating timely implementation of RACM/RACT (Moderate), an RFP plan (Moderate and Serious), quantitative milestones and quantitative milestone reports (Moderate and Serious), and contingency measures (Moderate and Serious). The only remaining attainment-related SIP elements for EPA action include baseline emission inventories, NNSR, and BACM/BACT.

C. Requirements for BACM/BACT

For any Serious 2006 24-hour $PM_{2.5}$ NAA, section 189(b)(1)(B) of the Act requires that a state submit provisions to assure that BACM/BACT for the control of $PM_{2.5}$ and $PM_{2.5}$ precursors shall be implemented no later than four years after the date the area is reclassified as a Serious area. The EPA defines BACM (including BACT) as, among other things, the maximum degree of emissions reduction achievable for a source or source category, which is determined on a case-by-case basis considering energy, economic and environmental impacts, and other costs.[9] We consider BACM a control level that goes beyond existing RACM-level controls, for example by expanding the use of RACM controls or by requiring preventative measures instead of remediation.[10] The level of stringency generally refers to the overall level of emissions reductions of a control measure or technology, or of such measures and technologies combined.

The $PM_{2.5}$ Requirements Rule explains that BACM/BACT are generally independent requirements, to be determined without regard to the specific attainment analysis (*i.e.,* attainment demonstration) for the area.[11] The EPA found it reasonable to interpret the statute as requiring a different analysis for determining BACM/BACT, *i.e.,* that while RACM emphasizes the attainment needs of the area, BACM has a greater emphasis on identifying measures that are feasible to implement. The Addendum to the General Preamble noted that the test for BACM puts a ''greater emphasis on the merits of the measure or technology alone,'' rather than on ''flexibility in considering other factors,'' in contrast to the approach for RACM/RACT.[12]

Section 189(b)(1)(B) of the Act allows states, in appropriate circumstances, to delay implementation of BACM until four years after reclassification. Because the EPA reclassified the Provo and Salt Lake City areas as Serious NAAs for the 2006 24-hour $PM_{2.5}$ NAAQS effective June 9, 2017 (82 FR 21711; May 10, 2017), the date four years after reclassification is June 9, 2021. In this case, however, all BACM for direct $PM_{2.5}$ and $PM_{2.5}$ precursors in the Salt Lake City area must be, and was, implemented no later than December 31, 2019, which is the outermost statutory attainment date for the Salt Lake City area under section 188(c)(2).[13]

Under the $PM_{2.5}$ Requirements Rule, control measures that can be implemented in whole or in part by the end of the fourth year after an area's reclassification to Serious are considered BACM, and control measures that can only be implemented after this period but before the attainment date are considered ''additional feasible measures.'' [14] The EPA has defined ''additional feasible measures'' as ''those measures and technologies that otherwise meet the criteria for BACM/BACT but that can only be implemented in whole or in part beginning 4 years after reclassification of an area, but no later than the statutory attainment date of the area.'' [15] Given that the statutory attainment date is less than three years from the effective date of the reclassification of the Provo and Salt Lake City areas, additional feasible measures are not required in this case.

The Addendum and the $PM_{2.5}$ Requirements Rule explain that the BACM/BACT selection process for implementation of the 2006 24-hour $PM_{2.5}$ NAAQS is designed to take into account the local facts and circumstances and the nature of the air pollution problem in a given NAA. The following steps are used in determining BACM/BACT: (1) Develop a comprehensive emission inventory of the sources of directly emitted $PM_{2.5}$ and $PM_{2.5}$ precursors; (2) Identify existing and potential control measures for the sources in the inventory; (3) Evaluate the technological feasibility of potential control measures; (4) Evaluate the economic feasibility of potential control measures; and (5) Determine the earliest date by which a control measure or technology can be implemented in whole or in part.[16]

Additionally, the information found within this action, coupled with the statutory and regulatory requirements, support the EPA's decision that BACT or lowest achievable emission rate (LAER) provisions for new sources (as distinct from BACT for existing sources), or best available retrofit technology (BART) for existing sources, could potentially qualify as BACM or BACT for purposes of meeting the Serious area attainment plan requirements.[17] However, as discussed further in the $PM_{2.5}$ Requirements Rule, it is not appropriate for a state to assume that just because a certain control technology was determined to meet BACT, LAER or BART criteria for a new source sometime in the past, that such a control will also automatically meet the criteria for BACM or BACT or additional feasible measures for attainment planning purposes. This is because the regulated pollutant or source applicability may differ and the analyses may be conducted years apart. Thus, a state may not simply rely on

[6] On November 6, 2020, (85 FR 71023), the EPA proposed approval of the redesignation requests, maintenance plans, and the Moderate and Serious $PM_{2.5}$ SIP submissions including BACM/BACT determinations.

[7] The EPA codified the Clean Data Policy in the $PM_{2.5}$ Requirements Rule for the implementation of current and future $PM_{2.5}$ NAAQS. See 81 FR at 58161; 40 CFR 51.1015(a).

[8] 40 CFR 51.1015(a) and (b).

[9] State Implementation Plans for Serious PM_{10} Nonattainment Areas, and Attainment Date Waivers for PM_{10} Nonattainment Areas Generally; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990 (''Addendum''), August 16, 1994; 59 FR 41998, 42010, 42013 (Aug. 16, 1994). The General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990 (''General Preamble'') was published at 57 FR 13498 (Apr. 16, 1992).

[10] *Id.* at 42011, 42013.

[11] 81 FR at 58081.

[12] 59 FR at 42011.

[13] CAA section 189(b)(1)(B) establishes an outermost deadline (''no later than four years after the date the area is reclassified'') and does not preclude an earlier implementation deadline for BACM where necessary to satisfy the attainment requirements of the Act.

[14] 40 CFR 51.1010(a)(4)(ii). ''Additional feasible measures'' may be necessary in certain circumstances to implement the requirements of CAA section 172(c)(6), which states that NAA plans shall include enforceable emission limitations and such other control measures, means or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to provide for attainment of the NAAQS by the applicable attainment date.

[15] 40 CFR 51.1000.

[16] Addendum at 42012–42014; 81 FR at 58084–58085.

[17] See 81 FR at 58086.

prior BACT, LAER or BART analyses for the purposes of showing that a source has also met BACT for the relevant 2006 24-hour $PM_{2.5}$ NAAQS. Rather, the EPA expects that in Step 2 (discussed above) of the BACM/BACT determination process, the state would identify such measures as ''existing measures'' that should be further evaluated as potential BACM or BACT, or additional feasible measures. At the same time, the EPA notes that the presence of previously installed control technology, and the technical and economic considerations that would be associated with upgrading to a measure that achieves greater reductions, is something that should be considered in the assessments of technological and economic feasibility of the newer measure.[18]

Once these analyses are complete, a state must use this information to develop enforceable control measures and submit them to the EPA for evaluation under CAA section 110. We use these steps from the Addendum and the $PM_{2.5}$ Requirements Rule, as guidelines in our evaluation of the BACM measures and related analyses in the Provo and Salt Lake City 2006 24-hour $PM_{2.5}$ Serious SIP.

D. What is parallel processing? [19]

Parallel processing refers to a process that utilizes concurrent state and Federal proposed rulemaking actions to process state SIP submissions in less time than the standard process. During parallel processing, generally, the state submits a copy of the proposed regulation or other revisions to the EPA before conducting its public hearing and completing its public comment process under state law. The EPA reviews this proposed state action and prepares a notice of proposed rulemaking under Federal Law. In some cases, the EPA's notice of proposed rulemaking is published in the **Federal Register** during the same time frame that the state is holding its public hearing and conducting its public comment process. The state and the EPA then provide for concurrent public comment periods on both the state action and Federal action. If, after completing the state and EPA's public comment process, the state changes its final submittal from the proposed submittal, the EPA evaluates those changes and decides on whether to publish another notice of proposed rulemaking in light of those changes or to proceed to taking the final action on its proposed action and describe the state's changes in its final rulemaking action. Any final rulemaking action by the EPA will occur only after the final submittal has been adopted by the state and formally provided to the EPA. Parallel processing is designed to require less time than the standard process, in which a state completes its entire state process before submitting a final SIP package to the EPA, only after which the EPA proposes action on the state submission, seeks public comment, and takes final action.

In this case, however, the EPA's and Utah's processes have not been perfectly concurrent. The State submitted the draft SIP revisions on May 20, 2025, with a public comment period starting March 1 and going through March 31, 2025, with a public hearing held online at 2:00 p.m. on March 13, 2025. The State's intention is to submit its final SIP revisions in July 2025. After Utah submits these formal SIP revisions, the EPA will evaluate the submittal. If the State changes the formal submittal from the proposed submittal, the EPA will evaluate those changes for significance. If the EPA finds any such changes to be significant, then the Agency intends to determine whether to re-propose the actions based on the revised submission or to proceed to take final action on the submittal as changed by the State. Although the EPA was unable to have a concurrent public comment process with the State, parallel processing allows the EPA to begin to take action on the State's proposed submittal in advance of a formal and final submission.

II. EPA's Evaluation of the May 20, 2025 Draft SIP Submission

A. BACM/BACT Revisions

1. BACM/BACT Analysis in the Serious $PM_{2.5}$ SIP

The UDAQ's BACM/BACT process and control measure evaluations for the identified sources are described in detail in their draft May 20, 2025 submission.[20] For each identified source, UDAQ identified its adopted control measures and potential additional control measures based on measures implemented in other areas, measures identified in EPA regulations or guidance (*e.g.,* in control technique guidelines (CTGs), alternative control technique documents (ACTs), new sources performance standards (NSPSs), or in the EPA's ''Cost Analysis Models/Tools for Air Pollution Regulations''), or measures identified in prior EPA rulemaking documents (*e.g.,* recommendations in SIP actions).[21] UDAQ evaluated these potential additional control measures to determine whether implementation of the measures would be technologically and economically feasible in the Salt Lake City area. Based upon their evaluation, UDAQ determined BACM/BACT to be the existing controls for all five facilities listed below.

In the following sections, we review key components of UDAQ's demonstrations concerning BACM/BACT for the identified sources of direct $PM_{2.5}$, nitrogen oxide (NO_X), volatile organic compounds (VOC), sulfur dioxide (SO_2), and ammonia (NH_3) emissions in the Salt Lake City NAA: (1) Big West Oil LLC Refinery; (2) Chevron Products Company—Salt Lake Refinery; (3) Hexcel Corporation: Salt Lake Operations; (4) Holly Frontier Sinclair Woods Cross Refinery; and (5) Tesoro Refining and Marketing Company LLC Marathon Refinery: Salt Lake City Refinery.

2. EPA's Evaluation and Conclusion of UDAQ's BACM/BACT Demonstrations for Identified Sources in the Salt Lake City NAA

EPA reviewed UDAQ's analysis and determination in the May 20, 2025 draft submission that the five major stationary source control measures represent BACM/BACT for direct $PM_{2.5}$ and $PM_{2.5}$ precursors within the Provo and Salt Lake City NAAs. As a result, the EPA proposes to determine that UDAQ's Utah SIP Part H emission limits provide for the implementation of BACM/BACT for the five major stationary sources of direct $PM_{2.5}$ and $PM_{2.5}$ precursors. Additional detail can be found in our technical support document (TSD) located in the docket for this action.

We are proposing to approve, through parallel processing, the May 20, 2025 draft submission of revisions to Utah SIP section IX.H.11. and 12. and to find that the May 20, 2025 draft submission provides for the implementation of BACM/BACT for all sources of direct $PM_{2.5}$ and $PM_{2.5}$ precursors as expeditiously as practicable, for purposes of the 2006 24-hour $PM_{2.5}$ NAAQS in the Salt Lake City area, in accordance with the requirements of CAA section 189(b)(1)(B) and 40 CFR 51.1010. Additional detail can be found in the TSD within the docket.

[18] *Id.*

[19] 40 CFR part 51, appendix V, section 2.3.1.

[20] On November 6, 2020, (85 FR 71023), the EPA proposed approval of the redesignation requests, maintenance plans, and the Moderate and Serious $PM_{2.5}$ SIP submissions including BACM/BACT determinations for all other sources (which included on-road mobile sources, off-road mobile sources, area sources, and major stationary sources).

[21] The Cost Analysis Models/Tools for Air Pollution Regulations can be found at *https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/cost-analysis-modelstools-air-pollution.*

B. Utah's Additional SIP Revisions in the May 20, 2025 Draft Submission

When certain sections of the Utah state SIP are amended by the Utah Air Quality Board (UAQB), those sections must be incorporated into the Utah Air Quality Rules in the UAC. Utah incorporates its state SIP sections within UAC section R307–110. These rules are amended as needed to change the effective dates to match the UAQB approval date of various amendments to the Utah state SIP. For this proposed action, we are also proposing to approve into the federally approved SIP, through the parallel process based on the information in the May 20, 2025 UDAQ submission, section IX., Control Measures for Area and Point Sources, Part H, Emission Limits,[22] which incorporates all the emission limits in the Utah state SIP section IX.H.11. and 12. Additionally, we are proposing to approve into the federally approved SIP the revisions within Utah SIP sections 11. and 12. through the parallel process based on the information May 20, 2025 UDAQ submission. In section I.C. above, we discuss the process of this type of action.

1. R307–110–17

Section R307–110–17 incorporates the amendments to Utah State SIP section IX., Control Measures for Area and Point Sources, Part H, Emission Limits into the UAC. This is a ministerial provision, which only revises the effective date within the rule to May 7, 2025, and does not by itself change any state SIP control measures.

2. Utah State SIP Section IX.H.11

Utah State SIP section IX.H.11. (General Requirements: Control Measures for Area and Point Sources, Emission Limits and Operating Practices, $PM_{2.5}$) establishes general requirements for recordkeeping, reporting, good combustion practices for emission minimization, and monitoring for the stationary sources subject to emission limits under Utah State SIP sections IX.H.12. and 13., except as otherwise outlined in individual conditions in sections IX.H.12. and 13. Additionally, this section establishes general refinery requirements, addressing limitations on emitting units common to the refineries in the NAAs. These general refinery requirements include limits at fluid catalytic cracking units, limits on refinery fuel gas and heat exchangers, requirements on tank degassing, restrictions on liquid fuel oil consumption, requirements for leak detections and repairs, and requirements for hydrocarbon flares. Furthermore, section IX.H.11. controls VOCs through catalytic oxidation at internal combustion engines and natural gas combustion turbines.

UDAQ revised IX.H.11.c. where subsections 'iv' and 'v' were created. These two subsections describe how each source under IX.H.12. and 13. are required to comply with all applicable recordkeeping and reporting sections of the facilities' most recently, federally, approved title V permit, which includes submissions of annual compliance certifications and bi-annual monitoring reports, unless a more stringent requirement is found under IX.H.12. and/or 13. Additionally, subsection 'v' requires that each source complies with applicable recordkeeping and reporting found in 40 CFR part 60 and 40 CFR part 63.

Additionally, UDAQ revised subsection IX.H.11.g.vii.B. and created two other subsections under IX.H.11.g. which includes IX.H.11.g.viii. and IX.H.11.g.ix. Subsection IX.H.11.g.vii.B. revised a reference of 40 CFR 80.510 to 1090.305. The two subsections that were created, create good combustion practices, and recordkeeping and reporting requirements specific to refineries located in the $PM_{2.5}$ NAAs. To ensure minimization of emissions, each owner/operator shall operate all combustion units in accordance with good combustion practices and maintain all combustion units following the manufacturer's recommendations. The additional recordkeeping and reporting requirements for refineries are in addition to IX.H.11.c. and each refinery shall comply with the listed requirements until such time as a title V operating permit is federally approved:

(a) All required monitoring data and support information required by IX.H.11 and IX.H.12 shall be retained by the source for a period of five years from the date of monitoring sample, measurement, report, or application. Support information includes all calibration and maintenance records, all original strip-charts or appropriate readings for continuous monitoring instrumentation, and copies of all reports required by IX.H.11 and IX.H.12.

(b) Monitoring reports, if applicable, shall be submitted to UDAQ as specified in IX.H.11.e. and IX.H.11.f.

The detailed analysis of our parallel process on the May 20, 2025 submission of draft revisions to Utah State SIP section IX.H.11., can be found in our TSD in the docket.

3. Utah State SIP Section IX.H.12

Utah State SIP section IX.H.12. (Source-Specific Emission Limitations in Salt Lake City—UT $PM_{2.5}$ Nonattainment Area) establishes specific emission limitations for 17 sources. These sources are ATK Launch Systems Inc. Promontory, Big West Oil LLC Refinery, Chemical Lime Company (LHoist North America), Chevron Products Company—Salt Lake Refinery, Compass Minerals Ogden Inc., Holly Frontier Sinclair Woods Cross Refinery, Kennecott Utah Copper (KUC): Mine, Kennecott Utah Copper (KUC): Power Plant, Kennecott Utah Copper: Smelter and Refinery, Nucor Steel Mills, PacifiCorp Energy: Gadsby Power Plant, Tesoro Refining and Marketing Company LLC Marathon Refinery: Salt Lake City Refinery, The Proctor & Gamble Paper Products Company, Utah Municipal Power Association: West Valley Power Plant, University of Utah: University of Utah Facilities, and Hill Air Force Base. Major stationary sources were identified based on their potential to emit (PTE) of 70 tpy or more of $PM_{2.5}$, NO_X, SO_2, VOC, and/or NH_3. With this draft submittal, UDAQ is completing major revisions to emission limitations for the following five sources in section IX.H.12.: (1) IX.H.12.b. Big West Oil LLC Refinery; (2) IX.H.12.d. Chevron Products Company—Salt Lake Refinery; (3) IX.H.12.f. Hexcel Corporation: Salt Lake Operations; (4) IX.H.11.g. Holly Frontier Sinclair Woods Cross Refinery; and (5) IX.H.12.m. Tesoro Refining and Marketing Company LLC Marathon Refinery: Salt Lake City Refinery. A summary of the proposed new emission limits is outlined below.

The detailed analysis of our parallel process on the May 20, 2025 submission of draft revisions and BACM/BACT analyses to Utah state SIP section IX.H.12., can be found in our TSD in the docket.

4. EPA's Evaluation and Conclusion of Utah's Additional SIP Revisions in the May 20, 2025 Draft Submission

We are proposing to approve, through parallel processing, the May 20, 2025 draft submission of revisions to the federally approved Utah SIP as listed in the Utah state SIP section IX.H.11. and 12. We are also proposing to find that the May 20, 2025 draft submission provides for the implementation of BACM/BACT for the five sources of direct $PM_{2.5}$ and $PM_{2.5}$ precursors listed above as expeditiously as practicable, for purposes of the 2006 24-hour $PM_{2.5}$ NAAQS in the Salt Lake City area, in accordance with the requirements of CAA section 189(b)(1)(B) and 40 CFR

[22] Utah's SIP for R307 series rules are located at: *https://deq.utah.gov/air-quality/air-quality-laws-and-rules;* and section IX.H. are located at: *https://deq.utah.gov/air-quality/sections-state-implementation-plan-sip.*

51.1010. Additional detail can be found within the TSD in the docket.

C. Did Utah follow the proper procedures for adopting their action?

Section 110(k) of the CAA addresses our actions on submissions of revisions to a SIP. The Act also requires states to observe procedural requirements in developing implementation plans and plan revisions for submission. Section 110(a)(2) of the Act provides that each implementation plan submitted by a state must be adopted after reasonable notice and public hearing. Section 110(l) of the Act similarly provides that each revision to an implementation plan submitted by a state under the Act must be adopted by the state after reasonable notice and public hearing.

We also must determine whether a submittal is complete and therefore warrants further review and action.[23] Our completeness criteria for SIP submittals is set out at 40 CFR part 51, appendix V. A submittal is deemed complete by operation of law under section 110(k)(1)(B) of the Act if a completeness determination is not made within six months after receipt of the submission.

On May 20, 2025, UDAQ submitted to the EPA for parallel processing a draft SIP revision based upon draft revisions to the Utah state SIP section IX.H.11. and 12., and R307–110–17. The comment period at the State level began March 1 and ended March 31, 2025, with a public hearing held online at 2:00 p.m. on March 13, 2025. UDAQ requested this parallel processing so as not to delay action on the 2006 24-hour $PM_{2.5}$ redesignations for the Salt Lake City and Provo NAAs. UDAQ is planning on submitting its final SIP revision early in July 2025. After the State formally submits these final revisions, the EPA will evaluate the final submittal for any changes between the proposed and final versions. As discussed above in section I.C., the EPA will determine if any changes to the draft submission would warrant another proposed rule, or if on the other hand the agency may proceed with a final action. This formal submission from the State of Utah will accompany either the final rule or the new proposed rule under this docket number.

III. Proposed Action

As mentioned in the sections above, we are proposing to approve, through parallel processing, Utah's draft May 20, 2025 submission to revise the federally approved Utah SIP based upon revisions to the Utah state SIP sections IX.H.11. and 12., and the accompanying R307–110–17. Additionally, the EPA is proposing to approve for incorporation into the federally approved Utah SIP the five major stationary sources BACM/BACT analyses/updates for the Salt Lake City 2006 24-hour $PM_{2.5}$ NAA that were submitted as a draft on May 20, 2025.

IV. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference R307–110–17 and Utah state SIP section IX.H.11. and 12, as discussed in sections I. and II. of this preamble. The EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 2, 2025.

Cyrus M. Western,

Regional Administrator, Region 8.

[FR Doc. 2025–13337 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

[23] CAA section 110(k)(1); 57 FR 13565.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2025–0292; FRL–12825–01–R9]

Determination of Attainment by the Attainment Date and Clean Data Determination; California, San Joaquin Valley 1997 Annual $PM_{2.5}$ Fine Particulate Matter Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the San Joaquin Valley, California fine particulate matter ($PM_{2.5}$) nonattainment area attained the 1997 annual $PM_{2.5}$ national ambient air

quality standards (NAAQS) by the December 31, 2024 applicable attainment date. This proposed determination is based on ambient air quality monitoring data from 2022 through 2024. We are also proposing to make a clean data determination (CDD) based on the 2022 through 2024 data and our evaluation of preliminary air quality monitoring data from 2025. We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2025–0292 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ashley Graham, Geographic Strategies and Modeling Section (AIR–2–2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; telephone number: (415) 972–3877; email address: *graham.ashleyr@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Background

A. $PM_{2.5}$ NAAQS

The Clean Air Act (CAA) requires the EPA to establish primary and secondary NAAQS for certain pervasive pollutants that ''may reasonably be anticipated to endanger public health and welfare.'' [1] The primary NAAQS is designed to protect public health with an adequate margin of safety, and the secondary NAAQS is designed to protect public welfare and the environment. The EPA has set standards for six common air pollutants, referred to as criteria pollutants. These standards represent the air quality levels an area must meet to comply with the CAA.

$PM_{2.5}$ can be particles emitted by sources directly into the atmosphere as a solid or liquid particle (''primary $PM_{2.5}$'' or ''direct $PM_{2.5}$'') or can be particles that form in the atmosphere as a result of various chemical reactions from $PM_{2.5}$ precursor emissions emitted by sources (''secondary $PM_{2.5}$''). The EPA established each of the $PM_{2.5}$ NAAQS after considering substantial evidence from numerous health studies demonstrating that serious health effects are associated with exposures to $PM_{2.5}$ concentrations above such levels. Epidemiological studies have shown statistically significant correlations between elevated $PM_{2.5}$ levels and premature mortality. Other important health effects associated with $PM_{2.5}$ exposure include aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions, emergency room visits, absences from school or work, and restricted activity dates), changes in lung function and increased respiratory symptoms, and new evidence for more subtle indicators of cardiovascular health. Individuals particularly sensitive to $PM_{2.5}$ exposure include older adults, people with heart and lung disease, and children.[2]

On July 18, 1997, the EPA revised the NAAQS for particulate matter by establishing new NAAQS for particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$).[3] The EPA established primary and secondary annual and 24-hour standards for $PM_{2.5}$.[4] The EPA set the annual primary and secondary standards at 15.0 micrograms per cubic meter ($\mu g/m^3$), based on a three-year average of annual mean $PM_{2.5}$ concentrations.[5] The EPA has since strengthened the primary annual $PM_{2.5}$ NAAQS;[6] however, the 1997 primary annual $PM_{2.5}$ NAAQS remains in effect in areas designated nonattainment for that NAAQS.[7]

B. The San Joaquin Valley $PM_{2.5}$ Nonattainment Area

Following promulgation of a new or revised NAAQS, the EPA is required under CAA section 107(d) to designate areas throughout the nation as attainment, nonattainment, or unclassifiable for the NAAQS. Effective April 5, 2005, the EPA established the initial air quality designations for the 1997 annual $PM_{2.5}$ NAAQS, using air quality monitoring data for the three-year periods of 2001–2003 and 2002–2004.[8] The EPA designated the San Joaquin Valley as nonattainment for the 1997 annual $PM_{2.5}$ NAAQS.[9]

The San Joaquin Valley $PM_{2.5}$ nonattainment area encompasses over 23,000 square miles and includes all or part of eight counties: San Joaquin, Stanislaus, Merced, Madera, Fresno, Tulare, Kings, and the valley portion of Kern.[10] The area is home to four million people and is one of the nation's leading agricultural regions. Stretching over 250 miles from north to south and averaging 80 miles wide, it is partially enclosed by the Coast Mountain range to the west, the Tehachapi Mountains to the south, and the Sierra Nevada range to the east.

The California Air Resources Board (CARB) is the state agency responsible for the adoption and submission to the EPA of California state implementation plan (SIP) submissions. Under

[1] CAA section 108(a).

[2] EPA, Air Quality Criteria for Particulate Matter, No. EPA/600/P–99/002aF and EPA/600/P–99/002bF, October 2004.

[3] 62 FR 38652.

[4] For a given air pollutant, ''primary'' NAAQS are those determined by the EPA as requisite to protect the public health, allowing an adequate margin of safety, and ''secondary'' standards are those determined by the EPA as requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. See CAA section 109(b).

[5] 40 CFR 50.7.

[6] 78 FR 3086 (January 15, 2013) and 89 FR 16202 (February 7, 2024).

[7] 40 CFR 50.13(d).

[8] 70 FR 944 (January 5, 2005).

[9] 40 CFR 81.305.

[10] For a precise description of the geographic boundaries of the San Joaquin Valley nonattainment area, see 40 CFR 81.305.

California law, air districts in California are generally responsible for the development of regional air quality plans. For the San Joaquin Valley area, the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or ''District'') develops and adopts air quality management plans to address CAA planning requirements applicable to the region. The District then submits such plans to CARB for adoption and submission to the EPA as proposed revisions to the California SIP.

The EPA approved most of the elements of the State's attainment plan for the San Joaquin Valley for the 1997 annual $PM_{2.5}$ NAAQS on December 14, 2023, including the State's demonstration that the area would attain the NAAQS by December 31, 2023.[11] On May 23, 2024, the State of California transmitted a letter to the EPA requesting that the EPA grant a one-year extension under CAA section 172(a)(2)(C) of the applicable ''Serious'' area attainment date for the San Joaquin Valley from December 31, 2023, to December 31, 2024.[12] In its request, the State certified that it has complied with all requirements and commitments pertaining to the area in the approved implementation plan and that certified monitoring data for the San Joaquin Valley for 2023 were below the level of the 1997 annual $PM_{2.5}$ NAAQS. On November 19, 2024, the EPA granted the State's request and extended the applicable attainment date to December 31, 2024.[13]

C. Clean Air Act Requirement for a Determination of Attainment

Sections 179(c) and 188(b)(2) of the CAA require that within six months following the applicable attainment date, the EPA shall determine whether a $PM_{2.5}$ nonattainment area attained the standard based on the area's design value[14] as of that date.[15] This determination, also referred to as a determination of attainment by the attainment date (DAAD), is based on certified data leading up to the attainment date, *i.e.,* in this case, data for 2022–2024. Section 179(c)(2) of the CAA requires the EPA to publish the determination in the **Federal Register**.

D. The EPA's Clean Data Policy

Under the EPA's longstanding Clean Data Policy, which was reaffirmed in the $PM_{2.5}$ Implementation Rule at 40 CFR 51.1015, when an area has attained the relevant $PM_{2.5}$ standard(s), the EPA may issue a CDD (also sometimes referred to as a determination of attainment for the purposes of the Clean Data Policy) after notice and comment rulemaking determining that a specific area is attaining the relevant standard(s). A CDD is not linked to any particular attainment deadline and is not necessarily equivalent to a determination that an area has attained the standard by its applicable attainment deadline (i.e., a DAAD). The effect of a CDD is to suspend the requirement for the area to submit an attainment demonstration, a reasonably available control measures demonstration, a reasonable further progress (RFP) plan, contingency measures, and any other planning requirements related to attainment for as long as the area continues to attain the standard.[16] A CDD does not suspend the requirements for an emissions inventory or for new source review.[17]

II. Determination of Attainment by the Attainment Date

A. Monitoring Network Review, Quality Assurance, and Data Completeness

A determination of whether an area is attaining the NAAQS is typically based upon complete, quality-assured data gathered at established State and Local Air Monitoring Stations (SLAMS) and entered into the EPA's Air Quality System (AQS) database. Data from ambient air monitors operated by state/local agencies in compliance with the EPA monitoring requirements must be submitted to AQS. Monitoring agencies annually certify that these data are accurate to the best of their knowledge. Accordingly, the EPA relies primarily on data in AQS when determining compliance with the NAAQS.[18] The EPA reviews all data to determine the area's air quality status in accordance with 40 CFR part 50, appendix N. Under EPA regulations in 40 CFR 50.7 and in accordance with appendix N, the 1997 annual $PM_{2.5}$ NAAQS are met when the annual arithmetic mean concentration, as determined in accordance with the rounding conventions in 40 CFR part 50, appendix N, is less than or equal to 15.0 $\mu g/m^3$ at each eligible monitoring site within the area.

For the annual $PM_{2.5}$ standard, eligible monitoring sites are those monitoring stations that meet the criteria specified in 40 CFR 58.11 and 58.30 and thus are approved for comparison to the annual $PM_{2.5}$ NAAQS.[19] Three years of valid annual means are required to produce a valid annual $PM_{2.5}$ NAAQS design value.[20] Data completeness requirements for a given year are met when at least 75 percent of the scheduled sampling days for each quarter have valid data.[21] We note that monitors with incomplete data in one or more quarters may still produce valid design values if the conditions for applying the EPA's data substitution test are met.[22] In determining whether data are suitable for regulatory determinations, the EPA uses a ''weight of evidence'' approach, considering the requirements of 40 CFR

[11] 88 FR 86581. We approved the State's best available control measures (BACM) demonstration, attainment demonstration, reasonable further progress (RFP) demonstration, quantitiatve milestone demonstration, five percent reduction in emisisons per year demonstration, and motor vehicle emissions budgets as meeting the ''Serious'' area and CAA section 189(d) planning requirements. We also affirmed that the base year emissions inventories in the plan, which we had previously approved (86 FR 67329, November 26, 2021), provided an adequate basis for the BACM, RFP, five percent, and modeled attainment demonstration analyses. We deferred action on the requirement for contingency measures; however, we subsequently approved the area's contingency measures submittal on October 4, 2024 (89 FR 80749).

[12] Letter dated May 23, 2024, from Steven S. Cliff, Executive Officer, CARB, to Martha Guzman, Regional Administrator, EPA Region 9.

[13] 89 FR 91263.

[14] A design value is the 3-year average NAAQS metric that is compared to the NAAQS level to determine when a monitoring site meets or does not meet the NAAQS. The specific methodologies for calculating whether the annual $PM_{2.5}$ NAAQS is met at each eligible monitoring site in an area is found in 40 CFR part 50, appendix N, section 4.1.

[15] A determination that an area has attained by the applicable attainment date does not constitute a redesignation to attainment.

[16] Because the EPA previously approved the State's attainment plan for the San Joaquin Valley for the 1997 annual $PM_{2.5}$ NAAQS (see footnote 11 of this document), the State would not be required to submit any additional planning elements following a DAAD. However, in *Little Manila Rising, et al.* v. *EPA,* 9th Cir. Case No. 24–6990, the question regarding the extent of the EPA's authority to grant a one-year extension of the applicable attainment date from December 31, 2023, to December 31, 2024, for the San Joaquin Valley for the 1997 annual $PM_{2.5}$ NAAQS is still pending before the court. In the event that the court finds that the EPA did not have the authority to grant the extension, the proposed CDD in this action would relieve the state of the requirement to adopt and submit a new plan for failing to attain by the applicable attainment date.

[17] In the context of CDDs, the EPA distinguishes between attainment planning requirements of the CAA, which relate to the attainment demonstration for an area and related control measures designed to bring an area into attainment for the given NAAQS as expeditiously as practicable, and other types of requirements, such as permitting requirements under the nonattainment new source review program, the emissions inventory requirement, and specific control requirements independent of those strictly needed to ensure timely attainment of the given NAAQS. 81 FR 58010, 58128.

[18] See 40 CFR 50.7; 40 CFR part 50, appendix L; 40 CFR part 53; 40 CFR part 58, and 40 CFR part 58, appendices A, C, D, and E.

[19] 40 CFR part 50, appendix N section 1.0(c).

[20] 40 CFR part 50, appendix N, section 4.1(b).

[21] Id.

[22] 40 CFR part 50, appendix N, section 4.1(b) and (c).

part 58, appendix A ''in combination with other data quality information, reports, and similar documentation that demonstrate overall compliance with Part 58.'' [23]

Section 110(a)(2)(B)(i) of the CAA requires states to establish and operate air monitoring networks to compile data on ambient air quality for all criteria pollutants. The monitoring requirements are specified in 40 CFR part 58. These requirements are applicable to state and, where delegated, local air monitoring agencies that operate criteria pollutant monitors. The regulations in 40 CFR part 58 establish specific requirements for operating air quality surveillance networks to measure ambient concentrations of $PM_{2.5}$, including requirements for measurement methods, network design, quality assurance procedures, and, in the case of large urban areas, the minimum number of monitoring sites designated as SLAMS.

In section 4.7 of appendix D to 40 CFR part 58, the EPA specifies minimum monitoring requirements for $PM_{2.5}$ to operate at SLAMS. SLAMS produce data comparable to the NAAQS, and therefore, the monitor must be an approved federal reference method (FRM) or federal equivalent method (FEM). The minimum number of SLAMS required is described in section 4.7.1 and can be met by either filter-based or continuous FRMs or FEMs. The monitoring regulations also provide that each core-based statistical area must operate a minimum number of $PM_{2.5}$ continuous monitors; [24] however, this requirement can be met by either an FEM or a non-FEM continuous monitor, and the continuous monitors can be located with other SLAMS or at a different location. Consequently, the monitoring requirements for $PM_{2.5}$ can be met with filter-based FRMs/FEMs, continuous FEMs, continuous non-FEMs, or a combination of monitors at each required SLAMS.

Under 40 CFR 58.10, states are required to submit annual monitoring network plans to the EPA.[25] Within the San Joaquin Valley, CARB and the District are the agencies responsible for assuring that the area meets $PM_{2.5}$ air quality monitoring requirements. CARB and SJVUAPCD submit monitoring network plans to the EPA annually. These plans describe and discuss the status of the air monitoring network, as required under 40 CFR 58.10. Each year, the EPA reviews these annual network plans for compliance with the applicable monitoring requirements in 40 CFR part 58. With respect to $PM_{2.5}$, we have found that the CARB and SJVUAPCD annual network plans meet the applicable requirements under 40 CFR part 58.[26]

During the 2022–2024 period, ambient $PM_{2.5}$ concentration data that are eligible for use in determining whether an area has attained the $PM_{2.5}$ NAAQS were collected at a total of 18 sites within the San Joaquin Valley. The District operates 12 of these sites while CARB operates 6 of these sites. All of the sites are designated SLAMS for $PM_{2.5}$.[27] Based on our review of the $PM_{2.5}$ monitoring network, we propose to find that the monitoring network in the San Joaquin Valley is adequate for the purpose of collecting ambient $PM_{2.5}$ concentration data for use in determining whether the San Joaquin Valley has attained the 1997 annual $PM_{2.5}$ NAAQS.

Under 40 CFR 58.15, monitoring agencies must submit a letter to the EPA each year to certify that all of the ambient concentration and quality assurance data for the previous year have been submitted to AQS and that the ambient concentration data are accurate to the best of their knowledge, taking into consideration the quality assurance findings. The letter must address data for all FRM and FEM monitors at SLAMS and special purpose monitoring stations that meet the criteria specified in 40 CFR part 58, appendix A. CARB annually certifies that the data the agency submits to AQS are quality assured, including the data collected at monitoring sites in the San Joaquin Valley.[28] SJVUAPCD does the same for data submitted to AQS from monitoring sites operated by the District.[29]

With respect to data completeness, we determined that the data collected by the CARB and the District met the quarterly completeness criterion for all 12 quarters of the three-year period at most of the $PM_{2.5}$ monitoring sites in the San Joaquin Valley. More specifically, among the 18 $PM_{2.5}$ monitoring sites from which regulatory data are available, the data from Merced-Vierra (AQS ID: 06–047–2024), Stockton-University (AQS ID: 06–077–1003), and Manteca (AQS ID: 06–077–2010) did not meet the 75 percent completeness criterion for one quarter; [30] however, the data from the sites are sufficient nonetheless to produce valid design values for the 1997 annual $PM_{2.5}$ NAAQS pursuant to the rules governing design value validity in 40 CFR part 50, appendix N, section 4.1.

Finally, the EPA conducts regular technical systems audits (TSAs) where we review and inspect state and local ambient air monitoring programs to assess compliance with applicable regulations concerning the collection, analysis, validation, and reporting of ambient air quality data. For the purposes of this proposal, we reviewed the findings from the EPA's most recent TSAs of CARB's and the District's ambient air monitoring programs.[31] The results of the TSAs do not preclude the EPA from determining that the San Joaquin Valley $PM_{2.5}$ nonattainment area has attained the 1997 annual $PM_{2.5}$ NAAQS.

In summary, based on the EPA's reviews of the relevant annual network plans, certifications, quality assurance data, and TSAs, we propose to find that the $PM_{2.5}$ data collected at San Joaquin Valley monitoring sites are suitable for determining whether the San Joaquin Valley $PM_{2.5}$ nonattainment area has attained the 1997 annual $PM_{2.5}$ NAAQS.

B. The EPA's Evaluation of Attainment

Table 1 of this document provides the $PM_{2.5}$ design values at each of the 18 monitoring sites within the San Joaquin Valley $PM_{2.5}$ nonattainment area, expressed as a single design value representing the 2022–2024 period and for each individual year. The $PM_{2.5}$ data show that the design values at the San Joaquin Valley monitoring sites were below the level of the 1997 annual $PM_{2.5}$ NAAQS of 15.0 $\mu g/m^3$. Consequently,

[23] 40 CFR part 58, appendix A, section 1.2.3.

[24] 40 CFR part 58, appendix D, section 4.7.2.

[25] 40 CFR 58.10(a)(1).

[26] Letter dated October 29, 2024, from Dena Vallano, Manager, Monitoring and Analysis Section, EPA Region IX, to Sylvia Vanderspek, Manager, Air Quality Planning Branch, CARB; and letter dated October 29, 2024, from Dena Vallano, Manager, Monitoring and Analysis Section, EPA Region IX, to Jon Klassen, Director, Air Quality Science, SJVUAPCD.

[27] There are a number of other $PM_{2.5}$ monitoring sites within the valley, including other sites operated by the District, the National Park Service, and certain Indian Tribes, but the data collected from these sites are non-regulatory and not eligible for comparison with the $PM_{2.5}$ NAAQS.

[28] For example, see letter dated April 18, 2025, from Jin Xu, Acting Chief, Air Quality Planning Branch, CARB, to Dena Vallano, Manager, Monitoring and Analysis Section, EPA Region 9, with enclosures, certifying calendar year 2024 ambient air quality data and quality assurance data.

[29] For example, see letter dated March 20, 2025, from Robert Gilles, Program Manager, SJVUAPCD, to Matt Lakin, Director, Air and Radiation Division, EPA Region IX, with attachments, certifying calendar year 2024 ambient air quality data and quality assurance data.

[30] EPA, AQS Combined Site Sample Values (AMP355), Report Request ID: 2290307, May 7, 2025.

[31] Letter dated March 14, 2024, from Matthew Lakin, Director, Air and Radiation Division, EPA Region IX, to Edie Chang, Executive Officer, CARB, with enclosure titled ''Technical Systems Audit of the Ambient Air Monitoring Program: California Air Resources Board December 2021–August 2022.''

the EPA is proposing to determine based upon three years of quality-assured and certified data from 2022 through 2024 that the San Joaquin Valley $PM_{2.5}$ nonattainment area attained the 1997 annual $PM_{2.5}$ NAAQS by the applicable December 31, 2024 attainment date.

TABLE 1—2022–2024 ANNUAL $PM_{2.5}$ DESIGN VALUES FOR THE SAN JOAQUIN VALLEY $PM_{2.5}$ NONATTAINMENT AREA

County	Site name (AQS ID)	Annual mean (μg/m³)			2022–2024 Annual design value (μg/m³)
		2022	2023	2024	
Fresno	Fresno-Garland (06–019–0011)	12.9	10.5	10.3	11.2
Fresno	Tranquillity (06–019–2009)	6.7	4.8	7.0	6.2
Fresno	Fresno-Founry (06–019–2016)	14.8	12.5	13.6	13.6
Fresno	Clovis-Villa (06–019–5001)	10.5	8.6	10.6	9.9
Fresno	Fresno-Pacific (06–019–5025)	13.5	12.6	12.7	12.9
Kern	Bakersfield-Golden/M-St (06–029–0010)	16.7	13.7	12.9	14.4
Kern	Bakersfield-California (06–029–0014)	15.8	12.0	12.7	13.5
Kern	Bakersfield-Airport (Planz) (06–029–0016)	16.1	12.5	15.6	14.7
Kings	Corcoran-Patterson (06–031–0004)	14.7	10.1	10.1	11.6
Kings	Hanford-Irwin (06–031–1004)	14.2	12.5	11.8	12.8
Madera	Madera-City (06–039–2010)	10.4	9.9	9.0	9.8
Merced	Merced-Vierra (06–047–2024)	9.8	8.4	7.2 (Inc)	8.4
Merced	Merced-M St (06–047–2510)	10.5	9.6	7.8	9.3
San Joaquin	Stockton-University Park (06–077–1003)	10.2	10.8 (Inc)	10.1	10.4
San Joaquin	Manteca (06–077–2010)	9.0 (Inc)	7.9	8.1	8.3
Stanislaus	Modesto-14th Street (06–099–0005)	13.4	10.5	9.0	11.0
Stanislaus	Turlock (06–099–0006)	10.8	10.1	9.3	10.1
Tulare	Visalia-W Ashland Avenue (06–107–2003)	15.0	11.7	13.0	13.2

Source: EPA, AQS Design Value Report (AMP480), Report Request ID: 2290291, May 7, 2025.
Notes: Inc = Incomplete Data.

III. Clean Data Determination

As described in section I.D. of this document, when an area has attained the relevant $PM_{2.5}$ standard(s), the EPA may issue a CDD after notice and comment rulemaking determining that a specific area is attaining the relevant standard.[32] Based on quality-assured and certified data for 2022–2024, the San Joaquin Valley $PM_{2.5}$ nonattainment area meets the 1997 annual $PM_{2.5}$ NAAQS. Furthermore, preliminary data available in AQS for 2025 (January through March) indicate that the area continues to show concentrations consistent with attainment of the 1997 annual $PM_{2.5}$ NAAQS.[33] Consequently, the EPA is proposing to issue a CDD.

If we finalize this proposed CDD, the obligation to submit attainment planning provisions to meet the requirements for an attainment plan for the 1997 annual $PM_{2.5}$ NAAQS, including an RFP plan, quantitative milestones and quantitative milestone reports, contingency measures, and an attainment demonstration, are suspended until such time as: (1) the area is redesignated to attainment, after which such requirements are permanently discharged; or (2) the EPA determines that the area has re-violated the $PM_{2.5}$ NAAQS, at which time the state shall submit such attainment plan elements for the nonattainment area by a future date to be determined by the EPA and announced through publication in the **Federal Register** at the time the EPA determines the area is violating the $PM_{2.5}$ NAAQS.

A CDD does not suspend the requirements for an emissions inventory or new source review (NSR). The EPA previously approved the base year emissions inventory element of the attainment plan for the 1997 annual $PM_{2.5}$ NAAQS as meeting the requirements of CAA section 172(c)(3) and 40 CFR 50.1008.[34] On January 21, 2025, the EPA proposed a limited approval and limited disapproval of nonattainment NSR SIP revisions submitted by California for the San Joaquin Valley.[35] We are not taking any further action on the submissions at this time.

IV. The EPA's Proposed Action

For the reasons discussed in this document, the EPA is proposing to determine, based on the most recent three years (2022–2024) of complete (or otherwise validated), quality-assured, and certified data meeting the requirements of 40 CFR part 50, appendix N, that the San Joaquin Valley $PM_{2.5}$ nonattainment area attained the 1997 annual $PM_{2.5}$ NAAQS by its December 31, 2024 attainment date. This action, when finalized, will fulfill the EPA's statutory obligation to determine whether the San Joaquin Valley $PM_{2.5}$ nonattainment area attained the NAAQS by the attainment date.

In accordance with 40 CFR 51.1015, we are also proposing to issue a CDD for the San Joaquin Valley $PM_{2.5}$ nonattainment area for the 1997 annual $PM_{2.5}$ NAAQS. Accordingly, the EPA is proposing to determine that the obligation to submit any attainment-related SIP revisions is not applicable for so long as the area continues to attain those NAAQS. This CDD does not constitute a redesignation to attainment. The San Joaquin Valley $PM_{2.5}$ nonattainment area will remain designated nonattainment for the 1997 annual $PM_{2.5}$ NAAQS until such time as the EPA determines, pursuant to sections 107 and 175A of the CAA, that the San Joaquin Valley $PM_{2.5}$ nonattainment area meets the CAA requirements for redesignation to attainment, including an approved maintenance plan showing that the area will continue to meet the standard for 10 years.

The EPA is soliciting public comments on the issues discussed in this document. We will accept comments from the public on this proposal for the next 30 days. We will

[32] 40 CFR 51.1015.

[33] EPA, AQS Combined Site Sample Values (AMP355), Report Request ID: 2296369, June 2, 2025; AQS Combined Site Sample Values (AMP355), Report Request ID: 2296793, June 4, 2025.

[34] 86 FR 67329, 67341 (November 26, 2021).

[35] 90 FR 6928.

consider these comments before taking final action.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is not expected to be an Executive Order 14192 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this proposed action does not impose additional requirements beyond those imposed by state law.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or Tribal governments, or to the private sector, will result from this action.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction, and it will not impose substantial direct costs on Tribal governments or preempt Tribal law. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it merely proposes a DAAD and a CDD. Furthermore, the EPA's Policy on Children's Health does not apply to this action.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 7, 2025.

Joshua F.W. Cook,

Regional Administrator, Region IX.

[FR Doc. 2025–13339 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2019–0418; FRL–12875–01–R8]

Air Quality State Implementation Plans; Approval and Promulgations: Montana: Infrastructure Requirements for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of a state implementation plan (SIP) submission from Montana regarding the infrastructure requirements of the Clean Air Act (CAA) for the 2015 ozone National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. Additionally, EPA is proposing to approve Montana's request to update their SIP, to incorporate the most current version of the ''Guideline on Air Quality Models.'' The EPA is taking this action pursuant to the CAA.

DATES: Written comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2019–0418 to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *https://www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

https://www2.epa.gov/dockets/commenting-epa-dockets.

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *https://www.regulations.gov.* Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Amrita Singh, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado, 80202–1129, telephone number: (303) 312–6103, email address: *singh.amrita@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

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I. What is the background of this SIP submission?

Whenever EPA promulgates a new or revised NAAQS, CAA section 110(a)(1) requires states to make SIP submissions to provide for the implementation, maintenance, and enforcement of the NAAQS. This type of SIP submission is commonly referred to as an ''infrastructure SIP.'' These submissions must meet the various requirements of CAA section 110(a)(2), as applicable. EPA has previously provided states with direction [1] on the application of these CAA provisions and through regional actions on infrastructure submissions. Unless otherwise noted below, we are following that existing approach in acting on this submission. In addition, in the context of acting on such infrastructure submissions, EPA evaluates the submitting state's SIP for factual compliance with statutory and regulatory requirements, not for the state's implementation of its SIP. EPA has other authority to address any issues concerning a state's implementation of the rules, regulations, consent orders, etc. that comprise its SIP.

The Montana Department of Environmental Quality (MDEQ) submitted the following revisions to its infrastructure SIP (ISIP):

- 2015 Ozone ISIP submitted on October 1, 2018, and
- Revisions to appendix W submitted on December 28, 2022.

II. What infrastructure elements are required under section 110(a)(1) and (2)?

CAA section 110(a)(1) provides the procedural and timing requirements for SIP submissions after a new or revised NAAQS is promulgated. Section 110(a)(2) lists specific elements the SIP must contain or satisfy. These infrastructure elements include requirements such as modeling, monitoring, and emission inventories, which are designed to ensure attainment and maintenance of the NAAQS. The elements that are subject to this action are listed below:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C): Program for enforcement of control measures/minor new source review (NSR)/prevention of significant deterioration (PSD).
- Section 110(a)(2)(D): Interstate transport.
- Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
- Section 110(a)(2)(F): Stationary source monitoring and reporting.
- Section 110(a)(2)(G): Emergency powers.
- Section 110(a)(2)(H): Future SIP revisions.
- Section 110(a)(2)(I): Plan revisions for nonattainment areas (under part D);
- Section 110(a)(2)(J): Consultation with government officials; public notification; and PSD and visibility protection.
- Section 110(a)(2)(K): Air quality modeling/data.
- Section 110(a)(2)(L): Permitting fees.
- Section 110(a)(2)(M): Consultation/participation by affected local entities.

III. EPA's Analysis of This SIP Submission

Montana provided a detailed synopsis of how various components of its SIP meet each of the applicable requirements in section 110(a)(2) for the 2015 ozone NAAQS. The following review evaluates the SIP's submission.

Section 110(a)(2)(A)—Emission Limits and Other Control Measures

This section requires SIPs to include enforceable emission limits and other control measures, means or techniques, schedules for compliance, and other related matters. EPA has long interpreted emission limits and control measures for attaining the standards as being due when nonattainment planning requirements are due.[2] In the context of an infrastructure SIP, EPA is not evaluating the existing SIP provisions for this purpose. Instead, EPA is only evaluating whether the State's SIP has basic structural provisions for the implementation of the NAAQS.

The Montana Code Annotated (MCA) 75–2–112 gives MDEQ the authority to ''adopt, amend, and repeal rules for the administration, implementation, and enforcement of this chapter.

Montana implements a statewide program for permitting major and minor stationary sources of air pollution, including sources of ozone precursors. Specific control measures adopted in Montana Board of Environmental Review (BER) Orders, along with multiple SIP-approved state air quality regulations within the Administrative Rules of Montana (ARM) and cited in Montana's certifications, provide enforceable emission limitations and other control measures, means of techniques, schedules for compliance, and other related matters necessary to meet the requirements of CAA section 110(a)(2)(A) for the 2015 ozone NAAQS. Montana's certifications generally list provisions and enforceable control measures within its SIP which regulate pollutants through various programs, including its stationary permitting program which requires sources to demonstrate that emissions will not cause or contribute to violation of any NAAQS (ARM 17.8.749). In the case of Montana, this meets the requirements of section 110(a)(2)(A) for the 2015 ozone NAAQS.

Section 110(a)(2)(B)—Ambient Air Quality Monitoring/Data System

This section requires SIPs to provide for establishing and operating ambient air quality monitors, collecting, and analyzing ambient air quality data, and upon request, to make these data available to EPA. Submission of annual monitoring network plans (AMNP) consistent with EPA's ambient air monitoring regulations at 40 CFR 58.10 is one way of satisfying requirements to

[1] Available at: *https://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance_on_Infrastructure_SIP_Elements_Multipollutant_FINAL_Sept_2013.pdf.* Hereinafter referred to as the ''EPA 2013 Guidance.''

[2] *See, e.g.,* EPA's final rule on ''National Ambient Air Quality Standards for Lead.'' 73 FR 66964 at 67034.

provide EPA information regarding air quality monitoring activities.[3] EPA's review of a state's annual monitoring plan includes EPA's determination that the state: (i) monitors air quality at appropriate locations throughout the state using EPA-approved Federal Reference Methods or Federal Equivalent Method monitors; (ii) submits data to EPA's Air Quality System in a timely manner; and, (iii) provides EPA Regional offices with prior notification of any planned changes to monitoring sites or the network plan.

A comprehensive AMNP, was submitted to EPA by Montana on July 1, 2018, and subsequently approved by the EPA.[4] Montana's SIP-approved regulations provide for the design and operation of its monitoring network, reporting of data obtained from the monitors, and annual network review including notification to the EPA of any changes, and public notification of exceedance of NAAQS. As described in the submission, Montana operates a comprehensive monitoring network, including ozone monitoring, compiles and analyzes collected data, and submits the data to the EPA's Air Quality System on a quarterly basis.

Based on this information, we are proposing to approve the Montana SIP as meeting the requirements of CAA section 110(a)(2)(B) for the 2015 ozone NAAQS.

Section 110(a)(2)(C)—Program for Enforcement of Control Measures/Minor NSR/PSD

Section 110(a)(2)(C) requires states to have a plan that includes a program providing for enforcement of all SIP measures, regulation of minor sources and minor modifications, and the regulation of the modification and construction of each stationary source, including a program to meet the Prevention of Significant Deterioration (PSD) of air quality. This section requires SIPs to set forth a program providing for enforcement of all SIP measures, and the regulation of construction of new and modified stationary sources to meet the NSR requirements under PSD and Nonattainment NSR (NNSR) programs. Part C of the CAA (sections 160–169B) addresses PSD, while part D of the CAA (sections 171–193) addresses NSR requirements. A state must also provide for the regulation of minor source and minor modifications (minor NSR).[5] The NNSR requirements of section 110(a)(2)(C) are generally outside the scope of infrastructure SIPs. The EPA is not evaluating nonattainment-related provisions, such as the NNSR program required by Part D of the CAA. The EPA is evaluating the State's PSD program as required by Part C of the CAA and the State's minor NSR programs as required by 110(a)(2)(C).

PSD Requirements

With respect to Element (C), each state is required to make an infrastructure SIP submission for a new or revised NAAQS demonstrating that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants.[6] The requirements for Element (J) in relation to a comprehensive PSD Permitting Program are the same as the requirements with respect to Element (C).[7]

Montana's submission has shown that is has a PSD program [8] in place that covers all regulated NSR pollutants.

Minor NSR

The State has adopted a minor NSR program [9] in the approved SIP, which is adopted under section 110(a)(2)(C) of the CAA. The minor NSR program was originally approved by EPA on March 22, 1972. Since approval of the minor NSR program, the State and EPA have relied on the program to assure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the NAAQS. Montana's minor NSR program, as approved in the SIP, covers the construction and modification of regulated NSR pollutants, including $PM_{2.5}$, lead, and ozone and its precursors.

The Montana submission refers to the following state rules and regulations which are SIP-approved, that address and provide for meeting all provisions and requirements of CAA section 110(A)(2)(C).

- 75–2–111, MCA.
- 75–2–112, MCA.
- ARM 17.8.130.
- ARM 17.8.801 *et seq.*
- ARM 17.8.901 *et seq.*
- ARM 17.8.10001 *et seq.*

The EPA is proposing to approve Montana's infrastructure SIP for the 2015 ozone NAAQS, with respect to the general requirements in section 110(a)(2)(C) to include a program in the SIP that regulates the enforcement, modification, and construction of any stationary sources as necessary to assure the NAAQS are achieved.

Section 110(a)(2)(D)—Interstate Transport

CAA section 110(a)(2)(D)(i) consists of four separate elements, or ''prongs''. CAA section 110(a)(2)(D)(i)(I) requires SIPs to contain adequate provisions prohibiting emissions that will contribute significantly to nonattainment of the NAAQS in any other state (prong 1), and adequate provisions prohibiting emissions that will interfere with maintenance of the NAAQS by any other state (prong 2). CAA section 110(a)(2)(D)(i)(II) requires SIPs to contain adequate provisions prohibiting emissions that will interfere with any other state's required measures to prevent significant deterioration of its air quality (prong 3), and adequate provisions prohibiting emissions which will interfere with any others state's required measures to protect visibility (prong 4). Under section 110(a)(2)(D)(i)(I) of the CAA, the EPA and states must give independent consideration to both the prong 1 ''significant contribution to nonattainment'' requirement and the prong 2 ''interference with maintenance'' requirement when evaluating downwind air quality problems under section 110(a)(2)(D)(i)(I).[10] For more information on Montana and EPA's analysis of prongs 1 and 2 for this NAAQS, see our proposed approval of the CAA section 110(a)(2)(D)(i)(I) portion of Montana's October 1, 2018 ISIP.[11]

The EPA took final action on the prong 1 and prong 2 requirements of the CAA section 110(a)(2)(D)(i)(I) for the 2015 ozone NAAQS for Montana on

[3] EPA 2013 Guidance.

[4] The July 1st, 2018 AMNP is referenced in this action because it reflects the version available and under consideration at the time of the October 1, 2018 SIP submittal by the State of Montana. Accordingly, EPA's evaluation is based on the information contained in the 2018 plan, which is included in this docket for this action. *See* ''Montana AMNP Approval 2018''. EPA has reviewed and approved subsequent AMNP's submitted by the State of Montana in the years since 2018.

[5] See EPA's 2013 Guidance on Infrastructure SIP elements

[6] In accordance with EPA's 2013 Guidance on Infrastructure SIP Elements, the NSR pollutants include the criteria pollutants—carbon monoxide, nitrogen dioxide, sulfur dioxide, ozone, particulate matter (PM 2.5 and PM_{10}), and lead.

[7] The ''Prong 3'' requirements of Element D(i)(II) may be satisfied in part by demonstrating that the air agency has a complete PSD permitting program that correctly addresses all regulated NSR pollutants. Our explanation of how the state has satisfied the Prong 3 requirement is below.

[8] *See* ARM 17.8.801 and ARM 17.8.818.

[9] *See* 79 FR 69374. MDEQ issues permits for minor sources of air pollution under ARM, Subchapter 07, Permit Construction and Operation of Air Containment Sources, 17.8.743.

[10] *See North Carolina* v. *EPA,* 531 F.3d 896, 909–911 (2008).

[11] 87 FR 6095, February 3, 2022.

April 12, 2022 (87 FR 21578). In that rulemaking, the EPA determined that Montana's SIP contains adequate provisions to prohibit emissions that will significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQs in any other state.[12] The prong 3 (PSD) requirement of the CAA section 110(a)(2)(D)(i)(II) may be met for all NAAQS by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a comprehensive EPA-approved PSD permitting program in the SIP that applies to all regulated NSR pollutants and that satisfies the requirements of the EPA's PSD implementation rule(s).[13] EPA is proposing approval of prong 3 in this rulemaking.

To meet the prong 4 (visibility) requirement of the CAA section 110(a)(2)(D)(i)(II) under the 2015 ozone NAAQS, a SIP must address the potential for interference with visibility protection caused by ozone, including precursors. An approved regional haze SIP that fully meets the regional haze requirements in 40 CFR 51.308 satisfies the 110(a)(2)(D)(i)(II) requirement for visibility protection as it ensures that emissions from the state will not interfere with measures required to be included in other state SIPs to protect visibility. In the absence of a fully approved regional haze SIP, a state can still make a demonstration that satisfies the visibility requirement section of 110(a)(2)(D)(i)(II).[14] EPA will consider Montana's visibility provisions through a future rulemaking.

CAA section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with the applicable requirements of CAA sections 126 and 115 (relating to interstate and international pollution abatement). CAA section 126 requires notification to neighboring states of potential impacts from a new or modified major stationary source and specifies how a state may petition the EPA when a major source or group of stationary sources in a state is thought to contribute to certain pollution problems in another state. CAA section 115 governs the process for addressing air pollutants emitted in the United States that cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare in a foreign country.

To address CAA section 110(a)(2)(D)(ii), Montana states that its SIP-approved PSD program (specifically, ARM 17.8.826(2)(d)) requires the MDEQ to notify potentially affected states, Trbes, and federal land managers (FLMs) of its intent to approve or disapprove a PSD permit application. Montana also states that nothing in its SIP precludes the state from ensuring compliance with CAA sections 126 and 115 with respect to the 2015 ozone NAAQS. Montana asserts that no sources within the state are the subject of an active finding under CAA section 126 with respect to the 2015 ozone NAAQS, nor are there any findings against Montana under CAA section 115 for this NAAQS. For these reasons, Montana concludes that its SIP meets the requirements of CAA section 110(a)(2)(D)(ii) for the 2015 ozone NAAQS.

For the EPA's analysis of CAA section 110(a)(2)(D)(ii), we reviewed the sections of the Montana SIP referenced by the State in its 2015 Ozone infrastructure SIP submission. As required by 40 CFR 51.166(q)(2)(iv), Montana's SIP-approved PSD program requires notice of proposed new sources or modifications to states whose lands may be significantly affected by emissions from the source or modification (*see* ARM 17.8.826(2)(d)). This provision satisfies the notice requirement of section 126(a). Montana also has no pending obligations under sections 126(c) or 115(b). Therefore, the Montana SIP currently meets the requirements of those sections. On these bases, the EPA is proposing to find that the Montana SIP meets the requirements of CAA section 110(a)(2)(D)(ii) for the 2015 ozone NAAQS.

Section 110(a)(2)(E)—Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies

Section 110(a)(2)(E)(i) requires each SIP to provide necessary assurances that the state will have adequate personnel, funding, and legal authority under state law to carry out its SIP. In addition, section 110(a)(2)(E)(ii) requires each state to comply with the requirements respecting state boards under CAA section 128. Finally, section 110(a)(2)(E)(iii) requires that, where a state relies upon local or regional governments or agencies for implementation of its SIP provisions, the state retains responsibility for ensuring implementation of SIP obligations with respect to relevant NAAQS.

The provisions contained in 75–2–102, MCA, 75–2–111, MCA, and 75–2–112, MCA, provide adequate authority for the State of Montana and the MDEQ to carry out its SIP obligations with respect to the 2015 ozone NAAQS. The State receives section 103 and 105 grant funds through its Performance Partnership Grant, along with required state matching funds to provide funding necessary to carry out Montana's SIP requirements. Montana's Performance Partnership Agreement with the EPA, documents that the State has the resources to carry out agreed environmental program goals, measures, and commitments, including developing and implementing appropriate SIPs for all areas of the State. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. Therefore, we propose to approve Montana's SIP meeting the requirements of section 110(a)(2)(E)(i) for the 2015 ozone NAAQS.

With respect to section 110(a)(2)(E)(iii), the regulations cited by Montana in their certifications (75–2–111 and 75–2–112, MCA) and contained within this docket also provide the necessary assurances that the state has the responsibility for adequate implementation of SIP provisions by local governments. Therefore, we propose to approve Montana's SIP meeting the requirements of section 110(a)(2)(E)(iii) for the 2015 ozone NAAQS.

Section 110(a)(2)(E)(ii) requires each SIP to contain provisions that comply with the state board requirements of section 128 of the CAA. That provision contains two explicit requirements: (1) that any board or body which approves permits or enforcement orders under this chapter shall have at least a majority of members who represent the public interest and do not derive any significant portion of their income from persons subject to permits and enforcement order under this chapter, and (2) that any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed. Section 128 further provides that a state may adopt more stringent conflicts of interest requirements and require EPA to approve such requirements submitted as part of a SIP.

The New Rules I (ARM 17.8.150), II (17.8.151) and III (ARM 17.8.152) adopted by the BER on October 16, 2015, were submitted and approved by the EPA for inclusion in the SIP on

[12] Since this time, EPA has conducted updated modeling which continues to demonstrate that Montana does not significantly contribute to nonattainment or interfere with the maintenance of the 2015 ozone NAAQS in any other state.

[13] *See* 2013 Memo.

[14] *See* 2013 Memo. In addition, the EPA approved the visibility requirement of 110(a)(2)(D)(i) for the 1997 Ozone and $PM_{2.5}$ NAAQS for Colorado before taking action on the State's regional haze SIP. 76 FR 22036 (April 20, 2011).

December 17, 2015, and contain provisions that meet the requirements of section 128(a)(1) and section 128(a)(2) (*See* 81 FR 4234). Montana's SIP continues to meet the requirements of section 110(a)(2)(E)(ii). EPA proposes that Montana meets the infrastructure requirements of this portion of section 110(a)(2)(E) for the 2015 ozone NAAQS.

Section 110(a)(2)(F)—Stationary Source Monitoring and Reporting

States must establish a system to monitor emissions from stationary sources and submit periodic emission reports. Each plan shall also require the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners, or operators of stationary sources to monitor emissions from such sources. The state plan shall also require periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and correlation of such reports by each state agency with any emission limitations or standards. Lastly, the reports shall be available at reasonable times for public inspection.

The provisions cited by Montana (ARM 17.8.105 and 17.8.106) pertain to testing requirements and protocols. Montana also incorporates by reference 40 CFR part 51, appendix P regarding minimum reporting requirements. (*See* ARM 17.8.103(1)(D)). In addition, Montana provides for monitoring, recordkeeping, and reporting requirements for sources subject to minor and major source permitting.

Furthermore, Montana is required to submit emissions data to the EPA for purposes of the National Emissions Inventory (NEI). The NEI is the EPA's central repository for air emissions data. The EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (*See* 73 FR 76539). The AERR shortened the time states had to report emissions data from 17 months to 12 months, giving states one calendar year to submit emissions data. All states are required to submit comprehensive emission inventories every three years and report emissions for certain larger sources annually through the EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and their associated precursors—nitrogen oxides, sulfur dioxides, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Montana made its latest update to the NEI in 2024, however for purposes of this proposed action the emissions data are based on the 2017 NEI released in February 2019 since that included the State's most recent NEI update at the time of the October 1, 2018 ISIP submittal. Based on the analysis above, we propose to approve the Montana SIP as meeting the requirements of CAA section 110(a)(2)(F) for the 2015 ozone NAAQS.

Section 110(a)(2)(G)—Emergency Powers

This section requires that a plan provide for state authority analogous to that provided to the EPA Administrator in section 303 of the CAA, and adequate contingency plans to implement such authority. Section 303 of the CAA provides authority to the EPA administrator to seek a court order to restrain any source from causing or contributing to emissions that present an ''imminent and substantial endangerment to public health or welfare or the environment'' in the event that ''it is not practicable to assure prompt protection. . . . by commencement of such civil action.''

Montana's SIP submittals with regard to the section 110(a)(2)(G) emergency order requirements explain that Montana has an EPA-approved Emergency Episode Avoidance Plan (EEAP) (*See* 71 FR 19, Jan. 3, 2006). According to the EEAP, ''the Department shall take the necessary precautions to protect public health as set forth in 75–2–402, MCA, ''Emergency Powers.'' These precautions include, but are not limited to, ordering a halt or curtailment of any operations, activities, processes, or conditions the Department believes are contributing to the air pollutant emergency episode.'' Montana's submission cites 75–2–402, MCA, as providing general authority comparable to CAA section 303. The submission also cites 75–2–112(2)(a) and 75–2–111(3), MCA. Under 75–2–111(3) MCA, Montana's environmental review board has broad authority to ''issue orders necessary to effectuate the purposes'' of Chapter 2. Also, under 75–2–112(2)(a) MCA, the MDEQ has the authority to use ''appropriate administrative and judicial proceedings'' to enforce orders issued by the board. Any air pollution discharge that created an emergency situation would constitute a violation of the chapter and its purposes; therefore, providing the BER and the MDEQ authority to issue administrative orders to stop discharges that cause emergencies effecting welfare and the environment.

While no single Montana statute mirrors the authorities of CAA section 303, we propose to find that the combination of MCA provisions discussed above provide for authority comparable to section 303 to immediately bring suit to restrain and issue emergency orders for applicable emergencies to take prompt administrative action against any person causing or contributing to air pollution that presents an imminent and substantial endangerment to public health or welfare, or the environment and, therefore are sufficient to meet the authority requirement of CAA section 110(a)(2)(G).

States must also have adequate contingency plans adopted into their SIP to implement the air agency's emergency episode authority (as discussed above). Requirements for contingency plans are provided in 40 CFR part 51, subpart H. The EPA approved Montana's EEAP in 71 FR 19 (Jan. 3, 2006). We find that Montana's air pollution emergency rules include ozone and establish stages of episode criteria; provide for public announcement whenever any episode stage has been determined to exist; and specify emission control actions to be taken at each episode stage. These are consistent with the EPA emergency episode SIP requirements set forth at 40 CFR part 51, subpart H (prevention of air pollution emergency episode) for ozone.

Based on the above analysis, we propose approval of Montana's SIP as meeting the requirements of CAA section 110(a)(2)(G) for the 2015 ozone NAAQS.

Section 110(a)(2)(H)—Future SIP Revisions

This section requires that a state's SIP provide for revision may be necessary, to take account of changes in the NAAQS or availability of improved methods for attaining the NAAQS and whenever EPA finds that the SIP is substantially inadequate.

Montana's statutory provisions in the Montana CAA at 75–2–101 et. seq., give the BER sufficient authority to meet the requirements of 110(a)(2)(H). Therefore, we propose to approve Montana's SIP as meeting the requirements of the CAA section 110(a)(2)(H).

Section 110(a)(2)(I)—Nonattainment Area Plan or Plan Revisions Under Part D

Section 110(a)(2)(I) provides that each plan, or plan revisions for an area designated as a nonattainment area, shall meet the applicable requirements of part D of the CAA. EPA interprets

section 110(a)(2)(I) to be inapplicable to the infrastructure SIP process because specific SIP submissions designated nonattainment areas, as required by part D, are subject to different submission schedule under subparts 2 through 5 of part D, extending as far as 10 years following areas of designation for some elements, whereas infrastructure SIP submissions are due within three years after adoption or revision of a NAAQS. Accordingly, EPA takes action on part D attainment plans through separate processes.

Section 110(a)(2)(J)—Consultation with Government Officials; Public Notifications; and PSD and Visibility Protection

Section 110(a)(2)(J) of the CAA requires that each SIP ''meet the applicable requirements of section 121 of this title (relating to consultation), section 127 of this title (relating to public notification) and part C of this subchapter (relating to PSD of air quality and visibility protection).''

The Montana submissions reference the following specific laws and regulations relating to consultation with identified officials on certain air agency actions, public notifications, prevention of significant deterioration, and visibility protection:

- MCA 2–3–203.
- ARM 17.8.801 *et seq.*—Prevention of Significant Deterioration of Air Quality.
- ARM 17.8.901 *et seq.*—Permit Requirements for Major Stationary Sources of Major Modifications Locating within Nonattainment Areas.
- ARM 17.8.1001 *et seq.*—Preconstruction Permit Requirements for Major Stationary Sources of Major Modifications Locating within Attainment or Unclassified areas.
- Montana's Emergency Episode Avoidance Plan (EEAP) SIP.

(i) Montana has demonstrated that it has authority and rules in place to provide a process a process of consultation with general purpose local governments, designated organizations of elected officials of local governments, designated organizations of elected officials of local governments and any FLM having authority over federal land to which the SIP applies, consistent with the requirements of CAA section 121 (59 FR 2988, Jan. 20, 1994). Moreover, Montana's Emergency Episode Avoidance Plan, approved into the SIP (71 FR 19, Jan, 3, 2006), meets the general requirements of CAA section 127.

Montana has demonstrated that it has the authority and rules in place to provide a process of consultation with general purpose local governments, designated organizations with elected officials of local governments and any FLM having authority over Federal land to which the SIP applies, consistent with the requirements of CAA section 121 (*See* 59 FR 2988, Jan. 20, 1994). Furthermore, Montana's Emergency Episode Avoidance Plan, approved into the SIP (*See* 71 FR 19, Jan, 3, 2006), meets the general requirements of the CAA section 127.

Addressing the requirement in CAA section 110 (a)(2)(J) that the SIP meet the applicable requirements of part C, title 1 of the CAA, we have evaluated this requirement in the context of CAA section 110(a)(2)(C). The EPA most recently approved revisions to Montana's PSD program on June 26, 2018 (*See* 83 FR 29694), updating the program consistency with CAA requirements. Therefore, we are proposing to approve the Montana SIP as meeting the requirements of CAA 110(a)(2)(J) with respect to PSD for the 2015 Ozone NAAQS.

With regard to applicable visibility protection requirements, the EPA recognizes that states are subject to visibility and regional haze program requirements under part C of the CAA. In the event of an establishment of a new NAAQS, however, the visibility and regional haze program requirements under part C does not change. Consequently, we find that there is no new applicable requirement relating to visibility triggered under CAA section 110(a)(2)(J) when a new NAAQS becomes effective.

Based on the above analysis, we are proposing to approve the Montana SIP as meeting the requirements of CAA section 110(a)(2)(J) for the 2015 Ozone NAAQS.

Section 110(a)(2)(K)—Air Quality Modeling/Data

Section 110(a)(2)(K) of the CAA requires that SIPs provide for (i) the performance of air quality modeling as the Administrator may prescribe for the purpose of predicating the effect on air quality of any emissions of any air pollutant for which the Administrator has established a NAAQS, and (ii) the submission, upon request, of data related to such air quality modeling to the Administrator.

The EPA's requirements for air quality modeling for criteria pollutants are found in 40 CFR part 51, appendix W Guideline on Air Quality Models. On January 17, 2017 (*See* 82 FR 5182), the EPA revised appendix W, effective February 16, 2017. The **Federal Register** document stated: ''For all regulatory applications covered under the Guideline, except for transportation conformity, the changes to appendix A preferred models and revisions to the requirements and recommendations of the Guidelines must be integrated into the regulatory processes of respective reviewing authorities and followed by applicants by no later than January 17, 2018.''

In the September 26, 2018 submission, Montana cites ARM 17.8.821 (MT's PSD Program) which requires estimates of ambient air concentrations be based on applicable air quality models specified in appendix W of 40 CFR part 51, pertaining to the Guidelines on Ambient Air Quality Models. Additionally, Montana cites in its State rules and regulations, as contained within ARM 17.8.701, ARM 17.8.801, ARM 17.8.901, and ARM 17.8.1001 (regulating construction of new or modified stationary sources consistent with PSD and NSR requirements) shall demonstrate the facility can be expected to operate in compliance with applicable law and that it will not cause or contribute to a violation of any NAAQS.

ARM 17.8.802(1)(b) incorporates appendix W by reference without a specific date. ARM 17.8.102(1)(a) provides:

(1) Unless expressly provided otherwise in this chapter, where the board has:

(a) Adopted a federal regulation by reference, the reference is to the July 1, 2016 edition of the Code of Federal Regulations (CFR), as it is published on the website of the U.S. Government Printing Office: *https://www.gpo.gov/fdsys/browse/collectionCfr.action?selectedYearFrom=2016&go=Go;*

In the December 28, 2022 appendix W revision [15] we received, Montana incorporates the most current version of the ''Guideline on Air Quality Models'', 40 CFR part 51, appendix W. ARM rule 17.8.802 Incorporation by Reference (b) is updated to comply with EPA's January 17, 2017 revisions to appendix W.

Based on the above information, we are proposing to approve the Montana SIP as meeting the requirements of CAA section 110(a)(2)(K) for the 2015 ozone NAAQS.

[15] *See* appendix W revisions in docket. In its most recent revision to appendix W, the EPA stated that revised requirements must be ''integrated into the regulatory processes of respective reviewing authorities and followed by applicants by no later than January 17, 2018.'' Final rule, Revisions to the Guideline of Air Quality Models: Enhancements to the AERMOD Dispersion Modeling System and Incorporation of Approaches to Address Ozone and Fine Particulate Matter, 82 FR 5182 (Jan. 17, 2017).

CAA Section 110(a)(2)(L): Permitting Fees

CAA section 110(a)(2)(L) provides that the SIP must require each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing, and enforcing a permit.

The Montana submission refers to its fully approved title V operating permit program, and references the ARM regulations for the assessment and collection of fees:

- ARM 17.8.504—Air Quality Permit Application Fees.
- ARM 17.8.505—Air Quality Operation Fees.
- ARM 17.8.1701, *et seq.*—Registration of Air Contaminant Sources.

ARM 17.8.48 requires new and modified sources to pay fees in accordance with ARM 17.8.504. With respect to title V sources, on January 22, 2001, the EPA fully approved Montana's part 70 title V operating permit program (*See* 65 FR 80785). Therefore, we are proposing that Montana has satisfied the requirements of CAA section 110(a)(2)(L) for the 2015 ozone NAAQS.

CAA Section 110(a)(2)(M): Consultation/Participation by Affected Local Entities

CAA section 110(a)(2)(M) requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP.

Montana refers to the following ARM and MCA regulations, which require the MDEQ to ''. . .advise, consult, contract, and cooperate with other agencies of the state, local governments, industries, other states, inter-local agencies, the United States, and any interested persons or groups''. Additionally, Montana law allows potentially affected parties of MDEQ actions to petition for hearings.

- ARM 17.8.140 Rehearing Procedures—Form and Filing of Petition.
- ARM 17.8.141 Rehearing Procedures—Filing Requirements.
- ARM 17.8.142 Rehearing Procedures—Board Review.
- 75–2–112, MCA—Powers and Responsibilities of Department.

The rules and regulations cited by Montana provide for the consultation and participation by local political subdivisions affected by the SIP; therefore, we are proposing to approve the Montana SIP as meeting the requirements of CAA section 110(a)(2)(M) for the 2015 ozone NAAQS.

IV. What action is EPA taking?

In this rulemaking, we are proposing to approve multiple elements of the infrastructure SIP requirements for the 2015 ozone NAAQS for Montana along with a proposed no action for three infrastructure elements for Montana. Additionally, we are proposing to approve the revisions to appendix W. Our proposed action is contained in table 1 below.

The EPA is proposing to approve Montana's September 26, 2018, SIP submission for the following CAA section 110(a)(2) infrastructure elements for the 2015 ozone NAAQS: (A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). The EPA is proposing no action on D(i)(I) Prongs 1 and 2, and D(i)(II) Prong 4.

In the table below, the key is as follows:

A—*Approve.*
D—*Disapprove.*
NA—*No Action.* We intend to address the element in a separate rulemaking action.

TABLE 1—INFRASTRUCTURE ELEMENTS THAT THE EPA IS PROPOSING TO ACT ON

2015 Ozone NAAQS infrastructure SIP elements	Montana
(A): Emission Limitations and Other Control Measures	A
(B): Ambient Air Quality Monitoring/Data System	A
(C): Program for Enforcement of Control Measures; minor NSR; PSD	A
(D)(i)(I): Prong 1 Interstate Transport—significant contribution	NA
(D)(i)(I): Prong 2 Interstate Transport—interference with maintenance	NA
(D)(i)(II): Prong 3 Interstate Transport—PSD	A
(D)(i)(II): Prong 4 Interstate Transport—visibility	NA
(D)(ii): Interstate and International Pollution Abatement	A
(E): Adequate Personnel. Funding, and Authority; State Boards; Local Implementation	A
(F): Stationary Source Monitoring	A
(G): Emergency Authority; Emergency Episode Plans	A
(H): Future SIP Revisions	A
(J): Consultation with Government Officials, Public Notification, PSD and Visibility Protection	A
(K): Air Quality Modeling/Data	A
(L): Permitting Fees	A
(M): Consultation/Participation by Affected Local Entities	A

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because State Implementation Plan approvals under the CAA are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive

Order 13132 (64 FR 43255, August 10, 1999);

- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

(Authority: 42 U.S.C. 7401 *et seq.*)

Dated: July 8, 2025.

Cyrus M. Western,

Regional Administrator, Region 8.

[FR Doc. 2025–13341 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0684; FRL–12805–01–R5]

Air Plan Approval; Minnesota; Exempt Source SIP Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Minnesota State Implementation Plan (SIP) which updates Minnesota's air program rules. The Minnesota Pollution Control Agency (MPCA) submitted the request to EPA on October 1, 2021. The revision to Minnesota's air quality rules will reflect changes that have occurred to the State air quality rules since July 2020. EPA is proposing to approve MPCA's submittal, which will result in consistent requirements of rules at both the State and Federal level.

DATES: Comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0684 at *http://www.regulations.gov,* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jennifer Darrow, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6315, *darrow.jennifer@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background
II. Review of State Submittal
III. What action is EPA taking?
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Background

A. Overview of Revisions Made by Minnesota

On October 1, 2021, MPCA submitted a request for a revision of Minnesota's SIP. The submittal includes amendments to permit rules, clarifications of permit requirements for small sources of air emissions, updates to rules governing small air pollution sources and the addition of four categories of conditionally exempt sources. Minnesota completed a State rulemaking to clarify exempt source and insignificant activities rules in 2019. This proposed SIP revision is intended to codify those amendments to State law in the Minnesota SIP. MPCA previously submitted a similar SIP revision in 2018, and EPA approved the revision on July 27, 2020 (85 FR 45094).

The following chapters of Minnesota's air program rules have undergone revisions: Minnesota Rules Chapter 7005 Definitions and Abbreviations; Chapter 7007 Permits and Offsets; Chapter 7008 Conditionally Exempt Stationary Sources and Conditionally Insignificant Activities; Chapter 7011 Standards for Stationary Sources; and Chapter 7019 Emissions Inventory Requirements. All rule changes were made under the MPCA's rulemaking authority and underwent appropriate public participation procedures as required by State law. EPA proposes to approve the revisions to the Minnesota SIP.

B. Summary of Relevant Statutes

Section 110 of the Clean Air Act (CAA), 42 U.S.C 7410, as amended, requires State and local air pollution control agencies to develop and submit for EPA approval, SIPs that provide for the attainment, maintenance, and enforcement of the NAAQS in each air quality control region (or portion thereof) within each State. Section 110(a) requires an assurance that states' air quality management programs contain the structural components in place to meet the state's responsibilities under the CAA. It also requires that the program attain and maintain the NAAQS.

Section 110(a)(2)(C) of the CAA requires that each SIP include a program to provide for the regulation of construction and modification of stationary sources as necessary to ensure that the NAAQS are achieved. Specific elements for an approvable construction permitting plan are found in the implementing regulations at 40 CFR 51 subpart I—Review of New Sources and Modifications. Requirements relevant to minor

construction programs are 40 CFR 51.160–51.163. EPA regulations have several specific criteria for State minor new source review (NSR) programs. Generally, State programs must set forth legally enforceable procedures that allow the State to determine if a planned construction activity would result in a violation of the State's SIP or a national standard and prevent any activity that would. In accordance with 40 CFR 51.162, the State plan must identify the responsible agency for making permitting decisions. 40 CFR 51.160 requires the plan to identify the types and sizes of facilities and installations that are subject to review under the plan, provide that sources undertaking an activity submit adequate information regarding the nature and amounts of emissions to be emitted, as well as information on the location, design construction, and operation of facilities to enable the State to make a determination of whether the planned construction would result in a violation of the SIP or a national standard. 40 CFR 51.161 provides specific criteria for public availability of information and opportunity for public comment. Finally, 40 CFR 51.164 requires the plan to identify the administrative procedures that will be followed in making permitting decisions.

Section 110(l) of the CAA states that a SIP revision cannot be approved if the revision would interfere with any applicable requirements concerning attainment and reasonable further progress toward attainment of a NAAQS or any other applicable requirement of the CAA.

The revisions to the Minnesota SIP are intended to recodify, refine and update Minnesota's air quality rules in the Minnesota SIP, at 40 CFR 52.1220. This SIP revision addresses the requirements of section 110 of the CAA.

II. Review of State Submittal

A. Chapter 7005: Definitions and Abbreviations

Chapter 7005 contains numerous definitions and abbreviations relevant to rules throughout the Minnesota SIP. In Chapter 7005, MPCA amended and added definitions in Minn. R. 7005.0100, to define new terms, clarify definitions, and re-number definitions. EPA finds these revisions approvable because they provide clarity to terms used in various rules throughout the SIP and do not change the requirements of the rules themselves. EPA proposes to approve the revisions to Minn. R. 7005.0100 into the Minnesota SIP.

B. Chapter 7007: Permits and Offsets

Chapter 7007 contains rules concerning permits and offsets and has undergone various changes. Because Chapter 7007 combines the State's preconstruction and operating permit programs into a single permitting program, MPCA uses the broad term ''Part 70 permit'' to reference several types of permits, including some permits that authorize construction. As used in this action, ''Part 70'' denotes preconstruction permits, unless otherwise specified as ''federal part 70.'' This rulemaking is limited solely to approval of revisions to the state's preconstruction permitting program and federally enforceable State operating permit program. This is not a rulemaking under the Federal rules at 40 CFR part 70.

Minn. R. 7007.0300 relates to sources that are not required to obtain a permit under parts 7007.0100 to 7007.1850. Minn. R. 7007.0300 subpart 1, has been revised to remove item D, which provided that stationary sources listed as insignificant activities, sources that are conditionally insignificant activities, or sources that qualify as both insignificant activities and conditionally insignificant activities, are not required to obtain a permit, subject to certain conditions and recordkeeping requirements. The substantive provisions of item D are now a category of conditionally exempt stationary sources found in Minn. R. 7008.2600, ''Insignificant Facility; Technical Standards,'' which is discussed further below. Therefore, these revisions simply reorganize the provisions and do not change the substance of the rules. EPA proposes to approve the revisions to Minn. R. 7007.0300 into the Minnesota SIP.

Minn. R. 7007.0400 subpart 2 has been revised to change the timeframe for the owner or operator to submit an application for renewal of a Federal part 70 permit. The revision clarifies that a permit will not require a renewal application sooner than 18 months prior to permit expiration. EPA finds these revisions approvable as they align State and Federal permitting rules. EPA proposes to approve the revisions to Minn. R. 7007.0400 into the Minnesota SIP.

Minn. R. 7007.0850 subpart 2 has been revised with changes to the public notice and comment requirements and procedures. The revisions remove the requirements to give public notice in a newspaper of general circulation in the area nearby the source or in the *Minnesota State Register* and require electronic posting of the public notice for the duration of the comment period on the MPCA's public notice website.

Revisions have been made to the minimum requirements of what must be included in the electronic notice to now include the draft permit and a statement of whether the facility has filed a pollution prevention progress report with the State commissioner. Revisions have also been made to paragraph numbering and to include electronic contact information for interested parties to request additional information. Minn. R. 7007.0850 subpart 3 revises the process to petition for meetings and hearings by removing the option of placing the permit onto the agenda of a MPCA board meeting. EPA finds these revisions approvable as they add requirements to align the rules with Federal permitting requirements and do not relax any previously approved SIP provisions. EPA proposes to approve the revisions to Minn. R. 7007.0850 into the Minnesota SIP.

Minn. R. 7007.1144 subpart 5 has been revised to clarify procedures for public participation for capped permits (''capped'' permits are rule-based permits designed for noncomplex facilities that do not require site-specific permit conditions), and removes the option of petitioning for meetings and hearings by placing the permit onto the agenda of a MPCA board meeting. EPA finds these revisions approvable as they do not conflict with any Federal requirement. EPA proposes to approve the revisions to Minn. R. 7007.1144 into the Minnesota SIP.

Minor language changes were made to Minn. R. 7007.1145, 7007.1147, and 7007.1250. EPA finds these revisions approvable as they do not change the substance of the rules. EPA proposes to approve the revisions to Minn. R. 7007.1145, 7007.1147 and 7007.1250 into the Minnesota SIP.

Revisions have been made to the list of insignificant activities in Minn. R. 7007.1300. The changes clarify whether certain activities, and the calculation of emissions from those activities, must be included in an air emissions permit application. Language clarifications related to heat input capacity are added, and certain processing, cleaning and other miscellaneous activities and operations are added to the list of insignificant activities. These revisions also add language to clarify that the thresholds for hazardous air pollutants listed in 7007.1300, subpart 5 are to be utilized in determining whether an emissions unit qualifies as an insignificant activity under 7007.1300, subpart 4. The intent of the insignificant activities list is to streamline the permit application process by specifying those

activities whose emissions are trivial or short-term by their very nature, or activities that fall below a certain size/production rate, and therefore require minimal regulatory oversight. As part of these rule revisions, the MPCA evaluated each of the activities added or moved and their associated emissions. Activities that were added or moved were based on MPCA's estimates of emissions or examples provided by EPA of activities states could add to their insignificant activities list. While the activities listed may have emissions, the rule changes themselves are not expected to change/increase emissions as they do not authorize stationary sources to bypass any other regulations or permitting requirements. Stationary sources that add new insignificant activities are still required to determine whether the change or modification requires a permit amendment or notice to MPCA. EPA finds these revisions approvable as they provide clarity and do not change the stringency of the rule. EPA proposes to approve the revisions to Minn. R. 7007.1300 into the Minnesota SIP.

C. Chapter 7008: Conditionally Exempt Stationary Sources and Conditionally Insignificant Activities

Chapter 7008 provides the conditions under which stationary sources are exempt from the requirement to apply for and obtain an air emission permit as provided for under Minn. R. 7007.0300. In the Chapter 7008 rule revisions, MPCA expands the conditionally exempt source categories to include auto-body refinishing facilities, coating facilities, woodworking facilities, and insignificant facilities. It establishes a permit by rule approach for these source categories that does not relax air quality standards. The revisions in Chapter 7008 specify applicable emission limitation and control requirements, operational restrictions and monitoring, recordkeeping, and other requirements in a similar manner to a traditional permit. The revisions outline the conditions under which stationary sources are exempt from the requirement to apply for and obtain an air emission permit as provided for under Minn R. 7007.0300. Chapter 7008 requires sources who claim their operations are conditionally exempt or conditionally insignificant to maintain records that demonstrate eligibility with the rule.

Minn. R. 7008.0100 has been revised to renumber several subparts and adds definitions pertinent to this category of conditionally exempt stationary sources and conditionally insignificant activities. EPA finds these revisions approvable as they provide clarity and do not change the stringency of the rule. EPA proposes to approve the revisions to Minn. R. 7008.0100 into the Minnesota SIP.

Minn. R. 7008.0200 establishes general requirements for conditionally exempt stationary sources and conditionally insignificant activities. This part has been revised to add a new item F. Item F has been added to clarify to owners and operators that if there is a change at the facility that affects the amount or type of air pollutants the facility emits, the owner or operator must determine whether a permit is needed and follow the permitting requirements at Minn. R. 7007.0400, subpart 4. EPA finds these revisions approvable as they strengthen current requirements in the SIP. EPA proposes to approve the revisions to Minn. R. 7008.0200 into the Minnesota SIP.

Minn. R. 7008.2100, subpart 1 identifies the eligibility requirements for the owner or operator of a gasoline service station to operate without a permit under chapter 7008. The requirements of this subpart have been renumbered. New item A, in subpart 1, revises existing rule language to clarify who is responsible for compliance with the rule and corrects the reference to the general requirements in Minn. R. 7008.2000, not Minn. R. 7008.0200. Subpart 1, item A has also been revised to remove the term ''general operating'' as a qualifier in front of requirements. The revisions also refer to the eligibility requirements in Minn. R. 7008.2000 rather than the general requirements of Minn. R. 7008.0200. New item B revises existing rule language to identify the correct rule citation for insignificant activities and conditionally insignificant activities. This revision provides clarification to the owner or operator that emissions from the gasoline service station must be from insignificant activities or conditionally insignificant activities, or both, in order to operate without a permit. Subpart 3, Notification, is revised to establish the requirements for notification when an owner or operator begins construction of a gasoline service station. The revisions also remove obsolete rule language that referred to a transition period for the original implementation of the rules. EPA finds these revisions approvable as they correct, clarify and strengthen current requirements in the SIP. EPA proposes to approve the revisions to Minn. R. 7008.2100 into the Minnesota SIP.

Minn. R. 7008.2200, subpart 1 identifies the eligibility requirements for the owner or operator of a concrete manufacturing stationary source to operate without a permit under chapter 7008. Subpart 1 has been revised to correct the reference to the general requirements in Minn. R. 7008.2000, not Minn. R. 7008.0200. Revisions also include the addition of a new subpart 6 with recordkeeping requirements for concrete manufacturing stationary sources. The recordkeeping requirements in Minn. R. 7008.2250 are proposed for repeal and are moved to a new subpart 6, items A through D. This change consolidates all requirements for concrete manufacturing stationary sources in one rule part. The revisions also modify language of existing recordkeeping requirements but does not change the content of the requirements. The revisions provide consistent language across the different conditionally exempt source categories. EPA finds these revisions approvable as they clarify and strengthen current requirements in the SIP. EPA proposes to approve the revisions to Minn. R. 7008.2200 into the Minnesota SIP.

Minn. R. 7008.2250 is proposed for repeal. This part provided recordkeeping requirements for concrete manufacturing plants. These requirements are moved to new subpart 6 in part 7008.2200. This consolidates and clarifies the rule so owners and operators can more easily locate, understand and comply with the recordkeeping requirements for concrete manufacturing plants. EPA finds these revisions approvable as they clarify current requirements in the SIP. EPA proposes to approve the revisions that repeal Minn. R. 7008.2250 from the Minnesota SIP.

Minnesota has created four new categories of conditionally exempt sources: Minn. R. 7008.2300 (auto-body refinishing); Minn. R. 7008.2400 (coating facilities); Minn. R. 7008.2500 (woodworking facilities); and Minn. R. 7008.2600 (insignificant facilities). For each of the new source categories, the rule amendments establish technical standards, operational and recordkeeping requirements that control and monitor air emissions in a similar manner to conditions that would be found in a site-specific, low-emitting facility permit.

Minn. R. 7008.2300 establishes technical standards for an owner or operator of an auto-body refinishing facility, by which the source may be exempt from an air emissions permit. Subpart 1 establishes the eligibility requirements for an auto-body refinishing facility to operate without a permit under chapter 7008, including limitations on activities and types of equipment allowed, to ensure there are no other significant sources of emissions

at the source that would otherwise require an air emissions permit. Revisions also establish the maximum amount of coating and cleaning materials that an auto-body refinishing facility can purchase or use each calendar year to be eligible to operate without a permit under this subpart. The limit is set at 2,000 gallons each calendar year. Subparts 2, 3 and 4 establish operational, recordkeeping and notification requirements.

Minn. R. 7008.2400 establishes technical standards for an owner or operator of a coating facility, that is not an auto-body refinishing facility, by which the source may be exempt from an air emissions permit. Subpart 1 establishes the eligibility requirements for a coating facility to operate without a permit under chapter 7008, including limitations on activities and types of equipment allowed, to ensure there are no other significant sources of emissions at the source that would otherwise require an air emissions permit. Revisions also establish a limit of 2,000 gallons per calendar year of coating and cleaning material usage to be eligible to operate without a permit under this subpart. Subparts 2, 3 and 4 establish operational, recordkeeping and notification requirements.

Minn. R 7008.2500 establishes technical standards for an owner or operator of a woodworking facility, by which the source may be exempt from an air emissions permit. Subpart 1 establishes the eligibility requirements for a woodworking facility to operate without a permit under chapter 7008, including limitations on activities and types of equipment allowed, to ensure there are no other significant sources of emissions at the source that would otherwise require an air emissions permit. Subparts 2, 3 and 4 establish operational, control and notification requirements. Subpart 3 establishes five control options that restrict emissions to below the State permitting thresholds for PM and PM_{10}.

Minn R. 7008.2600 establishes a new exempt category for stationary sources that have only insignificant and conditionally insignificant activities. To ensure that the presence of insignificant activities does not exceed a permitting threshold, the rule revision expands and clarifies the conditions that must be met by a stationary source with only insignificant and conditionally insignificant activities by adding conditions that make the technical requirements federally enforceable. Subpart 1 establishes eligibility requirements for an insignificant facility to operate without a permit under chapter 7008 by specifying the insignificant activities and conditionally insignificant activities that qualify and limits the number of emission units such that potential emissions do not exceed the listed permitting thresholds. Subparts 2 and 3 establish operational and recordkeeping requirements to qualify under this category. Subparagraph 4 requires the owner or operator of an insignificant facility to calculate emissions to determine eligibility.

The minor NSR provisions at 40 CFR 51.160 require State programs to determine whether activities would violate an applicable SIP or national standard and to prevent construction of an activity that would violate an applicable SIP provision or national standard. The new provisions exempt certain eligible stationary sources from air permitting requirements. When determining adequacy of State rules, EPA is concerned with the possibility that an exemption might allow an activity that should be subject to major source permitting requirements to escape appropriate review and permitting, that sources are required to maintain information adequate for the State to ensure that exemptions have been applied appropriately, and that the exemptions would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA.

Minnesota Chapter 7008 provides limitations on the use of the specific exemptions in Minn. R. 7008.0050–7008.4110 and requires sources using the exemptions to maintain certain records to demonstrate that the exemptions have been applied appropriately. Specific conditionally exempt sources may be required to implement additional monitoring and recordkeeping as required to ensure that the equipment is operating as required under the exemption. Section 110(l) of the CAA states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress toward attainment of a NAAQS or any other applicable requirement of the CAA. These conditionally exempt sources are expected to yield very low levels of actual emissions of regulated pollutants and are not expected to interfere with attainment and maintenance of the NAAQS. The rules also do not interfere with any other applicable requirement of the CAA, including the applicability of other SIP requirements, and those found in the New Source Performance Standards and the National Emission Standards for Hazardous Air Pollutants (NESHAPs). Therefore, EPA proposes to approve the revisions to Minn. R. 7008.2300, 7008.2400, 7008.2500, and 7008.2600.

The revisions to Minn R. 7008.4000 expand and clarify the conditions that must be met by insignificant and conditionally insignificant activities and are intended to improve the enforceability of restrictions on potential to emit for conditionally insignificant activities. This part is further revised to require that calculations from the activities described in parts 7008.4100 and 7008.4110 must be provided in a permit application for a part 70 permit or an amendment to a part 70 permit. EPA finds these revisions approvable as they strengthen current requirements in the SIP. EPA proposes to approve the revisions to Minn. R. 7008.4000.

The title of Minn. R. 7008.4100 is revised to ''Conditionally Insignificant Activity: Material Usage'' in order to provide clarification that the activities described are a conditionally insignificant activity. Revisions have been made in this part to the material usage emissions limits of volatile organic compounds (VOC) that qualify as an insignificant activity under this rule. Thresholds of eligibility for VOC emissions have been increased from less than 2,000 pounds to less than 10,000 pounds, and VOC-containing material usage limits have increased from less than 200 gallons to less than 1,000 gallons per calendar year. The limits have been increased to provide flexibility to owners and operators of stationary sources that have material usage that qualifies as a conditionally insignificant activity. It is estimated that this rule change would potentially result in maximum emissions of a single volatile HAP by no more than 5 tons per calendar year per source, which corresponds to 50% of the major source HAP threshold defined by the CAA section 112.

The rule also removes accounting of PM_{10} and $PM_{2.5}$ separately from particulate matter when calculating emissions for annual calculations. The calculation for particulate matter emissions in this part of the rule is based on the solids content (in lbs/gal or weight%) of the material used. Because the data used for this calculation is not specific to each pollutant (PM, PM_{10}, and $PM_{2.5}$), deleting the reference to PM_{10} and $PM_{2.5}$ simplifies the emission limit and provides consistency across the requirements in Minn. R. 7008.4100 that govern conditionally insignificant material usage.

Subparts 4 and 5 of this rule revise calculation requirements for VOC and particulate matter and add the ability to include control and transfer efficiencies in calculating particulate matter emissions under certain circumstances as allowed under Minn. R. 7011.

The revisions of Minn. R. 7008.4100 are consistent with CAA section 110(l). These revisions are expected to yield very low levels of actual emissions of regulated pollutants and are not expected to interfere with attainment and maintenance of the NAAQS. The revisions also do not interfere with any other applicable requirement of the CAA, including the applicability of other SIP requirements, and those found in the New Source Performance Standards and the National Emission Standards for Hazardous Air Pollutants (NESHAPs). As such, EPA proposes to approve the revisions to Minn. R. 7008.4100.

The title of Minn. R. 7008.4110 has been revised to ''Conditionally Insignificant Activity; Finishing Operations.'' The revision provides clarification that the activities described are a conditionally insignificant activity. The revision also establishes requirements specific to stationary sources that claim mechanical finishing operations emitting PM as a conditionally insignificant activity. The revisions further clarify that any activity emitting any other pollutant in addition to PM does not qualify under this part, including lead emissions.

Revisions are also made to identify the qualifications for mechanical finishing operations to be considered a conditionally insignificant activity. Revisions to subpart 2 add ''mechanical finishing operations'' and remove the example finishing activities (*e.g.,* buffing, polishing, carving, etc.) previously listed in the SIP. Subpart 2 is also revised to remove the requirement that emissions must be vented inside a building 100% of the time and filtered through an air cleaning system, adds control requirements for particulate emissions and limits particulate matter emissions from mechanical finishing operations to less than 10,000 pounds per calendar year.

Clarifying language is added to specify that the limit applies to all finishing operation activities at the stationary source. This revision disallows multiple activities that might qualify independently as conditionally insignificant finishing operations to exceed the emission limit when aggregated. Subparts 3 and 4 of the rule clarify language and add monitoring, recordkeeping and calculation requirements for sources subject to this subpart. EPA finds these revisions approvable as they strengthen current requirements in the SIP. EPA proposes to approve the revisions to Minn. R. 7008.4110.

C. Chapter 7011: Standards for Stationary Sources

Minn. R. 7011.0561 makes minor revisions to language, changing the title from ''Control of mercury from electric generating units'' to ''Controlling mercury from electric generating units'' and removes a reference to Minnesota Statutes, section 216B.687, subdivision 3. EPA finds these revisions approvable as they are minor language changes that do not affect the requirements of the rule. EPA proposes to approve Minn. R. 7011.0561.

Minn. R. 7011.1201 revises a statutory reference for the definition of refuse-derived fuel. EPA finds these revisions approvable as they do not change the applicability of the rule. EPA proposes to approve Minn. R. 7011.1201.

Minn. R. 7011.2300 makes minor language revisions and allows for an alternative sulfur dioxide limit in a permit or other enforceable document that models compliance with Minn. R. 7009.0090, the National Ambient Air Quality Standards as they are incorporated by reference into Minnesota's rules. EPA finds these revisions approvable as they are minor language changes that do not affect the requirements of the rule and strengthen current requirements in the SIP. EPA proposes to approve Minn. R. 7011.2300.

A. Chapter 7019: Emissions Inventory Requirements

Minn. R. 7019.3020 has been revised to change the words ''shall'' to ''must'' and renumbers a reference to subpart ''J'' to ''G''. EPA finds these revisions approvable as they are minor language changes that do not affect the requirements of the rule. EPA proposes to approve Minn. R. 7019.3020 into the Minnesota SIP.

As part of this submittal, Minnesota is also requesting that rule 7023 be removed from the SIP. This rule is obsolete given the November 2019 expiration of the carbon monoxide maintenance area.

III. What action is EPA taking?

EPA is proposing to approve MPCA's October 1, 2021, submittal, as a revision to its existing SIP.

IV. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference revisions to Minnesota Rules Chapter 7005 Definitions and Abbreviations; Chapter 7007 Permits and Offsets; Chapter 7008 Conditionally Exempt Stationary Sources and Conditionally Insignificant Activities; Chapter 7011 Standards for Stationary Sources; and Chapter 7019 Emissions Inventory Requirements, as discussed in sections I. and II. of this preamble. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA;

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rulemaking does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 30, 2025.

Anne Vogel,

Regional Administrator, Region 5.

[FR Doc. 2025–13327 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2025–0268; FRL–12868–01–R9]

Air Plan Approval; Guam; Base Year Emissions Inventory for the 2010 1-Hour Sulfur Dioxide National Ambient Air Quality Standard for the Piti-Cabras Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to Guam's State Implementation Plan (SIP) under section 110(k)(3) of the Clean Air Act (CAA or ''the Act''). This revision concerns the base year emissions inventory for the Piti-Cabras, Guam sulfur dioxide (SO_2) nonattainment area (''Piti-Cabras area'' or NAA) for the 2010 1-hour SO_2 National Ambient Air Quality Standard (NAAQS, ''standard,'' or ''2010 SO_2 NAAQS''). We are taking comments on a proposed approval of this revision and are simultaneously publishing a final action approving this revision in a direct final rule.

DATES: Comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2025–0268 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Khoi Nguyen, Geographic Strategies and Modeling Section, Planning & Analysis Branch, Air & Radiation Division, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; telephone number: 415–947–4120; email address: *Nguyen.Khoi@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA. In the ''Rules and Regulations'' section of this issue of the **Federal Register**, the EPA is approving Guam's submission as a direct final rule without prior proposal because we view this as a noncontroversial action and anticipate no adverse comments. A detailed rationale for the action is set forth in the preamble to the direct final rule. If the EPA receives no adverse comments, the EPA contemplates no further action. If the EPA receives adverse comments, the EPA will withdraw the direct final rule and will address all public comments in a subsequent final rule based on this proposed rule. We do not plan to open a second comment period on this action, so anyone interested in commenting should do so at this time. For additional information, see the direct final rule of the same title that is located in the Final Rules section of this **Federal Register**.

Dated: July 7, 2025.

Joshua F.W. Cook,

Regional Administrator, Region IX.

[FR Doc. 2025–13335 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0963; FRL–12589–03–R5]

Air Plan Approval; Indiana; Regional Haze Plan for the Second Implementation Period; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule published on June 18, 2025. The current comment period for the proposed rule was scheduled to close on July 18, 2025. EPA is extending the comment period for the proposed action by 30 days to August 18, 2025.

DATES: The comment period for the proposed rule published in the **Federal Register** on June 18, 2025, at 90 FR 25944 is extended. Comments now must be received on or before August 18, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0963 at *https://www.regulations.gov,* or via email to *langman.michael@epa.gov.* Additional instructions to comment can be found in the notice of proposed rulemaking published June 18,2025 (90 FR 25944).

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Air & Radiation Division (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 18, 2025, EPA proposed to approve the Indiana regional haze state implementation plan (SIP) revision submitted by the Indiana Department of

Environmental Management on December 29, 2021, as satisfying applicable requirements under the Clean Air Act and EPA's Regional Haze Rule for the program's second implementation period. EPA is extending the comment period for an additional 30 days.

Dated: July 1, 2025.

Anne Vogel,

Regional Administrator, Region 5.

[FR Doc. 2025–13325 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2024–0542; FRL–12793–01–R5]

Air Plan Approval; Ohio; Second Maintenance Plan for the Ohio Portion of the Campbell-Clermont, KY-OH SO_2 Maintenance Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve, under the Clean Air Act (CAA), the second 10-year maintenance plan submitted to EPA on November 7, 2024, by the Ohio Environmental Protection Agency (Ohio EPA) for the Ohio portion of the Campbell-Clermont Counties, Kentucky-Ohio maintenance area. The Ohio portion of this area consists of Pierce Township in Clermont County, Ohio. The plan addresses the second 10-year maintenance period for the 2010 sulfur dioxide (SO_2) National Ambient Air Quality Standards (NAAQS). EPA is proposing to approve Ohio EPA's submittal for the area because it provides for the continued maintenance of the 2010 SO_2 NAAQS through the end of the second 10-year portion of the maintenance period.

DATES: Comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2024–0542 at *https://www.regulations.gov* or via email to *arra.sarah@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit *https://wwww.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Cecilia Magos, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7336, *magos.cecilia@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives such comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

(Authority: 42 U.S.C. 7401 *et seq.*)

Dated: July 1, 2025.

Cheryl Newton,

Acting Regional Administrator, Region 5.

[FR Doc. 2025–13343 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2025–0196; FRL–12890–01–R1]

Air Plan Approval; Connecticut; State Implementation Plan Revisions Required as a Result of a Definition Change Due to the Ozone Reclassification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Connecticut. This action consists of revisions to Regulations of Connecticut State Agencies (RCSA) sections 22a–174–22e and 22a–174–22f, primarily to add compliance dates for sources brought into the applicability of these sections due to a change in the definition of ''severe non-attainment area for ozone,'' The definition change had previously been approved into Connecticut's SIP. This action is being taken in accordance with the Clean Air Act.

DATES: Written comments must be received on or before August 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2025–0196 at *https://www.regulations.gov,* or via email to *creilson.john@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or

other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that, if possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection.

FOR FURTHER INFORMATION CONTACT: John Creilson, Air Quality Branch, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code 5–MI), Boston, MA 02109–3912, telephone number (617) 918–1688, email *creilson.john@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Background

On November 27, 2023, the Connecticut Department of Energy and Environmental Protection (CT DEEP) submitted a revision to its State Implementation Plan (SIP). This action consists of revisions to Regulations of Connecticut State Agencies (RCSA) sections 22a–174–22e and 22a–174–22f, primarily to add compliance dates for sources brought into the applicability of these sections due to a change in the definition of ''severe non-attainment area for ozone'' in another section of Connecticut's regulations—specifically, RCSA § 22a–174–1. The revisions to RCSA §§ 22a–174–22e and 22a–17422f became effective on November 13, 2023. Connecticut's change to the definition of ''severe non-attainment area for ozone'' in RCSA § 22a–174–1 became effective the same day, and the Environmental Protection Agency (EPA) previously approved the new definition into the SIP on February 12, 2024 (89 FR 9771).

On March 20, 2023, CT DEEP proposed changes to the definition of ''severe non-attainment area for ozone'' within RCSA § 22a–174–1. The proposed change to the definition expanded the list of cities and towns in the definition, to include all cities and towns in New Haven County and Middlesex County. CT DEEP also retained the two towns in Litchfield County to ensure classification consistency in these communities and to comply with section 193 of the Clean Air Act (CAA), which prohibits any control measure in effect in a nonattainment area prior to the enactment of the CAA Amendments of 1990 to be modified after enactment, unless such modification yields equivalent or greater emission reductions. As a result of this definition change and as described in 89 FR 9771, the number of towns included in the ''severe non-attainment area for ozone'' increased, making RCSA §§ 22a–174–22e and 22a–174–22f applicable to more sources.

The entire state of Connecticut is divided into two nonattainment areas for ozone. One area consists of the southwest portion of the state (the Connecticut portion of the New York-New Jersey-Connecticut area), and the remainder of the state (Greater Connecticut) makes up the other nonattainment area. The area in the southwest portion of the state generally experiences higher ozone levels, and on October 7, 2022, the EPA published a final rule to reclassify, among other areas, the southwest Connecticut ozone nonattainment area to severe nonattainment from serious nonattainment based on the area's inability to attain the 2008 ozone National Ambient Air Quality Standard (NAAQS) by the attainment date (87 FR 60926).

Connecticut regulations define nonattainment areas in a geographic manner. The original definition of ''severe non-attainment area for ozone'' in RCSA § 22a–174–1, was based on the nonattainment area designation under the 1-hour ozone NAAQS of 1979. The area included all towns and cities in Fairfield County, except the town of Shelton, and two towns in Litchfield County (Bridgewater and New Milford). Currently, the southwest Connecticut ozone nonattainment area for the 2008 ozone NAAQS is larger than the older area for the 1979 ozone NAAQS, and it includes all of Fairfield County, New Haven County, and Middlesex County.

II. Summary and Evaluation of Connecticut's SIP Revision

Sections 22a–174–22e and 22a–174–22f of the RCSA impose requirements on sources based in part on the classification of the nonattainment area in which the source is located, and the quantity of emissions released. Sources emitting over certain threshold amounts of nitrogen oxides (NO_X) are subject to the control requirements of RCSA section 22a–174–22e. As a result of the revision to the definition of ''severe non-attainment area for ozone,'' RCSA §§ 22a–174–22e and 22a–174–22f became newly applicable to certain sources in Towns that were added to the definition. As Connecticut's regulatory revisions bring new sources under RCSA section 22a–174–22e, new provisions were necessary to specify the timing of compliance and of certain submissions the new sources must provide to CT DEEP. The main changes for section 22a–174–22e are (1) the addition of a definition for ''Bumped-up RACT unit'' in subsection (a), and (2) the addition of subsection (n), ''Compliance by bumped-up RACT units.'' Connecticut defines a ''Bumped-up RACT unit'' as ''an emission unit located at a facility with a potential to emit NO_X of not less than twenty-five (25) tons per year whereby such facility becomes a major stationary source of NO_X on or after November 7, 2022 solely as a result of the amendment of the definition of 'severe non-attainment area for ozone' in RCSA section 22a–174–1 effective on November 13, 2023.'' The revisions to § 22a–174–22e require such a bumped-up reasonably available control technology (RACT) unit to comply with emissions limitations already applicable to other sources covered by § 22a–174–22e, providing a timeframe for that compliance, pursuant to certain conditions. Connecticut also made minor corrections or updates to several provisions in RCSA § 22a–174–22e based on the two changes described above. Finally, Connecticut added timing provisions to RCSA § 22a–174–22f coordinated with those of § 22a–174–22e.

This action will ensure that Connecticut is applying RACT requirements and other NO_X control requirements to the appropriate sources in the state, thereby meeting nonattainment requirements for ozone as set out in Section 182(d) of the CAA. The EPA has reviewed Connecticut's November 27, 2023, submittal of revisions to RCSA §§ 22a–174–22e and 22a–174–22f and preliminarily determined that they represent approvable revisions to the versions previously approved into the Connecticut SIP. These revisions will appropriately apply requirements to sources in line with Connecticut's change to the definition of ''severe non-attainment area for ozone'' that the EPA

previously approved into the SIP. (89 FR 9771).

III. Proposed Action

The EPA is proposing to approve Connecticut's November 27, 2023, SIP submittal that addresses revisions to RCSA sections 22a–174–22e and 22a–174–22f. The EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference changes to Connecticut RCSA sections 22a–174–22e and 22a–174–22f as adopted on November 13, 2023. The changes primarily add compliance dates for sources brought into the applicability of these sections due to a change in the definition of ''severe non-attainment area for ozone.'' The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 10, 2025.

Mark Sanborn,

Regional Administrator, EPA Region 1.

[FR Doc. 2025–13324 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2024–0607; FRL–12598–01–R8]

Air Plan Partial Approval and Partial Disapproval; Colorado; Regional Haze Plan for the Second Implementation Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to partially approve and partially disapprove a regional haze state implementation plan (SIP) submission submitted by the State of Colorado under the Clean Air Act (CAA) and the EPA's Regional Haze Rule (RHR) for the program's second implementation period. Colorado's 2022 SIP submission addresses the requirement that states revise their long-term strategies every implementation period to make reasonable progress towards the national goal of preventing any future, and remedying any existing, anthropogenic impairment of visibility, including regional haze, in mandatory Class I Federal areas. We propose to base our partial disapproval of Colorado's long-term strategy on its inclusion of insufficiently justified enforceable source closures that are not consistent with statutory requirements. Colorado's 2022 SIP submission also addresses other applicable requirements for the second implementation period of the regional haze program. Concurrently, the EPA is proposing to approve a revision to Colorado's SIP consolidating existing regional haze provisions into the same regulation where the State's new, second planning period provisions are located.

DATES: Written comments must be received on or before September 15, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2024–0607, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *https://www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video,

etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *https://www.regulations.gov.* Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Jaslyn Dobrahner, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6252; email address: *dobrahner.jaslyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

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I. What action is the EPA proposing?

Pursuant to CAA section 110(k)(3), the EPA is proposing to partially approve and partially disapprove a SIP submission submitted by the State of Colorado to the EPA on May 20, 2022, and supplemented on August 2, 2022, and June 23, 2023, addressing the requirements of the second implementation period of the RHR.[1] Specifically, the EPA is proposing approval for the portions of Colorado's 2022 SIP submission relating to 40 CFR 51.308(f)(1): calculations of baseline, current, and natural visibility conditions, progress to date, and the uniform rate of progress; 40 CFR 51.308(f)(2)(ii)–(iv): long-term strategy; 40 CFR 51.308(f)(3): reasonable progress goals; 40 CFR 51.308(f)(4): reasonably attributable visibility impairment; 40 CFR 51.308(f)(5) and 40 CFR 51.308(g): progress report requirements; 40 CFR 51.308(f)(6): monitoring strategy and other implementation plan requirements; and 40 CFR 51.308(i): FLM consultation.

For the reasons described in section IV.C.1.b. of this document, the EPA is proposing to disapprove portions of Colorado's 2022 SIP submission relating to 40 CFR 51.308(f)(2)(i). The submission relies on enforceable source closures that the EPA proposes to disapprove on the basis that they were adopted without full information about grid reliability concerns, particularly because the Class I areas Colorado emissions contribute to are below the Uniform Rate of Progress and the state conducted four-factor analyses. The EPA also proposes to find that the State has not provided necessary assurances required by CAA section 110(a)(2)(E) that unconsented enforceable source closures would not be prohibited by state or federal law.

Concurrently, the EPA is proposing to approve a revision to Colorado's SIP consolidating existing regional haze provisions into the same regulation where the State's new, second planning period provisions are located. Together, these SIP revisions establish updated emission reduction requirements for nitrogen oxides (NO_X), sulfur dioxide (SO_2), and particulate matter (PM) emissions from certain sources identified as impacting Class I areas under the RHR for the second 10-year planning period.[2]

II. Background and Requirements for Regional Haze Plans

A detailed history and background of the regional haze program is provided in multiple prior EPA proposal actions.[3] For additional background on the 2017 RHR revisions, please refer to section III. Overview of Visibility Protection Statutory Authority, Regulation, and Implementation of ''Protection of Visibility: Amendments to Requirements for State Plans'' of the 2017 RHR.[4] The following is an abbreviated history and background of the regional haze program and 2017 Regional Haze Rule as it applies to the current action.

A. Regional Haze

In the 1977 CAA amendments, Congress created a program for protecting visibility in the nation's mandatory Class I Federal areas, which include certain national parks and wilderness areas.[5] CAA section 169A. The CAA establishes as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution.'' CAA section 169A(a)(1).

Regional haze is visibility impairment that is produced by a multitude of anthropogenic sources and activities that are located across a broad

[1] The EPA may partially approve portions of a submittal if those elements meet all applicable requirements and may disapprove the remainder so long as the elements are fully separable. *See* CAA section 110(k)(3) and July 1992 EPA memorandum titled ''Processing of State Implementation Plan (SIP) Submittals'' from John Calcagni, at *https://www.epa.gov/sites/default/files/2015-07/documents/procsip.pdf.* The EPA proposes to conclude that the elements at issue are fully separable, as described in greater detail later in this preamble.

[2] The EPA uses the terms ''implementation period'' and ''planning period'' interchangeably.

[3] *See* 90 FR 13516 (March 24, 2025).

[4] *See* 82 FR 3078 (January 10, 2017, located at *https://www.federalregister.gov/documents/2017/01/10/2017-00268/protection-of-visibility-amendments-to-requirements-for-State-plans#h-16*).

[5] Areas statutorily designated as mandatory Class I Federal areas consist of national parks exceeding 6,000 acres, wilderness areas and national memorial parks exceeding 5,000 acres, and all international parks that were in existence on August 7, 1977. CAA section 162(a). There are 156 mandatory Class I areas. The list of areas to which the requirements of the visibility protection program apply is in 40 CFR part 81, subpart D.

geographic area and that emit pollutants that impair visibility. Visibility impairing pollutants include fine and coarse particulate matter (PM) (*e.g.,* sulfates, nitrates, organic carbon, elemental carbon, and soil dust) and their precursors (*e.g.,* SO_2, NO_X, and, in some cases, volatile organic compounds (VOC) and ammonia (NH_3)). Fine particle precursors react in the atmosphere to form fine particulate matter ($PM_{2.5}$), which impairs visibility by scattering and absorbing light. Visibility impairment reduces the perception of clarity and color, as well as visible distance.[6]

To address regional haze visibility impairment, the 1999 RHR established an iterative planning process that requires states containing Class I areas and states containing sources whose emissions ''may reasonably be anticipated to cause or contribute to any impairment of visibility'' in a Class I area in another state to periodically submit SIP revisions to address such impairment. CAA section 169A(b)(2); see also 40 CFR 51.308(b), (f) (establishing submission dates for iterative regional haze SIP revisions); (64 FR at 35768, July 1, 1999).

On January 10, 2017, the EPA promulgated revisions to the RHR (82 FR 3078, January 10, 2017) that apply for the second and subsequent implementation periods. The reasonable progress requirements as revised by the 2017 rule (referred to here as the 2017 RHR Revisions) are codified at 40 CFR 51.308(f).

B. Roles of Agencies in Addressing Regional Haze

Because the air pollutants and pollution affecting visibility in Class I areas can be transported over long distances, successful implementation of the regional haze program requires long-term, regional coordination among multiple jurisdictions and agencies that have responsibility for Class I areas and the emissions that impact visibility in those areas. To address regional haze, states need to develop strategies in coordination with one another, considering the effect of emissions from one jurisdiction on the air quality in another. Five regional planning organizations (RPOs), which include representation from state and Tribal governments, the EPA, and FLMs, were developed in the lead-up to the first implementation period to address regional haze. RPOs evaluate technical information to better understand how emissions from state and Tribal land impact Class I areas across the country, pursue the development of regional strategies to reduce emissions of particulate matter and other pollutants leading to regional haze, and help states meet the consultation requirements of the RHR.

The Western Regional Air Partnership (WRAP), one of the five regional planning organizations described in the previous paragraph, is a collaborative effort of state governments, local air agencies, Tribal governments, and various federal agencies established to initiate and coordinate activities associated with the management of regional haze, visibility, and other air quality issues in the Western United States. Members include the states of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, and 28 Tribal governments.[7] The federal partner members of WRAP are the EPA, U.S. National Parks Service (NPS), U.S. Fish and Wildlife Service (USFWS), U.S. Forest Service (USFS), and the Bureau of Land Management (BLM). WRAP formed a workgroup to develop a planning framework for state regional haze second planning period SIPs. Based on emissions and monitoring data supplied by its membership, WRAP produced a technical system to support regional modeling of visibility impacts at Class I areas across the West. The WRAP Technical Support System consolidated air quality monitoring data, meteorological and receptor modeling data analyses, emissions inventories and projections, and gridded air quality/visibility regional modeling results. The Technical Support System is accessible by member states and allows for the creation of maps, figures, and tables to export and use in state plan development. It also maintains the original source data for verification and further analysis. Colorado collaborated with WRAP on various aspects of the State's 2022 SIP submission, including the identification of Class I areas outside of Colorado that may be affected by sources in the state, source selection, analysis of air quality monitoring data, preparation of emission inventories, development of reasonable progress goals, and air quality modeling, which together informed the development of its long-term strategy.

C. Status of Colorado's Regional Haze Plan for the First Implementation Period

The CAA requires that regional haze plans for the first implementation period (2008 through 2018) include, among other things, a long-term strategy for making reasonable progress and Best Available Retrofit Technology (BART) requirements for certain older stationary sources, where applicable.[8] On December 31, 2012, the EPA approved a regional haze SIP revision submitted May 25, 2011, by the State of Colorado as meeting the requirements of the CAA and RHR.[9] On February 25, 2013, the National Parks Conservation Association (NPCA) and Wild Earth Guardians (Guardians) filed petitions for review in the U.S. Court of Appeals for the Tenth Circuit of the EPA's final approval of the Colorado regional haze SIP.[10] Among other things, Guardians and NPCA challenged the NO_X BART limit for Craig Unit 1. The parties settled the challenge regarding Craig Unit 1.[11] Separately, on May 26, 2015, the EPA reissued its final approval of the May 25, 2011, SIP submission with respect to the State's BART determination for the Comanche Generating Station in response to a petition for review and as part of a voluntary remand, without vacatur, to more adequately respond to public comments concerning the Comanche Generating Station.[12]

D. Colorado's Regional Haze Plan for the Second Implementation Period

On May 20, 2022, Colorado submitted a SIP submission to address its regional haze obligations for the second implementation period (2018–2028). Colorado's 2022 SIP submission contains the State's long-term strategy to address regional haze visibility impairment for each Class I area within the State and each Class I area outside the State that may be affected by emissions from the State. In developing its long-term strategy, the State

[6] There are several ways to measure the amount of visibility impairment, *i.e.,* haze. One such measurement is the deciview, which is the principal metric used by the RHR. Under many circumstances, a change in one deciview will be perceived by the human eye to be the same on both clear and hazy days. The deciview is unitless. It is proportional to the logarithm of the atmospheric extinction of light, which is the perceived dimming of light due to its being scattered and absorbed as it passes through the atmosphere. Atmospheric light extinction (b^{ext}) is a metric used for expressing visibility and is measured in inverse megameters (Mm^{-1}). The formula for the deciview is 10 ln (b^{ext})/10 Mm^{-1}). 40 CFR 51.301.

[7] A full list of WRAP members is available at *https://www.westar.org/wrap-council-members/.*

[8] Requirements for regional haze SIPs for the first implementation period are also contained in CAA section 169A(b)(2).

[9] 77 FR 76871 (December 31, 2012).

[10] *WildEarth Guardians* v. *EPA,* No. 13–9520 (10th Cir.) and *National Parks Conservation Association* v. *EPA,* No. 13–9525 (10th Cir.).

[11] Following that settlement, on July 5, 2018, the EPA approved a SIP revision to include source-specific revisions to the NO_X BART determination for Craig Station Unit 1 and to the NO_X reasonable progress determination for the Nucla Station. 83 FR 31332 (July 5, 2018).

[12] 80 FR 29953 (May 26, 2015).

examined the need to implement additional enforceable emission limitations, compliance schedules, and other measures that may be necessary to make reasonable progress since the first implementation period. Specifically, Colorado's 2022 SIP submission contains an assessment of visibility progress made at Class I areas since the first implementation period and a long-term strategy to address regional haze visibility impairment at the twelve Class I areas the State identified, including: Colorado's selection of sources that may affect visibility in Class I areas within the State and outside the State for four-factor analysis; its evaluation of the selected sources to determine what emission reduction measures constitute reasonable progress for the long-term strategy; regional scale modeling of the State's long-term strategy to set reasonable progress goals for 2028; and ultimately, Colorado's determinations on what control measures are necessary for the long-term strategy to address regional haze visibility impairment in the twelve Class I areas. The State concluded that additional emission reduction measures for Colorado facilities are required for the second implementation period under its long-term strategy.

On May 20, 2022, Colorado submitted a separate SIP submission to move the regional haze provisions currently contained in Regulation Number 3 to Regulation Number 23. The Colorado Air Quality Control Commission previously approved regional haze requirements under Regulation Number 3, which included emission reduction requirements for sources subject to BART and reasonable progress determinations during the first planning period of the regional haze program. As part of Colorado's 2022 SIP submission, the State adopted revisions to Regulation Number 3 (Part F) to the newly created Regulation Number 23 which will serve as the central repository for new and existing provisions that comply with the RHR. Regulation Number 23 includes BART and reasonable progress determinations from the first planning period as well as emission reduction requirements to meet the reasonable progress goals for the second 10-year planning period.

III. Requirements for Regional Haze Plans for the Second Implementation Period

Under the CAA and the EPA's regulations, all 50 states, the District of Columbia, and the U.S. Virgin Islands were required to submit regional haze SIPs satisfying the applicable requirements for the second implementation period of the regional haze program by July 31, 2021. Each SIP must contain a long-term strategy for making reasonable progress toward meeting the national goal of remedying any existing and preventing any future anthropogenic visibility impairment in Class I areas. CAA section 169A(b)(2)(B). To this end, 40 CFR 51.308(f) lays out the process by which states determine what constitutes their long-term strategies, with the order of the requirements in 40 CFR 51.308(f)(1) through (3) generally mirroring the order of the steps in the reasonable progress analysis [13] and (f)(4) through (6) containing additional, related requirements.

Broadly speaking, a state first must identify the Class I areas within the state and determine the Class I areas outside the state in which visibility may be affected by emissions from the state. These are the Class I areas that must be addressed in the state's long-term strategy. See 40 CFR 51.308(f), (f)(2). For each Class I area within its borders, a state must then calculate the baseline (five-year average period of 2000–2004), current, and natural visibility conditions (*i.e.,* visibility conditions without anthropogenic visibility impairment) for that area, as well as the visibility improvement made to date and the ''uniform rate of progress'' (URP). The URP is the linear rate of progress needed to attain natural visibility conditions, assuming a starting point of baseline visibility conditions in 2004 and ending with natural conditions in 2064. This linear interpolation is used as a tracking metric to help states assess the amount of progress they are making towards the national visibility goal over time in each Class I area. See 40 CFR 51.308(f)(1).

Each state having a Class I area and/or emissions that may affect visibility in a Class I area must then develop a long-term strategy that includes the enforceable emission limitations, compliance schedules, and other measures that are necessary to make reasonable progress in such areas. A reasonable progress determination is based on applying the four factors in CAA section 169A(g)(1) to sources of visibility impairing pollutants that the state has selected to assess for controls for the second implementation period. Additionally, as further explained below, the RHR at 40 CFR 51.3108(f)(2)(iv) separately provides five ''additional factors'' [14] that states must consider in developing their long-term strategies. See 40 CFR 51.308(f)(2). A state evaluates potential emission reduction measures for those selected sources and determines which are necessary to make reasonable progress. Those measures are then incorporated into the state's long-term strategy.

After a state has developed its long-term strategy, it then establishes RPGs for each Class I area within its borders by modeling the visibility impacts of all reasonable progress controls at the end of the second implementation period, *i.e.,* in 2028, as well as the impacts of other requirements of the CAA. The RPGs include reasonable progress controls not only for sources in the state in which the Class I area is located, but also for sources in other states that contribute to visibility impairment in that area. The RPGs are then compared to the baseline visibility conditions and the URP to ensure that progress is being made towards the statutory goal of preventing any future and remedying any existing anthropogenic visibility impairment in Class I areas. 40 CFR 51.308(f)(2)–(3). There are additional requirements in the rule, including FLM consultation, that apply to all visibility protection SIPs and SIP revisions. *See e.g.,* 40 CFR 51.308(i).

While states have discretion to choose any source selection methodology that is reasonable, whatever choices they make should be reasonably explained. To this end, 40 CFR 51.308(f)(2)(i) requires that a state's SIP submission include ''a description of the criteria it used to determine which sources or groups of sources it evaluated.'' The technical basis for source selection, which may include methods for quantifying potential visibility impacts such as emissions divided by distance metrics, trajectory analyses, residence time analyses, and/or photochemical modeling, must also be appropriately documented, as required by 40 CFR 51.308(f)(2)(iii).

Once a state has selected the set of sources, the next step is to determine the emissions reduction measures for those sources that are necessary to make reasonable progress for the second implementation period.[15] This is

[13] The EPA explained in the 2017 RHR revisions that we were adopting new regulatory language in 40 CFR 51.308(f) that, unlike the structure in 51.308(d), ''tracked the actual planning sequence.'' (82 FR at 3091).

[14] The five ''additional factors'' for consideration in 40 CFR 51.308(f)(2)(iv) are distinct from the four factors listed in CAA section 169A(g)(1) and 40 CFR 51.308(f)(2)(i) that states must consider and apply to sources in determining reasonable progress.

[15] The CAA provides that, ''[i]n determining reasonable progress there shall be taken into consideration'' the four statutory factors. CAA section 169A(g)(1). However, in addition to four-factor analyses for selected sources, groups of sources, or source categories, a state may also

Continued

accomplished by considering the four factors—''the costs of compliance, the time necessary for compliance, the energy and non-air quality environmental impacts of compliance, and the remaining useful life of any existing source subject to such requirements.'' CAA section 169A(g)(1). The EPA has explained that the four-factor analysis is an assessment of potential emission reduction measures (*i.e.,* control options) for sources; ''use of the terms 'compliance' and 'subject to such requirements' in section 169A(g)(1) strongly indicates that Congress intended the relevant determination to be the requirements with which sources would have to comply to satisfy the CAA's reasonable progress mandate.'' 82 FR at 3091. Thus, for each source it has selected for four-factor analysis,[16] a state must consider a ''meaningful set'' of technically feasible control options for reducing emissions of visibility impairing pollutants. *Id.* at 3088.

The EPA has also explained that, in addition to the four statutory factors, states have flexibility under the CAA and RHR to reasonably consider visibility benefits as an additional factor alongside the four statutory factors.[17] Ultimately, while states have discretion to reasonably weigh the factors and to determine what level of control is needed, 40 CFR 51.308(f)(2)(i) provides that a state ''must include in its implementation plan a description of . . . how the four factors were taken into consideration in selecting the measure for inclusion in its long-term strategy.''

As explained above, 40 CFR 51.308(f)(2)(i) requires states to determine the emission reduction measures for sources that are necessary to make reasonable progress by considering the four factors. Pursuant to 40 CFR 51.308(f)(2), measures that are necessary to make reasonable progress towards the national visibility goal must be included in a state's long-term strategy and in its SIP. If the outcome of a four-factor analysis is that an emissions reduction measure is necessary to make reasonable progress towards remedying existing or preventing future anthropogenic visibility impairment, that measure must be included in the SIP.

The characterization of information on each of the factors is also subject to the documentation requirement in 40 CFR 51.308(f)(2)(iii). The reasonable progress analysis is a technically complex exercise, and also a flexible one that provides states with bounded discretion to design and implement approaches appropriate to their circumstances. Given this flexibility, 40 CFR 51.308(f)(2)(iii) plays an important function in requiring a state to document the technical basis for its decision making so that the public and the EPA can comprehend and evaluate the information and analysis the state relied upon to determine what emission reduction measures must be in place to make reasonable progress. The technical documentation must include the modeling, monitoring, cost, engineering, and emissions information on which the state relied to determine the measures necessary to make reasonable progress.

Additionally, the RHR at 40 CFR 51.3108(f)(2)(iv) separately provides five ''additional factors'' that states must consider in developing their long-term strategies: (1) Emission reductions due to ongoing air pollution control programs, including measures to address reasonably attributable visibility impairment; (2) measures to reduce the impacts of construction activities; (3) source retirement and replacement schedules; (4) basic smoke management practices for prescribed fire used for agricultural and wildland vegetation management purposes and smoke management programs; and (5) the anticipated net effect on visibility due to projected changes in point, area, and mobile source emissions over the period addressed by the long-term strategy.

Because the air pollution that causes regional haze crosses state boundaries, 40 CFR 51.308(f)(2)(ii) requires a state to consult with other states that also have emissions that are reasonably anticipated to contribute to visibility impairment in a given Class I area. If a state, pursuant to consultation, agrees that certain measures (*e.g.,* a certain emission limitation) are necessary to make reasonable progress at a Class I area, it must include those measures in its SIP. 40 CFR 51.308(f)(2)(ii)(A). Additionally, the RHR requires that states that contribute to visibility impairment at the same Class I area consider the emission reduction measures the other contributing states have identified as being necessary to make reasonable progress for their own sources. 40 CFR 51.308(f)(2)(ii)(B). If a state has been asked to consider or adopt certain emission reduction measures, but ultimately determines those measures are not necessary to make reasonable progress, that state must document in its SIP the actions taken to resolve the disagreement. 40 CFR 51.308(f)(2)(ii)(C). Under all circumstances, a state must document in its SIP submission all substantive consultations with other contributing states. 40 CFR 51.308(f)(2)(ii)(C).

Reasonable progress goals ''measure the progress that is projected to be achieved by the control measures states have determined are necessary to make reasonable progress based on a four-factor analysis.'' 82 FR at 3091. For the second implementation period, the RPGs are set for 2028. Reasonable progress goals are not enforceable targets, 40 CFR 51.308(f)(3)(iii). While states are not legally obligated to achieve the visibility conditions described in their RPGs, 40 CFR 51.308(f)(3)(i) requires that ''[t]he long-term strategy and the reasonable progress goals must provide for an improvement in visibility for the most impaired days since the baseline period and ensure no degradation in visibility for the clearest days since the baseline period.''

RPGs may also serve as a metric for assessing the amount of progress a state is making towards the national visibility goal. To support this approach, the RHR requires states with Class I areas to compare the 2028 RPG for the most impaired days to the corresponding point on the URP line (representing visibility conditions in 2028 if visibility were to improve at a linear rate from conditions in the baseline period of 2000–2004 to natural visibility conditions in 2064). If the most impaired days RPG in 2028 is above the URP (*i.e.,* if visibility conditions are improving more slowly than the rate described by the URP), each state that contributes to visibility impairment in the Class I area must demonstrate, based on the four-factor analysis required under 40 CFR 51.308(f)(2)(i), that no additional emission reduction measures would be reasonable to include in its long-term strategy. 40 CFR 51.308(f)(3)(ii). To this end, 40 CFR 51.308(f)(3)(ii) requires that each state contributing to visibility impairment in a Class I area that is projected to improve more slowly than the URP provide ''a robust demonstration, including documenting the criteria used to determine which sources or groups

consider additional emission reduction measures for inclusion in its long-term strategy, *e.g.,* from other newly adopted, on-the-books, or on-the-way rules and measures for sources not selected for four-factor analysis for the second implementation period.

[16] ''Each source'' or ''particular source'' is used here as shorthand. While a source-specific analysis is one way of applying the four factors, neither the statute nor the RHR requires states to evaluate individual sources. Rather, states have ''the flexibility to conduct four-factor analyses for specific sources, groups of sources or even entire source categories, depending on state policy preferences and the specific circumstances of each state.'' 82 FR at 3088.

[17] *See, e.g.,* Responses to Comments on Protection of Visibility: Amendments to Requirements for State Plans; Proposed Rule (81 FR 26942, May 4, 2016), Docket ID No. EPA–HQ–OAR–2015–0531, U.S. Environmental Protection Agency at 186.

[of] sources were evaluated and how the four factors required by paragraph (f)(2)(i) were taken into consideration in selecting the measures for inclusion in its long-term strategy.''

Section 51.308(f)(6) requires states to have certain strategies and elements in place for assessing and reporting on visibility. Individual requirements under this section apply either to states with Class I areas within their borders, states with no Class I areas but that are reasonably anticipated to cause or contribute to visibility impairment in any Class I area, or both. Compliance with the monitoring strategy requirement may be met through a state's participation in the Interagency Monitoring of Protected Visual Environments (IMPROVE) monitoring network, which is used to measure visibility impairment caused by air pollution at the 156 Class I areas covered by the visibility program. 40 CFR 51.308(f)(6), (f)(6)(i), (f)(6)(iv).

All states' SIPs must provide for procedures by which monitoring data and other information are used to determine the contribution of emissions from within the state to regional haze visibility impairment in affected Class I areas, as well as a statewide inventory documenting such emissions. 40 CFR 51.308(f)(6)(ii), (iii), (v). All states' SIPs must also provide for any other elements, including reporting, recordkeeping, and other measures, that are necessary for states to assess and report on visibility. 40 CFR 51.308(f)(6)(vi).

Section 51.308(f)(5) requires a state's regional haze SIP revision to address the requirements of paragraphs 40 CFR 51.308(g)(1) through (5) so that the plan revision due in 2021 will serve also as a progress report addressing the period since submission of the progress report for the first implementation period. The regional haze progress report requirement is designed to inform the public and the EPA about a state's implementation of its existing long-term strategy and whether such implementation is in fact resulting in the expected visibility improvement. See 81 FR 26942, 26950 (May 4, 2016), (82 FR at 3119, January 10, 2017). To this end, every state's SIP revision for the second implementation period is required to assess changes in visibility conditions and describe the status of implementation of all measures included in the state's long-term strategy, including BART and reasonable progress emission reduction measures from the first implementation period, and the resulting emissions reductions. 40 CFR 51.308(g)(1) and (2).

CAA section 169A(d) requires that before a state holds a public hearing on a proposed regional haze SIP revision, it must consult with the appropriate FLM or FLMs; pursuant to that consultation, the state must include a summary of the FLMs' conclusions and recommendations in the notice to the public. Consistent with this statutory requirement, the RHR also requires that states ''provide the [FLM] with an opportunity for consultation, in person and at a point early enough in the State's policy analyses of its long-term strategy emission reduction obligation so that information and recommendations provided by the [FLM] can meaningfully inform the State's decisions on the long-term strategy.'' 40 CFR 51.308(i)(2). For the EPA to evaluate whether FLM consultation meeting the requirements of the RHR has occurred, the SIP submission should include documentation of the timing and content of such consultation. The SIP revision submitted to the EPA must also describe how the state addressed any comments provided by the FLMs. 40 CFR 51.308(i)(3). Finally, a SIP revision must provide procedures for continuing consultation between the state and FLMs regarding the state's visibility protection program, including development and review of SIP revisions, five-year progress reports, and the implementation of other programs having the potential to contribute to impairment of visibility in Class I areas. 40 CFR 51.308(i)(4).

Finally, the state SIP must meet the approval requirements in CAA section 110(a)(2) for plans ''submitted by a State under this chapter'' to the extent not already addressed in the regulations described previously. As relevant here, the state must provide ''necessary assurances'' that the state has adequate personnel, funding, and authority to carry out the implementation plan, that the state ''is not prohibited by any provision of Federal or State law from carrying out such implementation plan or portion thereof,'' and that the state can lawfully rely on regional and local instrumentalities to implement the SIP, as applicable. CAA section 110(a)(2)(E)(i)–(iii).

IV. The EPA's Evaluation of Colorado's Regional Haze Plan for the Second Implementation Period

In section IV of this document, we describe Colorado's 2022 SIP submission and evaluate it against the requirements of the CAA and RHR for the second implementation period of the regional haze program.

A. Identification of Class I Areas

Section 169A(b)(2) of the CAA requires each state in which any Class I area is located or ''the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility'' in a Class I area to have a plan for making reasonable progress toward the national visibility goal. The RHR implements this statutory requirement at 40 CFR 51.308(f), which provides that each state's plan ''must address regional haze in each mandatory Class I Federal area located within the State and in each mandatory Class I Federal area located outside the State that may be affected by emissions from within the State,'' and (f)(2), which requires each state's plan to include a long-term strategy that addresses regional haze in such Class I areas.

There are twelve designated Class I areas within the State of Colorado, including four national parks managed by the U.S. National Park Service (Black Canyon of the Gunnison National Park, Great Sand Dunes National Park, Mesa Verde National Park, Rocky Mountain National Park) and eight wilderness areas managed by the U.S. Forest Service (Eagles Nest Wilderness Area, Flat Tops Wilderness Area, La Garita Wilderness Area, Maroon Bells-Snowmass Wilderness Area, Mount Zirkel Wilderness Area, Rawah Wilderness Area, Weminuche Wilderness Area, West Elk Wilderness Area).[18]

Using the 2021 Particulate Source Apportionment Technology (PSAT) product from the WRAP, Colorado identified five Class I areas outside the State where visibility may be affected by Colorado sources: Canyonland National Park in Utah (9.4%), Capitol Reef National Park in Utah (3.6%), Badlands National Park in South Dakota (7.5%), Wind Cave National Park in South Dakota (2.9%), and Wheeler Peak Wilderness in New Mexico (4.1%) based on combined percentages of nitrate + sulfate impairment at these Class I areas from Colorado sources. The State further highlighted that these Class I areas also experience visibility impairment due to five other aerosol species (sea salt, elemental carbon, organic carbon, fine soil, and coarse mass) which were not included in the 2021 PSAT modeling the State relied on to determine its contributions to Class I areas outside of the State.[19] Therefore, according to the State, Colorado's contribution to overall light extinction is less than the results of the 2021 PSAT modeling which only

[18] Colorado 2022 SIP submission at 7.

[19] Colorado 2022 SIP submission at 142.

evaluated nitrate + sulfate impairment. Furthermore, Colorado notes that the already announced retirements of coal-fired power plants driven by Colorado state rules and associated with the State's regional haze long-term strategy and incorporated into the SIP, along with state regulations for ozone, greenhouse gases, and other regulatory programs not part of the State's regional haze long-term strategy, will further reduce nitrate and sulfate contributions from Colorado sources.[20] Because Colorado addressed regional haze visibility impairment for each Class I area within the State, and each mandatory Class I area located outside the State that may be affected by emissions from the State, we find that Colorado did not unreasonably exclude any Class I areas from its analysis.

B. Calculation of Baseline, Current, and Natural Visibility Conditions; Progress to Date; and Uniform Rate of Progress for Class I Areas Within the State

Section 51.308(f)(1) requires states to determine the following for ''each mandatory Class I Federal area located within the State'': baseline visibility conditions for the most impaired and clearest days, natural visibility conditions for the most impaired and clearest days, progress to date for the most impaired and clearest days, the differences between current visibility conditions and natural visibility conditions, and the URP. This section also provides the option for states to propose adjustments to the URP line for a Class I area to account for visibility impacts from anthropogenic sources outside the United States and/or the impacts from wildland prescribed fires that were conducted for certain specified objectives. 40 CFR 51.308(f)(1)(vi)(B).

The IMPROVE monitoring network measures visibility impairment caused by air pollution at Class I areas. Colorado's 2022 SIP submission provides visibility conditions for each IMPROVE monitor and associated Class I area in Colorado (table 1).[21]

TABLE 1—VISIBILITY CONDITIONS (DECIVIEWS) FOR COLORADO IMPROVE STATIONS

Monitor ID	Class I areas	Baseline (2000–2004)	Period (2008–2012)	Current (2014–2018)	Natural (2064) [1]	Progress since baseline (2000–2004)—(2014–2018)	Progress during last implementation period (2008–2012)–(2014–2018)	Difference between current (2014–2018) and natural (2064)
Most Impaired Days								
GRSA1	Great Sand Dunes	9.66	8.88	8.02	4.45	−1.64	−0.86	3.57
MEVE1	Mesa Verde	9.22	8.13	6.51	4.20	−2.71	−1.62	2.31
MOZI1	Mount Zirkel, Rawah	7.29	6.26	5.47	3.16	−1.82	−0.79	2.31
ROMO1	Rocky Moutain National Park	11.12	9.36	8.41	4.94	−2.71	−0.95	3.47
WEMI1	Weminuche, La Garita, Black Canyon of Gunnison.	7.78	6.94	6.55	3.97	−1.23	−0.38	2.58
WHRI1	Eagles Nest, Flat Tops, Maroon Bells, White River, West Elk.	6.30	5.89	4.98	3.02	−1.32	−0.91	1.96
Clearest Days								
GRSA1	Great Sand Dunes	4.50	3.65	2.74	1.24	-1.76	-0.91	1.5
MEVE1	Mesa Verde	4.32	2.96	2.28	1.02	-2.04	-0.68	1.26
MOZI1	Mount Zirkel, Rawah	1.61	0.49	0.23	-0.47	-1.38	-0.26	0.7
ROMO1	Rocky Moutain National Park	2.29	1.69	1.37	0.28	-0.92	-0.32	1.09
WEMI1	Weminuche, La Garita, Black Canyon of Gunnison.	3.11	2.11	1.61	0.98	-1.5	-0.50	0.63
WHRI1	Eagles Nest, Flat Tops, Maroon Bells, White River, West Elk.	0.70	0.04	-0.16	-0.81	-0.86	-0.20	0.65

[1] Natural visibility conditions for the clearest days from EPA Memo, Data for regional haze technical addendum. June 3, 2020.

The State also determined the uniform rate of progress for the most impaired and clearest days for Colorado Class I areas.[22] Colorado also provided haze indices and the uniform rate of progress for IMPROVE monitors and associated Class I areas outside the State.[23]

Based on the information provided in Colorado's 2022 SIP submission, the EPA is proposing to approve the State's visibility condition calculations for Great Sand Dunes, Mesa Verde, Mount Zirkel, Rawah, Rocky Mountain National Park, Weminuche, La Garita, Black Canyon of the Gunnison, Eagles Nest, Flat Tops, Maroon Bells, White River, and West Elk [24] as meeting the requirements of 40 CFR 51.308(f)(1) related to the calculation of baseline, current, and natural visibility conditions; progress to date; and the URP.

C. Long-Term Strategy

Each state having a Class I area within its borders or emissions that may affect visibility in a Class I area must develop a long-term strategy for making reasonable progress towards the national visibility goal. CAA section 169A(b)(2)(B). After considering the four statutory factors, all measures that are determined to be necessary to make reasonable progress must be in the long-term strategy. In developing its long-term strategy, a state must also consider the five additional factors in 40 CFR 51.308(f)(2)(iv). As part of its reasonable progress determinations, the state must describe the criteria used to determine which sources or group of sources were evaluated (*i.e.,* subjected to four-factor analysis) for the second implementation period and how the four factors were taken into consideration in selecting the emission reduction measures for inclusion in the long-term strategy. 40 CFR 51.308(f)(2)(iii).

[20] Colorado 2022 SIP submission at 142.

[21] Colorado 2022 SIP submission at 21–22 and 157.

[22] Colorado 2022 SIP submission at 27, 42.

[23] Colorado 2022 SIP submission at 18–28.

[24] Mount Zirkel and Rawah are subject to the same visibility calculation. Weminuche, La Garita, and Black Canyon of the Gunnison are subject to the same visibility calculation. Eagles Nest, Flat Tops, Maroon Bells, White River, and West Elk are subject to the same visibility calculation.

1. Colorado's Long-Term Strategy Four-Factor Analysis

a. Summary of Colorado's Long-Term Strategy Four-Factor Analysis

Colorado identified twelve Class I areas that must be addressed in its long-term strategy.[25] Under 40 CFR 51.308(f)(2)(i), SIP submittals must include a description of the criteria a state used to determine which sources or groups of sources to evaluate through four-factor analysis. Colorado used a Q/d screening approach to identify sources for four-factor analysis. The Q/d screening metric uses a source's annual emissions in tons (Q) divided by the distance in kilometers (d) between the source and the nearest Class I area, along with a reasonably selected threshold for this metric. The larger the Q/d value, the greater the source's expected effect on visibility in each associated Class I area.

Specifically, the WRAP Reasonable Progress Screening protocol recommends a three-step process for screening sources that involves an initial screening of identifying stationary sources that emit combined NO_X, SO_2, SO_4, and PM_{10} emissions of over 25 tons/year, a secondary screening of assessing the Q/d for those stationary sources to determine whether a source Q/d exceeds ''10'' for a specific Class I area, and the use of the 2028 Weighted Emissions Potential (WEP) to determine the possible contribution of the source to visibility impairment in Class I areas for the 20% most impaired days. Using the WRAP-devised screening threshold of Q/d > 10 and emissions information from the 2014 National Emission Inventory (NEI), Colorado initially identified twenty-three sources in the State that may be affecting visibility at Class I areas in Colorado.[26] [27] The State reduced the number of facilities subject to a reasonable progress four-factor analysis to nineteen because two facilities have actual emissions below the WRAP screening protocol's threshold of 25 tons/year, one coal mine closed in 2015, and two adjacent coal mines were combined into one facility.[28] Ultimately, the State selected nineteen sources subject to a four-factor analysis (table 2).[29]

TABLE 2—FACILITIES SCREENED IN USING Q/D

Facility name	Closest Class I area	(d) Minimum of distance (km) to Class I area	(Q) Maximum of emissions (tons/year)	Q/d
Craig Power Plant *(Tri-State Generation)*	Flat Tops Wilderness	47.85	17,665.13	369.17
Hayden Power Plant *(Public Service Co)*	Mount Zirkel Wilderness	31.59	8,435.17	267.04
Cherokee Power Plant *(Public Service Co)*	Rocky Mountain National Park	65.09	8,194.22	125.89
Comanche Power Plant *(Public Service Co)*	Great Sand Dunes Wilderness	91.63	8,101.48	88.42
Valmont Power Plant[1] *(Public Service Co)*	Rocky Mountain National Park	34.69	2,986.64	86.10
Lyons Cement Kiln *(Cemex Construction Materials)*.	Rocky Mountain National Park	24.74	1,193.48	48.25
Pawnee Power Plant *(Public Service Co)*	Rocky Mountain National Park	155.67	7,340.60	47.15
Nixon Power Plant *(Colorado Springs Utilities)*.	Great Sand Dunes Wilderness	113.48	5,350.98	47.15
Rawhide Power Plant *(Platte River Power Authority)*.	Rocky Mountain National Park	56.45	2,438.39	43.20
Martin Drake Power Plant[2] *(Colorado Springs Utilities)*.	Great Sand Dunes Wilderness	125.41	5,214.47	41.58
Denver International Airport[3]	Rocky Mountain National Park	82.84	3,112.60	37.57
Molson Coors Boiler Support Facility[4]	Rocky Mountain National Park	54.23	1,825.35	33.66
Nucla Power Plant[5] *(Tri State Generation)*	Black Canyon of the Gunnison Wilderness	70.53	1,619.96	22.97
Portland Plant *(Holicm (Us) Inc.)*	Great Sand Dunes Wilderness	75.39	1,548.00	20.53
Denver Refinery *(Suncor Energy)*	Rocky Mountain National Park	67.03	1,278.79	19.08
South Taylor Mine/Colorado Mine *(Colowyo Coal Co.)*.	Flat Tops Wilderness	40.44/39.29	685.00/652.92	16.94/16.62
Pueblo Cement Plant *(GCC Rio Grande)*	Great Sand Dunes Wilderness	85.31	1,080.60	12.67
Rocky Mountain Bottle Company	Rocky Mountain National Park	56.97	712.94	12.51
Evraz Rocky Mountain Steel Mill	Great Sand Dunes Wilderness	90.41	967.11	10.70

[1] Valmont Power Plant closed in September 2017.
[2] Martin Drake Unit 5 closed in January 2017.
[3] After reviewing emissions for the point sources, Colorado determined that emissions from each point fell below the 10 tons/year for a full analysis of additional control options. Therefore, no point sources were subject to a full emissions control analysis.
[4] The Molson Coors Boiler Support Facility was formerly the Colorado Energy Nations Company (CENC).
[5] Nucla Power Plant closed in September 2019.

The State requested that each of the nineteen sources submit cost information for its review and consideration.[30] For three of these sources, the State determined that it was not necessary to conduct further review because those sources had closed prior to the State's development of its SIP.[31] For the remaining sources, Colorado then evaluated what is necessary to make reasonable progress by considering the four statutory factors[32] for each source:

- Cost of compliance;
- Time necessary for compliance;

[25] Colorado 2022 SIP submission at 7.
[26] Colorado 2022 SIP submission at 51.
[27] WRAP Reasonable Progress Source Identification and Analysis Protocol For Second 10-year Regional Haze State Implementation Plans. February 27, 2019.
[28] Colorado 2022 SIP submission at 51. The WRAP RP Screening protocol recommends a three step process for screening sources that involves (1) identifying stationary sources with combined NO_X, SO_2, SO_4, and PM_{10} emissions of over 25 tons/year, (2) assessing the Q/d for those stationary sources to determine whether a source Q/d exceeds ''10'' for a specific Class I area and (3) using the 2028 Weighted Emissions Potential (WEP) to confirm whether the identified source is located in a grid cell that impacts the specific Class I area for the 20% most impaired days.
[29] Colorado 2022 SIP submission at 52.
[30] Colorado 2022 SIP submission at 52.
[31] Martin Drake Unit 5, Nucla, and Valmont.
[32] 40 CFR 51.308(f)(2)(i)

• Energy and non-air quality environmental impacts of compliance; and

• Remaining useful life of any potentially affected sources.

The State documented these analyses in Colorado's 2022 SIP submission and associated technical support documents. Chapter 7 of the SIP submission contains Colorado's evaluation of the four statutory factors for each source and Colorado's determinations of the source-specific emission reduction measures necessary to make reasonable progress. As part of its four-factor evaluation, Colorado considered the already announced retirements of several units and facilities as part of its ''remaining useful life'' analysis and incorporated those retirements into the SIP.[33] Ultimately, the State concluded that the following enforceable reasonable progress source retirements (table 3) and emission limits (table 4) satisfy and exceed regional haze requirements for the second implementation period and that no other regional haze analyses or regional haze controls will be required by the State during the second regional haze implementation period.

TABLE 3—REASONABLE PROGRESS DETERMINATIONS FOR THE SECOND IMPLEMENTATION PERIOD IN THE COLORADO REGIONAL HAZE SIP—SOURCE CLOSURES [34]

Emission unit	Closure date	Additional requirements/notes
Rawhide Unit 1	December 31, 2029	Maintain existing emission limits until closure.
Martin Drake Unit 6	December 31, 2022	Maintain existing emission limits until closure.
Martin Drake Unit 7	December 31, 2022	Maintain existing emission limits until closure.
Nixon Unit 1	December 31, 2029	Maintain existing emission limits until closure.
Nixon Coal Handling	December 31, 2029	Cessation of coal unloading and crushing.
Comanche Unit 1	December 31, 2022	Maintain existing emission limits until closure.
Comanche Unit 2	December 31, 2025	Maintain existing emission limits until closure. Comply with additional NO_X and SO_2 limits when Comanche Unit 1 closes—see table 4.
Hayden Unit 1	December 31, 2028	Maintain existing emission limits until closure.
Hayden Unit 2	December 31, 2027	Maintain existing emission limits until closure.
Craig Unit 2	September 30, 2028	Maintain existing emission limits until closure.
Craig Unit 3	December 31, 2029	Maintain existing emission limits until closure.
ColoWyo Coal Mine	December 31, 2031	Not applicable.
Cherokee Unit 4	December 31, 2028	Maintain existing emission limits until closure.

TABLE 4—REASONABLE PROGRESS DETERMINATIONS FOR THE SECOND IMPLEMENTATION PERIOD IN THE COLORADO REGIONAL HAZE SIP—EMISSIONS LIMITS [35]

Emission unit	NO_X emission limit	SO_2 emission limit	PM emission limit
Nixon Coal Handling	N/A [1]	N/A [1]	1.46 tons PM_{10} per year, unloading, transfer, conveying, processing, and crushing (12-month rolling total). Cessation of coal unloading and crushing no later than 12/31/2029.
Nixon—Front Range Power Plant Turbine 1 and Turbine 2.	111 ppmvd at 15% O_2 (4-hour rolling average).	N/A [2]	N/A.[2]
Nixon—Clear Spring Ranch Solids Handling and Disposal Facility (SDHF).	N/A [2]	186.4 lb/hr (12-month rolling calculation). 52.20 tons/year (12-month rolling total). 5,000 ppmv H_2S in digester gas.	N/A.[2]
Comanche Unit 2 [3]	0.20 lb/MMBtu (30-day rolling average) 3,050 tons/year (12-month rolling average).	0.12 lb.MMBtu (30-day rolling average) 1,830 tons/year (12-month rolling average).	
Comanche Unit 3	0.08 lb/MMBtu (30-day rolling average) 0.07 lb/MMBtu (annual average)	0.10 lb/MMBtu (30-day rolling average)	0.02 lb/MMBtu. 0.012 lb/MMBtu (24-hour average).
Hayden Coal Ash Handling and Disposal and Unpaved Roads.	N/A [1]	N/A [1]	22.39 tons/year from coal ash, sorbent loading, unloading only (12-month rolling total).
Cherokee Turbine 5	Applicable limits in 40 CFR 60.4300 Table 1 (NSPS KKKK).	N/A [2]	0.1 lb/MMBtu.
Cherokee Turbine 6	Applicable limits in 40 CFR 60.4300 Table 1 (NSPS KKKK).	N/A [2]	0.1 lb/MMBtu.
Pawnee Unit 1	0.07 lb/MMBtu (30-day rolling average)	0.11 lb/MMBtu (30-day rolling average)	0.03 lb/MMBtu.
Pawnee Cooling Tower	N/A [1]	N/A [1]	36.5 tons/year (12-month rolling total).
Manchief Turbine 1	15 ppmvd at 15% O_2 (1-hr average) 100 ppmvd at 15% O_2 and 186 lb/hr during startup (1-hour average). 100 ppmvd at 15% O_2 and 140 lb/hr during shutdown (1-hour average). 25 ppmvd at 15% O_2 low load operation between March 1 and October 31 (1-hour average).	N/A [2]	N/A.[2]

[33] Colorado 2022 SIP submission at 56.

[34] Colorado Regulation Number 23, Part A, IV.F.1.

[35] Colorado Regulation Number 23, Part A, IV.F.3.

TABLE 4—REASONABLE PROGRESS DETERMINATIONS FOR THE SECOND IMPLEMENTATION PERIOD IN THE COLORADO REGIONAL HAZE SIP—EMISSIONS LIMITS [35]—Continued

Emission unit	NO_X emission limit	SO_2 emission limit	PM emission limit
Manchief Turbine 2	15 ppmvd at 15% O_2 (1-hr average) 100 ppmvd at 15% O_2 and 186 lb/hr during startup (1-hour average). 100 ppmvd at 15% O_2 and 140 lb/hr during shutdown (1-hour average). 25 ppmvd at 15% O_2 low load operation between March 1 and October 31 (1-hour average).	N/A [2]	N/A.[2]
CEMEX Lyons Kiln	1.85 lb/ton of clinker (30-day rolling average). 901.0 tons/year (12-month rolling average).	25.3 lb/hour (12-month rolling average) 95.0 tons/year (12-month rolling total).	N/A.[2]
CEMEX Dowe Flats and Lyons Quarries.	N/A [1]	N/A [1]	58.4 tons/year (Dowe Flats Quarry, 12-month rolling total). Current permitted limit for Lyons Quarry below 10 tons/year screening threshold.
CEMEX Raw Materials Grinding	N/A [1]	N/A [1]	Reporting based on the following factors: S010 (Raw Mill)—0.012 lb/ton of clinker S011 (Raw Mill Air Separator)—0.032 lb/ton of clinker. S012 (Raw Mill Weigh Feeders)—0.019 lb/ton of clinker. S013 (Iron/Silica Feed Belt—0.0031 lb/ton of clinker).
Holcim Florence Kiln	2.73 lb/ton of clinker (30-day rolling average). 2,086.8 tons/year (12-month rolling total).	1.3 lb/ton of clinker (30-day rolling average). 721.4 tons/year (12-month rolling total)	247.6 tons/year (12-month rolling total).
Holcim Florence Quarry	N/A [2]	N/A [2]	67.3 tons/year (12-month rolling total).
Holcim Florence Finish Mill	N/A [1]	N/A [1]	34.3 tons/year (12-month rolling total).
GCC Pueblo Kiln	2.70 lb/ton of clinker (30-day rolling average). 2.32 lb/ton of clinker (12-month rolling average). 1,100 tons/year (12-month rolling average).	N/A [2]	36.01 tons/year (Filterable, 12-month rolling total). 293.56 tons/year (Condensable, 12-month rolling total).
GCC Pueblo Clinker Cooler	N/A [1]	N/A [1]	33.92 tons/year (12-month rolling total).
Molson Coors Boiler Support Facility Boiler 1.	0.20 lb/MMBtu 625.4 tons/year (Combined 12-month rolling total for Boilers 1, 2, 4, and 5).	N/A [2]	N/A.[2]
Molson Coors Boiler Support Facility Boiler 2.	0.20 lb/MMBtu 625.4 tons/year (Combined 12-month rolling total for Boilers 1, 2, 4, and 5).	N/A [2]	N/A.[2]
Molson Coors Boiler Support Facility Boiler 4.	0.12 lb/MMBtu (30-day rolling average) 242.9 tons/year (12-month rolling total, Boiler 4 only). 625.4 tons/year (Combined 12-month rolling total for Boilers 1, 2, 4, and 5).	N/A [2]	N/A.[2]
Molson Coors Boiler Support Facility Boiler 5.	0.10 lb/MMBtu (30-day rolling average) 256.3 tons/year (12-month rolling total, Boiler 5 only). 625.4 tons/year (Combined 12-month rolling total for Boilers 1, 2, 4, and 5).	N/A [2]	N/A.[2]
EVRAZ Electric Arc Furnace (EAF)	0.28 lb/ton of steel (30-day rolling average). 189.0 tons/year (12-month rolling total)	0.15 lb/ton of steel (30-day rolling average). 101.25 tons/year (12-month rolling total).	0.0018 grains/dscf (filterable). 0.0052 grains/dscf (filterable+condensable). 163.11 tons/year (12-month rolling total).
EVRAZ Ladle Metallurgy Station (LMS)	84.1 tons/year (12-month rolling total)	2 tons/day (3-hour rolling average) 234.3 tons/year (12-month rolling total)	N/A.[2]
EVRAZ Round Caster	35.6 tons/year (12-month rolling total)	N/A [2]	19.10 tons/year (12-month rolling total).
EVRAZ Seamless Mill Rotary Furnace	169.26 tons/year (12-month rolling total).	N/A [2]	N/A.[2]
EVRAZ Seamless Mill Quench Furnace	Reporting based on 280 lbs/MMscf AP–42 emission factor.	N/A [2]	N/A.[2]
EVRAZ Seamless Mill Tempering Furnace.	Reporting based on 280 lbs/MMscf AP–42 emission factor.	N/A [2]	N/A.[2]
EVRAZ Rod/Bar Mill Furnace	0.07 lb/MMBtu 30.28 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
EVRAZ Rail Mill Furnace	0.07 lb/MMBtu (30-day rolling average) 32.34 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
EVRAZ Haul Roads	N/A [1]	N/A [1]	Compliance with Fugitive Dust Control Plan.
EVRAZ Vacuum Tank Degasser Boiler	16.21 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
EVRAZ Ladle Preheaters	23.91 tons/year (12-month rolling total, combined for 6 preheaters).	N/A [2]	N/A.[2]

TABLE 4—REASONABLE PROGRESS DETERMINATIONS FOR THE SECOND IMPLEMENTATION PERIOD IN THE COLORADO REGIONAL HAZE SIP—EMISSIONS LIMITS [35]—Continued

Emission unit	NO_X emission limit	SO_2 emission limit	PM emission limit
Rocky Mountain Bottle Company Furnaces B+ and C (common stack).	157.8 tons/year (12-month rolling total)	114.8 tons/year (12-month rolling total)	0.27 lb/ton of glass (Performance testing every 5 years). 38.7 tons/year (filterable + condensable, 12-month rolling total).
Suncor Plant 1 Fluidized Catalytic Cracking Unit Catalyst Regenerator (FCCU).	58.7 ppmvd at 0% O_2 (365-day rolling average).	25 ppmvd at 0% O_2 (365-day rolling average).	85.4 tons/year (12-month rolling total).
Suncor Plant 2 Fluidized Catalytic Cracking Unit Catalyst Regenerator (FCCU).	160 ppmvd at 0% O_2 (7-day rolling average). 80 ppmvd at 0% O_2 (365-day rolling average).	37.2 ppmvd at 0% O_2 (365-day rolling average).	53.1 tons/year (12-month rolling total).
Suncor Plant 1 Sulfur Recovery Unit Tail Gas Unit (SRC TGU).	N/A [2]	59.7 tons/year (12-month rolling total) ..	N/A.[2]
Suncor Plant 2 Sulfur Recovery Unit Tail Gas Incinerator (SRC TGI).	N/A [2]	1.20% volume SO_2 (12-hour rolling average) [4]. 271 tons/year (12-month rolling total). 120 tons/year (12-month rolling total).[5] Optimization no later than 12/31/2023 and compliance with 12-month rolling total 12 months after optimization is complete and no later than 12/31/2024. Application for permit modifications and limits based on operating data no later than 18 months after optimization project implementation or comply with alternative.[6].	N/A.[2]
Suncor Plant 1 Main Plant Flare		162 ppmv H_2S (3-hour rolling average)	N/A.[2]
Suncor Heater H–11	12.78 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–17	24.83 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–27	32.84 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–28/29/30	20.40 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–37	10.41 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–101	55.85 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–402	21.16 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Heater H–2101	52.19 tons/year (12-month rolling total)	N/A [2]	N/A.[2]
Suncor Boiler 4	0.06 lb/MMBtu (30-day rolling average)	N/A [2]	N/A.[2]
Suncor Boiler 505	0.044 lb/MMBtu (30-day rolling average).	N/A [2]	N/A.[2]

[1] This pollutant is not emitted.
[2] Emissions did not meet the screening threshold. Thus, this unit was not subject to a four-factor analysis for this pollutant.
[3] Compliance with NO_X and SO_2 emission limits beginning when Comanche Unit 1 closes and until Comanche Unit 2 closes.
[4] Beginning February 14, 2022, the Plant 2 sulfur recovery unit tail gas incinerator will meet a 1.20% volume SO_2 (12-hour rolling average) and an annual SO_2 limit of 271 tons per year (12-month rolling total).
[5] The owner/operator must implement optimization of air flow through the Plant 2 sulfur recovery unit no later than December 31, 2023. The Plant 2 sulfur recovery unit tail gas incinerator will meet an SO_2 limit of 120 tons per year (12 month rolling total) within twelve (12) months after optimization and by no later than December 31, 2024.
[6] Alternative for Suncor Plant 2 sulfur recovery unit tail gas incinerator: If the owner/operator fails to implement air flow optimization or fails to achieve the limit by the specified timeline, the owner/operator will install SUPERCLAUS 2+1 on the sulfur recovery unit by no later than December 31, 2028. The sulfur recovery unit must achieve at least a 98.65% sulfur recovery efficiency, by no later than December 31, 2029. The sulfur recovery unit tail gas incinerator will meet an SO_2 limit of 120 tons per year (12-month rolling total) within twelve (12) months after SUPERCLAUS 2+1 installation and by no later than December 31, 2029.

According to Colorado's 2022 SIP submission, each source must comply as expeditiously as practicable with the limits and averaging times, record keeping, and reporting requirements in addition to its applicable permit requirements, but in no event later than five years after EPA approval of Colorado's 2022 SIP submission.[36]

Section 51.308(f)(2) of the RHR requires states to include in their SIPs the enforceable emission limitations, compliance schedules, and other measures necessary to make reasonable progress. In addition to what is required by the RHR, general SIP requirements mandate that the SIP must also include adequate monitoring, recordkeeping, and reporting requirements for the regional haze emission limits and requirements. (*See* CAA section 110(a)). Colorado's 2022 SIP submission requires that sources maintain control equipment or operational practices required to comply with the limits and averaging times, recordkeeping, and reporting requirements, and establish procedures to ensure that such equipment or operational practices are properly operated and maintained.[37] Tables 3 and 4 specify reasonable progress emission limits and compliance schedules found in Colorado Regulation Number 23, Part A, IV. *Regional Haze Determinations,* which was submitted as part of Colorado's 2022 SIP submission.

Colorado's 2022 SIP submission also included Colorado Regulation Number 23, Part A, V. *Monitoring, Recordkeeping, and Reporting for Regional Haze Limits* which specifies the monitoring, recordkeeping, and reporting requirements for the State's regional haze determinations. Specifically, for NO_X and SO_2 emission limits, sources with continuous emission monitoring systems (CEMS) must operate and maintain CEMS in accordance with relevant EPA regulations, in particular, 40 CFR part 75 or 40 CFR part 60. Sources without NO_X and SO_2 emission CEMS are required to use stack testing, fuel sampling, fuel consumption, and associated emission factors, as applicable, and in accordance with EPA and ASTM test methods. For PM emission limits, sources must perform testing in accordance with EPA approved test methods, in particular, 40 CFR part 60 or 40 CFR part 63, and

[36] Colorado Regulation Number 23, Part A, IV.F.4.

[37] *Id.*

other PM monitoring/compliance determinations, as applicable, including compliance assurance monitoring plans developed and approved in accordance with 40 CFR part 64. In addition, sources must keep relevant records for five years and report relevant emissions.

b. The EPA's Evaluation of Colorado's Long-Term Strategy Four-Factor Analysis

Section 169A(b)(2) of the CAA requires each state in which any Class I area is located or ''the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility'' in a Class I area to have a plan for making reasonable progress toward the national visibility goal. CAA section 169A(g)(1) specifies: ''[I]n determining reasonable progress there shall be taken into consideration the costs of compliance, the time necessary for compliance, and the energy and nonair quality environmental impacts of compliance, and the remaining useful life of any existing source subject to such requirements.'' [38] The RHR implements this statutory requirement in 40 CFR 51.308(f) for the second and subsequent planning periods for regional haze. 40 CFR 51.308(f) requires states to submit a long-term strategy that addresses regional haze visibility impairment for each mandatory Class I area within the state and for each mandatory Class I area located outside the state that may be affected by emissions from the state. 40 CFR 51.308(f)(2)(i) lays out the CAA 169A four-factor criteria for the evaluation and development of the long-term strategy.

Based on the EPA's review, we find that Colorado's 2022 SIP submission satisfies the requirements of 40 CFR 51.308(f)(2)(i) insofar as Colorado's selection of nineteen sources, evaluation of the cost of compliance, time necessary for compliance, remaining useful life of any potentially affected sources statutory factors, and determinations of the emission reductions necessary to make reasonable progress contained in table 4 of section IV.C.1.a of this document, were reasonable. However, we find that Colorado's long-term strategy does not adequately consider the ''energy and nonair quality environmental impacts of compliance'' statutory factor as it pertains to the enforceable source closures contained in table 3 of section IV.C.1.a. of this document.

With respect to source selection, Colorado followed and provided a detailed description of the WRAP Reasonable Progress Screening protocol the State used to determine sources subject to four-factor analysis.[39] Applying this protocol, Colorado selected nineteen sources for analysis. As previously stated, 40 CFR 51.308(f)(2)(i) requires that a state's SIP submission include a ''description of the criteria it used to determine which sources or groups of sources it evaluated,'' and it must be appropriately documented, as required by 40 CFR 51.308(f)(2)(iii). In addition, states may rely on technical information developed by the RPOs of which they are members to select sources for four-factor analysis and to conduct that analysis, as well as to satisfy the documentation requirements under 40 CFR 51.308(f). Where an RPO has performed source selection and/or four-factor analyses (or considered the five additional factors in 40 CFR 51.308(f)(2)(iv)) for its member states, those states may rely on the RPO's analyses for the purpose of satisfying the requirements of 40 CFR 51.308(f)(2)(i) so long as the states have a reasonable basis to do so and all state participants in the RPO process have approved the technical analyses.[40] Because Colorado provided a detailed description of how the State used technical information to select a reasonable set of sources for an analysis of control measures for the second implementation period and reasonably relied on the selection of sources from the WRAP analysis, we find that Colorado's source selection was reasonable and consistent with the requirements of 40 CFR 51.308(f)(2).

Colorado submitted four-factor analyses for the selected sources and demonstrated that its determination of controls necessary for reasonable progress, and ultimately for inclusion in its long-term strategy, were an outgrowth of its consideration of the four statutory factors in accordance with 40 CFR 51.308(f)(2)(i). Ultimately, Colorado's 2022 SIP submission included both emission limits at fourteen facilities (covering over seventy emission units) and enforceable closures for already announced retirements at an additional eight facilities across 13 units in its long-term strategy under the regional haze program.

These measures are codified in Colorado Regulation Number 23, Part A, IV. *Regional Haze Determinations.* The State also included compliance schedules and other measures (*i.e.,* recordkeeping and reporting) codified in Colorado Regulation Number 23, Part A, V. *Monitoring, Recordkeeping, and Reporting for Regional Haze Limits.*

The EPA reviewed the State's long-term strategy to address regional haze visibility impairment for each Class I area affected by emissions from the State and concluded that the long-term strategy contains the enforceable emission limitations, compliance schedules, and other measures that are necessary to make reasonable progress. The State included in its implementation plan a description of the criteria it used to determine which sources it evaluated and how the four factors were taken into consideration in selecting the measures for inclusion in its long-term strategy as well as adoption of the emission limitations and compliance schedules codified in Colorado Regulation Number 23, Part A, IV. *Regional Haze Determinations* and Colorado Regulation Number 23, Part A, V. *Monitoring, Recordkeeping, and Reporting for Regional Haze Limits.* Because the State evaluated and determined the emission reduction measures contained in table 4 of section IV.C.1.a of this document that are necessary to make reasonable progress by considering the costs of compliance, the time necessary for compliance, the energy and non-air quality environmental impacts of compliance and the remaining useful life of the sources selected in accordance with 40 CFR 51.308(f)(2)(i), we find that Colorado's determination of the emission reduction measures contained in table 4 of section IV.C.1.a of this document that are necessary to make reasonable progress was reasonable and consistent with the requirements of 40 CFR 51.308(f)(2)(i).

However, the EPA proposes to partially disapprove Colorado's long-term strategy to the extent the SIP includes insufficiently justified enforceable source closures. As detailed in the paragraphs below, the EPA has substantial concerns that these enforceable source closures are inconsistent with applicable regulations and CAA sections 110 and 169A, including because the State has not provided necessary assurances that the enforceable closures would not violate State and Federal law as required by CAA section 110(a)(2)(E)(i).

First, we find that Colorado's long-term strategy did not adequately consider the energy impacts associated with the source closures contained in table 3 of section IV.C.1.a. of this document and therefore does not fully satisfy the requirements of CAA section 169A(g)(1) and 40 CFR 51.308(f)(2)(i). More specifically, we find Colorado did not sufficiently assess the closures'

[38] We refer to the CAA section 169A(g)(1) requirements as the four factors.

[39] Colorado 2022 SIP Submission at 51–52.

[40] 40 CFR 51.308(f)(2)(iii).

impacts on maintaining grid reliability and utilities' ability to meet energy demand. This finding is supported by documentation from an electrical utility regarding risk to energy availability and grid reliability due to source closures incorporated into Colorado's long-term strategy.

Colorado's 2022 SIP submission partially addressed the ''energy and nonair quality environmental impacts of compliance'' statutory factor by describing the increasing need to fluctuate the utilization of traditional, coal-fired power plants, which have historically provided baseload electric generating capacity, to balance the inherent variability of available capacity generated from renewable resources. Thus, as more baseload coal-fired power plant units retire, more renewable generation will be added to the grid, thereby increasing the demands on remaining baseload resources to respond to variations in electrical load and maintain a balanced grid.[41] According to the State, ''[m]aintaining grid reliability and meeting demand during this transition is critical to allow for flexibility.'' [42] However, the State did not adequately evaluate and address grid reliability and electrical demand associated with the closures of the coal-fired power plants. Although the State did recognize that accommodating concerns about grid reliability and electrical demand was ''key to the closure date announcements'' [43] of the coal-fired power plants, particularly related to the need for further tightening of existing interim emission limits on retiring units, the State's evaluation of the energy and nonair quality environmental impacts of compliance factor did not include how grid reliability and electrical demand was evaluated related to the closure of these units. Nor did the evaluation discuss what safeguards, if any, the State considered to ensure concerns about grid reliability and electrical demand would be addressed.

During the EPA's review of Colorado's assessment of its long-term strategy's energy impacts, the EPA learned some of those closures were more likely to impair grid reliability than had been previously evaluated. For example, Colorado Springs Utilities submitted information to the EPA on April 2, 2025, regarding the enforceable closure of Nixon Unit 1 in Colorado's 2022 SIP submission.[44] Colorado Springs Utilities asked the EPA to exclude the SIP's proposed closure of Nixon Unit 1 by December 29, 2029, from the EPA's final action on Colorado's 2022 SIP submission. In addition, Colorado Springs Utilities met with the State of Colorado on April 23, 2025, and asked the State to remove the December 29, 2029 closure of Nixon Unit 1 from its submission amid concerns regarding grid reliability.[45] According to Colorado Springs Utilities, the continued operation of Nixon Unit 1 is ''critically important'' for Colorado Springs Utilities to meet projected electricity demand and thereby ensure the reliability of the electric grid. Furthermore, Colorado Springs Utilities explained that ''potentially dire'' electric grid reliability impacts would likely result from Nixon Unit 1's retirement. The risks to grid reliability, according to Colorado Springs Utilities, are being driven by increasingly unfavorable market conditions for renewable energy development, the lack of immediately viable electricity transmission developments in Colorado, and increasing load demands for new electricity. Together, these factors compound Colorado Springs Utilities' inability to bring sufficient resources online prior to the Nixon Unit's planned retirement date of December 29, 2029, ultimately resulting in projected capacity deficits of 173 MW in 2030 and 257 MW in 2034, according to the utility.

In addition to accounting for this new information, we reviewed Colorado's assessment of these measures' energy impacts in light of the rise in electricity demand due to the resurgence of domestic manufacturing and the construction of artificial intelligence data processing centers. As noted in Executive Order 14241, this Administration has found as a matter of national interest, national security, and energy policy that power generated from coal resources is critical to addressing this surging demand.[46] In this instance, the EPA finds that Colorado did not adequately account for the energy impacts of including these source closures in its long-term strategy for regional haze as required by the CAA.

Second, even with all source closures removed from the SIP, Colorado is unlikely to contribute to visibility impairment at any Class I areas projected to be above the adjusted 2028 URP.[47] Because Colorado lacked material information about grid reliability, later provided to the EPA by Colorado Springs Utilities, we propose to find the State did not appropriately weigh the energy impacts of the closure measures against its substantial progress toward natural visibility conditions in a manner consistent with issued executive orders' priority on energy generation.

We also propose to find that Colorado has not provided the assurances required by CAA section 110 that implementing the SIP's forced closure provisions is not prohibited by state or federal law. CAA section 110(a)(2)(E)(i) provides that state plans must provide ''necessary assurances'' that the State ''is not prohibited by any provision of Federal or State law from carrying out such implementation plan or portion thereof.'' The best reading of this provision is that the EPA may not approve a SIP that risks violating Federal or State law in the course of implementation. This reading is consistent with the EPA's independent obligation to follow Federal constitutional and statutory law and with the structure of CAA section 110 as a whole, which sets out detailed requirements for state plans and for the EPA's review of such plans. The EPA proposes to find there is a risk that enforceable source closure provisions, without just compensation, would violate the Federal Takings Clause and possibly comparable provisions of State law, and that Colorado has not provided the necessary assurances that such violations would not occur.[48]

Although the application of the Takings Clause is necessarily fact-specific, an unconsented source closure could constitute either a per se or regulatory taking. The EPA notes that there is a lack of controlling precedent on application of the Takings Clause to forced source closures under CAA

[41] Colorado 2022 SIP submission at 68.

[42] Colorado 2022 SIP submission at 68, 71, 73, 80, 84, 85, 86, 88, 90, 95, 96, 97, 99.

[43] Colorado Regulation Number 23, Part B at 32.

[44] Colorado Springs Utilities meeting with EPA_ April 2, 2025.

[45] Overview of Colorado Springs Utilities meeting with CDPHE_April 23, 2025.

[46] Executive Order 14241, ''Reinvigorating America's Beautiful Clean Coal Industry and Amending Executive Order 14241,'' The White House (April 8, 2025), *https://www.whitehouse.gov/presidential-actions/2025/04/reinvigorating-americas-beautiful-clean-coal-industry-and-amending-executive-order-14241/*.

[47] As the EPA has announced in recent SIP rulemakings, the Agency is proposing to adopt a policy whereby states that are not contributing to visibility impairment at Class I areas projected to be above the Uniform Rate of Progress are presumed to be making reasonable progress toward natural visibility conditions provided they have considered the four statutory factors. *See* Air Plan Approval, West Virginia; Regional Haze Plan for the Second Implementation Period, 90 FR 16478 (April 18, 2025); Air Plan Approval; South Dakota; Regional Haze Plan for the Second Implementation Period, 90 FR 20425 (May 14, 2025).

[48] U.S. Const. amends. V, XIV; *see also* Colo. Const. art. II, § 15.

section 110 because states typically do not seek to implement their SIPs in a manner that forces closure on a nonconsenting source.[49] U.S. Supreme Court precedent suggests, however, that the EPA's approval of this course of action could amount to a per se taking. In *Cedar Point Nursery* v. *Hassid,* 594 U.S. 139 (2021), the U.S. Supreme Court explained that government action that appropriates property ''is no less a physical taking because it arises from a regulation.'' Particularly relevant here, the Court applied the per se bar on uncompensated takings in *Horne* v. *Department of Agriculture,* 576 U.S. 351 (2015), to a complex regulatory regime that required regulated parties to set aside a portion of their output to achieve governmental aims. The EPA proposes to conclude that Colorado has not provided the necessary assurances required by CAA section 110(a)(2)(E)(i) that the submitted closure provisions would not result in uncompensated per se takings in violation of Federal law.

Relatedly, a total regulatory taking could occur if the closure would fully deprive the source owner of all economic use of the land under the standard described in *Lucas* v. *S.C. Coastal Council,* 505 U.S. 1003, 1116 (1992). A partial regulatory taking could occur if the closure inflicted a significant economic impact upon the source owner, undermined distinct, investment-backed expectations, and shared characteristics with actions conventionally regarded as government takings. These factors and how courts should balance them are detailed in *Penn Central Transp. Co.* v. *New York City,* 438 U.S. 104, 123 (1978), and subsequent cases. The EPA proposes to find that Colorado has not provided the necessary assurances required by CAA section 110(a)(2)(E)(i) that Federal law would not prohibit the State from implementing the submitted closure provisions, including whether such unconsented source closures would amount to a taking without just compensation.

Finally, the EPA also proposes to conclude that the forced source closure contained in this portion of the State's submission is inconsistent with the structure of CAA sections 110 and 169A, which do not contemplate forced closures as a means to achieve compliance. In this context, we are referring to a source closure opposed by the source in question that would be made federally enforceable as a result of a SIP approval. The EPA is referring to such a closure as ''unconsented'' or ''forced.''

CAA section 110(a)(1)(A) provides that, as a general matter, a SIP must ''include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights)'' as ''may be necessary or appropriate to meet the applicable requirements of this chapter.'' The EPA is proposing that the ordinary meaning of ''emission limitations'' does not include forced closures that prohibit all operations against the will of the owner/operator, or in a timeframe unconsented to by the owner/operator. Similarly, we are proposing that the best reading of the phrase ''other control measures, means, or techniques'' does not encompass the authority to force a source to close, or to close on timeframe not agreed to by the owner/operator. This proposal is supported by reading the terms ''measures'' and ''means'' in context and informed by the surrounding statutory terms, including the parenthetical phrase discussing market-based incentives that contemplate ongoing operations. ''Measures'' and ''means'' must also be ''necessary or appropriate'' to meet applicable CAA requirements. As noted above, the EPA is proposing that unconsented closures are neither ''necessary'' under the circumstances here nor otherwise required by the CAA, and that such closures are not ''appropriate'' when they could amount to an uncompensated taking in violation of Federal and State law. The EPA seeks comment on this interpretation.

CAA section 169A similarly does not contemplate use of unconsented closures as part of the regional haze program. The statute provides that state plans must contain ''emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress,'' including through the use of ''retrofit technology'' and long-term strategies. Consistent with the interpretation of CAA section 110 proposed above, the EPA proposes that the best reading of the statute does not require or authorize the use of forced source closures to attain the statutory goals listed in CAA section 169A. The EPA seeks comment on this interpretation as well.

The EPA notes that at least one of the sources slated for closure in the SIP—Nixon Unit 1—has expressly stated that it does not consent to closing by the enforceable deadline. Additionally, we note that the North American Electric Reliability Corporation (NERC) stated in their 2024 Long-Term Reliability Assessment that ''most of the North American bulk power system faces mounting resource adequacy challenges over the next 10 years as surging demand growth continues and thermal generators announce plans for retirement.'' Ultimately, according to NERC, ''[t]he trends point to critical reliability challenges facing the industry: satisfying escalating energy growth, managing generator retirements, and accelerating resource and transmission development.'' [50] Industry assessments relied on by Colorado utilities indicate that increasing energy demand in the region may cause additional sources to reverse course on previously agreed-to closure provisions, and Colorado has not sufficiently addressed the legal implications of forcing these plants to close under the SIP provisions submitted by the State.

In summary, we are proposing to partially disapprove Colorado's long-term strategy under CAA section 169A and 40 CFR 51.308(f)(2)(i) because Colorado's 2022 SIP submission does not adequately consider the energy impacts associated with the state's enforceable source closures of coal and gas-fired power plants and associated units to energy availability and grid reliability and contains provisions that are inconsistent with the CAA and its implementing regulations. Our proposed disapproval would encompass, and therefore decline to incorporate, the enforceable source closures contained in Colorado's 2022 SIP submission (listed in table 3 of section IV.C.1.a. of this document) and in Colorado's Regulation Number 23.[51] If we receive information during the comment period that a source is permanently decommissioned (*i.e.,* rendered fully inoperable and its operating permit has been revoked), we could reevaluate our proposed disapproval of these units.

Despite our proposed partial disapproval of the State's long-term strategy as it pertains to source closures, we find that the regional haze requirements are satisfied by the portion of Colorado's 2022 SIP submission that we are approving. Therefore, because no outstanding obligations remain, there

[49] The EPA is not aware of *any* prior state submission under CAA section 110 that sought to force closure of a currently operating source without that source's consent. We seek comment on whether any such examples exist and request that commenters identify such an example with enough specificity to allow us to evaluate the circumstances in which such a forced closure was attempted through a CAA section 110 submission.

[50] North American Electric Reliability Corporation, *2024 Long-Term Reliability Assessment.* December 2024 at 6.

[51] IV.F.1.; IV.F.3. pertaining to the cessation of coal handling at Nixon, Coal Handling, Hayden Units 1 and 2, and Pawnee Unit 1; IV.F.5.; and I.V.F.6.

will be no additional regulatory action needed, either in the form of a federal implementation plan or another SIP revision, as a result of the partial disapproval.

2. Other Long-Term Strategy Requirements

States must meet the additional requirements specified in 40 CFR 51.308(f)(2)(ii)–(iv) when developing their long-term strategies. 40 CFR 51.308(f)(2)(ii) requires states to consult with other states that have emissions that are reasonably anticipated to contribute to visibility impairment in Class I areas to develop coordinated emission management strategies. Chapter 2.3 of Colorado's 2022 SIP submission describe the State's consultation with other states throughout the development of its regional haze plan.

40 CFR 51.308(f)(2)(iii) requires states to document the technical basis, including modeling, monitoring, costs, engineering, and emissions information, on which the state is relying to determine the emission reduction measures that are necessary to make reasonable progress in each mandatory Class I area it impacts. The State relied on WRAP technical information, modeling, and analysis to support development of its long-term strategy.[52]

40 CFR 51.308(f)(2)(iv) specifies five additional factors states must consider in developing their long-term strategies. The five additional factors are: emission reductions due to ongoing air pollution control programs, including measures to address reasonably attributable visibility impairment; measures to mitigate the impacts of construction activities; source retirement and replacement schedules; basic smoke management practices for prescribed fire used for agricultural and wildland vegetation management purposes and smoke management programs; and the anticipated net effect on visibility due to projected changes in point, area, and mobile source emissions over the period addressed by the long-term strategy.

Chapter 8.4 of Colorado's 2022 SIP submission describes each of the five additional factors it is required to consider under 40 CFR 51.308(f)(2)(iv) and explains how it considered them.[53] Pursuant to 40 CFR 51.308(f)(2)(iv)(A), Colorado detailed the existing and ongoing State and Federal emission control programs that contribute to emission reductions, including the designation status for all current and former non-attainment areas.[54] Many of these same measures, particularly the provisions found in Colorado's Regulation Number 1 and Regulation Number 3, also mitigate the impacts of construction activities as required by 40 CFR 51.308(f)(2)(iv)(B).[55] Pursuant to 40 CFR 51.308(f)(2)(iv)(C), the State considered source retirements schedules in the Colorado 2022 SIP submission[56] as well as in Colorado Regulation Number 23. In considering smoke management as required in 40 CFR 51.308(f)(2)(iv)(D), Colorado explained that it addresses smoke management through its smoke management program[57] as well as Colorado Regulation Number 9 which addresses open burning, prescribed fire, and permitting.[58] Colorado considered the anticipated net effect of projected changes in emissions on visibility as required by 40 CFR 51.308(f)(2)(iv)(E) by discussing the analytical results from the air quality monitoring, emission inventories, and air quality modeling for the second implementation period that it conducted in collaboration with the WRAP.[59]

After reviewing Colorado's 2022 SIP submission chapters addressing 40 CFR 51.308(f)(2)(ii)–(iv), the EPA finds that Colorado has satisfied these additional long-term strategy requirements of 40 CFR 51.308(f)(2)(ii)–(iv).

D. Reasonable Progress Goals

Section 51.308(f)(3)(i) requires a state in which a Class I area is located to establish RPGs—one each for the most impaired and clearest days—reflecting the visibility conditions that will be achieved at the end of the implementation period as a result of the emission limitations, compliance schedules and other measures required under paragraph (f)(2) in states' long-term strategies, as well as implementation of other CAA requirements.

After establishing its long-term strategy, Colorado developed reasonable progress goals for each Class I area for the 20% most impaired days and 20% clearest days based on the results of 2028 WRAP modeling (table 5).[60]

TABLE 5—REASONABLE PROGRESS GOALS FOR THE 20% MOST IMPAIRED DAYS AND 20% CLEAREST DAYS FOR COLORADO CLASS I AREAS

Class I area	20% Most impaired days			20% Clearest days	
	Average baseline conditions (2000–2004)	2028 Unadjusted [1] uniform progress goal	2028 Reasonable progress goal [2]	Average baseline conditions (2000–2004)	2028 Reasonable progress goal
	Deciviews				
Great Sand Dunes	9.66	7.58	7.50	4.5	2.44
Mesa Verde	9.22	7.21	6.10	4.32	2.01
Mount Zirkel, Rawah	7.29	5.64	4.93	1.61	0.02
Rocky Mountain National Park	11.12	8.65	7.56	2.29	1.17
Weminuche, La Garita, Black Canyon of Gunnison	7.78	6.26	6.03	3.11	1.39
Eagles Nest, Flat Tops, Maroon Bells, White River, West Elk	6.30	4.99	4.49	0.70	−0.35

[1] Colorado did not rely on the adjusted URP for either international emissions or international emissions plus wildland prescribed fire.
[2] Based on WRAP 2028OTBa2.

[52] Colorado 2002 SIP submission at 8, 51–52, 150–157.

[53] Colorado 2022 SIP submission at 143–155.

[54] Colorado 2022 SIP submission at 143–147.

[55] Colorado 2022 SIP submission at 148.

[56] Colorado 2022 SIP submission at 59–67; Regulation Number 23, Part A, IV.F.

[57] Consistent with the EPA's *Interim Air Quality Policy on Wildland Prescribed Fire, May 1998.*

[58] Colorado 2022 SIP submission at 148–150.

[59] Colorado 2022 SIP submission at 150–155.

[60] Colorado 2022 SIP submission at 156.

The reasonable progress goals are based on Colorado's long-term strategy, the long-term strategy of other states that may affect Class I areas in Colorado, and other CAA requirements. Per 40 CFR 51.308(f)(3)(iv), the EPA must evaluate the demonstrations the State developed pursuant to 40 CFR 51.308(f)(2) to determine whether the State's reasonable progress goals for visibility improvement provide for reasonable progress towards natural visibility conditions.

As previously explained in section IV.C.1.b., we are proposing to partially disapprove Colorado's long-term strategy relating to 40 CFR 51.308(f)(2)(i) and the associated source closures. The RPGs in table 5 are based on modeling of the measures included in the long-term strategy, namely the closures of Comanche Units 1 and 2, Craig Unit 1, and Nucla.[61] The closures of Craig Unit 1 and Nucla have already occurred and were previously incorporated into Colorado's federally enforceable SIP.[62] The closures of Comanche Units 1 and 2 are part of Colorado's 2022 SIP submission and are not proposed to be incorporated into this rulemaking. While the RPGs in Colorado's 2022 SIP submission are all below the unadjusted 2028 URP, and Colorado is not known to contribute to any Class I areas that are above the 2028 URP, our proposed action does not include the incorporation of the closures of Comanche Units 1 and 2 into the federally enforceable SIP and therefore may impact whether all Class I areas remain below the URP. The Class I area closest to the URP is Great Sand Dunes where the unadjusted 2028 URP is 7.58 and the 2028 RPG, based on Colorado's long-term strategy which includes the four aforementioned source closures, is 7.50. However, when we evaluate Colorado's 2028 RPG against the *adjusted* glidepaths, either adjusted for international emissions (2028 URP is 8.30) or adjusted for international emissions plus wildland prescribed fire (2028 URP is 8.36), Colorado's 2028 RPG without the closures of Comanche Units 1 and 2 would very likely remain below either adjusted glidepath.[63] If, on the other hand, Colorado's 2028 RPG provides for a slower rate of improvement in visibility due to the absence of the enforceable closures of Comanche Units 1 and 2 in Colorado's federally enforceable SIP, the EPA finds that in accordance with 40 CFR 51.308(f)(3)(ii)(A), Colorado: (1) demonstrated that there are no additional emission reduction measures that would be reasonable to include in its long-term strategy, and (2) provided a robust demonstration, including documenting the criteria used to determine which sources or groups of sources were evaluated and how the four-factors were taken into consideration in selecting the measures for inclusion in its long-term strategy. Specifically, Colorado selected nineteen sources to evaluate, resulting in over seventy emission control measures in the State's long-term strategy. Given the comprehensive set of sources selected and evaluated, the consideration of the four statutory factors for those sources, and the large number of emission control measures included in the SIP, the EPA agrees that there are no additional emissions reduction measures that would be necessary to include in the long-term strategy. Therefore, no additional requirements apply under 40 CFR 51.308(f)(3)(ii). Based on having satisfied the RPG rule requirements, we propose to approve Colorado's reasonable progress goals under 40 CFR 51.308(f)(3).

E. Reasonably Attributable Visibility Impairment (RAVI)

The RHR contains a requirement at 40 CFR 51.308(f)(4) related to any additional monitoring that may be needed to address visibility impairment in Class I areas from a single source or a small group of sources. This is called ''reasonably attributable visibility impairment,''[64] also known as RAVI. Under this provision, if the EPA or the FLM of an affected Class I area has advised a state that additional monitoring is needed to assess RAVI, the state must include in its SIP revision for the second implementation period an appropriate strategy for evaluating such impairment. The EPA has not advised the State to that effect; nor did the State indicate that FLMs for Great Sand Dunes National Park, Mesa Verda National Park, Mount Zirkel Wilderness, Rawah Wilderness, Rocky Mountain National Park, Weminuche Wilderness, Black Canyon of Gunnison NP, La Garita Wilderness, Eagles Nest Wilderness, Flat Tops Wilderness, Maroon Bells-Snowmass Wilderness, and West Elk Wilderness identified any RAVI from Colorado sources. For this reason, the EPA proposes to approve the portions of Colorado's 2022 SIP submission relating to 40 CFR 51.308(f)(4).

F. Monitoring Strategy and Other State Implementation Plan Requirements

Section 51.308(f)(6) specifies that each comprehensive revision of a state's regional haze SIP must contain or provide for certain elements, including monitoring strategies, emissions inventories, and any reporting, recordkeeping and other measures needed to assess and report on visibility. A main requirement of this section is for states with Class I areas to submit monitoring strategies for measuring, characterizing, and reporting on visibility impairment. Compliance with this requirement may be met through participation in the IMPROVE network.

Under 40 CFR 51.308(f)(6)(i), states must provide for the establishment of additional monitoring sites or equipment needed to assess whether reasonable progress goals to address regional haze for all mandatory Class I Federal areas within the state are being achieved. For states with Class I areas (including Colorado), 40 CFR 51.308(f)(6)(ii) requires SIPs to provide for procedures by which monitoring data and other information are used in determining the contribution of emissions from within the state to regional haze visibility impairment at mandatory Class I Federal areas both within and outside the state. Section 51.308(f)(6)(iv) requires the SIP to provide for the reporting of all visibility monitoring data to the Administrator at least annually for each Class I area in the state. 40 CFR 51.308(f)(6)(v) requires SIPs to provide for a statewide inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment, including emissions for the most recent year for which data are available. Section 51.308(f)(6)(v) also requires states to include estimates of future projected emissions. Finally, 40 CFR 51.308(f)(6)(vi) requires the SIP to provide for any other elements, including reporting, recordkeeping, and other measures, that are necessary for states to assess and report on visibility.

Colorado describes its participation in the IMPROVE network, which comprises 110 monitoring sites across the nation, six of which are in Colorado. The State relied on the IMPROVE monitoring network to assess visibility at Class I areas across Colorado[65] and considered the six monitoring sites GRSA1, MEVE1, MOZI1, ROMO1, WEMI1 and WHRI1 to be adequate for

[61] Colorado 2022 SIP submission at 150.

[62] 83 FR 31332 (July 5, 2018).

[63] WRAP, Visibility Progress and Projections. ''Adjustments to Uniform Rate of Progress Glidepath—Most Impaired Days. Great Sand Dunes.'' *https://views.cira.colostate.edu/tssv2/Express/ModelingTools.aspx.*

[64] The EPA's visibility protection regulations define ''reasonably attributable visibility impairment'' as ''visibility impairment that is caused by the emission of air pollutants from one, or a small number of sources.'' 40 CFR 51.301.

[65] Colorado 2022 SIP submission at 12–17.

assessing reasonable progress goals at the State's twelve Class I areas.[66] Using the monitoring data procedures described in its 2022 SIP submission along with other technical information supplied by WRAP,[67] [68] the State determined the contribution of in-State emissions to Class I areas inside and outside Colorado.[69] In addition, the State also provided a statewide inventory of emissions that are reasonably anticipated to cause or contribute to visibility impairment in Class I areas; the State relied primarily on 2014–2018 data but also estimated future projected emissions.[70]

The EPA finds that Colorado has met the requirements of 40 CFR 51.308(f)(6), including through its continued participation in the IMPROVE network and WRAP RPO and its ongoing compliance with the Air Emissions Reporting Requirements (AERR). There is no indication that further SIP elements are necessary at this time for Colorado to assess and report on visibility. Therefore, the EPA proposes to approve the monitoring strategy and other state implementation plan elements of Colorado's 2022 SIP submission as meeting the requirements of 40 CFR 51.308(f)(6).

G. Requirements for Periodic Reports Describing Progress Towards the Reasonable Progress Goals

40 CFR 51.308(f)(5) requires that periodic comprehensive revisions of states' regional haze plans also address the progress report requirements of 40 CFR 51.308(g)(1) through (5). The purpose of these requirements is to evaluate progress towards the applicable RPGs for each Class I area within the state and each Class I area outside the state that may be affected by emissions from within that state. Sections 51.308(g)(1) and (2) apply to all states and require a description of the status of implementation of all measures included in a state's first implementation period regional haze plan and a summary of the emission reductions achieved through implementation of those measures. Section 51.308(g)(3) applies only to states with Class I areas within their borders and requires such states to assess current visibility conditions, changes in visibility relative to baseline (2000–2004) visibility conditions, and changes in visibility conditions relative to the period addressed in the first implementation period progress report. Section 51.308(g)(4) applies to all states and requires an analysis tracking changes in emissions of pollutants contributing to visibility impairment from all sources and sectors since the period addressed by the first implementation period progress report. This provision further specifies the year or years through which the analysis must extend depending on the type of source and the platform through which its emission information is reported. Finally, 40 CFR 51.308(g)(5), which also applies to all states, requires an assessment of any significant changes in anthropogenic emissions within or outside the state that have occurred since the period addressed by the first implementation period progress report, including whether such changes were anticipated and whether they have limited or impeded expected progress towards reducing emissions and improving visibility.

In its 2022 SIP submission,[71] Colorado included the elements of the periodic progress report specified in 40 CFR 51.308(f)(5) and 40 CFR 51.308(g)(1)–(5). Colorado summarized the facility improvements made during and after the first implementation period, including emission control measures installed and emission reductions achieved by the facilities that most affected each Class I area, and summarized the associated emission reductions.[72] In addition, the State summarized the implementation status of ongoing air pollution control programs, measures to mitigate construction activities, source retirement and replacement schedules, and smoke management practices and programs.[73] The EPA finds that Colorado has met the requirements of 40 CFR 51.308(g)(1) and (2) because Colorado's 2022 SIP submission describes the measures included in the long-term strategy from the first implementation period, as well as the status of their implementation and the emission reductions achieved through such implementation.

Visibility conditions (in deciviews) are reported in Colorado's 2022 SIP submission for the most impaired and clearest days. Visibility conditions are expressed in terms of 5-year averages for the baseline period (2000–2004), 2010–2014 period, and current period (2015–2019), as well as the progress made since the baseline period ((2000–2004)–(2015–2019)) and during the last implementation period ((2010–2014)–(2015–2019)) for each Class I area.[74] The EPA therefore finds that Colorado has satisfied the requirements of 40 CFR 51.308(g)(3).

The State used the most current emissions inventory available–the 2017 NEI—to provide emissions inventories for NO_X, SO_2, VOC, ammonia (NH_3), and PM that identify the type of source, activity, and pollutant.[75] Colorado also provided an assessment and discussion of the significant changes in anthropogenic emissions since the first implementation period.[76] The EPA finds that the requirements of 40 CFR 51.308(g)(4) and (g)(5) are satisfied by providing emissions of pollutants contributing to visibility impairment within the State and assessing any significant changes in anthropogenic emissions within or outside the State that have occurred since the period addressed in the most recent plan.

Because Colorado's 2022 SIP submission addresses the requirements of 40 CFR 51.308(g)(1) through (5), the EPA finds that Colorado has met the progress report requirements of 40 CFR 51.308(f)(5). Therefore, we propose to approve Colorado's 2022 SIP submission as meeting the requirements of 40 CFR 51.308(f)(5) and 40 CFR 51.308(g) for periodic progress reports.

H. Requirements for State and Federal Land Manager Coordination

Section 169A(d) of the CAA requires states to consult with FLMs before holding the public hearing on a proposed regional haze SIP, and to include a summary of the FLMs' conclusions and recommendations in the notice to the public. In addition, the 40 CFR 51.308(i)(2) FLM consultation provision requires a state to provide FLMs with an opportunity for consultation that is early enough in the state's policy analyses of its emission reduction obligation so that information and recommendations provided by the FLMs can meaningfully inform the state's decisions on its long-term strategy. If the consultation has taken place at least 120 days before a public hearing or public comment period, the opportunity for consultation will be deemed early enough. Regardless, the opportunity for consultation must be

[66] *Id.* at 12–16.

[67] *Id.* at 13.

[68] Colorado relied on the WRAP Technical Support System (TSS) ''Analysis and Planning'' section to determine baseline, natural, and current conditions for Class I areas in Colorado. *https://views.cira.colostate.edu/tssv2/.*

[69] Colorado 2022 SIP submission at 13 and 143.

[70] *Id.* at 13, 17 and 29–38.

[71] Colorado's June 2023 supplement contained the elements of the periodic progress report.

[72] Colorado 2022 SIP submission, Regional Haze Progress Report at E–1–E–11.

[73] Colorado 2022 SIP submission, Regional Haze Progress Report at E–4–E–8.

[74] Colorado 2022 SIP submission, Regional Haze Progress Report at E–12–E–23.

[75] Colorado 2022 SIP submission, Regional Haze Progress Report at E–26–E–35.

[76] Colorado 2022 SIP submission, Regional Haze Progress Report at E–33–E–35.

provided at least sixty days before a public hearing or public comment period at the state level. Section 51.308(i)(2) also lists two substantive topics on which FLMs must be provided an opportunity to discuss with states: assessment of visibility impairment in any Class I area and recommendations on the development and implementation of strategies to address visibility impairment. Section 51.308(i)(3) requires states, in developing their implementation plans, to include a description of how they addressed FLMs' comments.

Colorado's 2022 SIP submission summarizes the State's consultation and coordination with the FLMs. Colorado consulted and coordinated with the FLMs during the development of its regional haze SIP through WRAP participation and direct FLM engagement. Colorado facilitated both in-person and virtual public stakeholder meetings in 2019 and 2020 to gather input early in the planning stages. The State also held multiple consultations directly with the FLMs in June 2019 to discuss Q/d thresholds and potential sources for analysis. Subsequent discussions occurred in August and October 2020, as well as in April, May, and June 2021 to refine analyses and address concerns raised by FLMs concerning additional control measures. These discussions occurred prior to the State's public hearing on the draft regional haze plan in November 2020. The State also held a public information meeting in August 2021 to provide information on its draft regional haze SIP prior to holding a public hearing in November 2021.[77] The State further shared the regional haze plan's technical support documents with the FLMs.

Colorado took administrative steps to provide the FLMs the opportunity to review and provide feedback on the State's draft regional haze plan. Therefore, the EPA proposes to approve the FLM consultation component of Colorado's SIP submission which meets the requirements of 40 CFR 51.308(i), as outlined in this section.

V. Proposed Action

The EPA is proposing partial approval and partial disapproval of Colorado's 2022 SIP submission addressing the requirements of the second implementation period of the RHR. Specifically, the EPA is proposing approval for the portions of Colorado's 2022 SIP submission relating to 40 CFR 51.308(f)(1): calculations of baseline, current, and natural visibility conditions, progress to date, and the uniform rate of progress; 40 CFR 51.308(f)(2)(ii)–(iv): long-term strategy; 40 CFR 51.308(f)(3): reasonable progress goals; 40 CFR 51.308(f)(4): reasonably attributable visibility impairment; 40 CFR 51.308(f)(5) and 40 CFR 51.308(g): progress report requirements; 40 CFR 51.308(f)(6): monitoring strategy and other implementation plan requirements; and 40 CFR 51.308(i): FLM consultation. The EPA is proposing disapproval of portions of Colorado's 2022 SIP submission relating to 40 CFR 51.308(f)(2)(i) and its corresponding regulatory provisions (Colorado Regulation Number 23 section IV.F.1.; IV.F.3. pertaining to the cessation of coal handling at Nixon, Coal Handling, Hayden Units 1 and 2, and Pawnee Unit 1; IV.F.5.; and IV.F.6.). Despite our proposed disapproval of the State's long-term strategy as it pertains to source closures, we find that the regional haze requirements are satisfied by the portion of Colorado's 2022 SIP submission that we are approving. Because no outstanding obligations remain, there will be no additional regulatory action needed, either in the form of a federal implementation plan or another SIP revision, as a result of the partial disapproval. Concurrently, the EPA is proposing to approve a revision to Colorado's SIP that moves the regional haze provisions in Regulation Number 3 to the newly adopted Regulation Number 23. Together, these SIP revisions establish updated emission reduction requirements for NO_X, SO_2, and PM emissions from certain reasonable progress sources identified as impacting Class I areas under the RHR for the second ten-year planning period.

VI. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, and as discussed in sections I. through V. of this preamble and set forth below in the proposed amendments to part 52, the EPA is proposing: to remove 5 CCR 1001–05, Regulation Number 3, Part F, Regional Haze Limits—Best Available Retrofit Technology (BART) and Reasonable Progress (RP) and the associated entries for VI. Regional Haze Determinations and VII. Monitoring, Recordkeeping, and Reporting for Regional Haze Limits, from the Colorado SIP; and to incorporate by reference 5 CCR 1001–27, Regulation Number 23, Part A, Regional Haze Limits—Best Available Retrofit Technology (BART) and Reasonable Progress (RP) and the associated entries for IV. Regional Haze Determinations and V. Monitoring, Recordkeeping, and Reporting for Regional Haze Limits. The EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

This action proposes to partially approve and partially disapprove state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as

[77] Colorado 2022 SIP submission at 8–11.

specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

(Authority: 42 U.S.C. 7401 *et seq.*)

Dated: _July 9, 2025.

Cyrus M. Western,

Regional Administrator, Region 8.

For the reasons stated in the preamble, the Environmental Protection Agency is proposing to amend 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—Colorado

■ 2. Amend § 52.320 by:

■ a. In the table in paragraph (c):

■ i. Removing the center heading ''5 CCR 1001–05, Regulation Number 3, Part F, Regional Haze Limits—Best Available Retrofit Technology (BART) and Reasonable Progress (RP)'' and the entries ''VI. Regional Haze Determinations'' and ''VII. Monitoring, Recordkeeping, and Reporting for Regional Haze Limits''; and

■ ii. Adding the center heading ''5 CCR 1001–27, Regulation Number 23, Part A, Regional Haze Limits—Best Available Retrofit Technology (BART) and Reasonable Progress (RP)'' and the entries ''IV. Regional Haze Determinations'' and ''V. Monitoring, Recordkeeping, and Reporting for Regional Haze Limits'' at the end of the table.

■ b. In the table in paragraph (e):

■ i. Adding the entry ''Colorado Visibility and Regional Haze State Implementation Plan for the Twelve Mandatory Class I Federal Areas in Colorado, Revised Regional Haze State Implementation Plan for the Second Implementation Period'' at the end of the table.

The additions read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

Title	State effective date	EPA effective date	Final rule citation/date	Comments
*	*	*	*	* * *
5 CCR 1001–27, Regulation Number 23, Part A, Regional Haze Limits—Best Available Retrofit Technology (BART) and Reasonable Progress (RP)				
IV. Regional Haze Determinations.	2/14/2021	[date 30 days after date of publication of the final rule in the **Federal Register**].	90 FR [**Federal Register** page where the document begins of the final rule], [date of publication of the final rule in the **Federal Register**].	Except for IV.F.1.; IV.F.3. pertaining to the cessation of coal handling at Nixon, Coal Handling, Hayden Units 1 and 2, and Pawnee Unit 1; IV.F.5.; and I.V.F.6.
V. Monitoring, Recordkeeping, and Reporting for Regional Haze Limits.	2/14/2021	[date 30 days after date of publication of the final rule in the **Federal Register**].	90 FR [**Federal Register** page where the document begins of the final rule], [date of publication of the final rule in the **Federal Register**].	

* * * * *

(e) * * *

Title	State effective date	EPA effective date	Final rule citation/date	Comments
*	*	*	*	* * *
Visibility				
*	*	*	*	* * *
Colorado Visibility and Regional Haze State Implementation Plan for the Twelve Mandatory Class I Federal Areas in Colorado, Revised Regional Haze State Implementation Plan for the Second Implementation Period.	1/30/22	[date 30 days after date of publication of the final rule in the **Federal Register**].	90 FR [**Federal Register** page where the document begins of the final rule], [date of publication of the final rule in the **Federal Register**].	Excluding the sections disapproved in this action. EPA disapproved the portions of Colorado's 2022 SIP submission relating to CAA section 169A and 40 CFR 51.308(f)(2)(i): long-term strategy corresponding to source closures.

[FR Doc. 2025–13342 Filed 7–15–25; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, and 9

[PS Docket Nos. 21–479 and 13–75; DA 25–580; FR ID 302998]

Facilitating Implementation of Next Generation 911 Services (NG911); Improving 911 Reliability

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; Extension of comment and reply comment periods.

SUMMARY: In this document, the Federal Communications Commission (Commission) extends the comment and reply comment periods of the Further Notice of Proposed Rulemaking (FNPRM) in PS Docket Nos. 21–479 and 13–75, FCC 25–21, that was released on March 28, 2025 and published in the **Federal Register** on June 4, 2025.

DATES: The deadline for filing comments is extended to August 4, 2025, and the deadline for filing reply comments is extended to September 17, 2025.

ADDRESSES: You may submit comments and reply comments, identified by PS Docket Nos. 21–479 and 13–75, by any of the following methods:

- *Electronic Filers:* Parties may file electronically using the internet by accessing the Commission's Electronic Comment Filing System (ECFS): *https://www.fcc.gov/ecfs.* See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998), *https://www.govinfo.gov/content/pkg/FR-1998-05-01/pdf/98-10310.pdf.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Paper filings can be sent by hand or messenger delivery, by commercial courier, or by the U.S. Postal Service. All filings must be addressed to the Secretary, Federal Communications Commission.
- Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8:00 a.m. and 4:00 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701. Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express must be sent to 45 L Street NE, Washington, DC 20554.
- *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

FOR FURTHER INFORMATION CONTACT: Rachel Wehr, Deputy Division Chief, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–1138 or *Rachel.Wehr@fcc.gov,* or Chris Fedeli, Attorney Advisor, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–1514 or *Christopher.Fedeli@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Public Safety and Homeland Security Bureau's (Bureau) Order in PS Docket Nos. 21–479 and 13–75; DA 25–580, adopted and released on July 8, 2025. The full text of the Order is available at *https://docs.fcc.gov/public/attachments/DA-25-580A1.pdf.*

Initial Paperwork Reduction Act of 1995 Analysis: This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

Synopsis

In the Order, the Bureau grants in part a Motion for Extension of Time (Motion) filed jointly on June 17, 2025 by the National Association of State 9–1–1 Administrators (NASNA), the National Emergency Number Association: The 9–1–1 Association (NENA), and the Industry Council for Emergency Response Technologies (iCERT) in PS Docket Nos. 21–479 and 13–75. The Motion seeks an extension of time for filing comments and reply comments in response to the Further Notice of Proposed Rulemaking (FNPRM) that was released on March 28, 2025 proposing and seeking comment on changes to the Commission's 911 reliability rules. The summary of the FNPRM was published in the **Federal Register**, 90 FR 23768 (June 4, 2025). For the reasons stated below, the Bureau finds that the extension request is warranted in part and thus extends the comment and reply comment deadlines to August 4, 2025 and September 17, 2025, respectively.

The joint filers request a 120-day extension to the comment and reply comment deadlines. The Bureau finds that a more limited extension will be sufficient to accommodate the concerns raised. As set forth in section 1.46 of the Commission's rules, 47 CFR 1.46, the Commission does not routinely grant extensions of time. In this case, however, the Bureau finds that a moderate extension of the initial comment deadline will provide additional time for parties to organize and coordinate their input to the Commission, and increasing the interval between initial comments and replies will create an expanded window for collaborative discussions among parties after the initial comments have been filed.

Ordering Clauses

Accordingly, *it is ordered,* that pursuant to 47 U.S.C. 154(i)–(j), and sections 0.204, 0.392, and 1.46 of the Commission's rules, 47 CFR 0.204, 0.392, 1.46, the Motion for Extension of Time is *granted in part and otherwise denied. It is further ordered* that the deadline to file comments in this proceeding *is extended* to August 4, 2025, and the deadline to file reply comments *is extended* to September 17, 2025.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2025–13307 Filed 7–15–25; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 2

[ET Docket No. 24–136; FR ID 302403]

Promoting the Integrity and Security of Telecommunications Certification Bodies, Measurement Facilities, and the Equipment Authorization Program

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) proposes and seeks comment on further measures to safeguard the integrity of the FCC's equipment authorization program. The Commission seeks comment on whether to extend recently adopted prohibitions to include entities subject to the jurisdiction of a foreign adversary or

alternatively apply a presumption-of-prohibition to a larger class of entities. Additionally, the Commission seeks comment on expanding the group of prohibited entities to include several additional lists from federal agencies or statutes and ways it can facilitate and encourage more equipment authorization testing to occur at test labs within the United States or allied countries. Lastly, the Commission encourages further comment on post-market surveillance procedures to ensure compliance to prohibitions on authorization of covered equipment.

DATES: Comments are due on or before August 15, 2025 and reply comments are due on or before September 15, 2025.

ADDRESSES: You may submit comments, identified by ET Docket No. 24–136, by any of the following methods:

Federal Communications Commission's Website: https://www.fcc.gov/ecfs/. Follow the instructions for submitting comments. *See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1988).*

- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People with Disabilities:* Contact the Commission to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jamie Coleman of the Office of Engineering and Technology, at *Jamie.Coleman@fcc.gov* or 202–418–2705.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Further Notice of Proposed Rulemaking,* ET Docket No. 24–136; FCC 25–27, adopted on May 22, 2025, and released on May 27, 2025. The full text of this document is available for public inspection and can be downloaded at *https://docs.fcc.gov/public/attachments/FCC-25-27A1.pdf.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Comment Period and Filing Procedures. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates provided in the **DATES** section of this document. Comments must be filed in ET Docket No. 24–136. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of the proceeding, filers must submit two additional copies for each additional docket or rulemaking number.
  - Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
  - U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

Ex Parte Presentations. The proceedings shall be treated as ''permit-but-disclose'' proceedings in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in the proceeding should familiarize themselves with the Commission's *ex parte* rules.

Procedural Matters

Regulatory Flexibility Act. The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 603, 605(b). The RFA, 5 U.S.C. 601–612, was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996). Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning the possible/potential impact of the rule and policy changes contained in the FCC document. The IRFA is found in Appendix D of the FCC document, *https://docs.fcc.gov/public/attachments/FCC-25-27A1.pdf.* The Commission invites the general public, in particular small businesses, to comment on the IRFA. Comments must have a separate and distinct heading designating them as responses to the IRFA and must be filed by the deadlines for comments on the Further Notice of Proposed Rulemaking indicated in the **DATES** section of this document.

Paperwork Reduction Act. This document may contain proposed or modified information collection requirements. Therefore, the Commission seeks comment on potential new or revised information collections subject to the Paperwork

Reduction Act of 1995. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the **Federal Register** inviting the general public and the Office of Management and Budget to comment on the information collection requirements, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comments on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Accessing Materials

Providing Accountability Through Transparency Act. Consistent with the Providing Accountability Through Transparency Act, Public Law 1189–9, a summary of the Notice of Proposed Rulemaking will be available at *https://www.fcc.gov/proposed-rulemakings.*

OPEN Government Data Act. The OPEN Government Data Act, requires agencies to make ''public data assets'' available under an open license and as ''open Government data assets,'' *i.e.,* in machine-readable, open format, unencumbered by use restrictions other than intellectual property rights, and based on an open standard that is maintained by a standards organization. 44 U.S.C. 3502(20), (22), 3506(b)(6)(B). This requirement is to be implemented ''in accordance with guidance by the Director'' of the OMB. (OMB has not yet issued final guidance. The term ''public data asset'' means ''a data asset, or part thereof, maintained by the Federal Government that has been, or may be, released to the public, including any data asset, or part thereof, subject to disclosure under [the Freedom of Information Act (FOIA)].'' 44 U.S.C. 3502(22). A ''data asset'' is ''a collection of data elements or data sets that may be grouped together,'' and ''data'' is ''recorded information, regardless of form or the media on which the data is recorded.'' 44 U.S.C. 3502(17), (16).

Synopsis

In the Further Notice of Proposed Rulemaking (FNPRM), the Commission seeks to expand upon its efforts to ensure the integrity of the FCC's equipment authorization program, particularly through prohibitions on ownership, direction, or control by untrustworthy actors that pose a risk to national security. Specifically, the Commission looks at additional sources of entities that pose a risk to national security and seeks comment on whether and how it should expand the FCC's list of prohibited entities. To balance these efforts, the Commission also solicits feedback on ways to increase equipment testing and certification within the United States or allied countries. The Commission also explores other opportunities to build upon these efforts by proposing tighter controls over post-market surveillance procedures, avoiding conflicts between test labs and the telecommunication certification bodies (TCBs) that review their test reports, and requiring equipment authorized under the Supplier's Declaration of Conformity (SDoC) procedure to be tested at an accredited and FCC-recognized laboratory.

A. Expanding Equipment Authorization Program Prohibitions

Other Entities Potentially Controlled by a Foreign Adversary. In the Report & Order portion of the proceeding, the Commission imposed restrictions on TCBs, test labs, and laboratory accreditation bodies owned by certain entities on one or more federal agency or statutory lists. In the Notice of Proposed Rulemaking (NPRM) (89 FR 55530), the Commission also sought comment ''on whether there are other types of direct or indirect ownership or control, or other types of influences beyond the Covered List determinations that potentially could adversely affect a TCB's or test lab's trustworthiness, or otherwise undermine the public's confidence.'' The Commission seeks further comment on various additions to the list of prohibited entities.

The Commission is concerned, based on the record before us, that limiting the FCC's restriction to TCBs, test labs, and laboratory accreditation bodies that are owned by, or under the direction or control of, prohibited entities, may not be sufficient to address the threats to the integrity of the FCC's equipment authorization processes posed by malign foreign actors. Now that the Commission has included foreign adversaries, as defined by the Department of Commerce, as prohibited entities, should the Commission prohibit recognition of any TCB, test lab, or laboratory accreditation body that conducts operations related to the Commission's equipment authorization program within foreign adversary countries? In other words, should the Commission extend the prohibitions in this rule beyond TCBs, test labs, and laboratory accreditation bodies that are owned by, controlled by, or subject to the direction of a foreign adversary or other prohibited entity to also include those TCBs, test labs, and laboratory accreditation bodies that are subject to the *jurisdiction* of a foreign adversary country? Should the Commission fully extend the prohibitions adopted in the Report and Order portion of the proceeding to any TCB, test lab, or laboratory accreditation body that meets the Commerce Department's definition of ''owned by, controlled by, or subject to the jurisdiction of or direction of a foreign adversary''? If so, how should the Commission implement such a prohibition? For example, would the Commission base the prohibition on any activity that physically occurs within the relevant foreign adversary country or any activity performed by an entity that is subject to the jurisdiction of such, regardless of physical location? Should the Commission require disclosure of the location of employees or activity conducted by the TCB, test lab, or laboratory accreditation body within the jurisdiction of a foreign adversary or other prohibited entity? What other methods of implementation should the Commission consider to protect the integrity of its equipment authorization program against foreign adversary countries?

In what ways would foreign adversary countries have the capability to effectively control any and all entities organized under or doing business within their jurisdiction? Would such action be under- or over-inclusive? What would the economic effects of such action be? In particular, could TCBs and test labs conducting equipment authorization functions in China, or any other foreign adversary, be rapidly replaced by TCBs and test labs conducting such functions outside of a foreign adversary country? What are the estimated costs associated with such a prohibition? How much of the costs are estimated to be passed on to U.S. consumers? Commenters have also raised concerns that the withdrawal of recognition of a significant number of testing facilities would slow down the equipment approval process for manufacturers and require ample time for U.S. companies to identify alternative testing facilities and make new arrangements for certifications, and may even require breaking commercial agreements. How, if at all, should the Commission weigh these economic concerns against potential national security threats? What could the Commission do to assist this transition and mitigate economic harms? As an alternative to wholesale prohibitions, should the Commission consider other limitations on TCBs and test labs operating in foreign adversary countries to mitigate the potential risks to national security and the integrity of the

equipment authorization program? If so, what sort of mitigation measures would suffice to ensure the integrity of the equipment authorization program against national security risks?

The Commission also seeks comment on the extent to which the existence of test labs in foreign adversary countries, particularly China, encourage trade and supply chain dependencies for radio frequency (RF)-emitting equipment. Does the prominence of FCC–recognized test labs in China encourage greater manufacturing and production of finished equipment and components in China? If so, how much? Do test labs in China offer favorable treatment for equipment produced in China or by Chinese companies? Should the Commission prohibit test labs in China from participation in the equipment authorization program in part as a means of reducing these trade and supply chain dependencies on foreign adversaries, given the potential risks to national security threats such dependencies pose? How, if at all, do these considerations relate to the goals of the proceeding?

As the Commission weighs the national security threat posed by test labs and test lab accreditation bodies located in foreign adversary nations, to what extent should the Commission consider the President's determination that nominally private companies in China in particular are not really ''private,'' but functionally controlled by, and answerable to, the Chinese government and the Chinese Communist Party, which is a foreign adversary? For example, Executive Order 13959 states President Donald J. Trump's finding that, ''key to the development of the PRC's military, intelligence, and other security apparatuses is the country's large, *ostensibly private* economy. Through the national strategy of Military-Civil Fusion, China increases the size of the country's military-industrial complex by compelling civilian Chinese companies to support its military and intelligence activities. Those companies, *though remaining ostensibly private and civilian,* directly support China's military, intelligence, and security apparatuses and aid in their development and modernization.'' Indeed, in February of this year, President Trump wrote to several of his Cabinet secretaries recognizing that ''[t]hrough its national Military-Civil Fusion strategy, [China] increases the size of its military-industrial complex by compelling civilian Chinese companies and research institutions to support its military and intelligence activities.'' Even the Supreme Court has accepted that a private company in China ''is subject to Chinese laws that require it to assist or cooperate with the Chinese Government's intelligence work and to ensure that the Chinese Government has the power to access and control private data the company holds.'' As the Public Safety and Homeland Security Bureau has previously recognized, ''the Chinese government is highly centralized and exercises strong control over commercial entities in its sphere of influence, permitting the government, including state intelligence agencies, to demand that private communications sector entities cooperate with governmental requests, including revealing customer information and network traffic information. Demands for such information could come in the form of legal pressure, as in the case of the Chinese National Intelligence Law, or in the form of extralegal political pressure taken through control of subsidy funding, employee unions, or threats and/or coercion. Several commenters also made this point.

The Commission seeks comment as well on whether and to what extent the Commission should factor in the military situation in the Indo-Pacific in recognizing test labs and laboratory accreditation bodies. To what extent should the Commission consider the threat China poses to U.S. interests in the Indo-Pacific region, particularly with regard to a possible invasion of Taiwan, potentially as soon as 2027? If such a conflict erupts, there would no doubt be a substantial, if not total, rupture in trade and economic relations between the U.S. and China, raising significant concerns if the Commission's authorization program is partially reliant on test labs in China. Should the Commission treat test labs in China differently from those in other foreign adversary countries given this consideration of potential military conflicts? The Commission seeks comment on whether it should consider this possibility in determining whether to prohibit recognition of a broader array of test labs in China. How, if at all, do these considerations relate to the goals of the proceeding?

Are there other considerations appropriate for the Commission to consider related to the goals of the proceeding, for example, should the Commission consider the extent to which there is a lack of reciprocity with another country with regard to equipment testing and certification? For example, should the Commission take into account whether China requires domestic testing for all equipment sold in China? If so, to what extent does that unfairly encourage entities that want to sell equipment both in the U.S. and China to test their equipment in China-based test labs?

Alternative Approaches. Congress recently twice codified a definition of ''controlled by a foreign adversary'' in statutes involving data privacy. In this context, Congress defines a ''company or other entity'' as ''controlled by a foreign adversary'' if it satisfies one of three conditions:

(A) a foreign person that is domiciled in, is headquartered in, has its principal place of business in, or is organized under the laws of a foreign adversary country;

(B) an entity with respect to which a foreign person or combination of foreign persons described in subparagraph (A) directly or indirectly own at least a 20 percent stake; or

(C) a person subject to the direction or control of a foreign person or entity described in subparagraph (A) or (B).

The Commission seeks comment on whether to revise the definitions adopted in the Report & Order portion of the proceeding to include entities that meet one of these three conditions to be considered ''controlled by a foreign adversary.'' Should the Commission consider ''historical patterns of behavior by affiliated organizations,'' as suggested by the Foreign Investment Review Section, National Security Division, U.S. Department of Justice? Can any entity that Congress has, in the context of data privacy considerations, twice found to be ''controlled by a foreign adversary'' be trusted not to undermine the integrity and security of the equipment authorization program? Would such a definition be under- or over-inclusive? What would be the economic harms or implementation burden of such a prohibition? What steps, if any, could the Commission undertake to mitigate those concerns? As an alternative to outright prohibition of participation by such entities, should the Commission impose mitigation requirements on entities ''controlled by foreign adversaries''?

Should the Commission adopt the definition used in the CHIPS Act for a ''foreign entity of concern''? This definition lists various ways for an entity to be a ''foreign entity of concern,'' including being ''owned by, controlled by, or subject to the jurisdiction or direction of'' China, Russia, Iran, or North Korea, which is similar to the statutory definition of ''controlled by a foreign adversary.'' However, the CHIPS Act also includes numerous other ways for an entity to be a ''foreign entity of concern,'' including being designated as a foreign terrorist

organization and being alleged to have been involved in various activities for which a conviction was obtained. Is one of these definitions preferable? Should the Commission adopt some amalgamation of this definition along with the other statutory definition?

Alternatively, should the Commission adopt a different definition? If so, what should that definition be and why? The Commission welcomes comment on which category of entities are ''controlled by a foreign adversary.'' Should the Commission adopt a more limited or expansive definition? Does the definition need to be clearly defined? To what extent should the definition be aligned with other Commission rules on foreign ownership?

As an alternative to an outright prohibition on TCBs, test labs, and laboratory accreditation bodies located in or subject to the jurisdiction of a foreign adversary, should the Commission adopt a presumption-of-prohibition policy? Under this policy, any entity subject to the jurisdiction of a foreign adversary would need to provide clear-and-convincing evidence that there was no national security risk from its participation in the equipment authorization program. What are some potential benefits and drawbacks of such an approach? If the Commission adopts such an approach, should the Commission use a different standard than clear-and-convincing? Should the Commission consult the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector and require its approval before recognizing for participation in the equipment authorization program TCBs, test labs, or laboratory accreditation bodies ''controlled by a foreign adversary''? Should the Commission adopt any alternative mechanism to screen such entities for participation?

Other Federal Agency Lists. In the NPRM, the Commission sought comment on ''whether the Commission should consider any other Executive Branch agency lists to rely upon as a source to identify entities that raise national security concerns and to restrict participation of those entities in the FCC's equipment authorization program. The Report & Order portion of the proceeding incorporated several of these lists in the FCC's determination regarding prohibited entities. What other federal agency lists, or entities identified by federal agencies, or lists created by statute, should the Commission consider including in its definition of ''prohibited entity''? The Commission welcomes comment on which ''lists'' are particularly appropriate and which are not.

The Commission is particularly interested in and seeks comment on the usefulness of relying on the following sources:

- The Protecting Americans from Foreign Adversary Controlled Applications Act (''PFACA'') imposed restrictions on the domestic operations of certain foreign adversary-controlled social media applications. In particular, the PFACA imposed restrictions on applications directly or indirectly operated by ByteDance, Ltd., TikTok, their subsidiaries, entities they controlled, or any other entity that the President determines ''is controlled by a foreign adversary'' and ''present[s] a significant threat to the national security of the United States.'' Should the Commission rely on this list to impose restrictions with regard to participation in the equipment authorization program given that either Congress or the President has expressly determined such entities to be national security threats? The Commission welcomes comment on the usefulness and applicability of this list in terms of the equipment authorization program.
- Pursuant to various statutory authorities and Executive Orders, the Office of Foreign Assets Control (''OFAC'') in the U.S. Department of Treasury publishes a Specially Designated Nationals and Blocked Persons List (''SDN List'') of entities subject to certain prohibitions. ''Collectively, such individuals and companies are called 'Specially Designated Nationals' or 'SDNs.' Their assets are blocked, and U.S. persons are generally prohibited from dealing with them.'' The justifications for these sanctions are wide ranging, but entities on the SDN List are generally subject to the most extreme form of sanctions, suggesting that such entities should have no role in the Commission's TCB and test lab program. Additionally, although the SDN List is long, it is published, and businesses have well-established compliance mechanisms. Should the Commission include entities on the SDN List in its definition of prohibited entities?
- The National Defense Authorization Act for Fiscal Year 2024 prohibits the DOD from procuring batteries produced by several Chinese entities, starting in 2027. This list included leading battery manufacturers and their successors. Should the Commission consider this list of battery manufacturers as part of its definition of prohibited entities? Would this list be relevant or useful in determining the integrity and security of TCBs, test labs, and laboratory accreditation bodies?

Are there any other federal agency or statutory ''lists'' that the Commission should consider including within its prohibition?

B. Increasing Equipment Authorization Testing and Certification Within the United States

The actions the Commission takes in the Report and Order portion of the proceeding are the first steps in ensuring the integrity of the FCC's equipment authorization program against ownership, direction, or control by untrustworthy actors that pose a risk to national security. To further the FCC's goals in this area, the Commission seeks comment on ways in which it can facilitate and encourage more equipment authorization testing and certification within the United States and allied countries, such as those with which the Commission has a mutual recognition agreement (MRA). In addition to financial, what other hinderances or advantages (*i.e.,* costs and benefits) would entities seeking equipment authorization encounter in relying primarily on TCBs, test labs, and laboratory accreditation bodies located in the U.S.? What conflicts or other concerns might arise? What rules or processes could the Commission implement or modify to encourage equipment authorization processes that rely primarily upon domestic TCBs, test labs, and laboratory accreditation bodies? How can the Commission encourage the establishment of new, or expansion of existing, TCBs and test labs in the U.S.? What are the primary barriers limiting the presence of TCBs and test labs in the U.S.? Are there actions the Commission can take to reduce regulatory barriers to TCBs and test labs? Should the Commission offer incentives for utilization of domestic TCBs and test labs, and, if so, what sort of incentives? Should any of these incentives or efforts to increase testing be similarly directed toward utilization of TCBs and test labs in allied countries, such as those with which the U.S. has an MRA? If so, which ones and why?

To what extent would having more equipment authorization testing and certification in the United States reduce risks and threats to national security in terms of the equipment supply chain or in other ways? Given the importance of a strong industrial base for national security, should the Commission consider such reindustrialization goals in crafting a program of incentives? The Commission seeks comment on the overall benefits and costs, with quantifiable data, associated with any

proposed measures to encourage more equipment authorization testing and certification within the United States or allied countries.

C. Other Matters

Post-market surveillance procedures. Commission rules impose certain obligations on each TCB to perform post-market surveillance, based on ''type testing a certain number of samples of the total number of product types'' that the TCB has certified. In light of issues discussed in the Report and Order portion of the proceeding to ensure the integrity of the FCC's equipment authorization program, the Commission invites further comment on whether the Commission should revise the post-market surveillance rules, policies, or guidance to address such concerns. The Commission seeks comment on reasonable practices TCBs could implement to better identify equipment that may be noncompliant with Commission rules, despite authorization. In particular, should the Commission change the post-market surveillance requirements to require that TCBs review certification grants by other TCBs? How would such a requirement work? Should the Commission require, instead, that TCBs engage independent reviewers/auditors to conduct their required post market surveillance? If so, what would be the criteria for such third-party reviewers? The Commission invites comment on this and any other measures the Commission might take to strengthen the integrity of the post-market surveillance process.

TCB and test lab relationships. The FCC's rules incorporate ISO/IEC 17025 and ISO/IEC 17065 standards, against which accreditation bodies assess test labs and TCBs, respectively to ensure, in part, that these entities operate in a competent, consistent, and impartial manner. TCBs also are required under the FCC's rules to have the technical expertise and capability to test the equipment it will certify and be accredited to ISO/IEC 17025. The Commission recognizes that this results in most, or all, TCBs in a position to not only verify the test reports received with an application for authorization but also to produce such test reports. The Commission seeks comment on any potential for this current structure to raise questions as to the integrity of the FCC's equipment authorization program or the impartiality of TCBs or test labs. What types of procedures have TCBs and test labs put into place to ensure impartiality, particularly when a TCB reviews an authorization application for which a test lab under the same ownership as the TCB conducted the required testing? What additional information should the Commission require regarding the relationship between the individuals who each performed a defined role in the review and approval process? The Commission seeks comment on additional safeguards that it should consider to further ensure the impartiality of our TCBs and test labs. Specifically, the Commission seeks comment on whether it should restrict the relationships between TCBs and test labs to prevent TCBs from reviewing authorization applications for which the equipment was tested by a test lab owned by, or under the direction or control of the same entities that own, direct, or control the TCB.

Supplier's Declaration of Conformity Procedures. By the Report and Order portion of this proceeding, the Commission prohibits reliance upon test labs owned by, or under the direction or control of, a prohibited entity for SDoC authorization measurement requirements. The ownership information required to be collected pursuant to these new rules will be retained by the responsible party and made available to the Commission upon request. To further the FCC's efforts to ensure the integrity of the equipment authorization program, the Commission is considering additional measures to strengthen the integrity of laboratories upon which entities rely for the SDoC procedure. Specifically, the Commission proposes to require that all equipment authorized under the SDoC procedure be tested at an accredited and FCC-recognized laboratory. The Commission seeks comment on some of the impacts such an action could have on the supply chain and to the testing process, particularly with regard to the confidence in the integrity of the test labs and thereby the security of the U.S. equipment supply chain.

Ordering Clauses

Accordingly, *it is ordered,* pursuant to the authority found in sections 1, 4(i), 229, 301, 302, 303, 309, 312, 403, and 503 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 229, 301, 302a, 303, 309, 312, 403, and 503, section 105 of the Communications Assistance for Law Enforcement Act, 47 U.S.C. 1004; the Secure and Trusted Communications Networks Act of 2019, 47 U.S.C. 1601–1609; and the Secure Equipment Act of 2021, Public Law 117–55, 135 Stat. 423, 47 U.S.C. 1601 note, that the Further Notice of Proposed Rulemaking *is hereby adopted.*

It is further ordered that the Office of the Secretary, *shall send* a copy of the Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 2

Administrative practice and procedures, Communications, Communications equipment, Reporting and recordkeeping requirements, Telecommunications, and Wiretapping and electronic surveillance.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Proposed Rules

For the reasons discussed in the document, the Federal Communications Commission proposes to amend 47 CFR part 2 as follows:

Part 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336 unless otherwise noted.

■ 2. Amend § 2.902 by revising the entry for ''Prohibited entities'' to add paragraphs (2)(vii) through (ix) to read as follows:

§ 2.902 Terms and definitions.

* * * * *

Prohibited entities.

* * * * *

(2) * * *

(vii) The Protecting Americans from Foreign Adversary Controlled Applications Act (15 U.S.C. 9901 note);

(viii) Department of Treasury, Office of Foreign Assets Control, Specially Designated Nationals and Blocked Person List; and

(ix) Section 154(b) of the National Defense Authorization Act for Fiscal Year 2024 (Pub. L. 118–31).

(3) * * *

* * * * *

■ 2. Amend § 2.948 by revising paragraphs (a) and (b) to read as follows:

§ 2.948 Measurement facilities.

(a) Equipment authorized under the procedures set forth in this subpart must be tested at a laboratory that is:

* * * * *

(b) A laboratory that makes measurements of equipment subject to an equipment authorization must compile a description of the measurement facilities employed.

* * * * *

■ 3. Amend § 2.949 by revising paragraphs (b)(5), (c), and (e), and

adding paragraphs (c)(4) and (e)(4) to read as follows:

§ 2.949 Recognition of laboratory accreditation bodies.

* * * * *

(b) * * *

(5) Certification to the Commission that the laboratory accreditation body is not:

(i) Owned by, controlled by, or subject to the direction of a prohibited entity pursuant to § 2.902; or

(ii) Physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

(c) * * *

(3) Fails to provide, or provides false or inaccurate, information regarding equity or voting interests of 5% or greater as required in this section; or

(4) Is physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

(e) The Commission will withdraw recognition of any laboratory accreditation body that:

(2) Fails to provide, or provides a false or inaccurate, certification, as required by this section;

(3) Fails to provide, or provides false or inaccurate, information regarding equity or voting interests of 5% or greater, as required by this section; or

(4) Is physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

■ 4. Amend § 2.951 by revising paragraphs (a)(10), (b)(2) and (3), adding paragraph (b)(4), revising paragraphs (d)(2) and (3), and adding paragraph (d)(4) to read as follows:

§ 2.951 Recognition of measurement facilities.

(a) * * *

(10) Certification to the Commission that the laboratory is not:

(i) Owned by, controlled by, or subject to the direction of a prohibited entity pursuant to § 2.902; or

(ii) Physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

(b) * * *

* * * * *

(2) That fails to provide, or that provides a false or inaccurate, certification as required in this section;

(3) That fails to provide, or provides false or inaccurate, information regarding equity or voting interests of 5% or greater as required in this section; or

(4) That is physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

(d) * * *

(2) Fails to provide, or provides a false or inaccurate, certification, as required in this section;

(3) Fails to provide, or provides false or inaccurate, information regarding equity or voting interests of 5% or greater, as required in this section; or

(4) Is physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

■ 5. Amend § 2.960 by revising paragraphs (a)(2), (b)(2) and (3), adding paragraph (a)(4), revising paragraphs (h)(2) and (3), and adding paragraph (h)(4) to read as follows:

§ 2.960 Recognition of Telecommunication Certification Bodies (TCBs).

(a) * * *

* * * * *

(2) Certified to the Commission that:

(i)The TCB is not owned by, controlled by, or subject to the direction of a prohibited entity pursuant to § 2.902; or

(ii) Physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

(b) * * *

* * * * *

(2) That fails to provide, or provides a false or inaccurate, certification as required in paragraph (a) of this section;

(3) That fails to provide, or provides false or inaccurate, information regarding equity or voting interests of 5% or greater; or

(4) That is physically or legally located within the geographical jurisdiction of a foreign adversary country.

(h) * * *

(2) Fails to provide, or provides a false or inaccurate, certification, as required in this section;

(3) Fails to provide, or provides false or inaccurate, information regarding equity or voting interests of 5% or greater, as required in this section; or

(4) Is physically or legally located within the geographical jurisdiction of a foreign adversary country.

* * * * *

■ 6. Amend § 2.962 by adding (a)(3) and revising paragraphs (d)(2) and (i) introductory text to read as follows:

§ 2.962 Requirements for Telecommunication Certification Bodies.

(a) * * *

(3) A TCB is prohibited from reviewing an application that includes test data, as required under this part, that was prepared by a measurement facility that is owned by, controlled by, or subject to the direction of any entity that also owns, controls, or directs the TCB.

* * * * *

(d) * * *

* * * * *

(2) Accept test data from any Commission-recognized accredited test laboratory, except as provided in paragraph (a)(3), subject to the requirements in ISO/IEC 17065, and must not unnecessarily repeat tests.

* * * * *

(i) In accordance with ISO/IEC 17065 a TCB must perform appropriate post-market surveillance activities. These activities must be based on type testing a certain number of samples of the total number of product types that a different TCB has certified.

* * * * *

[FR Doc. 2025–13308 Filed 7–15–25; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2023–0033; FXES1113090FEDR–256–FF09E22000]

RIN 1018–BH98

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the Blue Tree Monitor

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period and announcement of public hearing.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are reopening the comment period on our December 26, 2024, proposed rule to list the blue tree monitor (*Varanus macraei*), a lizard species from Indonesia, as an endangered species under the Endangered Species Act of 1973, as amended (Act). We are taking this action to allow interested parties an additional opportunity to comment on the proposed rule and to conduct a public hearing. Comments previously submitted need not be resubmitted and will be fully considered in preparation of the final rule.

DATES: *Comment submission:* The public comment period on the proposed

rule that published on December 26, 2024, at 89 FR 104952 is reopened. We will accept comments received on or before August 15, 2025. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES,** below) must be received by 11:59 p.m. Eastern Time on the closing date, and comments submitted by U.S. mail must be received by that date to ensure consideration.

Public hearing: On July 31, 2025, we will hold a public hearing on the proposed rule to list the blue tree monitor as an endangered species under the Act from 12 to 2 p.m. Eastern Time, using the Zoom platform (for more information, see Public Hearing, below).

ADDRESSES: *Comment submission:* You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–HQ–ES–2023–0033, which is the docket number for the proposed rule. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–HQ–ES–2023–0033, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Document availability: The December 26, 2024, proposed rule and its supporting documents, including the species status assessment report, are available at *https://www.regulations.gov* under Docket No. FWS–HQ–ES–2023–0033.

Public hearing: Interested parties may present verbal testimony (formal, oral comments) at a public hearing, which will be held virtually using the Zoom platform. See Public Hearing, below, for more information.

FOR FURTHER INFORMATION CONTACT: Rachel London, Manager, Branch of Delisting and Foreign Species, Ecological Services Program, U.S. Fish and Wildlife Service; telephone 703–358–2171; *Rachel_London@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please see Docket No. FWS–HQ–ES–2023–0033 on *https://www.regulations.gov* for a document that summarizes the December 26, 2024, proposed rule.

SUPPLEMENTARY INFORMATION:

Information Requested

We intend that any final action resulting from our December 26, 2024, proposed rule (89 FR 104952) will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning our proposed rule. In addition to the information requested in our proposed rule, we also seek comments concerning:

(1) Verifiable information demonstrating successful breeding of blue tree monitors in captivity, particularly evidence of legal acquisition of breeding stock and production of a second filial (F2) generation, or subsequent generation.

(2) New information that leads us to conclude the blue tree monitor is threatened instead of endangered and information to assist us with applying or issuing protective regulations under section 4(d) of the Act (a ''4(d) rule'') that may be necessary and advisable to provide for the conservation of the blue tree monitor. In particular, we seek information concerning:

(a) The extent to which we should include any of the Act's section 9(a)(1) prohibitions in the 4(d) rule (including import, export, take, activities with unlawfully taken specimens, and activities in interstate or foreign commerce);

(b) Whether we should consider any modifications or additional exceptions from the prohibitions in the 4(d) rule (for example, an exception for interstate commerce of live blue tree monitors bred in captivity in the United States in accordance with the requirements of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); or an exception for interstate commerce of live blue tree monitors from one public institution to another public institution);

and

(c) Additional information describing the adequacy or inadequacy of protections afforded to the blue tree monitor via CITES trade regulations, regulations of the range country, or any other relevant regulations.

Please include sufficient information with your submission (such as scientific journal articles or other publications; evidence of legal acquisition of breeding stock and specimens successfully bred-in-captivity; copies of relevant laws, regulations, or permits) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act (16 U.S.C. 1533(b)(1)(A)) directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available. Comments or information already submitted on the proposed rule (89 FR 104952, December 26, 2024) need not be resubmitted. Any such comments are already incorporated as part of the public record of the rulemaking proceeding, and we will fully consider them as part of the action.

You may submit your comments and materials concerning the December 26, 2024, proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing the December 26, 2024, proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Our final determination may differ from the December 26, 2024, proposal because we will consider all comments we receive during the comment period as well as any information that may become available after the proposal. Based on the new information we receive (and, if relevant, any comments

on that new information), we may conclude that the species is threatened instead of endangered, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from the December 26, 2024, proposal.

Background

On December 26, 2024, we published a proposed rule (89 FR 104952) to list the blue tree monitor as an endangered species under the Act (16 U.S.C. 1531 *et seq.*). The proposed rule opened a 60-day public comment period, ending February 24, 2025. During the open comment period, we received a request for a public hearing on the proposed rule. Therefore, we are reopening the comment period on the proposal and announcing a public hearing (see **DATES**, above) to allow the public an additional opportunity to provide comments on the proposed rule to list the blue tree monitor.

For a description of previous Federal actions concerning the blue tree monitor and more information on the types of comments that would be helpful to us in promulgating this rulemaking action, please refer to the December 26, 2024, proposed rule (89 FR 104952).

Public Hearing

We are holding a public hearing to accept comments on our December 26, 2024, proposed rule (89 FR 104952) on the date and at the time listed above in **DATES**. We are holding the public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. All participants must register in order to listen and view the hearing via Zoom, listen to the hearing by telephone, or provide oral public comments at the hearing by Zoom or telephone. For information on how to register, or if technical problems occur joining Zoom on the day of the hearing, visit *https://www.fws.gov/event/virtual-public-hearing-proposed-listing-blue-tree-monitor.*

Registrants will receive the Zoom link and the telephone number for the public hearing. If applicable, interested members of the public not familiar with the Zoom platform should view the Zoom video tutorials (*https://support.zoom.us/hc/en-us/articles/206618765-Zoom-video-tutorials*) prior to the public hearing.

The public hearing will provide interested parties an opportunity to present verbal testimony (formal, oral comments) regarding the December 26, 2024, proposed rule to list the blue tree monitor as an endangered species (89 FR 104952). The public hearing will not be an opportunity for dialogue with the Service but rather a forum for accepting formal verbal testimony. In the event there is a large attendance, the time allotted for oral statements may be limited. Therefore, anyone wishing to make an oral statement at the public hearing for the record is encouraged to provide a prepared written copy of their statement to us through the Federal eRulemaking Portal or U.S. mail (see **ADDRESSES**, above). There are no limits on the length of written comments submitted to us. Anyone wishing to make an oral statement at the public hearing must register before the hearing (*https://www.fws.gov/event/virtual-public-hearing-proposed-listing-blue-tree-monitor*). The use of a virtual public hearing is consistent with our regulations at 50 CFR 424.16(c)(3).

Reasonable Accommodation

The Service is committed to providing access to the public hearing for all participants. Closed captioning will be available during the public hearing. Further, a full audio and video recording and transcript of the public hearing will be posted online at *https://www.fws.gov/event/virtual-public-hearing-proposed-listing-blue-tree-monitor* after the hearing. Participants will also have access to live audio during the public hearing via their telephone or computer speakers. Persons with disabilities requiring reasonable accommodations to participate in the hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the date of the hearing to help ensure availability. See *https://www.fws.gov/event/virtual-public-hearing-proposed-listing-blue-tree-monitor* for more information about reasonable accommodation.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Signing Authority

Paul Souza, Regional Director, Region 8, Exercising the Delegated Authority of the Director of the U.S. Fish and Wildlife Service, approved this action on June 13, 2025, for publication. On June 18, 2025, Paul Souza authorized the undersigned to sign the document electronically and submit it to the Office of the Federal Register for publication as an official document of the U.S. Fish and Wildlife Service.

Madonna Baucum,

Regulations and Policy Chief, Division of Policy, Economics, Risk Management, and Analytics of the Joint Administrative Operations, U.S. Fish and Wildlife Service.

[FR Doc. 2025–11539 Filed 7–15–25; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 90, No. 134
Wednesday, July 16, 2025

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Economic Development Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regional Economic Development Data Collection Instrument

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on December 12, 2024 during a 60-day comment period (89 FR 96636). This notice allows for an additional 30 days for public comments.

ADDRESSES: Interested persons are invited to submit written comments email to Hallie Davis, Program Manager and Analyst, U.S. Department of Commerce, at *HDavis1@doc.gov* or *PRAcomments@doc.gov.* Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Hallie Davis, Economic Development Administration, 1401 Constitution Ave NW, Washington DC 20230, by phone 202.579.0218 or at *TechHubs@eda.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Economic Development Administration (EDA) leads the Federal economic development agenda by promoting innovation and competitiveness and preparing American regions for growth and success in the worldwide economy. Guided by the basic principle that sustainable economic development should be driven locally, EDA works directly with communities and regions to help them build the capacity for economic development based on local business conditions and needs. Section 28 of the Stevenson-Wydler Technology Innovation Act of 1980 (Regional Technology and Innovation Hub Program (15 U.S.C. 3722a) is the legal authority under which EDA awards financial assistance and designee status under the Fiscal Year (FY) 23 Regional Technology and Innovation Hub Program (''Tech Hubs''). Under Tech Hubs, EDA seeks to strengthen U.S. economic and national security through place-based investments in regions with the assets, resources, capacity, and potential to become globally competitive, within approximately ten years, in the technologies and industries of the future—and for those industries, companies, and the good jobs they create to start, grow, and remain in the U.S. in order to support the growth and modernization of U.S. manufacturing, improve commercialization of the domestic production of innovative research, and strengthen U.S. economic and national security. Tech Hubs is a two-phase program: in Phase 1, EDA funded Strategy Development grants and designated 31 regions as Tech Hubs. In Phase 2, designated Tech Hubs are eligible to compete for funding for implementation projects. Further information on Tech Hubs can be found at *www.eda.gov.*

The purpose of this notice is to seek comments from the public and other Federal agencies on a request for a new information collection for designated Tech Hubs to help ensure that Tech Hub investments are evidence-based, data driven, and accountable to participants and the public.

Lead consortium members of the 31 designated Tech Hubs will submit identified program metrics and qualitative information to help assess specific program objectives. A one-time questionnaire will be sent to each of the Tech Hubs consortium leads, which will gather the relevant data and stories for each of the 31 Tech Hubs designee consortia, resulting in consortia regional impact evaluation, resources, and tools for regional economic development decision-makers. The 31 designated Tech Hubs will provide information on the following objectives:

(1) Accelerating technology innovation, commercialization, demonstration, and deployment, which may include information on the number of patents filed, licensing agreements, approximate levels of research and development expenditures, adoption of new technologies, and acceleration of current technologies.

(2) Enabling infrastructure and advancing manufacturing, which may include information on specific facility information.

(3) Integrating an agile workforce system, which may include information on skills needed by employers, available training, hard-to-fill vacancies, policies and strategies for worker retention, and strategies for engagement with underserved workers.

(4) Increasing business and entrepreneurial capacity, which may include assessing employer competitiveness, relationships with federal, state, and local entities, current partnerships, and information about sources of capital to start and grow businesses and to adopt innovative approaches and technologies.

(5) Strengthening national security, which may include information on procurement processes, critical inputs, sourcing, supply chains, and strategic implications of technologies and their use cases.

Tech Hubs designees must submit this data one time to provide a baseline status of the Tech Hub and to help assess the results of designee status as well as potential future federal investments.

EDA is particularly interested in public comment on how the proposed data collection will support the assessment of job quality, including in ways that rely on pairing this information administrative data for analysis and other ways to minimize burden, or if alternative information should be considered.

II. Method of Collection

Data will be collected electronically.

III. Data

OMB Control Number: 0610–0113.

Form Number(s): None.

Type of Review: Revision with extension.

Affected Public: Tech Hubs designees, which may include a(n): Institution of higher education; State, territorial, local or Tribal governments or other political subdivisions of a State, including State and local agencies, or a consortium thereof; Industry groups or firms in relevant technology, innovation, or manufacturing sectors; Economic development organizations or similar entities that are focused primarily on improving science, technology, innovation, entrepreneurship, or access to capital; Labor organizations or workforce training organizations, which may include State and local workforce development boards; Economic development entities with relevant expertise, including a district organization; Organizations that contribute to increasing the participation of underserved populations in science, technology, innovation, and entrepreneurship; Venture development organizations; Organizations that promote local economic stability, high wage domestic jobs, and broad-based economic opportunities, such as employee ownership membership associations and State or local employee ownerships and cooperative development centers, financial institutions and investment funds, including community development financial institutions and minority depository institutions; Elementary schools and secondary schools, including area career and technical education schools; National laboratories; Federal laboratories; Manufacturing extension centers; Manufacturing U.S.A. Institutes; Transportation planning organizations; A cooperative extension services; Organizations that represent the perspectives of underserved communities in economic development initiatives; and Institutions receiving an award under the National Science Foundation's (NSF) Regional Innovation Engines Program.

Preliminary Estimated Number of Respondents: Consortium Lead Members/Tech Hubs Designee Consortia: 31 respondents, responding once.

Estimated Time Per Response: Consortium Lead Members/Tech Hubs Designee Consortia: 3 hours.

Estimated Total Annual Burden Hours: 186 hours.

Type of respondent (one time)	Number of respondents	Hours per response	Number of responses per year	Total estimated time (hours)
Lead Consortium Members/Tech Hubs Designee Consortia	31	3	2	186
Total	31	3	2	186

Estimated Total Annual Cost to Public: $115,394 (cost assumes application of U.S. Bureau of Labor Statistics second quarter 2022 mean hourly employer costs for employee compensation for professional and related occupations of $62.04).

Respondent's Obligation: Mandatory for Consortium Lead Members.

Legal Authority: Stevenson Wydler Technology Innovation Act of 1980, Section 28 (15 U.S.C. 3722a).

IV. Request for Comments

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments.''

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2025–13321 Filed 7–15–25; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 250709–0121]

XRIN 0694–XC128

Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Polysilicon and its Derivatives

AGENCY: Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce.

ACTIONS: Notice of request for public comments.

SUMMARY: On July 1, 2025, the Secretary of Commerce initiated an investigation to determine the effects on the national security of imports of polysilicon and its derivatives. This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended (Section 232). Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's (Department) Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security. This notice identifies issues on which the Department is especially interested in obtaining the public's views.

DATES: Comments may be submitted at any time but must be received by August 6, 2025.

ADDRESSES: Comments on this notice may be submitted to the Federal rulemaking portal at: *www.regulations.gov.* The *regulations.gov* ID for this notice is BIS–2025–0028. Please refer to XRIN 0694–XC128 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. The corresponding non-confidential version

of those comments must be clearly marked ''PUBLIC.'' The file name of the non-confidential version should begin with the character ''P.'' Any submissions with file names that do not begin with either a ''BC'' or a ''P'' will be assumed to be public and will be made publicly available at: *https://www.regulations.gov.* Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: Stephen Astle, Director, Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, U.S. Department of Commerce (202) 482–4506, *Polysilicon232@bis.doc.gov*. For more information about the Section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232.*

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2025, the Secretary of Commerce initiated an investigation under Section 232 (19 U.S.C. 1862) to determine the effects on national security of imports of polysilicon and its derivatives.

Request for Public Comments

This investigation is being undertaken in accordance with part 705 of the National Security Industrial Base Regulations (15 CFR parts 700 to 709) (NSIBR). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to BIS's Office of Strategic Industries and Economic Security no later than August 6, 2025. The Department is particularly interested in comments and information directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

(i) the current and projected demand for polysilicon and its derivatives in the United States;

(ii) the extent to which domestic production of polysilicon and its derivatives can meet domestic demand;

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for polysilicon and its derivatives;

(iv) the concentration of U.S. imports of polysilicon and its derivatives from a small number of suppliers and the associated risks;

(v) the impact of foreign government subsidies and predatory trade practices on the competitiveness of the polysilicon and its derivatives, in the United States;

(vi) the economic impact of artificially suppressed prices of polysilicon and its derivatives due to foreign unfair trade practices and state-sponsored overproduction;

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over supplies of polysilicon and its derivatives;

(viii) the feasibility of increasing domestic capacity for polysilicon and its derivatives to reduce import reliance;

(ix) the impact of current trade policies on domestic production of polysilicon and its derivatives, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

(x) any other relevant factors.

Material submitted by members of the public that is business confidential information will be exempted from public disclosure as provided for by § 705.6 of the regulations (see the **ADDRESSES** section of this notice). Communications from agencies of the United States Government will not be made available for public inspection. BIS does not maintain a separate public inspection facility. Requesters should first view the Bureau's web page, which can be found at: *https://efoia.bis.doc.gov/* (see ''Electronic FOIA'' heading). If requesters cannot access the website, they may call (202) 482–0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published at 15 CFR 4.1, *et seq.*

Julia Khersonsky,

Deputy Assistant Secretary for Strategic Trade.

[FR Doc. 2025–13345 Filed 7–14–25; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Emerging Technology Technical Advisory Committee

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Notice of partially closed meeting.

SUMMARY: The Emerging Technology Technical Advisory Committee (ETTAC) advises and assists the Secretary of Commerce and other Federal officials on matters related to export control policies; the ETTAC will meet to review and discuss these matters. The meeting will be partially closed to the public pursuant to the exemptions under the Federal Advisory Committee Act (FACA) and the Government in the Sunshine Act.

DATES: The meeting will be held on August 1, 2025, from 9:30 a.m. to 4:00 p.m., Eastern Time (all times are Eastern Time). The closed session will start at 9:30 a.m. and end at approximately 3:00 p.m., and the open session will start at approximately 3:00 p.m. and will end no later than 4:00 p.m. Individuals requiring special accommodations to access the open session should contact *TAC@bis.doc.gov* no later than 11:59 p.m. on July 25, 2025, so that appropriate arrangements can be made. Individuals interested in participating virtually should contact *TAC@bis.doc.gov* no later than 11:59 p.m. on July 29, 2025.

ADDRESSES: The open session of the meeting will be held in Room 38026 of the Herbert C. Hoover Building, 1401 Constitution Avenue NW, Washington, DC (enter through the Main Entrance on 14th Street between Constitution and Pennsylvania Avenues). The open session will be accessible to the public via teleconference.

FOR FURTHER INFORMATION CONTACT: Kevin Coyne, Committee Liaison Officer, Bureau of Industry and Security, U.S. Department of Commerce. For additional information, contact *TAC@bis.doc.gov* or by phone 202–482–4933.

SUPPLEMENTARY INFORMATION:

Background

The Emerging Technology Technical Advisory Committee (ETTAC) advises and assists the Secretary of Commerce (Secretary) and other Federal officials and agencies with respect to actions designed to carry out the policy set forth in Section 1752 of the Export Control Reform Act. The purpose of the meeting is to have ETTAC members and U.S. Government representatives mutually review updated technical data and policy-driving information that has been gathered.

Agenda

The open session will include open business discussions and industry presentations. The closed session will include discussion of matters determined to be exempt from the open meeting and public participation requirements found in Sections 1009(a)(1) and 1009(a)(3) of the Federal Advisory Committee Act (FACA) (5

U.S.C. 1001–1014). The exemption is authorized by Section 1009(d) of the FACA, which permits the closure of advisory committee meetings, or portions thereof, if the head of the agency to which the advisory committee reports determines such meetings may be closed to the public in accordance with subsection (c) of the Government in the Sunshine Act (5 U.S.C. 552b(c)). In this case, the applicable provisions of 5 U.S.C. 552b(c) are subsection 552b(c)(4), which permits closure to protect trade secrets and commercial or financial information that is privileged or confidential, and subsection 552b(c)(9)(B), which permits closure to protect information that would be likely to disclose information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action. The closed session of the meeting will involve committee discussions and guidance regarding U.S. Government strategies and policies.

Open Session Attendance

The open session will be accessible via teleconference. Registration in advance is required to receive the meeting invite for virtual attendance. Individuals interested in participating virtually should contact *TAC@bis.doc.gov* no later than 11:59 p.m. Eastern Time on July 29, 2025. A limited number of seats will be available for members of the public to attend the open session in person on a first-come basis. Reservations to attend in person are not accepted. Registration in advance is not required for in-person attendance, but you will be asked to sign an attendance log when you arrive.

Special Accommodations

Individuals requiring special accommodations to access the open session should contact *TAC@bis.doc.gov* no later than 11:59 p.m. Eastern Time on July 25, 2025, so that appropriate arrangements can be made.

Public Participation

To the extent that time permits, members of the public may present oral statements to the ETTAC. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of materials to the ETTAC members, the ETTAC suggests that members of the public forward their materials prior to the meeting via email to *TAC@bis.doc.gov*. Materials submitted by the public will be made public and therefore should not contain confidential information. Materials submitted by the public will be accessible via the Technical Advisory Committee (TAC) site at *https://tac.bis.doc.gov,* within 30 days after the meeting.

Closure Determination

The Deputy Assistant Secretary for Administration, performing the non-exclusive functions and duties of the Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined pursuant to 5 U.S.C. 1009(d), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. 1009(a)(1) and 1009(a)(3). The remaining portions of the meeting will be open to the public.

Meeting Cancellation

If the meeting is cancelled, a cancellation notice will be posted on the TAC website at *https://tac.bis.doc.gov*.

Kevin Coyne,

Committee Liaison Officer.

[FR Doc. 2025–13309 Filed 7–15–25; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials and Equipment Technical Advisory Committee

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Notice of partially closed meeting.

SUMMARY: The Materials and Equipment Technical Advisory Committee (METAC) advises and assists the Secretary of Commerce and other Federal officials on matters related to export control policies; the METAC will meet to review and discuss these matters. The meeting will be partially closed to the public pursuant to the exemptions under the Federal Advisory Committee Act (FACA) and the Government in the Sunshine Act.

DATES: The meeting will be held on August 7, 2025, from 10:00 a.m. to 3:30 p.m., Eastern Time (all times are Eastern Time). The open session will start at 10:00 a.m. and end at approximately 12:00 p.m., and the closed session will start at approximately 1:00 p.m. and will end no later than 3:30 p.m. Individuals requiring special accommodations to access the open session should contact *TAC@bis.doc.gov* no later than 11:59 p.m. on July 31, 2025, so that appropriate arrangements can be made. Individuals interested in participating virtually should contact *TAC@bis.doc.gov* no later than 11:59 p.m. on August 5, 2025.

ADDRESSES: The meeting will be held in Room 38026 of the Herbert C. Hoover Building, 1401 Constitution Avenue NW, Washington, DC (enter through the Main Entrance on 14th Street between Constitution and Pennsylvania Avenues). The open session will be accessible to the public via teleconference.

FOR FURTHER INFORMATION CONTACT: Kevin Coyne, Committee Liaison Officer, Bureau of Industry and Security, U.S. Department of Commerce. For additional information, contact *TAC@bis.doc.gov* or by phone 202–482–4933.

SUPPLEMENTARY INFORMATION:

Background

The Materials and Equipment Technical Advisory Committee (METAC) advises and assists the Secretary of Commerce (Secretary) and other Federal officials and agencies with respect to actions designed to carry out the policy set forth in Section 1752 of the Export Control Reform Act. The purpose of the meeting is to have Committee members and U.S. Government representatives mutually review updated technical data and policy-driving information that has been gathered.

Agenda

The open session will include open business discussions and industry presentations. The closed session will include discussion of matters determined to be exempt from the open meeting and public participation requirements found in Sections 1009(a)(1) and 1009(a)(3) of the Federal Advisory Committee Act (FACA) (5 U.S.C. 1001–1014). The exemption is authorized by Section 1009(d) of the FACA, which permits the closure of advisory committee meetings, or portions thereof, if the head of the agency to which the advisory committee reports determines such meetings may be closed to the public in accordance with subsection (c) of the Government in the Sunshine Act (5 U.S.C. 552b(c)). In this case, the applicable provisions of 5 U.S.C. 552b(c) are subsection 552b(c)(4), which permits closure to protect trade secrets and commercial or financial information that is privileged or confidential, and subsection 552b(c)(9)(B), which permits closure to protect information that would be likely to disclose information the premature

disclosure of which would be likely to significantly frustrate implementation of a proposed agency action. The closed session of the meeting will involve committee discussions and guidance regarding U.S. Government strategies and policies.

Open Session Attendance

The open session will be accessible via teleconference. Registration in advance is required to receive the meeting invite for virtual attendance. Individuals interested in participating virtually should contact *TAC@bis.doc.gov* no later than 11:59 p.m. Eastern Time on August 5, 2025. A limited number of seats will be available for members of the public to attend the open session in person on a first-come basis. Reservations to attend in person are not accepted. Registration in advance is not required for in-person attendance, but you will be asked to sign an attendance log when you arrive.

Special Accommodations

Individuals requiring special accommodations to access the open session should contact *TAC@bis.doc.gov* no later than 11:59 p.m. Eastern Time on July 31, 2025, so that appropriate arrangements can be made.

Public Participation

To the extent that time permits, members of the public may present oral statements to the METAC. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of materials to the METAC members, the METAC suggests that members of the public forward their materials prior to the meeting via email to *TAC@bis.doc.gov.* Materials submitted by the public will be made public and therefore should not contain confidential information. Materials submitted by the public will be accessible via the Technical Advisory Committee (TAC) site at *https://tac.bis.doc.gov,* within 30 days after the meeting.

Closure Determination

The Senior Advisor, performing the non-exclusive functions and duties of the Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined pursuant to 5 U.S.C. 1009(d), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. 1009(a)(1) and 1009(a)(3). The remaining portions of the meeting will be open to the public.

Meeting Cancellation

If the meeting is cancelled, a cancellation notice will be posted on the TAC website at *https://tac.bis.doc.gov.*

Kevin Coyne,

Committee Liaison Officer.

[FR Doc. 2025–13311 Filed 7–15–25; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 250709–0122; XRIN 0694–XC130]

Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Unmanned Aircraft Systems (UAS) and Their Parts and Components

AGENCY: Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce.

ACTION: Notice of request for public comments.

SUMMARY: On July 1, 2025, the Secretary of Commerce initiated an investigation to determine the effects on the national security of imports of unmanned aircraft systems (UAS) and their parts and components. This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended (Section 232). Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's (Department) Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security. This notice identifies issues on which the Department is especially interested in obtaining the public's views.

DATES: Comments may be submitted at any time but must be received by August 6, 2025.

ADDRESSES: Comments on this notice may be submitted to the Federal rulemaking portal at: *www.regulations.gov.* The *regulations.gov* ID for this notice is BIS–2025–0059. Please refer to XRIN 0694–XC130 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. The corresponding non-confidential version of those comments must be clearly marked ''PUBLIC.'' The file name of the non-confidential version should begin with the character ''P.'' Any submissions with file names that do not begin with either a ''BC'' or a ''P'' will be assumed to be public and will be made publicly available at: *https://www.regulations.gov.* Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: Stephen Astle, Director, Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482–4506, *UAS232@bis.doc.gov.* For more information about the Section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232.*

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2025, the Secretary of Commerce initiated an investigation under Section 232 (19 U.S.C. 1862) to determine the effects on national security of imports of unmanned aircraft systems (UAS) and their parts and components.

Request for Public Comments

This investigation is being undertaken in accordance with part 705 of the National Security Industrial Base Regulations (15 CFR parts 700 to 709) (NSIBR). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to BIS's Office of Strategic Industries and Economic

Security no later than August 6, 2025. The Department is particularly interested in comments and information directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

(i) the current and projected demand for UAS and their parts and components in the United States;

(ii) the extent to which domestic production of UAS and their parts and components can meet domestic demand;

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for UAS and their parts and components;

(iv) the concentration of U.S. imports of UAS and their parts and components from a small number of suppliers or foreign nations and the associated risks;

(v) the impact of foreign government subsidies and predatory trade practices on the competitiveness of the UAS and their parts and components industry, in the United States;

(vi) the economic impact of artificially suppressed prices of UAS and their parts and components due to foreign unfair trade practices and state-sponsored overproduction;

(vii) the potential for foreign nations and companies to weaponize their control over supplies of UAS and their parts and components;

(viii) the potential for foreign nations and companies to weaponize the capabilities or attributes of foreign-built UAS systems and their parts or components;

(ix) the feasibility of increasing domestic capacity for UAS and their parts and components to reduce import reliance;

(x) the impact of current trade policies on domestic production of UAS and their parts and components, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

(xi) any other relevant factors.

Material submitted by members of the public that is business confidential information will be exempted from public disclosure as provided for by § 705.6 of the regulations (see the **ADDRESSES** section of this notice). Communications from agencies of the United States Government will not be made available for public inspection. BIS does not maintain a separate public inspection facility. Requesters should first view the Bureau's web page, which can be found at: *https://efoia.bis.doc.gov/* (see ''Electronic FOIA'' heading). If requesters cannot access the website, they may call (202) 482–0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published at 15 CFR 4.1, *et seq.*

Julia Khersonsky,

Deputy Assistant Secretary for Strategic Trade.

[FR Doc. 2025–13365 Filed 7–14–25; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Domestic and International Client Export Services and Customized Forms Renewal

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 15, 2025.

ADDRESSES: Interested persons are invited to submit written comments to Katelynn Byers, PRA Process Administrator by email, *Katelynn.Byers@trade.gov* or *PRA@trade.gov.* Please refer to OMB Control Number 0625–0143 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Katelynn Byers, PRA Process Administrator by phone, 202–989–5979, and by email, *Katelynn.Byers@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The International Trade Administration's (ITA) is mandated by Congress to broaden and deepen the U.S. exporter base and to attract inward foreign direct investment. It accomplishes this by providing counseling, programs and services to help U.S. organizations export and conduct business in overseas markets. This information collection package enables ITA to provide appropriate global trade services to U.S. businesses and international buyers.

ITA offers a variety of services to enable clients to begin exporting and global trade or to expand existing export and global trade efforts. Clients may learn about available services from business related entities such as the National Association of Manufacturers, Federal Express, State Economic Development offices, the internet or word of mouth. ITA provides a standard set of services to assist clients with identifying potential overseas partners, establishing meeting programs with appropriate overseas business contacts and providing due diligence reports on potential overseas business partners. ITA also provides other global trade related services considered to be of a ''customized nature'' because they do not fit into the standard set of services but are driven by unique business needs of individual clients.

The dissemination of international market information and potential business opportunities for U.S. companies interested and actively exporting and conducting business globally are critical components of the ITA's global trade assistance programs and services. U.S. companies are able to conveniently access and indicate their interest in services by completing the appropriate forms via multiple ways, including via a website (*e.g.* trade.gov), web-based survey or form links, or paper-based forms.

ITA works closely with clients to educate them about the exporting/importing process and to help prepare them for global trading opportunities. When a client is ready to begin the process the field staff provide counseling to assist in the development of a global trade strategy. ITA provides fee-based, global trade related services designed to help a client's business presence internationally. The type of service that is offered to a client depends upon a client's business goals and where they are in the export/import process. Some clients are at the beginning of the process and require assistance with identifying potential distributors, whereas other clients may be ready to sign a contract with a potential distributor and require due diligence assistance.

Before ITA can provide global trade and export-related services to clients, such as assistance with identifying potential partners or providing due diligence, specific information is required to determine the client's business objectives and needs. For example, before ITA can provide a service to identify potential business partners, information is needed regarding if the client would like a potential partner to have specific technical qualifications, coverage in a specific market, English or foreign language ability or warehousing requirements. This information collection is designed to elicit such data so that appropriate services can be proposed and conducted to most effectively meet the client's global trading goals. Without these forms ITA is unable to provide services when requested by clients.

The forms ask U.S. businesses standard questions about their company details, demographic information, export/import experience, information about the products or services they wish to export/import and their goals. A few questions are tailored to a specific program type and will vary slightly with each program. ITA staff use this information to gain an understanding of clients' needs and objectives so that they can provide appropriate and effective assistance tailored to each U.S. business' particular global trade requirements.

II. Method of Collection

Clients will be asked to provide their information in multiple ways, including via a website (*e.g.* trade.gov), web-based survey or form links, or paper-based forms.

III. Data

OMB Control Number: 0625–0143.

Form Number(s): None.

Type of Review: Regular submission, revision of a current information collection.

Affected Public: Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government.

Estimated Number of Respondents: 200,000.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 34,133 hours.

Estimated Total Annual Cost to Public: $1,030,485.

Respondent's Obligation: Voluntary.

Legal Authority: U.S. Code: 15 U.S.C. 4724.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2025–13320 Filed 7–15–25; 8:45 am]

BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–187]

Overhead Door Counterbalance Torsion Springs From the People's Republic of China: Preliminary Affirmative Determination of Critical Circumstances, in Part, in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that critical circumstances exist, in part, with respect to imports of overhead door counterbalance torsion springs (overhead door springs) from certain producers and exporters from the People's Republic of China (China). Interested parties are invited to comment on this preliminary determination of critical circumstances.

DATES: Applicable July 16, 2025.

FOR FURTHER INFORMATION CONTACT: Laurel Smalley, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–3456.

SUPPLEMENTARY INFORMATION:

Background

On October 29, 2024, Commerce received a countervailing duty (CVD) petition concerning imports of overhead door springs from China filed in proper form on behalf of the petitioners, IDC Group Inc., Iowa Spring Manufacturing, Inc., and Service Spring Corp (collectively, the petitioners).[1] On November 25, 2024, we initiated this investigation [2] and, on April 3, 2025, Commerce published its affirmative *Preliminary Determination*.[3]

Commerce selected Foshan Nanhai Xulong Spring Factory (Xulong Spring) and Tianjin Wangxia Spring Co., Ltd. (Tianjin Wangxia) as the individually-examined respondents in this investigation.[4]

On June 24, 2025, the petitioners alleged that critical circumstances exist with respect to imports of overhead door springs from China, pursuant to section 703(e)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 531.206.[5]

In accordance with section 703(e)(1) of the Act and 19 CFR 351.206(c)(1), because the petitioners submitted the critical circumstances allegation more than 30 days before the scheduled date of the final determination,[6] Commerce will make a preliminary finding as to whether there is a reasonable basis to

[1] *See* Petitioners' Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties,'' dated October 29, 2024 (Petitions).

[2] *See Overhead Door Counterbalance Torsion Springs from the People's Republic of China and India: Initiation of Countervailing Duty Investigations,* 89 FR 92901 (November 25, 2024) (*Initiation Notice*).

[3] *See Overhead Door Counterbalance Torsion Springs from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 90 FR 14630 (April 3, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[4] *See* Memorandum, ''Respondent Selection,'' dated December 17, 2024.

[5] *See* Petitioners' Letter, ''Petitioners' Allegation of Critical Circumstances,'' dated June 24, 2025 (Critical Circumstances Allegation).

[6] The final determination for this CVD investigation is currently due no later than August 11, 2025. *See Preliminary Determination,* 90 FR at 14631.

believe or suspect that critical circumstances exist. Commerce is issuing its preliminary finding of critical circumstances within 30 days after the petitioners submitted the allegation.[7]

Period of Investigation (POI)

The POI is January 1, 2023, through December 31, 2023.

Critical Circumstances Allegation

The petitioners allege that there was a massive increase of imports of overhead door springs from China and provided monthly import data for the period June 2024 through March 2025.[8] The petitioners state that a comparison of total imports, by quantity, for the base period June 2024 through October 2024 to the comparison period November 2024 through March 2025, shows that imports of overhead door springs from China increased by 25.44 percent,[9] which is considered ''massive'' under 19 CFR 351.206(h)(2). The petitioners also allege that there is a reasonable basis to believe that there are subsidies in this investigation which are inconsistent with the Subsidies and Countervailing Measures Agreement of the World Trade Organization (SCM Agreement).[10]

Critical Circumstances Analysis

Section 703(e)(1) of the Act provides that Commerce will preliminarily determine that critical circumstances exist in a CVD investigation if there is a reasonable basis to believe or suspect that: (A) the alleged countervailable subsidy is inconsistent with the SCM Agreement;[11] and (B) there have been massive imports of the subject merchandise over a relatively short period.

In determining whether there are ''massive imports'' over a ''relatively short period,'' pursuant to section 703(e)(1)(B) of the Act and 19 CFR 351.206(h) and (i), Commerce normally compares the import volumes of the subject merchandise for at least three months immediately preceding the filing of the petition (*i.e.,* the base period) to a comparable period of at least three months following the filing of the petition (*i.e.,* the comparison period). However, the regulations also provide that if Commerce finds that importers, or exporters or producers, had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely, Commerce may consider a period of not less than three months from the earlier time.[12] Imports must increase by at least 15 percent during the comparison period to be considered massive.[13]

Alleged Countervailable Subsidies Are Inconsistent With the SCM Agreement

Xulong Spring

In the *Preliminary Determination,* we found that Xulong Spring, pursuant to section 776(b) of the Act, received countervailable subsidies inconsistent with the SCM Agreement under section 703(e)(1)(A) of the Act.[14] Such programs include the Export Loans from Chinese State-Owned Banks, Export Seller's Credit, Export Buyer's Credit, Export Credit Guarantees, Government of China and Sub-Central Government Subsidies for the Development of Famous Brands and China World Top Brands, Foreign Trade Development Fund Grants, Export Assistance Grants, Small and Medium-Sized Enterprises International Market Exploration/Development Fund programs, which were found to be export contingent in the *Preliminary Determination.*[15] Thus, because we preliminarily found that these programs are export contingent, we preliminarily find that the criterion under section 703(e)(1)(A) of the Act has been met.[16]

Tianjin Wangxia

In the *Preliminary Determination,* we found that Tianjin Wangxia did not receive any measurable countervailable subsidies found to be inconsistent with the SCM Agreement under section 703(e)(1)(A) of the Act.[17] However, on April 4, 2025, Tianjin Wangxia withdrew from the CVD investigation, and subsequently, Commerce cancelled verification of Tianjin Wangxia.[18] Therefore, because Commerce was unable to verify Tianjin Wangxia's claims of non-use for certain countervailable, export-contingent programs, we find that Tianjin Wangxia also received export-contingent countervailable subsidies under the Export Loans from Chinese State-Owned Banks, Export Seller's Credit, Export Buyer's Credit, Export Credit Guarantees, Government of China and Sub-Central Government Subsidies for the Development of Famous Brands and China World Top Brands, Foreign Trade Development Fund Grants, Export Assistance Grants, Small and Medium-Sized Enterprises International Market Exploration/Development Fund programs. Thus, because we preliminarily found that these programs are export contingent, we preliminarily find that the criterion under section 703(e)(1)(A) of the Act has been met with respect to Tianjin Wangxia.

Non-Responsive Companies

As explained in the *Preliminary Determination,* we preliminarily applied total adverse facts available (AFA) to Beled Co., Ltd./Beled (Shenxhen) Commerce Co., Ltd.; Jiaxing Taike Springs Co., Ltd; Kowloon Metal Spring Factory; Ningbo I Promise Import Export; and Xiamen Globe Truth GT Industries, pursuant to section 776(b) of the Act.[19] In applying total AFA to these five companies, we preliminarily determined that each benefited from countervailable subsidies under the Export Loans from Chinese State-Owned Banks, Export Seller's Credit, Export Buyer's Credit, Export Credit Guarantees, Government of China and Sub-Central Government Subsidies for the Development of Famous Brands and China World Top Brands, Foreign Trade Development Fund Grants, Export Assistance Grants, Small and Medium-Sized Enterprises International Market Exploration/Development Fund programs. Because we found that these programs are export contingent and therefore inconsistent with the SCM Agreement in the *Preliminary Determination,* we now preliminarily find, pursuant to section 776(b) of the Act, that the five non-responsive companies meet the criterion delineated by section 703(e)(1)(A) of the Act.

Massive Imports

There are no cooperative respondents under investigation. Therefore, in accordance with section 703(e)(1), and sections 776(a) and (b) of the Act, Commerce preliminarily determines that critical circumstances exist with respect to imports of overhead door springs from China for Xulong Spring,

[7] *See* 19 CFR 351.206(c)(2)(ii). In this case, 30 days after the petitioners submitted the allegation would place the deadline on Thursday, July 24, 2025.

[8] *See* Critical Circumstances Allegation at 7 and Attachment.

[9] *Id.* at 7.

[10] *Id.* at 4–5.

[11] Commerce limits its critical circumstances findings to those subsidies contingent upon export performance or use of domestic over imported goods (*i.e.,* those prohibited under Article 3 of the SCM Agreement). *See, e.g., Final Affirmative Countervailing Duty Determination and Final Negative Critical Circumstances Determination: Carbon and Certain Alloy Steel Wire from Germany,* 67 FR 55808–10 (August 30, 2002).

[12] *See* 19 CFR 351.206(i).

[13] *See* 19 CFR 351.206(h)(2).

[14] *See Preliminary Determination* PDM at 18–23.

[15] *Id.*

[16] *Id.*

[17] *See Preliminary Determination* PDM at 31–36.

[18] *See* Tianjin Wangxia's Letter, ''Tianjin Wangxia's Withdrawal of Participation in the Investigation,'' dated April 4, 2025; *see also* Commerce's Letter, ''Cancellation of Tianjin Wangxia Spring Co., Ltd. Verification,'' dated April 4, 2025.

[19] *See Preliminary Determination* PDM at 18–19.

Tianjin Wangxia, and the non-responsive companies.

To determine whether imports are massive within the meaning of 19 CFR 351.206(h) for all other exporters or producers, Commerce's normal practice is to subtract shipments reported by the cooperating mandatory respondents from the shipment data of subject merchandise. However, as stated above, there are no cooperative respondents under investigation. Therefore, for all other exporters and producers, we compared the monthly shipment data using import data from Trade Data Monitor (TDM) for the six months immediately preceding and following the filing of the petition. Because the petition was filed on October 29, 2024, in order to determine whether there was a massive surge in imports, Commerce compared the total volume of shipments during the period May 2024 through October 2024 with the volume of shipments during the period November 2024 through April 2025.[20] The quantity of shipments recorded in the TDM data for U.S. harmonized tariff schedule codes 7320.20.5020, 7320.20.5045, and 7320.20.5060 during the comparison period did not exceed the quantity of shipments recorded for the base period by 15 percent.[21] Therefore, we determine that the record does not support a determination that there is a massive surge in imports between the base and comparison periods for all other exporters and producers of overhead door springs from China.[22]

Accordingly, consistent with section 703(e)(1) of the Act, Commerce preliminarily determines that critical circumstances exist for imports of overhead door springs from China with respect to Xulong Spring, Tianjin Wangxia, and the non-responsive companies under investigation, and that critical circumstances do not exist for all other exporters or producers not individually examined. For the underlying data and results of Commerce's analysis, *see* the Critical Circumstances Analysis Memorandum.

Final Determination

We will make a final determination concerning critical circumstances in the final determination of this investigation, which is currently scheduled for August 11, 2025.

Public Comment

Case briefs or other written comments limited to Commerce's preliminary critical circumstances determination may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which this notice is published in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[23] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[24]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[25] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[26]

Suspension of Liquidation

In accordance with section 703(e)(2)(A) of the Act, for Xulong Spring, Tianjin Wangxia, and the non-responsive companies, we intend to direct U.S. Customs and Border Protection (CBP) to suspend liquidation of any unliquidated entries of subject merchandise from China entered, or withdrawn from warehouse for consumption, on or after January 3, 2025, which is 90 days prior to the date of publication of the *Preliminary Determination* in the **Federal Register**. For such entries, CBP shall require a cash deposit equal to the estimated preliminary subsidy rates established in the *Preliminary Determination.* This suspension of liquidation will remain in effect until further notice.

U.S. International Trade Commission (ITC) Notification

In accordance with section 703(f) of the Act, Commerce intends to notify the ITC of this preliminary determination of critical circumstances.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: July 11, 2025.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2025–13323 Filed 7–15–25; 8:45 am]

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[20] *See* Memorandum, ''Preliminary Critical Circumstances Analysis,'' dated concurrently with this memorandum (Critical Circumstances Analysis Memorandum), at Attachment.

[21] *Id.*

[22] *See, e.g., Prestressed Concrete Steel Wire from the Republic of Turkey: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination in Part,* 85 FR 59287 (September 21, 2020), and accompanying PDM at 5–7.

[23] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[24] *See* 19 351.309(c)(2) and (d)(2).

[25] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[26] *See APO and Service Final Rule.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–192]

Erythritol from People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that erythritol from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2024, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable July 16, 2025.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Hannah Lee, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–1216, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on January 2, 2025.[1] On May 7, 2025, Commerce postponed the preliminary determination of this investigation and the deadline is now July 11, 2025.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is erythritol from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*.[6] For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[7] Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily has relied upon facts otherwise available, with adverse inferences, for the China-wide entity. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[8] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[9]

Separate Rates

We have preliminarily granted a separate rate to certain companies that we did not select for individual examination.[10] In calculating the estimated weighted-average dumping margin for non-individually examined separate rate companies in a non-market economy LTFV investigation, Commerce normally looks to section 735(c)(5)(A) of the Act, which pertains to the calculation of the all-others rate in a market economy LTFV investigation, for guidance. Pursuant to section 735(c)(5)(A) of the Act, normally this rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for those companies individually examined, excluding zero and *de minimis* dumping margins, and any dumping margins based entirely under section 776 of the Act. The estimated weighted-average dumping margins in this preliminary determination are based entirely under section 776 of the Act. In an investigation where no estimated weighted-average dumping margins other than zero, *de minimis,* or those determined entirely under section 776 of the Act have been established for individually examined respondents, in accordance with section 735(c)(5)(B) of the Act, Commerce typically calculates a simple average of the dumping margins alleged in the petition and applies the results to all other producers and exporters not individually examined.[11] Therefore, in this preliminary determiantion, we are applying the simple average of the dumping margins alleged in the petition to the non-individually examined companies eligible for a separate rate. The simple average of the dumping margins allged in the Petition is 371.62 percent.[12]

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Beijing Refine Biology Co., Ltd	Chuzhou Refine Biology Co., Ltd	371.62	371.53

[1] *See Erythritol From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 90 FR 1957 (January 10, 2025) (*Initiation Notice*).

[2] *See Erythritol From the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation,* 90 FR 19269 (May 7, 2025).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Erythritol from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[5] *See Initiation Notice.*

[6] *See* Icon Foods, Inc.'s Letter, ''Request for Amended Scope Language,'' dated May 9, 2025; *see also* Sanyuan's Letter, ''Scope Comments,'' dated May 9, 202;, and Cargill, Incorporated Letter, ''Rebuttal Scope Comments'' dated May 23, 2025.

[7] *See* Memorandum, ''Less-Than-Fair-Value and Countervailing Duty Investigations of Erythritol from the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated concurrently with this preliminary determination (Preliminary Scope Decision Memorandum).

[8] *See Initiation Notice,* 90 FR at 1961.

[9] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *https://enforcement.trade.gov/policy/bull05-1.pdf.*

[10] *See* the Prelimimary Decision Memorandum for additional details.

[11] *See, e.g., Certain Preserved Mushrooms from Spain: Final Affirmative Determination of Sales Less Than Fair Value,* 88 FR 18120 (March 27, 2023).

[12] The dumping margins alleged in the Petition are 270.00 percent, 305.86 percent, 393.28 percent, 438.32 percent, and 450.64 percent. *See Initiation Notice,* and accompanying Checklist, ''Antidumping Duty Investigation Initiation Checklist,'' dated January 2, 2025, at 7.

[13] The China-wide entity includes Dongxiao Biotechnology Co., Ltd. (Dongxiao) and Shandong Sanyuan Biotechnology Co., Ltd. (Sanyuan) the two producers selected as mandatory respondents in this investigation. *See* Preliminary Decision Memorandum at 2.

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Hunan Nutramax Inc	Hunan Nutramax Inc	371.62	371.53
Shandong Newnature Biotechnology Co., Ltd	Shandong Sanyuan Biotechnology Co., Ltd	371.62	371.53
China-Wide Entity [13]		450.64	450.64

* This rate is based on facts available with adverse inferences.

Suspension of Liquidation and Cash Deposit Requirements

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit for estimated antidumping duties equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above as follows: (1) for the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of China producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the China producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the ''Preliminary Determination'' section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits for estimated antidumping duties at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions and cash deposit requirements will remain in effect until further notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the China-wide entity, including the mandatory respondents, in this investigation, in accordance with section 776 of the Act, and the applied AFA rate is based solely on the information included in the Petition, there are no calculations to disclose.[14]

Verification

Because the two mandatory respondents in this investigation did not provide information requested by Commerce, and Commerce preliminarily determines that both of the mandatory respoondents have been uncooperative, verification will not be conducted.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of this preliminary determination in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[15] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[16]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[17] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests

[14] *Id.*

[15] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[16] *See* 19 351.309(c)(2) and (d)(2).

[17] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[18] *See APO* and *Service Final Rule.*

should contain: 1) the party's name, address, and telephone number; 2) the number of participants and whether any participant is a foreign national; and 3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On June 16 and 17, 2025, pursuant to 19 CFR 351.210(e), both mandatory respondents, Dongxiao and Sanyuan, requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[19] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the ITC of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: July 11, 2025.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The product within the scope of this investigation is erythritol, which is a sugar alcohol, commonly referred to as a polyol, typically produced by the fermentation of glucose using enzymes and yeast or yeast-like fungi (though the scope includes erythritol produced using any other feedstock or organism). Erythritol is an organic compound with the molecular formula $C_4 H_{10} O_4$ and a Chemical Abstracts Service (CAS) registry number of 149–32–6. Other names for erythritol include *meso*–erythritol, (2R, 3S)–butan–1,2,3,4–tetrol, butane–1,2,3,4–tetrol, or *meso*–1,2,3,4–Tetrahydryoxybutane.

Erythritol typically appears as a white crystalline, odorless product that rapidly dissolves in water. While erythritol is typically produced in the crystalline form or as a fine powder or in directly compressible form, the scope of this investigation covers all physical forms and grades of erythritol, including organic erythritol.

The merchandise covered by this investigation is classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2905.49.4000. Erythritol may also enter under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings and the CAS registry number are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Discussion of the Methodology
V. Adjustment Under Section 777(A)(f) of the Act
VI. Adjustments to Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
VII. Recommendation

[FR Doc. 2025–13322 Filed 7–15–25; 8:45 am]

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[19] *See* Dongxiao's Letter, ''Dongxiao's Request to Postpone Final Determination,'' dated June 16, 2025; *see also* Sanyuan's Letter, ''Request for Postponement of Final AD Determination,'' dated June 17, 2025.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE835]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Washington Department of Transportation Mukilteo Wingwalls Repair Project in Puget Sound, Washington

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the Washington Department of Transportation (WSDOT) for authorization to take marine mammals incidental to the Mukilteo Wingwalls Repair Project in Puget Sound, Washington. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than August 15, 2025.

ADDRESSES: Comments should be addressed to Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.Fleming@noaa.gov.* Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed below.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or

received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Kate Fleming, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms used above are included in the relevant sections below and can be found in section 3 of the MMPA (16 U.S.C. 1362) and NMFS regulations at 50 CFR 216.103.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Summary of Request

On February 27, 2025, NMFS received a request from the Washington Department of Transportation (WSDOT) for an IHA to take marine mammals incidental to the Mukilteo Wingwalls Repair Project in Puget Sound, Washington. Following NMFS' review of the application, and discussions between NMFS and WSDOT, the application was deemed adequate and complete on April 24, 2025. WSDOT submitted a final revised version on May 30, 2025. WSDOT's request is for take of nine species of marine mammals by Level B harassment and, for a subset of six of these species, Level A harassment. Neither WSDOT nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued IHAs to WSDOT for similar work. On July 25, 2014, NMFS issued a requested IHA for the Mukilteo Ferry Terminal Replacement Project, to place the new terminal at Tank Farm. Work was delayed and a new IHA was issued on August 2, 2015. On August 3, 2017, NMFS issued a requested IHA for Phase 2 of the Mukilteo Multimodal Project in Mukilteo, Washington, between August 1, 2017 and July 31, 2018 (82 FR 44164, September 21, 2017). This project was designed to relocate the Mukilteo Ferry Terminal approximately one-third of a mile east of the existing terminal. On August 20, 2018, NMFS issued a subsequent IHA to cover work that was not completed under the prior IHA (83 FR 43849, August 28, 2018), which was subsequently reissued because work was delayed (84 FR 39263, August 9, 2019). An IHA to cover the anticipated final year of the project was issued on July 27, 2020 (85 FR 47737, August 6, 2020). WSDOT's monitoring reports are available online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities* and information regarding WSDOT's monitoring results may be found in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat.

Description of Proposed Activity

Overview

At the Mukilteo Ferry Terminal, wingwalls are used to guide the Mukilteo ferry into the slip during landings. The Mukilteo-Clinton ferry route is part of State Route (SR) 525, the major transportation corridor crossing Possession Sound (the portion of Puget Sound that separates Island County/Whidbey Island from the mainland). The wingwalls are designed to withstand glancing impacts from the ferries. However, the left wingwall was moved out of position by approximately two feet during a normal ferry landing. The purpose of this project is to strengthen the left wingwall to withstand normal landing impacts.

The activities that have the potential to cause take of marine mammals include installation of six 30-inch (76 centimeter) (cm)) steel piles by vibratory or impact pile driving, and installation and removal of two 30-in (76 cm) steel piles by vibratory pile driving. A total of 6 construction days are planned between October 2025 and February 2026.

Dates and Duration

The proposed IHA would be valid for the statutory maximum of one year from the date of effectiveness, and will become effective upon written notification from the applicant to NMFS, but not beginning later than one year from the date of issuance or extending beyond two years from the date of issuance. All in-water work would be conducted during the Washington Department of Fish and Wildlife (WDFW) authorized work times in saltwater areas. WSDOT indicates that the in-water work window in this area is July 15 through February 15 to avoid working when ESA-listed salmonids are most likely to be present. While in-water work associated with this project could occur between August 1, 2025 and February 15, 2026, WSDOT indicates that October 2025 is the target project start date.

The project would require 6 days of in-water construction. In-water construction activities would occur during daylight hours only.

Specific Geographic Region

The Mukilteo Ferry Terminal is in the City of Mukilteo, Snohomish County, Washington. The terminal is in Township 28N, Range 4E, Section 33 (figure 1). Land use in the Mukilteo area is a mix of residential, commercial, industrial, and open space and/or undeveloped lands.

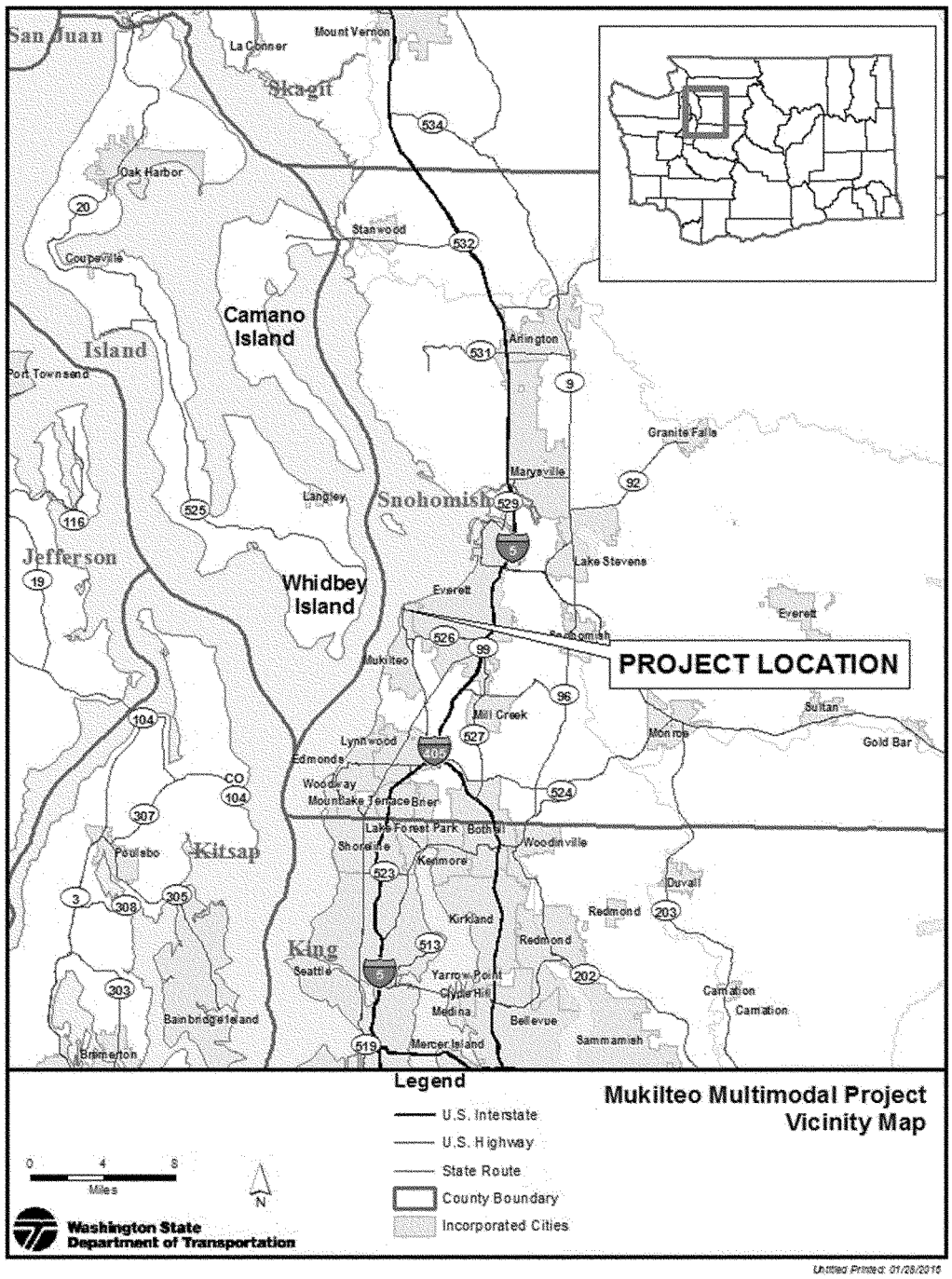

Figure 1—Location of Mukilteo Ferry Terminal

Detailed Description of the Specified Activity

WSDOT is repairing the left wingwalls at the Mulkiteo Terminal by adding two new wingwall bents. To do so, six 30-in (76 cm) permanent steel piles would be installed with a vibratory hammer, then proofed (impacted). A bubble curtain would be used during all impacting. Four piles would be driven plumb (vertical) and two would be driven battered (driven at an angle) to provide additional support to the wingwall. Two temporary 30-in (76 cm) steel piles would be installed and removed with a vibratory hammer (no impacting). The temporary piles would support a guide to drive the two battered permanent piles.

TABLE 1—PILE TYPES, INSTALLATION METHODS, AND DURATIONS

Method	Steel pile size (inch)	Total number	Minutes (strikes) per pile	Piles per day	Minutes (strikes) per day	Construction days
Permanent						
Vibratory Install (vertical)	30	4	60	4	240	1
Impact Install (vertical)			60 (200)		240 (4800)	1
Vibratory Install (battered)	30	2	60	2	120	1
Impact Install (battered)			60 (1200)		120 (2400)	1
Temporary						
Vibratory Install	30	2	60	2	120	1
Vibratory Removal			60	2	120	1

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 2 lists all species or stocks for which take is expected and proposed to be authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality (M/SI) from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Pacific SARs. All values presented in table 2 are the most recent available at the time of publication (including from the draft 2024 SARs) and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 2—SPECIES [1] WITH ESTIMATED TAKE FROM SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
Family Eschrichtiidae:						
Gray whale	*Eschrichtius robustus*	Eastern N Pacific	-, -, N	26,960 (0.05, 25,849, 2016)	801	131
Family Balaenopteridae (rorquals):						
Minke whale	*Balaenoptera acutorostrata*	CA/OR/WA	-, -, N	915 (0.792, 509, 2018)	4.1	≥0.19
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Killer whale	*Orcinus orca*	West Coast Transient	-, -, N	349 (N/A[5], 349, 2018)	3.5	0.4
Family Phocoenidae (porpoises):						
Dall's porpoise	*Phocoenoides dalli*	CA/OR/WA	-, -, N	16,498 (0.61, 10,286, 2018)	99	≥0.66
Harbor porpoise	*Phocoena phocoena*	Washington Inland Waters	-, -, N	11,233 (0.37, 8,308, 2015)	66	≥7.2
Order Carnivora—Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California sea lion	*Zalophus californianus*	U.S.	-, -, N	257,606 (N/A, 233,515, 2014).	14,011	>321
Steller sea lion	*Eumetopias jubatus*	Eastern	-, -, N	36,308 (N/A[6], 36,308, 2022)	2,178	93.2

TABLE 2—SPECIES [1] WITH ESTIMATED TAKE FROM SPECIFIED ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Washington Northern Inland Waters.	-, -, N	UNK [7] (UNK, UNK, UNK)	UND	9.8
Northern elephant seal	*Mirounga angustirostris*	CA Breeding	-, -, N	187,386 (N/A, 85,369, 2013)	5,122	13.7

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/*).

[2] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[5] N_{est} is based upon count of individuals identified from photo-ID catalogs in analysis of a subset of data from 1958–2018.

[6] N_{est} is best estimate of counts, which have not been corrected for animals at sea during abundance surveys. Estimates provided are for the U.S. only.

[7] While the draft 2024 SAR suggests the abundance estimates for the Washington Northern Inland Waters stock of harbor seal is unknown (UNK), Pearson *et al.,* 2024. Indicates that the most recent N_{est} is 15,898 and the N_{min} is 14,005.

As indicated above, all nine species (with nine managed stocks) in table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. All species that could potentially occur in the proposed project area are included in table 3–1 of the IHA application. While humpback whales (Central America/ Southern Mexico—CA/OR/WA; Mainland Mexico—CA/OR/WA; and Hawai'i stocks), and southern resident killer whales have been documented in the area, take is not proposed for authorization. WSDOT proposes, with NMFS' concurrence, to avoid take of these species by implementing monitoring and mitigation measures (see Proposed Mitigation and Proposed Monitoring and Reporting sections below).

Generally, southern resident killer whales and humpback whales are considered common in the Puget Sound (Olson *et al.,* 2018; Olson *et al.,* 2024), though the greatest density of humpback whale sightings are off the south end of Vancouver Island in the Strait of Juan de Fuca (Olsen *et al.,* 2024) and the occurrence of southern resident killer whale depends on prey abundance. During the multi-year WSDOT Multimodal Construction Project, PSOs located at the project site, on the Mukilteo—Clinton ferry, and additional locations on Whidbey Island, Camano Island, and north of Everett, Washington, monitored for 169 days 2015 and 2021, between the months of August and February. Across 169 monitoring days, a total of 29 southern resident killer whales in 6 groups were observed, all within the same project year. During the same 169 day monitoring period, a single humpback whale was observed on two occasions. For this project, WSDOT would establish shutdown zones for southern resident killer whale and humpback whale at the extent of the estimated Level B harassment zone. WSDOT would shut down if a southern resident killer whale, a killer whale in which the stock has been unidentified, a humpback whale, or an unidentified mysticete is observed near or approaching the Level B harassment zone. WSDOT would also monitor marine mammal occurrence and movement with the Orca Network and the Whale Report Alert System (WRAS) networks daily for this project to ensure PSOs are aware of these species locations in Puget Sound. Due to these mitigation and monitoring measures, which WSDOT has experience designing and implementing, and the fact that these species are highly conspicuous, incidental take of southern resident killer whales and humpback whales are not expected to occur during this project.

Gray Whale

During migration from Mexico to the Arctic, a subpopulation of the Eastern North Pacific stock of Gray whales, commonly referred to as the Pacific Coast Feeding Group (PCFG), stops and feeds along the coasts of Oregon and Washington including the Northern Puget Sound (Calambokidis *et al.,* 2024). A subgroup of the PCFG that feed in the Puget Sound, recently termed as ''Sounders'' gray whales occurs in highest concentrations on the Southern ends of Whidbey and Camano Islands in the North Puget Sound (Calambokidis *et al.,* 2024). However, they typically arrive in March and generally leave the area before June 1, when project activities are not planned to occur.

Across 169 Mukilteo Multimodal Project monitoring days between 2015 and 2021, a single gray whale was observed on two occasions by PSOs.

Minke Whale

Minke whales are reported in Washington inland waters year-round, although a few are reported in the winter (Calambokidis and Baird 1994). Minke whales are relatively common in the San Juan Islands and Strait of Juan de Fuca (especially around several of the banks in both the central and eastern Straits) but are relatively rare in Puget Sound. Across 169 monitoring days between 2015 and 2021, no minke whales were observed by PSOs during the Mukilteo Multimodal Project. However, an occurrence of minke whale was reported near the project area by the Pacific Whale Watching Foundation in 2022 (Gless and Krieger, 2023).

Transient Killer Whale

West coast transient killer whales are documented intermittently year-round in Washington inland waters. Within Puget Sound, transient killer whales primarily hunt pinnipeds and porpoises. Across 169 monitoring days between 2015 and 2021, 43 transient killer whales (11 groups) were reported by PSOs. The maximum pod size reported by PSOs was eight.

Dall's Porpoise

Within the inland waters of Washington and British Columbia, this species is most abundant in the Strait of Juan de Fuca east to the San Juan Islands (Nyswander *et al.,* 2005). Dall's porpoises may be most abundant in Puget Sound during the winter

(Nysewander *et al.,* 2005; WDFW 2007). While sightings appear to be decreasing (Evenson *et al.,* 2016), Dall's porpoises may occur in all areas of inland Washington at all times of year, but with different distributions throughout Puget Sound from winter to summer.

Across 169 monitoring days between 2015 and 2021, a total of 2 Dall's porpoises were observed by PSOs during the Mukilteo Multimodal Project from the Mukilteo—Clinton Ferry monitoring location.

Harbor Porpoise

Harbor porpoise are known to occur year-round in the inland trans-boundary waters of Washington and British Columbia, Canada and along the Oregon/Washington coast (Barlow *et al.,* 1988). There was a significant decline in harbor porpoise sightings within southern Puget Sound between the 1940s and 1990s but sightings have increased seasonally more recently (Carretta *et al.,* 2019). Annual winter aerial surveys conducted by the WDFW from 1995 to 2015 revealed an increasing trend in harbor porpoise in Washington inland waters, including the return of harbor porpoise to Puget Sound. The data suggest that harbor porpoise were already present in Juan de Fuca, Georgia Straits, and the San Juan Islands from the mid-1990s to mid-2000s, and then expanded into Puget Sound and Hood Canal from the mid-2000s to 2015, areas they had used historically but abandoned (Evenson *et al.,* 2016).

Across 169 monitoring days between 2015 and 2021, between 194 and 214 harbor porpoises were observed by PSOs during the Mukilteo Multimodal Project, for an average daily occurrence of 1.3 harbor porpoises and average group size of two.

California Sea Lion

Only male California sea lions migrate into Pacific Northwest waters, with females remaining in waters near their breeding rookeries off the coast of California and Mexico. They use haul-out sites along the outer coast, Strait of Juan de Fuca, and in Puget Sound. Haul-out sites are located on jetties, offshore rocks and islands, log booms, marina docks, and navigation buoys. This species also may be frequently seen resting in the water, rafted together in groups in Puget Sound. The closest documented California sea lion haul out sites to the Mukilteo Ferry Terminal are 3.2 miles northeast on the Everett Harbor buoys (Figure 3–1 in application). The number of California sea lions using the buoys is less than 20 (Jeffries, *et al.,* 2000).

Across 169 monitoring days between 2015 and 2021, between 2,029 and 2,125 California sea lions were observed by PSOs during the Mukilteo Multimodal Project, for an average daily occurrence of 12 California sea lions and average group size of 1.

Steller Sea Lion

Steller sea lions use haul-out locations in Puget Sound, and may occur at the same haul-outs as California sea lions. Across 169 monitoring days between 2015 and 2021, 43 Steller sea lions were observed by PSOs during the Mukilteo Multimodal Project, for an average daily occurrence of 0.25 Steller sea lions and average group size of 1.

Harbor Seal

Harbor seals are the most common and the only pinniped that breeds and remains in the inland marine waters of Washington year-round (Calambokidis and Baird 1994a). Harbor seals haul out on rocks, reefs and beaches, and feed in marine, estuarine and occasionally fresh waters. Harbor seals display strong fidelity for haul out sites (Pitcher and McAllister 1981).

There is a documented California sea lion/harbor seal haulout approximately 8 km NE of the project site. (Figure 3–1). Seals and sea lions also make use of undocumented docks, buoys, and beaches in the area.

Across 169 monitoring days between 2015 and 2021, between 3,506 and 3,513 harbor seals were observed by PSOs during the Mukilteo Multimodal Project, for an average daily occurrence of 20.8 harbor seals and average group size of 1.

Northern Elephant Seal

Elephant seals are generally considered rare in Puget Sound. However, a female elephant seal has been reported hauled out in Mutiny Bay on Whidbey Island periodically since 2010. She was observed alone for her first three visits to the area, but in March 2015, she was seen with a pup. Since then, she has produced three more pups between 2018 and 2021 (Orca Network 2025). Northern elephant seals generally give birth in January but this individual has repeatedly given birth in March. She typically returns to Mutiny Bay (not included in the ensonified area) in April and May to molt (when project activities are not planned). Her pups have also repeatedly returned to haul out on nearby beaches and one has also had a pup (Orca Network 2025).

Across 169 monitoring days between 2015 and 2021, one to two northern elephant seals were observed by PSOs during the Mukilteo Multimodal Project from the New Mukilteo Ferry Terminal monitoring location.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Generalized hearing ranges were chosen based on the ~65 decibel (dB) threshold from composite audiograms, previous analyses in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS 2024) as reflected below in table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS

[NMFS, 2024]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36 kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	200 Hz to 165 kHz.

TABLE 3—MARINE MAMMAL HEARING GROUPS—Continued

[NMFS, 2024]

Hearing group	Generalized hearing range *
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65 dB threshold from composite audiogram, previous analysis in NMFS 2018, and/or data from Southall *et al.,* 2007; Southall *et al.,* 2019. Additionally, animals are able to detect very loud sounds above and below that ''generalized'' hearing range. Hz = Hertz. kHz = Kilohertz.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far (American National Standards Institute (ANSI), 1995). The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity), but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the project would include impact pile driving, and vibratory pile driving and removal. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive. Impulsive sounds (*e.g.,* explosions, gunshots, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high peak sound pressure with rapid rise time and rapid decay (ANSI, 1986; National Institute of Occupational Safety and Health (NIOSH), 1998; NMFS, 2018). Non-impulsive sounds (*e.g.,* aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with rapid rise/decay time that impulsive sounds do (ANSI, 1995; NIOSH, 1998; NMFS, 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997, in Southall *et al.,* 2007).

Two types of hammers would be used on this project: impact and vibratory. Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce significantly less sound than impact hammers. Peak sound pressure levels (SPLs) may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.,* 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.,* 2005).

The likely or possible impacts of WSDOT's proposed activity on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of equipment and personnel; however, any impacts to marine mammals are expected to be primarily acoustic in nature. Acoustic stressors include effects of heavy equipment operation during pile installation and removal.

Acoustic Effects

The introduction of anthropogenic noise into the aquatic environment from pile driving is the means by which marine mammals may be harassed from WSDOT's specified activity. In general, animals exposed to natural or anthropogenic sound may experience behavioral, physiological, and/or physical effects, ranging in magnitude from none to severe (Southall *et al.,* 2007, 2019). In general, exposure to pile driving noise has the potential to result in behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior) and, in limited cases, an auditory threshold shift (TS). Exposure to anthropogenic noise can also lead to

non-observable physiological responses such an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions such as communication and predator and prey detection. The effects of pile driving on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mom with calf), duration of exposure, the distance between the sampling site and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.,* 2004; Southall *et al.,* 2007). Here we discuss physical auditory effects (TSs) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced TS as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018, 2024). The amount of TS is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018, 2024), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.,* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral).

Auditory injury and permanent threshold shift (PTS)—NMFS defines auditory injury (AUD INJ) as ''damage to the inner ear that can result in destruction of tissue . . . which may or may not result in PTS'' (NMFS, 2024). NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024). Available data from humans and other terrestrial mammals indicate that a 40-dB TS approximates PTS onset (Ward *et al.,* 1958, 1959; Ward 1960; Kryter *et al.,* 1966; Miller, 1974; Ahroon *et al.,* 1996; Henderson *et al.,* 2008). PTS levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Reichmuth 2019), there are no empirical data measuring PTS in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary threshold shift (TTS)—A temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from cetacean TTS measurements (Southall *et al.,* 2007, 2019), a TTS of 6 dB is considered the minimum TS clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.,* 2000; Finneran *et al.,* 2000, 2002). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with cumulative sound exposure level (SEL_{cum}) in an accelerating fashion: At low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in *Masking,* below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present.

Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.,* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound. While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. For cetaceans, published data on the onset of TTS are limited to captive bottlenose dolphin (*Tursiops truncatus*), beluga whale, harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*) (Southall *et al.,* 2019). For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*) and California sea lions (*Zalophus californianus*) (Kastak *et al.,* 1999, 2007; Kastelein *et al.,* 2019b, 2019c, 2021, 2022a, 2022b; Reichmuth *et al.,* 2019; Sills *et al.,* 2020). TTS was not observed in spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to single airgun impulse sounds at levels matching previous predictions of TTS onset (Reichmuth *et al.,* 2016). These studies examine hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of threshold shift at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity for a species or hearing group, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.,* a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.,* 2019a, 2019c). Note that in general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.,* 2009; Finneran *et al.,* 2010; Kastelein *et al.,* 2014, 2015). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from

intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.,* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*)) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echolocating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.,* 2021). Data available on noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2018). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above that inducing mild TTS (*e.g.,* a 40-dB threshold shift approximates PTS onset (Kryter *et al.,* 1966; Miller, 1974), while a 6-dB threshold shift approximates TTS onset (Southall *et al.,* 2007, 2019). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007, 2019). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Activities for this project include impact and vibratory pile driving and removal. For the proposed project, these activities would not occur at that same time and there would likely be pauses in activities producing the sound during each day. Given these pauses and the fact that many marine mammals are likely moving through the project areas and not remaining for extended periods of time, the potential for TS declines.

Behavioral Harassment—Exposure to noise from pile driving and DTH also has the potential to behaviorally disturb marine mammals. Generally speaking, NMFS considers a behavioral disturbance that rises to the level of harassment under the MMPA a non-minor response—in other words, not every response qualifies as behavioral disturbance, and for responses that do, those of a higher level, or accrued across a longer duration, have the potential to affect foraging, reproduction, or survival. Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses may include changing durations of surfacing and dives, changing direction and/or speed; reducing/increasing vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); eliciting a visible startle response or aggressive behavior (such as tail/fin slapping or jaw clapping); and avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2004; Southall *et al.,* 2007, 2019; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B and C of Southall *et al.* (2007) and Gomez *et al.,* (2016) for reviews of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2004). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

As noted above, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; Wartzok *et al.,* 2004; National Research Council (NRC), 2005). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997; Finneran *et al.,* 2003). Observed responses of wild marine mammals to loud pulsed sound sources (*e.g.,* seismic airguns) have been varied but often consist of avoidance behavior or other behavioral changes (Richardson *et al.,* 1995; Morton and Symonds, 2002; Nowacek *et al.,* 2007).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely and may consist of increased or

decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Costa *et al.,* 2003; Ng and Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013a, 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.,* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2001, 2005, 2006; Gailey *et al.,* 2007). For example, harbor porpoise respiration rate increased in response to pile driving sounds at and above a received broadband SPL of 136 dB (zero-peak SPL: 151 dB re 1 micropascal (µPa); SEL of a single strike: 127 dB re 1 μPa^2-s) (Kastelein *et al.,* 2013).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003) or vocalizations (Foote *et al.,* 2004), respectively, while North Atlantic right whales (*Eubalaena glacialis*) have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.,* 1994).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.,* 1984). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Bowers *et al.,* 2018). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (England *et al.,* 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fishes and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a 5-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than 1 day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive (*i.e.,* meaningful) behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Between 2015 and 2021, during the months of August through February, the WSDOT documented observations of marine mammals during construction activities at the same project site (New Mukilteo Terminal) (see 85 FR 47737, August 6, 2020; 84 FR 39263, August 9, 2019; 83 FR 43849, August 28, 2018; 82 FR 21793, May 10, 2017; 80 FR 54535,

September 10, 20215) for a total of 169 monitoring days. During the 2020–2021 season, 86 California sea lions were observed within the estimated Level B harassment zone during pile driving activities, mostly traveling. Other behaviors reported while pile driving was occurring were loafing, diving, resting, surfacing, and spy hopping. Eleven harbor porpoises were observed mostly traveling during this time but two were observed spy hopping. A total of 119 harbor seals and 7 Steller sea lions were observed, primarily traveling and looking, but some of both species were also observed diving, resting, surfacing and spy hopping. Similar behaviors were observed during prior years in addition to foraging. No other species were documented within any harassment zones while pile driving was being conducted.

Given the similarities in activities and habitat and the fact the same species are involved, we expect similar behavioral responses of marine mammals to the WSDOT's specified activity. That is, disturbance, if any, is likely to be temporary and localized (*e.g.,* small area movements).

Stress Response—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar projects in the area.

Auditory Masking—Since many marine mammals rely on sound to find prey, moderate social interactions, and facilitate mating (Tyack, 2008), noise from anthropogenic sound sources can interfere with these functions, but only if the noise spectrum overlaps with the hearing sensitivity of the receiving marine mammal (Southall *et al.,* 2007; Clark *et al.,* 2009; Hatch *et al.,* 2012). Chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.,* 2009). Acoustic masking is when other noises such as from human sources interfere with an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995; Erbe *et al.,* 2016). Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions (Hotchkin and Parks, 2013).

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is human-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect (though not necessarily one that would be associated with harassment).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2010; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors

(Hotchkin and Parks, 2013). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Marine mammals at or near the proposed WSDOT project site may be exposed to anthropogenic noise which may be a source of masking. Vocalization changes may result from a need to compete with an increase in background noise and include increasing the source level, modifying the frequency, increasing the call repetition rate of vocalizations, or ceasing to vocalize in the presence of increased noise (Hotchkin and Parks, 2013). For example, in response to loud noise, beluga whales may shift the frequency of their echolocation clicks to prevent masking by anthropogenic noise (Eickmeier and Vallarta, 2022).

Masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as vibratory pile driving and removal. Energy distribution of pile driving covers a broad frequency spectrum, and sound from pile driving would be within the audible range of pinnipeds and cetaceans present in the proposed action area. While some construction during the WSDOT's activities may mask some acoustic signals that are relevant to the daily behavior of marine mammals, the short-term duration and limited areas affected make it very unlikely that the fitness of individual marine mammals would be impacted.

Airborne Acoustic Effects—Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would previously have been ''taken'' because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Marine Mammal Habitat Effects

The WSDOT's proposed construction activities could have localized, temporary impacts on marine mammal habitat and their prey by increasing in-water SPLs and slightly decreasing water quality. Increased noise levels may affect acoustic habitat (see *Masking*) and adversely affect marine mammal prey in the vicinity of the project area (see discussion below). During impact and vibratory pile driving and removal, elevated levels of underwater noise would ensonify a portion of Puget Sound, where both fish and mammals occur, and could affect foraging success. Additionally, marine mammals may avoid the area during construction; however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects to the individuals or populations. In-water pile driving activities would also cause short-term effects on water quality due to increased turbidity. Temporary and localized increase in turbidity near the seafloor would occur in the immediate area surrounding the area where piles are installed or removed. In general, turbidity associated with pile installation is localized to about a 25 ft (7.6 m) radius around the pile (Everitt *et al.,* 1980). The sediments of the project site would settle out rapidly when disturbed. Cetaceans are not expected to be close enough to the pile driving areas to experience effects of turbidity, and any pinnipeds could avoid localized areas of turbidity.

In-water Construction Effects on Potential Foraging Habitat—The proposed activities would not result in permanent impacts to habitats used directly by marine mammals. The areas likely impacted by the proposed action are relatively small compared to the total available habitat in Puget Sound. The total seafloor area affected by piling activities is small compared to the vast foraging areas available to marine mammals at either location. At best, the areas impacted provide marginal foraging habitat for marine mammals and fishes. Furthermore, pile driving at the project locations would not obstruct movements or migration of marine mammals.

Avoidance by potential prey (*i.e.,* fish or, in the case of transient killer whales, other marine mammals) of the immediate area due to the temporary loss of this foraging habitat is also possible. The duration of fish and marine mammal avoidance of this area after pile driving activities is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. Any behavioral avoidance by fish or marine mammals of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity.

In-water Construction Effects on Potential Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although

several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.,* Pena *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Cott *et al.,* 2012). More commonly, though, the impacts of noise on fish are temporary.

SPLs of sufficient strength have been known to cause auditory injury, non-auditory injury, and mortality in fish. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012a) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013).

The greatest potential impact to fishes during construction would occur during impact pile installation of 30-in steel piles, which is estimated to occur on up to 6 days for a maximum of 4800 strikes per day for up to 4 hours over the course of the day. In-water construction activities would only occur during daylight hours, allowing fish to forage and transit the project area in the evening. Vibratory pile driving and removal would possibly elicit behavioral reactions from fishes such as temporary avoidance of the area but is unlikely to cause injuries to fishes or have persistent effects on local fish populations.

The most likely impact to fishes from pile driving and removal activities in the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of the area after pile driving stops is unknown but a rapid return to normal recruitment, distribution, and behavior is anticipated. There are times of known seasonal marine mammal foraging when fish are aggregating but the impacted areas are small portions of the total foraging habitats available in the regions. In general, impacts to marine mammal prey species are expected to be minor and temporary. Further, it is anticipated that preparation activities for pile driving and removal (*i.e.,* positioning of the hammer) and upon initial startup of devices would cause fish to move away from the affected area where injuries may occur. Therefore, relatively small portions of the proposed project area would be affected for short periods of time, and the potential for effects to fish would be temporary and limited to the duration of sound-generating activities.

Additionally, the time of the proposed construction activity would avoid the spawning season of ESA-listed salmonid species.

In summary, given the short daily duration of sound associated with individual pile driving and removal, and the relatively small areas being affected, pile driving and removal activities associated with the proposed action are not likely to have a permanent adverse effect on any fish habitat, or populations of fish species. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. Thus, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the IHA, which will inform NMFS' consideration of ''small numbers,'' the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (*i.e.,* vibratory and impact pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (AUD INJ) (Level A harassment) to result, primarily for very high-frequency species, phocids, and otariids because predicted AUD INJ zones are larger in comparison to the observability of such species. Auditory injury is unlikely to occur for high and low-frequency cetaceans. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic criteria above which NMFS believes the best available science indicates marine mammals will likely be behaviorally harassed or incur some degree of AUD INJ; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Criteria

NMFS recommends the use of acoustic criteria that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur AUD INJ of some degree (equated to Level A harassment). We note that the criteria for AUD INJ, as well as the names of two hearing groups, have been updated (NMFS 2024) as reflected below in the Level A harassment section.

Level B Harassment—hough significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the

source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μPa)) for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

The WSDOT Mukilteo Wingwalls Repair Project includes the use of continuous (vibratory pile driving and removal) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μPa are applicable.

Level A harassment—NMFS' Updated Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 3.0) (Updated Technical Guidance, 2024) identifies dual criteria to assess AUD INJ (Level A harassment) to five different underwater marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The WSDOT's Mukilteo Wingwalls Repair Project includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving and removal) sources.

The 2024 Updated Technical Guidance criteria include both updated thresholds and updated weighting functions for each hearing group. The thresholds are provided in the table below. The references, analysis, and methodology used in the development of the criteria are described in NMFS' 2024 Updated Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools.*

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

Hearing group	AUD INJ onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 222 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,HF,24h}$: 193 dB	*Cell 4:* $L_{E,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,VHF,24h}$: 159 dB	*Cell 6:* $L_{E,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 223 dB; $L_{E,PW,24h}$: 183 dB	*Cell 8:* $L_{E,PW,24h}$: 195 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 230 dB; $L_{E,OW,24h}$: 185 dB	*Cell 10:* $L_{E,OW,24h}$: 199 dB.

* Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

Note: Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μPa^2s. In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.,* 7 Hz to 165 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* vibratory pile driving and removal, and impact pile driving).

In order to calculate distances to the Level A harassment and Level B harassment thresholds for the methods and piles used in the proposed project, WSDOT and NMFS used acoustic monitoring data from previous pile driving such as WSDOTs Bainbridge Island Ferry Terminal Project (impact pile driving of 30-inch (76 cm) steel, with a bubble curtain in place) and WSDOT's Keystone Ferry terminal Project (vibratory pile driving of 30-inch (76 cm) steel), and also used WSDOT's Biological Assessment Reference (vibratory and impact pile driving of 30-inch (76 cm) steel). A bubble curtain was in place for all impact pile driving measurements and a bubble curtain would be in place during impact pile driving associated with this project.

Source levels for vibratory installation and removal of piles of the same diameter are assumed to be the same.

TABLE 5—ESTIMATES OF MEAN UNDERWATER SOUND LEVELS GENERATED DURING VIBRATORY AND IMPACT PILE DRIVING AND VIBRATORY REMOVAL OF 30-INCH (76 cm) STEEL PILES

Method	dB RMS	dB SEL	dB Peak	References
Vibratory installation and removal.	172.6	N/A	N/A	WSDOT. 2025. Biological Assessment Reference. Ch. 7, tables 7–15/16. Washington State Ferries, Washington State Department of Transportation. Seattle, Washington. January 2025. —Coupeville (Keystone) terminal, Laughlin 2010. —Colman dock terminal, Laughlin, 2012b. —Vashon Ferry Terminal, Laughlin 2010b. —Port Townsend Terminal (test pile), WSDOT 2010. —Edmonds Terminal, Laughlin 2017b. —WSDOT 2010. Keystone Ferry Terminal—Vibratory Pile Monitoring Technical Memorandum. May 4, 2010.
Impact installation *	187.3	179.3	203.7	WSDOT. 2025. Biological Assessment Reference. Ch. 7, tables 7–15/16. Washington State Ferries, Washington State Department of Transportation. Seattle, Washington. January 2025. —Friday Harbor Terminal, Laughlin, 2005b. —Port Townsend Terminal, Magnoni et al., 2014. —SR 520 Bridge, 2013. —Vashon Ferry Terminal, Laughlin 2010a. —1–90, Yakima River, Laughlin, 2019c. —Eagle Harbor Maintenance, Jasco 2005. —Mukilteo terminal, Laughlin, 2007, Laughlin 2018b. —WSDOT 2023. Bainbridge Island Ferry Terminal Overhead Loading Replacement Project. Underwater Noise Monitoring Report. February 2023.

Note: dB peak = peak sound level; rms = root mean square; SEL = sound exposure level.
* a bubble curtain was in place for all impact pile driving measurements.

TL is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. *TL* parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater *TL* is:

$TL = B \times \text{Log10}\ (R_1/R_2)$, where

TL = transmission loss in dB
B = transmission loss coefficient
R_1 = the distance of the modeled SPL from the driven pile, and
R_2 = the distance from the driven pile of the initial measurement

Absent site-specific acoustical monitoring with differing measured *TL,* a practical spreading value of 15 is used as the *TL* coefficient in the above formula. Site-specific *TL* data for the Womens Bay are not available; therefore, the default coefficient of 15 is used to determine the distances to the Level A harassment and Level B harassment thresholds.

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the 2024 Updated Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving and DTH, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur AUD INJ. Inputs used in the optional User Spreadsheet tool (*e.g.,* number of piles per day, duration, and/or strikes per pile), are presented in table 1, the sound levels are presented in table 5, and the resulting estimated isopleths, are reported below.

TABLE 6—PROJECTED DISTANCES TO LEVEL A AND LEVEL B HARASSMENT ISOPLETHS (m) AND ASSOCIATED AREAS [1] (*km²*) BY MARINE MAMMAL HEARING GROUP FOR VIBRATORY INSTALLATION AND REMOVAL AND IMPACT INSTALLATION OF FOUR 30-INCH (76 cm) STEEL PILES PER DAY [2]

Activity	Level A harassment zones (m)					[1] Level B harassment zones	
	LF	HF	VHF	PW	OW	Distance (km)	Area (km²)
Vibratory	138	53	113	178	60	32	107
Impact	1,604	205	2,483	1,425	531	0.7	3.7

[1] Land is reached at a maximum of 20.6 km.
[2] Although the production rate for battered piles is two per day, all isopleths are estimated based on a production rate of four piles per day.

Level A harassment zones are typically smaller than Level B harassment zones. However, during impact pile driving, the calculated Level A harassment isopleth is greater than the calculated Level B harassment

isopleth for very high-frequency cetaceans and phocids (however, because all activities are assumed as potentially occurring on the same day, we functionally reference the largest Level A and Level B harassment zones for purposes of estimating take). Calculation of Level A harassment isopleths includes a duration component, which in the case of impact pile driving, is estimated through the total number of daily strikes and the associated pulse duration. For a stationary sound source such as impact pile driving, we assume here that an animal is exposed to all of the strikes expected within a 24-hour period. Calculation of a Level B harassment zone does not include a duration component.

Marine Mammal Occurrence and Take Estimation

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

Additionally, we describe how the occurrence information is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization. Available information regarding marine mammal occurrence in the vicinity of the project area includes site-specific and nearby survey information from WSDOT. Specifically, data sources consulted included PSO monitoring completed on 169 days between 2015 and 2021, between the months of August and February, during the multi-year WSDOT Multimodal Construction Project. PSOs were located at the project site as well as on the Mukilteo—Clinton ferry and additional positions on Whidbey Island, Camano Island, and north of Everett, Washington.

To estimate take by Level B and Level A harassment, NMFS and WSDOT referred to the data reported at all PSO monitoring locations from each of the above referenced data sets. For take by Level B harassment, WSDOT and NMFS predicted a daily occurrence probability in which the average daily occurrence for each species is multiplied by the number of days of each type of pile driving activity, generally using the following equation;

Take by Level B harassment = marine mammal occurrence × days of pile driving activities.

However, WSDOT generated different daily average marine mammal occurrence rates based on the size of the Level B harassment zone for impact pile driving and vibratory pile driving. Since impact and vibratory pile driving could occur on any construction day, NMFS instead used the marine mammal occurrence estimated within the largest Level B harassment zone across all activities to estimate take by Level B harassment.

In cases where marine mammals are expected to occasionally occur within the project area (*e.g.,* harbor porpoise or transient killer whale), NMFS and WSDOT define marine mammal occurrence by one group of the average (harbor porpoise) or maximum (transient killer whale) group size for that species. In cases where marine mammals are expected to occur frequently in the project area, marine mammal occurrence is defined by the daily average occurrence of marine mammals documented by PSOs during the Mukilteo Multimodal Project within the largest Level B harassment zones.

Finally, WSDOT rounded daily average occurrence of less than one up to one. However, in such cases where species are unlikely to occur in the project area, but for which there is some potential, NMFS proposes to predict that one group of each species may occur in the project area during the six days of planned construction rather than each construction day (*i.e.,* low-frequency cetaceans and Dall's porpoise).

For take by Level A harassment, WSDOT attempted to estimate the occurrence of marine mammals occurring within the largest Level A harassment zone across all hearing groups. However, WSDOT referred to data reported at all PSO monitoring locations during the Mukilteo Multimodal Project. In general, WSDOT reporting includes the distance of the marine mammal to the PSO rather than the source. Therefore, NMFS instead refers to marine mammal data reported from the Mukilteo Ferry Terminal location only, as it is reasonable to assume the distance of the marine mammal to the PSO reported at that location would be near the source. NMFS also reviewed the data to estimate marine mammal occurrence according to the largest Level A harassment zone of each species' respective hearing group, rather than the largest Level A harassment zone across all hearing groups.

For hearing groups where proposed shutdown zones are greater or equal to the calculated Level A harassment zones, take by Level A harassment is not proposed for authorization (low-frequency and high-frequency cetaceans).

In cases where the Level A harassment zones are larger than the proposed shutdown zones, NMFS proposes to authorize take by Level A harassment. The same general equation is used for take by Level A harassment that is used for take by Level B harassment: marine mammal occurrence × days of pile driving activities. For species that are common in the project area (*i.e.,* California sea lion, Steller sea lion, and harbor seal), marine mammal occurrence is defined by daily average occurrence within the largest Level A harassment zone for that hearing group. For species that are occasionally or rarely expected to occur in the project area, because the Level A harassment zones are large, it is assumed that takes by Level B harassment could also be by Level A harassment.

Gray Whale

As discussed the Description of Marine Mammals in the Area of Specified Activities, gray whales occurring near the project area are the most abundant from March through May, when project activities are not planned to occur. As such, although some exposure to individual gray whales could occur, the project timing will contribute to limiting potential exposures. Therefore, NMFS predicts that one gray whale could occur within the Level B harassment zone across the six day project period, to account for the low, but not discountable, likelihood that this species could occur within the project area. NMFS proposes to authorize one take by Level B harassment of gray whale.

WSDOT initially requested authorization of take by Level A harassment for gray whales. However, NMFS suggested and WSDOT agreed to shut down at a distance larger than the Level A harassment zone for this hearing group. Additionally, no gray whales have been observed anywhere near previous estimated Level A harassment zones. As such, no take by Level A harassment of gray whales is anticipated or proposed for authorization.

Humpback Whale

WSDOT plans to shut down in-water pile driving upon observation of a humpback whale or any unknown large whale approaching the estimated Level B harassment zone. Given the plan to shut down and because humpback whales are conspicuous, no takes by Level B or Level A harassment are anticipated and none are proposed for authorization.

Minke Whale

While rare, it is possible that minke whales could occur within the project

area. Therefore, NMFS predicts that one group of two minke whales could occur within the Level B harassment zone across the six day project period, to account for the low, but not discountable, likelihood that this species could occur within the project area. Therefore, NMFS proposes to authorize two takes by Level B harassment of minke whales.

WSDOT initially requested authorization of take by Level A harassment for minke whale. However, NMFS suggested and WSDOT agreed to shut down at a distance larger than the Level A harassment zone for the low-frequency cetacean hearing group. As such, no take by Level A harassment of minke whale is anticipated or proposed for authorization.

Killer Whale

Southern Resident

WSDOT plans to shut down operations upon observation of a southern resident killer whales or any unknown killer whale approaching the estimated Level B harassment zone. Given the plan to shut down and because killer whales are conspicuous, no takes by Level B or Level A harassment are expected to occur and none are proposed for authorization.

West Coast Transient

Because transient killer whales occasionally occur within the project area and can linger, NMFS conservatively predicts one group of eight transient killer whales could occur within the project area each construction day. Therefore, NMFS proposes to authorize 48 takes by Level B harassment of transient killer whale (1 group × 8 killer whales × 6 construction days = 48 takes by Level B harassment).

WSDOT initially requested authorization of take by Level A harassment for transient killer whales. However, WSDOT plans to shut down at a distance larger than the Level A harassment zone for the high frequency cetacean hearing group. As such, take by Level A harassment is not expected to occur and no take by Level A harassment of transient killer whales is proposed for authorization.

Dall's Porpoise

NMFS predicts that two Dall's porpoise could occur within the Level B harassment zone across the six-day project period. Because exposure estimates are low and the Level A harassment zones are larger than are likely observable during impact pile driving, NMFS proposes to authorize these two takes as Level A harassment, acknowledging that instead the takes could be by the less severe Level B harassment.

Harbor Porpoise

NMFS predicts that two harbor porpoises could occur within the Level B harassment zone across the six day project period. This results in 12 takes by Level B harassment (1 group × 2 harbor porpoises × 6 construction days = 12 takes by Level B harassment). Because exposure estimates are low and the Level A harassment zones are larger than are likely observable during impact pile driving, NMFS proposes to authorize these 12 takes as Level A harassment, acknowledging that instead the takes could be by the less severe Level B harassment.

California Sea Lion

NMFS predicts that 12 California sea lions could occur within the Level B harassment zone each construction day. This results in 72 takes by Level B harassment (12 California sea lions × 6 construction days = 72 takes by Level B harassment).

Across 169 monitoring days between 2015 and 2021, an average of 4.3 California sea lions were observed within 300 m from the PSO at Mukilteo New Terminal, which corresponds to the largest Level A harassment zone for this hearing group. As such, NMFS predicts that an average of 4.3 California sea lions could occur within the Level A harassment zone each construction day. This results in 24 takes by Level A harassment (4.3 California sea lions × 6 construction days = 26 takes by Level A harassment).

Takes by Level B harassment were modified to deduct the proposed amount of take by Level A harassment estimated (*i.e.,* 72 takes by Level B harassment − 26 takes by Level A harassment = 46 takes by Level B harassment). Therefore, for California sea lions, NMFS proposes to authorize 46 takes by Level B harassment and 26 takes by Level A harassment for a total of 72 takes across the 6 day project period.

Steller Sea Lion

NMFS predicts that 1 Steller sea lion could occur within the Level B harassment zone each construction day. This results in six takes by Level B harassment (1 Steller sea lion × 6 construction days = 1 takes by Level B harassment).

Across 169 monitoring days between 2015 and 2021, an average of 0.1 Steller sea lions were observed within 531 m from the PSO at Mukilteo New Terminal, which corresponds to the largest Level A harassment zone for this hearing group. Given the lower occurrence, NMFS conservatively predicts that two Steller sea lions could occur within the Level A harassment zone across the 6 day project period. This results in two takes by Level A harassment (1 group × 2 Steller sea lions across the 6-day project period = 2 takes by Level A harassment).

Takes by Level B harassment were modified to deduct the proposed amount of take by level A harassment estimated (*i.e.,* 6 takes by Level B harassment − 2 takes by Level A harassment = 4 takes by Level B harassment). Therefore, for Steller sea lions, NMFS proposes to authorize four takes by Level B harassment and two takes by Level A harassment for a total of six takes across the project period.

Harbor Seal

NMFS predicts that 21 harbor seals could occur within the Level B harassment zone each construction day. This results in 126 takes by Level B harassment (20.8 harbor seals × 6 construction days = 125 takes by level B harassment).

Across 169 monitoring days between 2015 and 2021, an average of 8.3 harbor seals were observed within 1,425 m from the PSO at Mukilteo New Terminal, which corresponds to the largest Level A harassment zone for this hearing group. As such, NMFS predicts that 50 harbor seals could occur within the Level A harassment zone across the 6-day project period (1 group × 8.3 California sea lions × 6 construction days = 50 takes by level A harassment).

Takes by Level B harassment were modified to deduct the proposed amount of take by Level A harassment estimated (*i.e.,* 125 takes by level B harassment − 50 takes by Level A harassment = 75 takes by Level B harassment). Therefore, for harbor seals, NMFS proposes to authorize 75 takes by Level B harassment and 50 takes by Level A harassment for a total of 126 takes across the project period.

Northern Elephant Seal

Because northern elephant seal can linger and a small number are known to use Whidbey Island in recent years, NMFS predicts that 1 northern elephant seal could occur within the project area each day of the 6-day project period. This results in 6 takes by level B harassment. Because exposure estimates are low and the Level A harassment zones are larger than are likely observable during impact pile driving, NMFS proposes to authorize these six takes as Level A, acknowledging that

instead the takes could be by the less severe Level B harassment.

TABLE 7—TAKE BY STOCK AND HARASSMENT TYPE AND AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Level B harassment	Level A harassment	Total harassment proposed	Take as percentage of stock abundance
Gray whale	Eastern north pacific	1	0	1	<1
Minke whale	CA-OR-WA	1	0	1	<1
Killer whale	West Coast Transient	48	0	48	14
Dall's porpoise	CA-OR-WA	2		2	<1
Harbor porpoise	Washington Northern Inland	12		12	<1
California sea lion	U.S. Stock	46	26	72	<1
Steller sea lion	Eastern U.S.	4	2	6	<1
Harbor seal	Washington Northern Inland	75	50	125	*1
Northern elephant seal	California Breeding	6		.....	<1

*Reliable abundance estimates for this stock is currently unavailable.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

Shutdown Zones

For all pile driving and removal activities, WSDOT proposes to implement shutdowns within designated zones. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones vary based on the activity type and marine mammal hearing group (table 8).

For humpback whales and southern resident killer whales, WSDOT proposes to shut down at distances based on the estimated Level B harassment zones for each activity. During vibratory pile driving and removal, this corresponds to 20.6 km, which is the maximum Level B harassment distance before reaching land, and during impact pile driving, this corresponds to 0.8 km. If a southern resident killer whale, or killer whale of unknown stock, or humpback whale, or unidentified mysticete is observed approaching the Level B harassment zone (*i.e.,* the shutdown zone) WSDOT would implement shutdown measures.

WSDOT also plans to take measures to ensure that they are aware of southern resident killer whales and humpback whale locations, so that work is not conducted when these species are within the vicinity of the project area. Such measures include, but are not limited to, contacting and/or reviewing the latest sightings data from the Orca Network and the Whale Report Alert System on a daily basis (see Monitoring and Reporting section).

With WSDOT's proposed shutdown zones, and efforts to determine the locations of the nearest marine mammal sightings, all incidental harassment would be prevented for southern resident killer whale and any stock of humpback whale.

For all other low-frequency and high-frequency cetaceans, the proposed shutdown zones are based on the estimated Level A harassment isopleths during all activities. The shutdown zones are also based on the estimated Level A harassment isopleths for very high-frequency cetaceans and otariids during vibratory pile driving and removal.

In cases where it would be challenging to detect marine mammals at the Level A harassment isopleth, (*e.g.,* very high-frequency cetaceans, phocids, and otariids during most impact pile driving), or where shutting down at the Level A harassment zone would create practicability concerns (*e.g.,* phocids during vibratory pile driving), smaller shutdown zones have been proposed (table 8).

Construction supervisors and crews, PSOs, and relevant WSDOT staff must avoid direct physical interaction with marine mammals during construction activity. If a marine mammal comes within 10 m of such activity, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions, as necessary to avoid direct physical interaction. If an activity is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone indicated in table 8, or

15 minutes have passed without re-detection of the animal.

Finally, construction activities must be halted upon observation of a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met entering or within any harassment zone. If a marine mammal species for which take is not authorized enters a harassment zone, all in-water activities will cease until the animal leaves the zone or has not been observed for at least 15 minutes. Pile driving will proceed if the unauthorized species is observed leaving the harassment zone or if 15 minutes have passed since the last observation.

TABLE 8—PROPOSED SHUTDOWN ZONES FOR 30-INCH (76 cm) STEEL PILES (m)

Pile driving method	LF	HF	VHF	PW	OW	Southern resident killer whale, humpback whale, or unknown killer whale or mysticete
Vibratory Installation and Removal	140	110	115	50	60	20.6 km.*
Impact Pile Driving	1,604	205	115	50	60	0.7 km.

* The calculated Level B harassment isopleth is 32 km, but 20.6 km is the maximum distance to land.

PSOs

The number and placement of PSOs during all construction activities (described in the Proposed Monitoring and Reporting section) would ensure that the shutdown zones are generally visible, such that PSOs are reasonably confident of their ability observe species at relevant distances. WSDOT would employ at least six PSOs during all vibratory pile driving and removal activities and at least four PSOs during all impact pile driving activities.

Monitoring for Level A and Level B Harassment

PSOs would monitor the shutdown zones and beyond to the extent that PSOs can see. Monitoring beyond the shutdown zones enables observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre-and-Post-Activity Monitoring

Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs would observe the shutdown zones and as much of the harassment zones as possible for a period of 30 minutes. Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine that the shutdown zones are clear of marine mammals for which take is authorized. If the shutdown zone for which take is authorized is obscured by fog or poor lighting conditions, in-water construction activity will not be initiated until the entire shutdown zone is visible. Pile driving may commence following 30 minutes of observation when the determination is made that the shutdown zones are clear of marine mammals. If a marine mammal is observed entering or within shutdown zones, pile driving activity must be delayed or halted. If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal. If a marine mammal for which take by Level B harassment is authorized is present in the Level B harassment zone, activities may begin. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones would commence.

Soft Start

The use of soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors would be required to provide an initial set of three strikes from the hammer at reduced energy, with each strike followed by a 30-second waiting period. This procedure would be conducted a total of three times before impact pile driving begins. Soft start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer. Soft start is not required during vibratory pile driving activities.

Bubble Curtain

A bubble curtain would be employed during impact installation or proofing of steel piles. A noise attenuation device would not be required during vibratory pile driving. If a bubble curtain or similar measure is used, it would distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column. Any other attenuation measure would be required to provide 100 percent coverage in the water column for the full depth of the pile. The lowest bubble ring would be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring would ensure 100 percent mudline contact. No parts of the ring or other objects would prevent full mudline contact.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

—Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);

—Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
—Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
—How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
—Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
—Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring during pile driving activities must be conducted by NMFS-approved PSOs in a manner consistent with the following:
—PSOs must be independent of the activity contractor (for example, employed by a subcontractor), and have no other assigned tasks during monitoring periods;
—At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
—Other PSOs may substitute other relevant experience, education (degree in biological science or related field) or training for experience performing the duties of a PSO during construction activities pursuant to NMFS-issued take authorization;
—Where a team of three or more PSOs is required, a lead observer or monitoring coordinator will be designated. The lead observer will be required to have prior experience working as a marine mammal observer during construction activity pursuant to a NMFS-issued incidental take authorization; and,
—PSOs must be approved by NMFS prior to beginning any activity subject to this IHA.

PSOs should also have the following qualifications:
—Ability to conduct field observations and collect data according to assigned protocols;
—Experience or training in the field identification of marine mammals, including identification of behaviors;
—Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
—Writing skills sufficient to prepare a report of observations including, but not limited to, the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and,
—Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Visual monitoring would be conducted by trained PSOs positioned at suitable vantage points to generally be able to observe the entirety of the shutdown zones (see figures 1 and 2 in WSDOT's marine mammal monitoring plan), which includes the full extent of the Level B harassment zones for southern resident killer whale and humpback whale. WSDOT would place at least 6 PSOs during vibratory pile driving and removal at locations such as Mabana Beach, Camano Island State Park, Tuliap, Harborview Park, Mukilteo Terminal, and Clinton Ferry Terminal, and at least four PSOs would be placed during impact pile driving at locations at or near Mukilteo Ferry Terminal. At least one PSO would be placed near the pile driving site during all pile driving and removal activities.

Monitoring would be conducted 30 minutes before, during, and 30 minutes after all in water construction activities. In addition, PSOs will record all incidents of marine mammal occurrence, regardless of distance from activity, and will document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Coordination With Local Marine Mammal Research Network

Before the project begins, WSDOT would contact the Orca Network and ask to be notified of sightings in the project area. Prior to pile driving each day, PSOs would also monitor the Orca Network Facebook page to stay informed about marine mammal sightings. The Orca Network consists of a list of over 600 (and growing) residents, scientists, and government agency personnel in the United States and Canada. Sightings are called or emailed into the Orca Network and immediately distributed to the NMFS Northwest Fisheries Science Center, the Center for Whale Research, Cascadia Research, the Whale Museum Hotline, and the British Columbia Sightings Network.

Sightings information collected by the Orca Network includes detection by hydrophone. The SeaSound Remote Sensing Network is a system of interconnected hydrophones installed in the marine environment of Haro Strait (west side of San Juan Island) to study orca communication, in-water noise, bottom fish ecology, and local climatic conditions. A hydrophone at the Port Townsend Marine Science Center measures average in-water sound levels and automatically detects unusual sounds. These passive acoustic devices allow researchers to hear when different marine mammals come into the region. This acoustic network, combined with the volunteer visual sighting network allows researchers to document presence and location of various marine mammal species.

WSDOT also participates in the Whale Report Alert System (WRAS/WhaleReport Alert System—Ocean Wise). In October 2018, the Ocean Wise Sightings Network (formerly the B.C. Cetacean Sightings Network) launched an alert system that broadcasts details of whale presence to large commercial vessels. Information on whale presence is obtained from real-time observations reported to the Ocean Wise Sightings Network via the WhaleReport app. The alerts inform shipmasters and pilots of cetacean occurrence in their vicinity. This awareness better enables vessels to undertake adaptive mitigation measures, such as slowing down or altering course in the presence of cetaceans, to reduce the risk of collision and disturbance.

All WSDOT ferry vessel crews have been trained in the use of WRAS, and input new sightings of cetaceans so data would be available to other vessels and to PSOs on the project. The lead PSO will check the WRAS sightings regularly during the day to be aware of cetacean reports in the area.

With this level of coordination in the region of activity, WSDOT would be able to get additional real-time information on the presence or absence of cetaceans prior to start of in-water construction each day.

Reporting

WSDOT would submit a draft marine mammal monitoring report to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to a requested date of issuance of any future IHAs for the project, or other projects at the same location, whichever comes first. The marine mammal monitoring report will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report will include:

—Dates and times (begin and end) of all marine mammal monitoring;
—Construction activities occurring during each daily observation period, including: (1) the number and type of piles that were driven and the method (*e.g.,* impact or vibratory); and (2) total duration of driving time for each pile (vibratory driving) and number of strikes for each pile (impact driving);
—PSO locations during marine mammal monitoring;
—Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
—Upon observation of a marine mammal, the following information: (1) name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; (2) time of sighting; (3) identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; (4) distance and location of each observed marine mammal relative to the pile being driven for each sighting; (5) estimated number of animals (min/max/best estimate); (6) estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); (7) animal's closest point of approach and estimated time spent within the harassment zone; (8) description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
—Number of marine mammals detected within the harassment zones, by species; and,
—Detailed information about implementation of any mitigation (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

A final report must be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report. If no comments are received from NMFS within 30 calendar days of receipt of the draft report, the report shall be considered final. All PSO data would be submitted electronically in a format that can be queried such as a spreadsheet or database and would be submitted with the draft marine mammal report.

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the WSDOT must report the incident to the OPR, NMFS (*PR.ITP.Monitoring Reports@noaa.gov* and *itp.fleming@noaa.gov*) and West Coast region (WCR) Regional Stranding as soon as feasible. If the death or injury was clearly caused by the specified activity, the WSDOT must immediately cease the activities until NMFS OPR is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of this IHA. WSDOT must not resume their activities until notified by NMFS. The report must include the following information:

—Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
—Species identification (if known) or description of the animal(s) involved;
—Condition of the animal(s) (including carcass condition if the animal is dead);
—Observed behaviors of the animals(s), if alive;
—If available, photographs or video footage of the animal(s); and,
—General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition the majority of our analysis applies to all the species listed in table 2, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Pile driving and removal associated with this project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment and, for some species, Level A harassment from underwater sounds generated by pile driving and removal. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

No serious injury or mortality is expected in either year, even in the absence of required mitigation measures, given the nature of the activities. Further, no take by Level A harassment is anticipated for any low-frequency or high-frequency cetaceans, due to the rarity of the species near the project area and/or the application of proposed mitigation measures, such as shutdown zones that encompass the

Level A harassment zones for these species (see Proposed Mitigation section).

Level A harassment is proposed for very high-frequency cetaceans and pinnipeds that may occur in the project area (Dall's porpoise, harbor porpoise, California sea lion, Steller sea lion, harbor seal, and northern elephant seal). Any take by Level A harassment is expected to arise from, at most, a small degree of AUD INJ (*i.e.,* minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by impact pile driving such as the low-frequency region below 2 kHz), not severe hearing impairment or impairment within the ranges of greatest hearing sensitivity. Animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS.

Additionally, the amount of take by Level A harassment proposed for authorization is very low. As stated above, for low-frequency and high-frequency cetaceans (three species), NMFS anticipates no take by Level A harassment over the duration of WSDOT's planned activities; NMFS expects no more than 2 takes by Level A harassment for Dall's porpoise; 12 takes by Level A harassment for harbor porpoise; 6 takes by Level A harassment for northern elephant seal; and 2 takes by Level A harassment for Steller sea lion. The proposed amount of take by Level A harassment for California sea lions and harbor seal is a bit larger—24 takes and 49 takes, respectively. However, for all hearing groups, if hearing impairment occurs, it is most likely that the affected animal would lose only a few dB in its hearing sensitivity. Due to the small degree anticipated, any AUD INJ potentially incurred would not be expected to affect the reproductive success or survival of any individuals, much less result in adverse impacts on the species or stock.

Additionally, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. However, since the hearing sensitivity of individuals that incur TTS is expected to recover completely within minutes to hours, it is unlikely that the brief hearing impairment would affect the individual's long-term ability to forage and communicate with conspecifics, and would therefore not likely impact reproduction or survival of any individual marine mammal, let alone adversely affect rates of recruitment or survival of the species or stock.

Effects on individuals that are taken by Level B harassment in the form of behavioral disruption, on the basis of reports in the literature as well as monitoring from other similar activities, would likely be limited to reactions such as avoidance, increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006). Most likely, individuals would simply move away from the sound source and temporarily avoid the area where pile driving is occurring. If sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activities are occurring. We expect that any avoidance of the project areas by marine mammals would be temporary in nature and that any marine mammals that avoid the project areas during construction would not be permanently displaced. Short-term avoidance of the project areas and energetic impacts of interrupted foraging or other important behaviors is unlikely to affect the reproduction or survival of individual marine mammals, and the effects of behavioral disturbance on individuals is not likely to accrue in a manner that would affect the rates of recruitment or survival of any affected stock.

The project is also not expected to have significant adverse effects on affected marine mammals' habitats. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may cause a low level of turbidity in the water column and some fish may leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected (with no known particular importance to marine mammals), the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

There is a Biologically Important Area for feeding gray whale that intersects with the project area, but it is active between February and May (Calambokidis et al., 2024), which does not intersect with the time period when project activities are planned (October). This suggests that impacts from the project would have minimal to no impact on gray whales and would therefore not affect reproduction and survival.

Finally, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the reproduction or survival of any individuals, much less these stocks' annual rates of recruitment or survival. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities would have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and would therefore not result in population-level impacts.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

—No serious injury or mortality is anticipated or proposed for authorization;

—No take by Level A harassment is proposed for low and high-frequency cetaceans;

—Take by Level A harassment would be very small amounts for most species and of a low severity;

—Proposed takes by Level B harassment are relatively low for most stocks. Level B harassment would be primarily in the form of behavioral disturbance, resulting in avoidance of the project areas around where impact or vibratory pile driving is occurring, with some low-level TTS that may limit the detection of acoustic cues for relatively brief amounts of time in relatively confined footprints on their populations

—The lack of anticipated significant or long-term negative effects to marine mammal habitat.

—Effects on species that serve as prey for marine mammals from the activities are expected to be short-term and, therefore, any associated impacts on marine mammal feeding are not expected to result in significant or long-term consequences for individuals, or to accrue to adverse impacts on their populations from either project;

—The ensonified areas are small relative to the overall habitat ranges of all species and stocks, and overlap with known areas of important habitat is minimal;

—WSDOT would implement mitigation measures including visual monitoring and shutdown zones to minimize the numbers of marine mammals exposed to injurious levels of sound.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the

proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers (see 86 FR 5322, January 19, 2021). Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

We propose to authorize incidental take of nine marine mammal stocks each project year (table 7). The total amount of taking proposed for authorization is less than 1 percent for 8 of these stocks and 14 percent for one stock. Though the most recent SAR includes an unreliable population estimate for the Washington northern inland stock of harbor seal because it is more than 8 years old, Pearson *et al.,* 2024 reports that the peak population estimate for this stock is 15,898. As such, the 77 proposed takes by Level B harassment, and 49 proposed takes by Level A harassment, compared to the abundance estimate, suggests that about 1 percent of the stock would be expected to be impacted. We consider these relatively small percentages and thus, small numbers.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to WSDOT for conducting the Mukilteo Wingwalls Repair Project in Puget Sound, Washington, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed Mukilteo Wingwalls Repair Project. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

—A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).

—The request for renewal must include the following:

1. An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

2. A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

—Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: June 25, 2025.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2025–13270 Filed 7–15–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Guidance on Referrals for Potential Criminal Enforcement

AGENCY: Office of General Counsel, Department of Defense (DoD).

ACTION: Guidance document.

SUMMARY: This guidance document describes DoD's plans to address criminally liable regulatory offenses under the recent executive order (E.O.) on Fighting Overcriminalization in Federal Regulations.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Dziecichowicz, Associate Deputy General Counsel, Office of the General

Counsel (Legal Counsel), Department of Defense, Office of the Secretary, Pentagon, Room 3B688, Arlington, VA 22202, 571–256–0695.

SUPPLEMENTARY INFORMATION: On May 9, 2025, the President issued E.O. 14294, ''Fighting Overcriminalization in Federal Regulations,'' which published in the **Federal Register** on May 14, 2025 (90 FR 20363–20365) and is available at *https://www.govinfo.gov/content/pkg/FR-2025-05-14/pdf/2025-08681.pdf.* Section 7 of E.O. 14294 provides that within 45 days of the order, and in consultation with the Attorney General, each agency should publish guidance in the **Federal Register** describing its plan to address criminally liable regulatory offenses.

The E.O. does not apply to the enforcement of immigration laws or regulations promulgated to implement such laws, nor does it apply to the enforcement of laws or regulations related to national security or defense. To the extent that DoD takes any criminal enforcement actions not within one of those exemptions, DoD will apply the policy in this guidance document to such actions.

That policy, subject to appropriate exceptions and to the extent consistent with law, states that when DoD is deciding whether to refer alleged violations of criminal regulatory offenses to the Department of Justice (DOJ), officers and employees of the DoD should consider, among other factors:

- the harm or risk of harm, pecuniary or otherwise, caused by the alleged offense;
- the potential gain to the putative defendant that could result from the offense;
- whether the putative defendant held specialized knowledge, expertise, or was licensed in an industry related to the rule or regulation at issue; and
- evidence, if any is available, of the putative defendant's general awareness of the unlawfulness of his conduct as well as his knowledge or lack thereof of the regulation at issue.

Further, this general policy is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Consistent with the E.O., DoD also advises the public that by May 9, 2026, the Department, in consultation with the Attorney General, will provide to the Director of the Office of Management and Budget a report containing: (1) a list of all criminal regulatory offenses [1] enforceable by the DoD or the DOJ; and (2) for each such criminal regulatory offense, the range of potential criminal penalties for a violation and the applicable mens rea standard [2] for the criminal regulatory offense.

Dated: July 11, 2025.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025–13267 Filed 7–15–25; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2025–OS–0144]

Proposed Collection; Comment Request

AGENCY: United States Transportation Command (USTRANSCOM), Department of Defense (DoD).

ACTION: 60-day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the United States Transportation Command announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 15, 2025.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24 Suite 05F16, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Military Surface Deployment and Distribution Command (SDDC), 1 Soldier Way, Scott AFB, IL 62225, Mr. Dennis A. White, 618–220–6932.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Standard Tender of Freight Services; SDDC Form 364–R; OMB Control Number 0704–0634.

Needs and Uses: The information derived from the DoD tenders on file with the Military SDDC is used by SDDC subordinate commands and DoD shippers to select the best value carriers to transport surface freight shipments. Freight carriers furnish information in a uniform format so that the Government can determine the cost of transportation, accessorial, and security services, and select the best value carriers for 1.1 million Bill of Lading shipments annually. The DoD tender is the source document for the General Services Administration post-shipment audit of carrier freight bills.

Affected Public: Business or other for-profit.

Annual Burden Hours: 27,351.

Number of Respondents: 82,053.

Responses Per Respondent: 1.

Annual Responses: 82,053.

Average Burden Per Response: 20 minutes.

Frequency: On occasion.

Dated: July 11, 2025.

Stephanie J. Bost,

Alternate OSD and Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025–13274 Filed 7–15–25; 8:45 am]

BILLING CODE 6001–FR–P

[1] ''Criminal regulatory offense'' means a Federal regulation that is enforceable by a criminal penalty. E.O. 14294, sec. 3(b).

[2] ''Mens rea'' means the state of mind that by law must be proven to convict a particular defendant of a particular crime. E.O. 14294, sec. 3(c).

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2025–OS–0145]

Proposed Collection; Comment Request

AGENCY: Pentagon Force Protection Agency (PFPA), Department of Defense (DoD).

ACTION: 60-day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Pentagon Force Protection Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 15, 2025.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24 Suite 05F16, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Pentagon Force Protection Agency, 9000 Defense Pentagon, Washington, DC 20301–9000, Rosalind Taylor, or call 703–692–7842.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Pentagon Force Protection Agency Request for U.S. Flag(s) to be Flown over the Pentagon; PFPA Form 55; 0704–0637.

Needs and Uses: This information collection is needed to process requests for U.S. Flags to be flown over the Pentagon.

Affected Public: Individuals and households.

Annual Burden Hours: 93.1.

Number of Respondents: 1,862.

Responses per Respondent: 1.

Annual Responses: 1,862.

Average Burden per Response: 3 minutes.

Frequency: On occasion.

Dated: July 11, 2025.

Stephanie J. Bost,

Alternate OSD and Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025–13273 Filed 7–15–25; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5274–001]

New Hampshire Department of Environmental Services; Notice of Application for Surrender of Exemption Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Surrender of Exemption.

b. *Project No:* 5274–001.

c. *Date Filed:* June 2, 2025, as supplemented on June 13, 2025.

d. *Applicant:* New Hampshire Department of Environmental Services.

e. *Name of Project:* Squam Lake Dam Hydroelectric Project.

f. *Location:* The project is located on the Squam River, in Grafton County, New Hampshire. The project does not occupy any federal lands.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708.

h. *Applicant Contact:* Corey Clark, P.E., Chief Engineer, New Hampshire Department of Environmental Services, Dam Bureau, 29 Hazen Drive, Concord, NH 03302, *corey.clark@des.nh.gov.*

i. *FERC Contact:* Kelly Fitzpatrick, (202) 502–8435, *kelly.fitzpatrick@ferc.gov.*

j. *Cooperating agencies:* With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests:* August 12, 2025.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–5274–001. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Request:* The applicant proposes to surrender the project exemption. The generating

equipment has not operated since 2002. No significant modifications to the existing dam, buildings, or structures and no ground disturbing activities are proposed. The applicant has already disconnected the phase leads from the electrical grid. The applicant proposes to remove the electrical connections to the generators within the powerhouse and disable and/or remove the generating equipment and ancillary electrical equipment from the powerhouse. There will be no work on the dam or spillway. Upon surrender of the exemption, the penstock gates will be left in the closed and locked position. The dam will remain in place with no changes to its components, ownership, operation, maintenance procedures, or monitoring procedures. Flows will continue to pass over the spillway and through three low-level outlet sluice gates. Outlet gates and equipment needed for regular dam operation will remain operable.

m. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 11, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–13352 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD24–7–000]

Federal and State Current Issues Collaborative; Notice of Meeting and Agenda

As first announced in the Commission's June 23, 2025 Notice in the above-captioned docket,[1] the second public meeting of the Federal and State Current Issues Collaborative (Collaborative) will be held on July 27, 2025, from approximately 9:30 am–12:00 pm EDT, at the Omni Boston Hotel at the Seaport in Boston, Massachusetts. Commissioners may attend and participate in this meeting. Attached to this Notice is the agenda for the meeting.

The purpose of this meeting is to discuss generic issues related to the states' role in Regional Transmission Organization (RTO) governance, including on resource adequacy issues. Commissioners do not intend to discuss at this meeting any specific proceeding before the Commission, including proceedings that involve similar issues. These proceedings include, but are not limited to:

California Independent System Operator Corp.	Docket No. ER24–2671–001.
Meeting the Challenge of Resource Adequacy in Regional Transmission Organization and Independent System Operator Regions.	Docket No. AD25–7–000.
Midcontinent Independent System Operator, Inc	Docket No. ER25–2247–000.
Midcontinent Independent System Operator, Inc	Docket No. ER25–2298–000.
Midcontinent Independent System Operator, Inc	Docket No. ER25–2454–000.
PJM Interconnection, LLC	Docket Nos. ER24–1790–000 et al.b; ER24–1787–000 et al.
PJM Interconnection, LLC	Docket No. EL25–76–000.
PJM Interconnection, LLC	Docket No. ER25–682–000.
PJM Interconnection, LLC	Docket No. ER25–785–002.
PJM Interconnection, LLC	Docket No. ER25–712–001.
PJM Interconnection, LLC	Docket Nos. ER24–148–000; EL25–18–000.
Southwest Power Pool, Inc	Docket Nos. ER25–2296–000; ER25–2297–000.
Southwest Power Pool, Inc	Docket No. ER25–89–000.

[1] *Fed. and State Current Issues Collaborative,* Notice, Docket No. AD24–7–000 (issued June 23, 2025).

The meeting will be open to the public for listening and observing and will be on the record. There is no fee for attendance and registration is not required. The public may attend in person or via Webcast.[2] This meeting will be transcribed. Transcripts will be available for a fee from Ace Reporting, 202–347–3700.

Commission meetings are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

More information about the Collaborative is available here: *https://www.ferc.gov/federal-state-current-issues-collaborative.* For questions related to the Collaborative, please contact: Robert Thormeyer, 202–502–8694, *robert.thormeyer@ferc.gov,* CeCe Coffey, 202–502–8040, *cecelia.coffey@ferc.gov,* or Kimberly Duffley, 202–898–1305, *kduffley@naruc.org.*

Dated: July 11, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–13298 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP25–513–000]

Spire MoGas Pipeline LLC & Spire STL Pipeline LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on June 27, 2025, Spire MoGas Pipeline LLC (Spire MoGas), 329 Josephville Road, Wentzville, Missouri 63385, and Spire STL Pipeline LLC (Spire STL), 700 Market Street, St. Louis, Missouri 63101, filed a joint application with the Federal Energy Regulatory Commission under sections 7(b) and 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations. The applicant's request authorization for Spire MoGas to acquire and operate the jurisdictional facilities of Spire STL as part of its existing interstate natural gas system (Project). The Project includes the abandonment by transfer of Spire STL's facilities to Spire MoGas, the creation of a new rate Zone 3, and the consolidation of both pipeline systems into one integrated network. The Project is expected to increase administrative efficiency, enhance reliability and operational flexibility, and maintain existing service and rates for customers. No new construction is proposed, and no environmental or landowner impacts are anticipated, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions concerning this request should be directed to Alexander Kass, Associate General Counsel, Spire Midstream, 3773 Richmond Avenue, Suite 300, Houston, Texas 77046, by phone at (346) 619–6496 or via email at *Alex.Kass@SpireEnergy.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on August 1, 2025. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before August 1, 2025.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please

[2] A link to the Webcast will be available here on the day of the event: *https://www.ferc.gov/federal-state-current-issues-collaborative.*

[1] 18 CFR 157.9.

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

reference the Project docket number CP25–513–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP25–513–000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[7] and the regulations under the NGA[8] by the intervention deadline for the project, which is August 1, 2025. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP25–513–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP25–513–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail at: Alexander Kass, Associate General Counsel, Spire Midstream, 3773 Richmond Avenue, Suite 300, Houston, Texas 77046 or by email (with a link to the document) at *Alex.Kass@SpireEnergy.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed[9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on August 1, 2025.

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

Dated: July 11, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–13349 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2711–025]

Northern States Power Company; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 2711–025.

c. *Date filed:* November 30, 2023.

d. *Applicant:* Northern States Power Company (Northern States Power).

e. *Name of Project:* Trego Hydroelectric Project (Trego Project).

f. *Location:* The Trego Project is located on the Namekagon River in Washburn County, Wisconsin.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Donald Hartinger, Director of Renewable Operation-Hydro, Xcel Energy, 414 Nicollet Mall, 2, Minneapolis, MN 55401; phone (651) 261–7668; or Matthew Miller, Environmental Analyst, Xcel Energy, 1414 W. Hamilton Ave., PO Box 8, Eau Claire, WI 54702–0008; phone 715–737–1353.

i. *FERC Contact:* Laura Washington at (202) 502–6072; or email at *Laura.Washington@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* on or before 5:00 p.m. Eastern Time on September 9, 2025.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Trego Hydroelectric Project (P–2711–025).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted, but is not ready for environmental analysis at this time.

l. *The Trego Project consists of the following facilities:* (1) a 435.2-acre reservoir; (2) a 642-foot-long, 43.5-foot-high concrete dam; (3) a 59.5-foot-long, 74-feet-high powerhouse containing two James Leffel Company vertical Francis-type turbines with a total generating capacity of 1.2 megawatts; (4) a tailwater; and (5) a 49-foot-long transmission line. Northern States Power is not proposing any changes to project facilities or operation.

m. A copy of the application is available for review via the internet through the Commission's Home Page (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

o. Procedural schedule: The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Comments on Scoping Document 1 due.	July 2025
Request Additional Information (*if necessary*).	August 2025
Issue Scoping Document 2 (*if necessary*).	September 2025

Dated: July 11, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–13301 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25–384–000.

Applicants: Great Prairie Energy Storage, LLC.

Description: Great Prairie Energy Storage, LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.

Filed Date: 7/10/25.
Accession Number: 20250710–5128.
Comment Date: 5 p.m. ET 7/31/25.
Docket Numbers: EG25–385–000.
Applicants: Alpaugh BESS, LLC.
Description: Alpaugh BESS, LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.
Filed Date: 7/11/25.
Accession Number: 20250711–5071.
Comment Date: 5 p.m. ET 8/1/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24–2017–002.
Applicants: PacifiCorp.
Description: Compliance filing: Order Nos. 2023 et al Second Compliance Filing to be effective 7/14/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5068
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER24–2459–003.
Applicants: Tenaska Virginia Partners, L.P.
Description: Compliance filing: Informational Filing Regarding Upstream Transfer of Ownership to be effective N/A.
Filed Date: 7/10/25.
Accession Number: 20250710–5122.
Comment Date: 5 p.m. ET 7/31/25.
Docket Numbers: ER25–1933–001.
Applicants: ITC Energy Solutions LLC.
Description: Tariff Amendment: Response to Deficiency Letter, Request for Shortened Comment Period to be effective 6/11/2025.
Filed Date: 7/10/25.
Accession Number: 20250710–5109.
Comment Date: 5 p.m. ET 7/31/25.
Docket Numbers: ER25–2232–002.
Applicants: Illinois Generation LLC.
Description: Tariff Amendment: Request to Defer Action on Shared Facilities Agreement to be effective 12/31/9998.
Filed Date: 7/11/25.
Accession Number: 20250711–5127.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2234–001.
Applicants: Heritage Prairie Solar LLC.
Description: Tariff Amendment: Request to Defer Action on Certificate of Concurrence to SFA to be effective 12/31/9998.
Filed Date: 7/11/25.
Accession Number: 20250711–5132.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2284–001.
Applicants: American Electric Power Service Corporation, Ohio Power Company.
Description: Tariff Amendment: Ohio Power Company submits tariff filing per 35.17(b): AEP submits Amendment to revised ILDSA—SA No. 1420 ATT 1 to be effective 10/1/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5142.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2826–000.
Applicants: ORNI 30 LLC.
Description: Initial Rate Filing: Petition for Approval of Initial Market-Based Rate Tariff to be effective 7/11/2025.
Filed Date: 7/10/25.
Accession Number: 20250710–5111.
Comment Date: 5 p.m. ET 7/31/25.
Docket Numbers: ER25–2827–000.
Applicants: FirstEnergy Service Company, The Potomac Edison Company.
Description: § 205(d) Rate Filing: The Potomac Edison Company submits tariff filing per 35.13(a)(2)(iii: Potomac Edison's Request for Order Authorizing Abandoned Plant Incentive to be effective 9/10/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5018.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2828–000.
Applicants: American Transmission Systems, Incorporated.
Description: § 205(d) Rate Filing: ATSI submits Amended CAs, SA No. 7170, 7171, 7178 to be effective 9/10/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5030.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2829–000.
Applicants: New York State Electric & Gas Corporation, New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: NYISO–NYSEG Joint 205: Standard IA Brookside Solar (SA2899) (CEII) to be effective 6/26/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5036.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2830–000.
Applicants: Southwest Power Pool, Inc., ITC Great Plains, LLC.
Description: § 205(d) Rate Filing: ITC Great Plains, LLC submits tariff filing per 35.13(a)(2)(iii: 4419 Clark County Solar & ITCGP Facilities Service Agr to be effective 9/10/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5049.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2831–000.
Applicants: Southwest Power Pool, Inc., ITC Great Plains, LLC.
Description: § 205(d) Rate Filing: ITC Great Plains, LLC submits tariff filing per 35.13(a)(2)(iii: 4420 Clark County Storage & ITCGP Facilities Service Agr to be effective 9/10/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5050.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2832–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to GIA, SA No. 7509; Project Identifier No. AF1–268 to be effective 9/10/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5069.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2833–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: Enhancements to PacifiCorp Large Generator Interconnection Procedures to be effective 9/9/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5070.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2834–000.
Applicants: Trade Post Solar LLC.
Description: Initial Rate Filing: Shared Facilities Agreement to be effective 9/10/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5077.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2835–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Three Rocks Solar Amended and Restated LGIA Filing to be effective 6/27/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5095.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2836–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: West Fork Solar Amended and Restated LGIA Filing to be effective 6/27/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5096.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2837–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: § 205(d) Rate Filing: 2025–07–11 CapX—Fargo 4—LRTP—CMA—727 to be effective 6/13/2025.
Filed Date: 7/11/25.
Accession Number: 20250711–5105.
Comment Date: 5 p.m. ET 8/1/25.
Docket Numbers: ER25–2838–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: 2025–07–11 CapX—Fargo 4—LRTP—OMA—307 to be effective 6/13/2025.

Filed Date: 7/11/25.

Accession Number: 20250711–5117.

Comment Date: 5 p.m. ET 8/1/25.

Docket Numbers: ER25–2839–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: 2025–07–11 Big Oaks—Underbuild Owner Agrmt—775 to be effective 6/13/2025.

Filed Date: 7/11/25.

Accession Number: 20250711–5125.

Comment Date: 5 p.m. ET 8/1/25.

Docket Numbers: ER25–2840–000.

Applicants: Tenaska Virginia Partners, L.P.

Description: Request for Limited Tariff Waiver of the 90-day prior notice requirement set forth in Schedule 2 to the PJM OATT of Tenaska Virginia Partners, L.P.

Filed Date: 7/10/25.

Accession Number: 20250710–5138.

Comment Date: 5 p.m. ET 7/31/25.

Docket Numbers: ER25–2841–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 7038; Queue No. AE2–047 to be effective 9/10/2025.

Filed Date: 7/11/25.

Accession Number: 20250711–5138.

Comment Date: 5 p.m. ET 8/1/25.

Docket Numbers: ER25–2842–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: 2025–07–11 CapX—Fargo 4—LRTP—TCEA—281 to be effective 6/13/2025.

Filed Date: 7/11/25.

Accession Number: 20250711–5139.

Comment Date: 5 p.m. ET 8/1/25.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organization, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 11, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–13299 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2417–067]

Northern Power States Company; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* P–2417–067.

c. *Date filed:* November 30, 2023.

d. *Applicant:* Northern States Power Company (Northern States Power).

e. *Name of Project:* Hayward Hydroelectric Project (Hayward Project).

f. *Location:* The Hayward Project is located on the Namekagon River in the City of Hayward in Sawyer, Country, Wisconsin.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)—825(r).

h. *Applicant Contact:* Donald Hartinger, Director of Renewable Operation-Hydro, Xcel Energy, 414 Nicollet Mall, 2, Minneapolis, MN 55401; phone (651) 261–7668; or Matthew Miller, Environmental Analyst, Xcel Energy, 1414 W Hamilton Ave., PO Box 8, Eau Claire, WI 54702–0008; phone 715–737–1353.

i. *FERC Contact:* Laura Washington at (202) 502–6072; or email at *Laura.Washington@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* on or before 5:00 p.m. Eastern Time on September 9, 2025.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Hayward Hydroelectric Project (P–2417–067).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted, but is not ready for environmental analysis at this time.

l. *The Hayward Project consists of:* (1) a 246.9-acre reservoir; (2) a 442-foot-long the concrete overflow dam; (3) a 18-foot-wide, 24-foot long powerhouse with intake channel containing one S. Morgan Smith vertical Francis-Type turbine with a total installed capacity of 0.168 megawatts; (4) a tailrace; and (5) a 150-foot-long underground transmission line. Northern States Power is not proposing any changes to project facilities or operation.

m. A copy of the application is available for review via the internet through the Commission's Home Page (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

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n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

o. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Comments on Scoping Document 1 due.	July 2025.
Request Additional Information (*if necessary*).	August 2025.
Issue Scoping Document 2 (*if necessary*).	September 2025.

Dated: July 11, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–13351 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 175–032]

Pacific Gas and Electric Company; Notice of Reasonable Period of Time for Water Quality Certification Application

On July 7, 2025, Pacific Gas & Electric Company submitted to the Federal Energy Regulatory Commission (Commission) a copy of its application for Clean Water Act Section 401(a)(1) water quality certification filed with the California State Water Resources Control Board (Water Board), in conjunction with the above captioned project. The submittal also included a response from the Water Board stating that it received the application on July 3, 2025. Pursuant to the Commission's regulations,[1] we hereby notify the Water Board of the following:

Date of Receipt of the Certification Request: July 3, 2025.

Reasonable Period of Time to Act on the Certification Request: July 3, 2026.

If the Water Board fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: July 11, 2025.

Debbie-Anne Reese,

Secretary.

[FR Doc. 2025–13350 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the commission received the following accounting Request filings:

Filings Instituting Proceedings

Docket Numbers: AC25–118–000.

Applicants: Equitrans, L.P.

Description: Equitrans, L.P. submits proposed accounting entries re abandonment by sale of well numbers 602702 and 602796, in its Hunters Cave Storage Field in Greene County, Pennsylvania.

Filed Date: 7/11/25.

Accession Number: 20250711–5042.

Comment Date: 5 pm ET 8/1/25.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

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Dated: July 11, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–13300 Filed 7–15–25; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–12556–01–R6]

Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permit for Valero Refining-Texas, L.P., Harris County, Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition.

SUMMARY: The Environmental Protection Agency (EPA) former Acting

[1] 18 CFR 5.23(b).

Administrator signed an Order dated January 07, 2025, granting in part and denying in part a petition dated August 20, 2024, from Texas Environmental Justice Advocacy Services, Caring for Pasadena Communities, Lone Star Chapter of the Sierra Club, and Environmental Integrity Project (the Petitioners). The petition requested that the EPA object to a Clean Air Act (CAA) title V operating permit issued by the Texas Commission on Environmental Quality (TCEQ) to Valero Refining-Texas, L.P., for its Valero Houston Refinery located in Harris County, Texas.

FOR FURTHER INFORMATION CONTACT: Jonathan Ehrhart, EPA Region 6 Office, Air Permits Section, (214) 665–2295, *ehrhart.jonathan@epa.gov.* The final order and petition are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

SUPPLEMENTARY INFORMATION: The EPA received a petition from Texas Environmental Justice Advocacy Services, Caring for Pasadena Communities, Lone Star Chapter of the Sierra Club, and Environmental Integrity Project dated August 20, 2024, requesting that the EPA object to the issuance of operating permit No. O1381, issued by TCEQ to Valero Refining-Texas, L.P., for its Valero Houston Refinery located in Harris County, Texas. On January 07, 2025, the EPA former Acting Administrator issued an Order granting in part and denying in part the petition. The order itself explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request judicial review of those portions of an order that deny issues in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than September 15, 2025.

Dated: June 30, 2025.

James McDonald,

Director, Air and Radiation Division, Region 6.

[FR Doc. 2025–13326 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2025–0077; FRL–12476–05–OCSPP]

Certain New Chemicals or Significant New Uses; Statements of Findings—May 2025

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from May 1, 2025 to May 31, 2025.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2025–0077, is available online at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1667 email address: *edelstein.rebecca@epa.gov.*

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave. Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the applicable period.

C. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA Section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of ''not likely to present an unreasonable risk of injury to health or the environment'' may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA identifies the PMNs, MCANs and SNUNs for which EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. For the findings made during this period, the following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as confidential).

- P–16–0218, Acetoacetylated glycerin (Generic Name).

• P–25–0017, Reaction product of aromatic acid with trifunctional polyol and pelargonic acid (Generic Name).

To access EPA's decision document describing the basis of the ''not likely to present an unreasonable risk'' finding made by EPA under TSCA section 5(a)(3)(C), lookup the specific case number at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/determined-not-likely.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 14, 2025.

Shari Z. Barash,

Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2025–13319 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2023–0329; FRL–10681–02–OW]

Issuance of a General Permit for Ocean Disposal of Marine Mammal and Sea Turtle Carcasses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of final general permit.

SUMMARY: The Environmental Protection Agency (EPA) is re-issuing a general permit under the Marine Protection, Research and Sanctuaries Act (MPRSA) to authorize the transport of marine mammal and sea turtle carcasses from the United States and disposal of marine mammal and sea turtle carcasses in ocean waters. Permit re-issuance is necessary because the most recent permit expired on January 4, 2024. The EPA has not made substantive changes to the content of the recently expired general permit, though it has revised the scope and eligibility provisions, and general permittees will be able to resume permitted deposition of marine mammal carcasses in ocean waters pursuant to the re-issued permit terms.

DATES: This permit is effective on August 15, 2025 and expires on July 16, 2032.

ADDRESSES: The EPA established a docket for this action under Docket ID No. EPA–HQ–OW–2023–0329. All documents in the docket are listed on the *https://www.regulations.gov* website.

FOR FURTHER INFORMATION CONTACT: Cheryl Zulick, Freshwater and Marine Regulatory Branch; Oceans, Wetlands, and Communities Division, Mail Code 4504T, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone (202) 566–0583; email address: *zulick.cheryl@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

The authorization in this general permit is available for any officer, employee, agent, department, agency, or instrumentality of Tribal, Federal, State or local unit of government, as well as any Marine Mammal Health and Stranding Response Program (MMHSRP) Stranding Agreement Holder, authorized members of the Sea Turtle Stranding and Salvage Network (STSSN), any Alaska Native, and members of the Makah Indian Tribe already authorized to take a marine mammal under the Endangered Species Act (ESA) or Marine Mammal Protection Act (MMPA), to transport from the United States and dispose of a marine mammal or sea turtle carcass in ocean waters.

B. Does this action require the disposal of marine mammal or sea turtle carcasses in ocean waters?

The general permit does not require ocean disposal of marine mammal or sea turtle carcasses; it merely authorizes ocean disposal when there is a need for disposition of such carcasses in ocean waters.

C. Why does the EPA permit ocean disposal of marine mammal and sea turtle carcasses?

The disposition of marine mammal and sea turtle carcasses in ocean waters is not excluded from the statutory definition of ''dumping'' or otherwise excluded from the scope of the Marine Protection, Research, and Sanctuaries Act (MPRSA), as such the transportation and disposition of any material, including carcasses, in ocean waters requires a permit under the MPRSA.

D. Why does this action require reporting?

Given the natural and unnatural deaths of marine mammals and sea turtles at sea, the disposal of marine mammal or sea turtle carcasses into the ocean is not anticipated to have any adverse effect on human health, fisheries resources, or marine ecosystems. Under the MPRSA regulations (40 CFR 224.1 and 224.2), each person dumping materials under a general permit must maintain records of the physical and chemical characteristics of the material dumped, the times and locations of the dumping, and any other information required as a condition of the permit. Dumping records must be reported to the EPA as required under the general permit. Additionally, to meet the United States' international treaty obligation for reporting under the London Convention, the EPA reports information about disposals under this general permit, and all other activities authorized under the MPRSA, annually to the International Maritime Organization, which provides administrative support on behalf of the treaty parties.

II. Federal Law and International Conventions

Except as excluded from the definition of dumping in the MPRSA (or otherwise excluded), the transportation for the purpose of dumping and dumping of any material in ocean waters requires authorization under the MPRSA. The MPRSA defines the term ''dumping'' broadly to encompass the disposition of material both for the purpose of disposal and for purposes other than disposal. The exclusion for purposes other than disposal is limited. Section 102(a)(A) of the MPRSA and implementing regulations at 40 CFR 227.14 through 227.16 direct the EPA, in issuing a permit and/or evaluating a permit application, to consider the need for ocean dumping as well as alternatives to ocean dumping.

The MPRSA implements the United States' obligations under the London Convention, the international treaty that protects the marine environment from the dumping of wastes and other matter into the ocean. Contracting Parties to the London Convention agreed to control dumping by implementing regulatory programs to assess the need for, and the potential impact of, dumping. The London Convention requires Contracting Parties to issue a permit for the dumping of wastes and other matter at sea, to prohibit dumping of some materials, and to report annually on all permits issued and monitoring activities undertaken.

For the at-sea disposition of marine mammal and sea turtle carcasses, the EPA establishes terms for MPRSA permit authorization, but other Federal laws also are implicated. The MPRSA general permit only purports to authorize the transportation for the purposes of disposal and disposal of marine mammal and sea turtle carcasses at sea; it does not itself provide for compliance with those other Federal laws.

The Marine Mammal Protection Act (MMPA), for example, regulates human interactions with ''marine mammals''. The term marine mammal refers to any

mammal that is morphologically adapted to the marine environment (including sea otters and members of the orders Sirenia, Pinnipedi, and Cetacea) or primarily inhabits the marine environment (*e.g.,* polar bears). The Marine Turtle Conservation Act defines a sea turtle using the term ''marine turtle'', which means any member of the taxonomic family Cheloniidae or Dermochelyidae.

The EPA does not anticipate that the disposition of marine mammal or sea turtle carcasses will occur except in circumstances, such as but not limited to beached and floating marine mammal or sea turtle carcasses and/or mass strandings of marine mammals or sea turtles resulting in mortalities. In those circumstances, disposition into the ocean may be necessary to protect human health, for example, when other disposal options are not available.

Before 2017, the EPA permitted the ocean disposal of cetacean (whales and related species) and pinniped (seals and related species) carcasses on a case-by-case basis, with MPRSA emergency permits. The EPA issued a general permit for the ocean disposal of marine mammal carcasses, which became effective in January 2017, to streamline MPRSA authorization and reduce burdens associated with case-by-case permitting. That general permit provided authorization from January 5, 2017, through January 4, 2024. Under the MPRSA, general permits may be issued for a period no longer than seven years. By re-issuing the general permit, the general permit's authorization to transport marine mammal and sea turtle carcasses for the purpose of disposal and to dispose marine mammal and sea turtle carcasses in ocean waters would be available for another seven-year period. From January 5, 2017, through January 4, 2024, the effective period for the prior MPRSA general permit for ocean disposal of marine mammal carcasses, the EPA authorized 32 marine mammal carcass disposals in ocean waters under the general permit. During that same period of time, the EPA authorized an additional 43 marine mammal carcass disposals using emergency permits. Re-issuance of the general permit avoids the need for emergency permitting for marine mammal or sea turtle carcasses when such emergencies arise.

Federal laws providing protection and conservation of marine mammals and sea turtles include the MMPA, the Endangered Species Act (ESA), the Marine Turtle Conservation Act, the Whaling Convention Act (WCA), the Fur Seal Act, and international conventions, including the Inter-American Convention for the Protection and Conservation of Sea Turtles, the International Convention for the Regulation of Whaling, which established the International Whaling Commission (IWC), and the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Although this general permit applies only to marine mammal or sea turtle carcasses, certain international regulations are relevant. The United States is a party to the IWC and IWC regulations are self-implementing. The EPA is not the Federal agency charged with primary implementation of the United States' obligations under IWC regulations, but the MPRSA general permit is consistent with them.

IWC regulations recognize indigenous or aboriginal subsistence whaling. As relevant to subsistence whaling in the United States, the IWC sets catch limits for the Western Arctic stock of bowhead whales and Eastern North Pacific gray whales based upon the needs of subsistence fishing in Alaska villages and subsistence needs of the Makah Indian Tribe, respectively. The bowhead whale hunt is managed cooperatively by the National Marine Fisheries Service (NMFS) and the Alaska Eskimo Whaling Commission under the WCA and the MMPA. The gray whale hunt is managed cooperatively by NMFS and the Makah Tribal Council under the WCA and under a waiver of the MMPA (50 CFR 216.100 through 216.119). As such, any Alaska Native or member of the Makah Indian Tribe, who already may take a marine mammal under the MMPA and the ESA, is provided authority under this general permit should marine mammal carcasses need to be transported and disposed at sea. In re-issuing this general permit the EPA does not intend to change, alter, or otherwise affect any ceremonial, cultural, religious and/or subsistence practices involving marine mammals or sea turtles.

The other relevant Federal programs under the MMPA and the ESA are implemented by NMFS. MMHSRP Stranding Agreement Holders are provided authority to dispose of marine mammal carcasses in the ocean under this MPRSA general permit because Stranding Agreement Holders are authorized to take marine mammals subject to the provisions of the MMPA (16 U.S.C. 1361 *et seq.*) and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*). Members of the STSSN are provided authority to dispose of sea turtle carcasses under this MPRSA general permit because they are authorized to take sea turtles subject to the provisions of the ESA (16 U.S.C. 1531 *et seq.*), individual ESA Section 10 permits and/or the implementing regulations governing the taking, importing, and exporting of endangered and threatened marine species and designated critical habitat (50 CFR parts 222 through 226). As such, MMHSRP Stranding Agreement Holders and/or authorized members of the STSSN may have a need for ocean disposal should stranded marine mammals or sea turtles die.

III. Hazard to Public Safety and Navigation

A floating carcass near shore, for example, near a recreational beach or in a harbor or ship channel, may pose a risk to public safety before making land fall to the extent it might attract predators (*e.g.,* sharks) to a recreation area or may pose a hazard to navigation. Per regulations promulgated by the U.S. Army Corps of Engineers (USACE), at 33 CFR 245.20, the determination of a navigation hazard is made jointly by the USACE and the U.S. Coast Guard (USCG). If such a determination is made, the USACE determines appropriate remedial action as described in USACE regulations at 33 CFR 245.25, which may include carcass removal. MPRSA authorization to transport a carcass for the purpose of ocean disposal would be available through this MPRSA general permit if the navigation hazard removal operation requires ocean disposal of such carcasses.

IV. Strandings and Beachings

Marine mammals and sea turtles that have died or have become sick or injured can reach the ocean shoreline by a variety of mechanisms. Possible mechanisms include: beaching, which involves a marine mammal or sea turtle carcass being driven ashore by currents or winds; stranding (single or multiple) of live marine mammal(s) or sea turtle(s) that subsequently die; and transport on the bow of vessels. In most stranding cases, the causes of marine mammal and sea turtle strandings are unknown, but some causes may include the following: disease, parasite infestation, harmful algal blooms, injuries due to ship strikes, fishery entanglements, pollution exposure, unusual weather or oceanographic events, trauma and starvation. While many marine mammals and sea turtles die every year, most carcasses never reach the shore; rather, the carcasses are consumed by other organisms or decompose sufficiently to sink to the ocean bottom where, depending upon size, the carcass may form the basis of an ''organic fall'' ecosystem.

Stranding or beaching of marine mammals, sea turtles and/or marine mammal or sea turtle carcasses may pose a risk to public health due to the potential to transfer communicable diseases (*e.g.,* brucellosis, poxvirus and mycobacteriosis) to the exposed public. Marine carcasses present a significant disposal concern not only because of their size but also due to the frequency with which carcasses reach the shoreline. From 2006—2021, an average of 6,300 marine mammals stranded on United States shorelines per year (NMFS, 2024). A large majority of marine mammals that strand either are dead or die shortly after stranding (NMFS, 2022).

V. Disposal and Management Options

Generally, MMHSRP Stranding Agreement Holders and members of the STSSN are authorized to respond to marine mammals and sea turtles, respectively, that are found floating near shore or beached or stranded along the shore. While Stranding Agreement Holders and members of the STSSN do not and cannot respond to every stranded marine mammal and sea turtle, when they do respond and deem disposal necessary, the carcass must be disposed of properly. The MMHSRP has prepared a programmatic Environmental Impact Statement that describes, among other things, disposal and management options for carcasses of deceased marine mammals (NMFS, 2022).

For a dead marine mammal or sea turtle encountered, generally available methods for carcass disposal and management fall into two main categories: remove-from-the-environment and remain-in-the-environment. Remove-from-the-environment methods entail moving the carcass for disposal through controlled means and include disposing of a carcass in a landfill, or incinerating, rendering, or composting the carcass. Remain-in-the-environment methods involve leaving the marine mammal or sea turtle carcass in the environment to decompose naturally and include the following: allowing the carcass to remain and decompose in place; burying the carcass in place; and transporting the carcass to sea for ocean disposal. No single method is recommended for every carcass, and several factors are necessarily considered to determine the best disposal method for any particular carcass. Selection of a disposal method depends on factors such as number and size of the animals, carcass condition, the location, if chemicals were administered (including as antibiotics, sedatives and/or chemical euthanasia agents), availability of local resources and transportation logistics. Location considerations include coastal geography, currents, proximity to areas used extensively by the public, and Tribal, Federal, State, and/or local laws and regulations. While this **Federal Register** publication discusses other disposal methods briefly, the MPRSA general permit itself only concerns the disposal method to tow or otherwise transport the carcass of a marine mammal or sea turtle to sea for ocean disposal and the at-sea disposition of the remains.

A. Remove-from-the-Environment Methods

One benefit of removing the carcass from the environment is minimizing the likelihood of infectious disease transmission to humans, domesticated animals and wildlife. These methods either sequester the carcass or destroy the carcass and any associated pathogens and should be considered if the animal is suspected to have died from a disease that can easily spread to human or other animal populations. Remove-from-the-environment approaches can also be beneficial if the carcass contains toxic chemicals, such as certain chemical euthanasia agents, like pentobarbital. Some of these methods effectively remove these substances from the environment.

1. Disposal in a Licensed Landfill

The most widespread remove-from-the-environment method is disposal in a landfill. With this method, the carcass is removed from the beaching or stranding location and brought to a nearby landfill in a lined or contained transport vehicle. Disposal in a licensed landfill can minimize the likelihood and adverse effect of releasing any toxic substances contained in the carcass, including any euthanasia drugs, because the substances can be contained to one location. However, not all licensed landfills may be able to accept animals that have been euthanized with barbiturates. Therefore, authorities would contact local landfills to ensure that the landfill can accept carcasses that contain these drugs.

2. Incineration

Incineration is the process by which carcass tissues are disintegrated by burning. Incineration, particularly at an incineration facility, destroys the physical integrity of a carcass and the remaining ashes and hard parts (*i.e.,* teeth, bones, etc.) are buried in a landfill. Disposal via incineration can prevent the spread of diseases, toxic materials and veterinary drugs contained in the carcass from entering the environment. Disposal via the incineration method may require preplanning and coordination with the local facility to fully understand the biological load that the incineration facility can manage. Incineration can be very expensive. Incineration facilities are not commonly found in all areas of the United States and the availability of commercial or municipal incinerators may be limited by the transportability of the carcass.

3. Rendering

Rendering is an activity in which the carcass is rapidly reduced and recycled into new products. Rendering uses all parts of the animal and often creates a protein by-product (*e.g.,* protein meal) and a fat by-product (*e.g.,* tallow and grease). Disposal via rendering exposes the carcass to high heat to eliminate pathogens and prevent the spread of diseases. However, if a carcass contains euthanasia drugs some facilities may not be able to accept or process the carcasses depending on the drug. Disposal via rendering requires preplanning and coordination with the rendering facility to fully understand its policies for disposal of animals that were chemically euthanized. Rendering may be very expensive. Rendering facilities are not commonly found in all areas of the United States and the availability of rendering facilities may be limited by the transportability of the carcass.

4. Composting

Composting marine mammal or sea turtle carcasses would involve bringing a carcass to a commercial composting facility (which may or may not require a State or local operating license) or to a site designated specifically for carcass composting or composting in a carcass digester. While composting is similar to disposal in a landfill, it offers the added benefit that the nutrients contained within the carcass are transformed into biologically available material. Disposal via composting can minimize the threat of releasing any pathogens or toxic substances contained in the carcass, including euthanasia drugs, because composted carcasses are contained to one location. However, if a carcass contains certain veterinary drugs, some facilities may not be able to accept or process the carcasses. Disposal via composting requires preplanning and coordination with the local facility to fully understand their policies for disposal of animals that were chemically euthanized and to ensure that all carcass compost will be used in accordance with local and State

regulations on wildlife compost. Composting facilities are not commonly found in all areas of the United States and the availability of composting facilities may be limited by the transportability of the carcass.

B. Remain-in-the-Environment Methods

The remain-in-environment methods of disposal involve leaving marine mammal or sea turtle carcasses to naturally break down in the same, or similar, area in which it was found. Natural decomposition or burial in place may be used for both small and large marine mammal or sea turtle carcasses and is often the most preferred method if the carcass size or remoteness of the carcass location avoids logistical issues related to transportation. Remain-in-the-environment disposal methods should not be used for animals that were chemically euthanized with drugs known to cause secondary poisoning.

1. In-Place Decomposition

Allowing a carcass to remain in place to decompose may be an acceptable disposal method if the carcass does not pose a human exposure risk for public health and animal health or result in unacceptable odor or visual aesthetic impacts. In-place decomposition may also be the most practical when the carcass is located in an area that is remote or inaccessible to heavy equipment, thereby making other options, such as burying in place or moving to a different disposal location, infeasible.

2. In-Place Burial

In-place burial of a marine mammal or sea turtle carcass involves burying the carcass in the same or a similar location where the animal was found and may be used as a disposal method, especially when the carcass is located near population centers or near areas used for recreational activities. In-place burial involves excavating a trough above the high tide line, placing the carcass in the trench and covering the carcass with the excavated material. Burying the carcass creates a barrier that minimizes the smell and sight of the decaying carcass and reduces the likelihood of transmitting infectious diseases and attracting scavengers. Utilizing the in-place burial disposal method also depends on other factors such as the sediment substrate in the area (*e.g.,* fine sediments versus rocks and boulders), the availability of appropriate excavation equipment, and ability to avoid potential environmental damage (*e.g.,* destruction of dunes, beach grass, or nesting sites) caused by the transportation and operation of excavation equipment.

3. Ocean Disposal

The ocean disposal method is the only method to which the MPRSA general permit applies and imposes requirements. If a carcass cannot be moved to a land-based disposal location, left above ground to decay, or be buried in-place, then it would be appropriate to tow (or transport offshore via another method) and dispose of the carcass in the ocean, provided that an acceptable ocean disposal ''site'' or location can be identified. Ocean disposal of a marine mammal or sea turtle carcass entails selection of an appropriate location for the carcass to be released or sunk to prevent the carcass from drifting or washing back onshore with all reasonable effort, becoming a hazard to navigation, or damaging protected and sensitive habitats. The carcass may float due to gas formation from decomposition. To facilitate rapid sinking, opening the body cavity may be necessary. If the carcass is to be sunk rather than released at the disposal site, appropriate carcass preparation may be necessary (*e.g.,* piercing the body cavity, attaching weights, cement barriers or chains) at the ocean disposal site so that the carcass will not return to shore or pose a hazard to navigation.

VI. Potential Consequences of Marine Mammal and Sea Turtle Carcass Disposal in the Ocean and Why a General Permit Is Appropriate

Leaving a marine mammal or sea turtle carcass in the environment to decompose, for example through in-place decomposition or burial or ocean disposal, provides a number of benefits to terrestrial, pelagic and benthic ecosystems (NMFS, 2022). Marine mammal and sea turtle carcasses that become stranded onshore and are left in-place to decompose or are buried are an integral part of coastal ecosystems providing a key source of food to scavengers and nutrients to the sediments, which may be used by algae and plants potentially increasing landscape heterogeneity (Bui 2009; Laidre et al., 2018; Quaggiotto et al., 2022; Schultz et al., 2022). Marine mammal and sea turtle carcasses that decompose while floating in ocean waters provide an energy-rich source of food for other marine animals, such as orcas and sharks (Leclerc et al., 2011; Quaggiotto et al., 2022; Schultz et al., 2022; Tucker et al., 2019; Whitehead and Reeves, 2005). Most marine mammal and sea turtle carcasses sink to the seafloor and decompose naturally (Quaggiotto et al., 2022; Schultz et al., 2022). Whale carcasses are a significant source of carrion in the marine environment, representing a huge food supply to scavengers and decomposers (Smith and Baco, 2003).

Whale falls, which occur naturally, are the most studied examples of marine mammal carcass decomposition on the seafloor (Smith et al., 2015). Whale falls are sites of intense and lasting enrichment of organic material and sulfides on the seafloor which attract and sustain diverse communities of vertebrate and invertebrate scavengers (Quaggiotto et al., 2022). Most deep-sea benthic ecosystems are organic-carbon limited and, in many cases, are dependent upon organic matter from surface waters (Smith and Baco, 2003). A sunken carcass provides a large load of organic carbon to the seafloor and enhances the structural complexity of the seafloor, provides habitats for chemosynthetic organisms and results in the establishment of specialized biological assemblages (Smith and Baco, 2003; Oldach et al., 2022; Smith et al., 2015). Over 20 macrofaunal species are known to exclusively inhabit the microenvironment formed by large organic falls and over 30 other macrofaunal species are known to inhabit these sites (Smith and Baco, 2003). The deep-sea benthic ecosystem response to whale falls has been the subject of scientific study and several stages of succession have been observed in the assemblages (Smith and Baco, 2003).

The duration of these stages of a whale fall varies greatly with carcass size, but generally occur as follows. The first stage is marked by the formation of bathyal scavenger assemblages that include hagfishes, sleeper sharks, crabs and amphipods. During the second stage, sediments surrounding the carcass, which have become enriched with organic carbon, become colonized by high densities of worms (*e.g., Dorvilleidae, Chrysopetalidae*). Once the consumption of soft tissue is complete, decomposition proceeds dominantly via anaerobic microbial digestion of bone lipids. The efflux of sulfides from the bones may, depending upon the size of the skeleton, provide for the formation of chemoautotrophic assemblages, which marks the third stage of succession. Chemoautotrophic assemblages typically consist of organisms such as heterotrophic bacteria, mussels, snails, worms, limpets and amphipods.

Water and sediment quality in the area adjacent to the fall may be negatively affected by at-sea disposals of marine mammal carcasses because a carcass could release contaminants into

the water during decomposition (NMFS, 2022). Because contaminants would dilute rapidly in the water or break down over time in the tissues, the adverse impact would be minor and no different than what would happen naturally had the carcass sank to the seafloor and decomposed (NMFS, 2022).

The EPA has permitted numerous at-sea disposals of marine mammal carcasses under the MPRSA. In 2020, the EPA conducted biological, chemical and physical monitoring of a location offshore where several marine mammal carcasses had been sunk for disposal between 2009 and 2020, with the most recent disposal occurring six months prior to monitoring. The purpose of the survey was to determine any adverse impacts the decomposing whales may have caused to the immediate benthic community and surrounding area. Monitoring results from a recently disposed humpback whale carcass revealed that the carcass was reduced to whale bones with minimal whale tissue remaining within six months and found no measurable impact on sediment quality parameters (including total organic carbon, grain size and polychlorinated biphenyl concentration) from decomposition.

Less research is available regarding at-sea decomposition of sea turtle carcasses. When a sea turtle dies at sea, however, the carcass typically sinks until decomposition gases cause the body to bloat and float to the surface (Schultz et al., 2022). Partially submerged, sea turtle carcasses may drift as they are transported by winds and currents until it washes onshore or decomposes further and sinks to the seafloor (Santos et al., 2018). Once settled on the seafloor, sea turtle carcasses would decompose naturally (Schultz et al., 2022).

The EPA seeks to minimize the adverse impacts to the marine environment from the materials used when necessary to sink carcasses through a coordination between the general permittee and the regional EPA MPRSA Coordinator. Environmentally benign materials that have been used for sinking marine mammal carcasses include sandbags, jute rope, concrete and steel cables. These materials do not cause adverse impacts on water or sediment quality or harm the marine environment (NMFS, 2022). The small volume of sand used to sink carcasses does not cause an adverse effect on the seafloor substrate type. Burlap sandbags and jute rope (used to sink smaller carcasses), which are non-plastic materials that are biodegradable, do not persist in the marine environment or cause an ingestion hazard (Araya-Schmidt and Queirolo, 2019; Rautenbach et al., 2024; Unsworth et al., 2019; Wang et al., 2021; Zhang et al., 2015). When jute rope is used to tie sandbags to the animal, the shortest length possible is used to minimize the risk of entanglement by other marine organisms. Concrete keel blocks and steel cable used to sink larger carcasses are made from non-plastic, inert materials that are not anticipated to degrade the water quality of the seafloor or the water column (Melchers et al., 2022; Moffat et al., 2017; NMFS, 2022; Sun et al., 2022).

Generally, marine mammal and sea turtle strandings represent a minimum measure of actual at-sea mortality based on scientific studies that estimate that stranding events represent only 10–20% of total mortalities in open ocean environments (Epperly et al., 1996; Hart et al., 2006; Santos et al., 2018). Considering the available scientific information on marine mammal and sea turtle strandings, marine mammal and sea turtle *in situ* decomposition and organic falls, the EPA finds that the potential adverse effects of ocean disposal of marine mammal or sea turtle carcasses under the MPRSA permit are minimal for the following reasons: (1) except in rare instances, most marine mammal or sea turtle carcasses would sink to and decompose on the ocean floor rather than wash ashore; (2) the formation of an organic fall is a naturally occurring phenomenon with no known adverse environmental impacts; (3) the materials used for sinking carcasses are chosen to minimize adverse environmental impacts; (4) the site selection for sinking carcasses requires consultation to avoid adverse environmental impacts; and (5) transporting a marine mammal or sea turtle carcass to sea for ocean disposal, when other disposal methods are not viable, presents a minimal perturbation to a naturally occurring phenomenon.

The EPA's findings are consistent with the statutory considerations applicable to permit issuance under the MPRSA because: (1) the general permit requires consideration of the need for ocean disposal and consideration of land-based alternatives; (2) marine mammal and sea turtle carcass disposals will not cause a significant adverse effect on human health and welfare, fisheries resources, marine ecosystems, or alternate uses of the ocean; (3) marine mammal and sea turtle carcass disposals will not cause any persistent or permanent adverse effects; and (4) the release and disposal locations will be appropriately considered to protect human health and to minimize interference with navigation.

VII. Statutory and Regulatory Background

MPRSA Section 101, 33 U.S.C. 1411, prohibits the unpermitted transportation of any material for the purpose of dumping it into ocean waters. MPRSA Section 102(a)(1), 33 U.S.C. 1412(a), authorizes the EPA, after notice and the opportunity for public hearings, to issue MPRSA permits. Section 102(a) of the MPRSA directs the EPA, in issuing a permit and/or evaluating a permit application, to consider, among other things, the need for ocean dumping as well as alternatives to ocean dumping. MPRSA Section 104(c), 33 U.S.C. 1414(c), authorizes the EPA to issue general permits for the transportation for the purpose of dumping, dumping, or both for specified materials, or classes of materials, it determines will have a minimal adverse environmental impact. The EPA regulations explain that the EPA may issue general permits for the dumping of materials that have a minimal adverse environmental impact and are generally disposed of in small quantities, or emergency permits for specific classes of materials that must be disposed of in emergency situations (40 CFR 220.3(a) and (c)). The towing or other method of transportation to move a marine mammal or sea turtle carcass offshore by any person for disposal at sea constitutes transportation of material for the purpose of dumping in ocean waters, and thus is subject to the MPRSA. Because the material to be disposed will consist of the carcass or carcasses, and in some cases environmentally benign material used to sink the carcass or carcasses, there will be no materials present that are prohibited by 40 CFR 227.5.

VIII. Consideration of Subsistence Uses Authorized Under the MMPA

In re-issuing this general permit, the EPA attempts, to the maximum extent allowable, to avoid interference with long-standing subsistence uses and traditional cultural practice of Alaska natives and the Makah Indian Tribe engaged in ceremonial and subsistence practices. Recognition of subsistence uses is incorporated into the MMPA and the EPA derived permit terms for such users consistent with the MMPA's designed recognition of those uses. In re-issuing this general permit, the EPA does not intend to change, alter or otherwise affect subsistence uses of marine mammals by Alaska Natives and members of the Makah Indian Tribe.

The general permit does not in any way *require* ocean disposal of marine mammal carcasses. Instead, the permit

merely provides the required Federal permit authorization of ocean disposal of marine mammal carcasses when there is a need for disposition of carcasses at sea. Subsistence activities of Alaska Natives and members of the Makah Indian Tribe that fall outside the scope of ocean disposition of carcasses may include: hunting, harvesting, salvaging, hauling, dressing, butchering, distribution, and consumption of marine mammals (or any other species used for subsistence purposes); the transportation and disposition of marine mammal carcasses at inland locations, such as in whale boneyards or in inland waters (*i.e.,* waters that are landward of the baseline of the territorial sea, such as rivers, lakes, and certain enclosed bays or harbors); or leaving marine mammal carcasses to decompose in place, where there is no transportation by vessel or other vehicle for the purpose of ocean disposal. The purpose of this general permit is to expedite the required MPRSA permit authorizations the EPA manages for the ocean disposal of marine mammal carcasses.

A. Consideration of Alaska Natives Engaged in Subsistence Uses

Alaska Natives engaged in subsistence uses are not required to, but may, transport and dispose of marine mammal carcasses in ocean waters. The EPA developed Section B of the general permit taking into consideration the subsistence use patterns and needs of Alaska Native persons. For purposes of this general permit, the EPA uses the term ''Alaska Native'' with reference to the MMPA exemption specifically, the exemption for ''any Indian, Aleut, or Eskimo who resides in Alaska and who dwells on the coast of the North Pacific Ocean or the Arctic Ocean'' who takes a marine mammal ''for subsistence purposes'' or ''for purposes of creating and selling authentic native articles of handicrafts and clothing'' and provided such taking is not in a wasteful manner (16 U.S.C. 1371(b)).

Section B of the general permit provides separate terms for authorized ocean disposal of marine mammal carcasses by an Alaska Native engaged in subsistence uses for two reasons. First, marine mammals are comparatively abundant and widely distributed throughout coastal Alaska, and Alaska Natives depend upon these natural resources for many customary and traditional uses. Collectively, the customary and traditional uses (*e.g.,* food, clothing) are referred to as ''subsistence uses.'' Alaska Natives have been using marine mammals for subsistence for thousands of years. The United States recognizes the importance of Alaska Native subsistence uses under the MMPA, which expressly exempts Alaska Natives engaged in subsistence uses from the general prohibition on ''taking'' marine mammals under certain circumstances (16 U.S.C. 1371(b)). The MPRSA, by comparison, does not include a similar exemption for the transport and disposal in ocean waters by Alaska Natives when marine mammal carcasses (or parts thereof) have no further use for subsistence purposes. Section B of the general permit accommodates the absence of an MPRSA exemption similar to the MMPA exemption by facilitating authorization of ocean disposal of marine mammal carcasses by Alaska Natives, including through annual rather than episodic reporting. Second, many coastal communities of Alaska Natives who engage in subsistence uses are located in remote locations and thus face a time-critical public safety issue, for example, when a marine mammal carcass washes ashore near a village or town, or a marine mammal is harvested or salvaged and the carcass is hauled ashore near a village or town. Such carcasses may attract bears or other scavenger animals, which may increase the risk of human injury or mortality. For these reasons, there are specific provisions in the general permit for Alaska Natives engaged in subsistence activities to expedite the transport and disposal of marine mammals in ocean waters, if necessary.

With these considerations in mind, the EPA's re-issuance of the Alaska Native-specific permit conditions (see Section B) is intended, to the maximum extent allowable, to avoid unnecessary interference with long-standing subsistence uses and traditional cultural practices, and to recognize the unique circumstances of Alaska Natives engaged in subsistence uses. In re-issuing this general permit, the EPA does not intend to change, alter, or otherwise affect subsistence uses of marine mammals by Alaska Natives engaged in subsistence uses. Section B sets forth requirements designed to address these considerations while also complying with international treaties, the MPRSA, and the EPA's regulations at 40 CFR subchapter H. The primary differences between Sections A and B relate to Federal agency concurrence, distance from land requirements for ocean disposal, and reporting requirements.

B. Consideration of Members of the Makah Indian Tribe

Members of the Makah Indian Tribe engaged in ceremonial and subsistence uses of marine mammals may, but are not required to, transport and dispose of marine mammal carcasses in ocean waters. For purposes of this general permit, Section C of the general permit authorizes ocean disposal of marine mammal carcasses by any member of the Makah Indian Tribe engaged in subsistence uses. The Makah Indian Reservation occupies a reservation located on the remote, northwestern tip of Washington State where the Strait of Juan de Fuca meets the Pacific Ocean. For thousands of years, the Makah Indian Tribe has depended on resources from the ocean for their subsistence, culture, and economy and hunting and harvesting whales, seals, other marine mammals, and marine fish have always been integral and essential to the Makah Indian Tribe.

The United States recognizes the importance of ceremonial and subsistence uses of marine mammals by the Makah Indian Tribe through the Treaty of Neah Bay. Through the Treaty of Neah Bay, the United States recognizes sovereign rights of the Makah Indian Tribe to natural resources and cultural practices, including the right to hunt and harvest whales, seals, other marine mammals, and marine fish, as well as the Makah Indian Reservation. By regulation, the Secretary of Commerce has issued a conditional waiver from the MMPA moratorium on the take of Eastern North Pacific gray whales for enrolled members of the Makah Indian Tribe (50 CFR 216.10 through 216.119; 16 U.S.C. 1371(a)(3)(A)). By comparison, the MPRSA does not provide the EPA with authority to waive permitting requirements for the transport and disposal in ocean waters when marine mammal carcasses (or parts thereof) have no further subsistence or ceremonial use. For reasons similar to the accommodations for Alaska Natives, the EPA includes Makah Indian Tribe-specific permit conditions (see Section C) to minimize interference with long-standing marine mammal subsistence uses and traditional cultural practices of the Makah Indian Tribe.

Though EPA did not propose the Makah Indian Tribe-specific provisions, the inclusion of these provisions in this final general permit merely recognizes the existing MMPA waiver of the Eastern North Pacific gray whale moratorium applicable to the Makah Indian Tribe. The difference between Sections A and C (for the Makah Indian Tribe) relates to one aspect of prior consultation. Section C of the general permit does not require that members of the Makah Indian Tribe conduct prior consultation with a Stranding Agreement Holder for the disposal of

carcasses (or parts thereof) that have no further subsistence or ceremonial use. In addition, Section C includes conditions required as part of the Clean Water Act section 401 water quality certification process, as explained below, regardless of how unlikely it may be that a member of the Makah Indian Tribe might transport carcasses (or parts thereof) to the waters where those additional conditions apply.

IX. Discussion

Considering the information presented in the previous sections, the EPA determines that the potential adverse environmental impacts of marine mammal or sea turtle carcass disposals at sea, in compliance with the permit's terms, are minimal and that marine mammal and sea turtle carcasses often must be disposed of to mitigate threats to public safety (*e.g.,* recreational uses in nearby waters) as well as risks of navigation hazards. As such, issuance of a general permit for the transportation for the purpose of disposal and the ocean disposal of marine mammal and sea turtle carcasses is appropriate under the MPRSA.

Authorization under Section A of the general permit is available to Tribal, Federal, State, and local government officials and employees acting in the course of official duties and to MMHSRP Stranding Agreement Holders and members of the STSSN. Section A authorizes such persons to transport and dispose of marine mammal or sea turtle carcasses in ocean waters. Section A requires that each such permittee consult with the MMHSRP of NMFS or the STSSN—and recommends that each such general permittee consults with the applicable USCG District Office—prior to initiating any ocean disposal activities with respect to a marine mammal or sea turtle carcass. Permittees authorized under Section A would need to consult with and obtain concurrence from the applicable EPA Regional Office on selection of an ocean disposal site, which must be at a location three miles seaward of the mean lower low water line (ordinary low water mark) along the coast or a ''closing line'' across river mouths and openings of bays as demarcated on nautical charts. Disposal sites in the ocean waters of Puget Sound are not subject to the distance-from-shore restriction; however, permittees would need to consult with and obtain concurrence from EPA Region 10 on selection of the site. The EPA requested certification under Clean Water Act section 401 that discharges under this permit will comply with applicable provisions of Clean Water Act sections 301, 302, 306 and 307 from the State of Washington and from Tribes in the Puget Sound area for disposals in the ocean waters of Puget Sound that are not subject to the permit's distance-from-shore restriction. Only one entity, the Port Gamble S'Klallam Tribe, required additional conditions as part of the certification process, and those conditions are included in the permit. All permittees authorized under Section A also need to submit a report to the applicable EPA Regional Office on the ocean disposal activities after the disposal.

Alaska Natives engaged in subsistence uses are not required to, but may, transport and dispose of marine mammal carcasses in ocean waters. When disposal in ocean waters is the selected disposal approach, Section B of the general permit authorizes any Alaska Native engaged in subsistence uses to transport and dispose of a marine mammal carcass in ocean waters. Under Section B, the Alaska Native general permittee selects an ocean disposal site sufficiently far offshore so that currents and winds are not expected to return the carcass to shore, and the carcass is not expected to pose a hazard to navigation and afterwards submits, on an annual basis, a report to EPA Region 10 on ocean disposal activities conducted in the prior calendar year. Section B does not require a statement of need for selecting ocean disposal nor does it specify a distance requirement. The EPA requested certification under Clean Water Act section 401 that discharges under Section B of this permit will comply with applicable provisions of Clean Water Act Sections 301, 302, 306 and 307 from the State of Alaska for disposals in ocean waters by any Alaska Native at any distance from shore. The State of Alaska certified discharges associated with this general permit under Clean Water Act section 401 without additional conditions.

X. Response to Comments Received

The EPA published notice of the proposed re-issuance of the general permit on October 8, 2024, and invited public comment for a 60-day period that concluded on December 9, 2024. The EPA received four comment letters from private citizens, a non-governmental organization and an Alaska Native Village. All comments received supported re-issuance of this general permit and agreed with the EPA's assessment that the activities would not result in long-lasting adverse impacts. The EPA has developed a Response to Comments documents explaining the EPA's consideration of public comments received during the comment period. In response to the comments received, the EPA modified the final permit with expansions in the scope of eligibility and clarifications, including to improved language clarity and organization.

XI. Statutory and Executive Order Reviews

A. Paperwork Reduction Act

The information collections under this general permit are covered under the MPRSA Information Collection Request (ICR) that has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The ICR document that the EPA prepared for all MPRSA activities has been assigned EPA ICR number 0824.08.

Under section 104(e) of the MPRSA, 33 U.S.C. 1414(e) and implementing regulations at 40 CFR 221.1 and 221.2, applicants for an MPRSA permit must provide information that the EPA determines is necessary to review and evaluate such application, for example, to ensure that ocean dumping is appropriately regulated and will not harm human health or the marine environment. To meet United States' reporting obligation under the London Convention, the EPA reports some of this information in the annual United States ocean dumping report, which is transmitted to the International Maritime Organization for treaty compliance purposes.

Respondents/affected entities: Any officer, employee, agent, department, agency, or instrumentality of Tribal, Federal, State, or local unit of government, as well as any MMHSRP Stranding Agreement Holder and/or authorized member of the STSSN, who disposes of a marine mammal or sea turtle carcass in ocean waters and any Alaska Natives or members of the Makah Indian Tribe engaged in subsistence uses who disposes of a marine mammal carcass in ocean waters will be affected by this general permit. Under this general permit, respondents do not need to request permit authorization because the general permit authorizes ocean disposal of a marine mammal or sea turtle carcass by an eligible person.

Respondent's obligation to respond: Pursuant to regulations implementing section 104(e) of the MPRSA, 33 U.S.C. 1414(e), at 40 CFR 221.1 through 221.2, the EPA requires all ocean dumping permittees to supply specified reporting information.

B. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This MPRSA permitting action has Tribal implications, but the general permit will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law. The general permit has Tribal implications because it may affect traditional practices of some Tribes.

The EPA consulted with Tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of reviewing the previous general permit and preparing to re-issue this general permit to allow them to have meaningful and timely input into its development.

On February 14, 2023, the EPA emailed a consultation notification letter with a consultation and coordination plan to all 574 federally recognized Tribes, notifying them of this upcoming action and inviting Tribal leaders and designated consultation representatives to participate in the Tribal consultation and coordination process.

In early 2024, when the EPA was considering expanding the scope of the general permit to include ocean waters of Puget Sound, it held an additional Tribal coordination and consultation period for the Tribes in the Puget Sound area that could be affected by any such expansion of the permit's scope.

On April 2, 2024, the EPA emailed a consultation notification letter with a consultation and coordination plan to federally recognized Tribes in the Puget Sound area, notifying the Tribes of the proposal to modify the scope of the permit, and inviting Tribal leaders and designated consultation representatives to participate in the Tribal consultation and coordination process. A summary of the Tribal consultation and coordination effort, the Tribal input received, and how the EPA considered the input received may be found in the docket for this action (Docket ID No. EPA–HQ–OW–2023–0329).

XII. References

Araya Schmidt, T., & Queirolo, D. (2019). Breaking strength evaluation of biodegradable twines to reduce ghost fishing in the pot and trap fisheries of Chile. Latin American Journal of Aquatic Research, 47(1), 201–205. *https://doi.org/10.3856/vol47-issue1-fulltext-24.*

Bui, A. (2009). Beach burial of cetaceans: implications for conservation, and public health and safety.

Epperly, S. P., Braun, J., Chester, A. J., Cross, F. A., Merriner, J. v., Tester, P. A., & Churchill, J. H. (1996). Beach Strandings as an Indicator of At-Sea Mortality of Sea Turtles. Bulletin of Marine Science, 59(2), 289–297.

Hart, K. M., Mooreside, P., & Crowder, L. B. (2006). Interpreting the spatio-temporal patterns of sea turtle strandings: Going with the flow. Biological Conservation, 129(2), 283–290. *https://doi.org/10.1016/j.biocon.2005.10.047.*

Laidre, K. L., Stirling, I., Estes, J. A., Kochnev, A., & Roberts, J. (2018). Historical and potential future importance of large whales as food for polar bears. Frontiers in Ecology and the Environment, 16(9), 515–524. *https://doi.org/10.1002/fee.1963.*

Leclerc, L.-M., Lydersen, C., Haug, T., A. Glover, K., T. Fisk, A., & M. Kovacs, K. (2011). Greenland sharks (Somniosus microcephalus) scavenge offal from minke (Balaenoptera acutorostrata) whaling operations in Svalbard (Norway). Polar Research, 30(1), 7342. *https://doi.org/10.3402/polar.v30i0.7342.*

Melchers, R. E., & Tan, M. Y. (2022). Predicting the lifespan and corrosion behaviour of decommissioned oil and gas metallic infrastructure in the ocean. National Decommissioning Research Initiative: Newcastle, Australia).

Moffatt, E. G., Thomas, M. D. A., & Fahim, A. (2017). Performance of high-volume fly ash concrete in marine environment. Cement and Concrete Research, 102, 127–135. *https://doi.org/10.1016/j.cemconres.2017.09.008.*

Oldach, E., Killeen, H., Shukla, P., Brauer, E., Carter, N., Fields, J., Thomsen, A., Cooper, C., Mellinger, L., Wang, K., Hendrickson, C., Neumann, A., Bøving, P. S., & Fangue, N. (2022). Managed and unmanaged whale mortality in the California Current Ecosystem. Marine Policy, 140, 105039. *https://doi.org/10.1016/j.marpol.2022.105039.*

Quaggiotto, M.-M., Sánchez-Zapata, J. A., Bailey, D. M., Payo-Payo, A., Navarro, J., Brownlow, A., Deaville, R., Lambertucci, S. A., Selva, N., Cortés-Avizanda, A., Hiraldo, F., Donázar, J. A., & Moleón, M. (2022). Past, present and future of the ecosystem services provided by cetacean carcasses. Ecosystem Services, 54, 101406. *https://doi.org/10.1016/j.ecoser.2022.101406.*

Rautenbach, S. A., Pieraccini, R., Nebel, K., & Engelen, A. H. (2024). Marine biodegradation of natural potential carrier substrates for seagrass restoration. Marine Ecology. *https://doi.org/10.1111/maec.12813.*

Santos, B. S., Friedrichs, M. A. M., Rose, S. A., Barco, S. G., & Kaplan, D. M. (2018). Likely locations of sea turtle stranding mortality using experimentally-calibrated, time and space-specific drift models. Biological Conservation, 226, 127–143. *https://doi.org/10.1016/j.biocon.2018.06.029.*

Schultz, E. A., Cook, M., Nero, R. W., Caillouet, R. J., Reneker, J. L., Barbour, J. E., Wang, Z., & Stacy, B. A. (2022). Point of No Return: Determining Depth at Which Sea Turtle Carcasses Experience Constant Submergence. Chelonian Conservation and Biology, 21(1). *https://doi.org/10.2744/CCB-1518.1.*

Smith, C. R., & Baco, A. R. (2003). Ecology of whale falls at the deep-sea floor. In Oceanography and marine biology (pp. 319–333). CRC Press.

Smith, C. R., Glover, A. G., Treude, T., Higgs, N. D., & Amon, D. J. (2015). Whale-Fall Ecosystems: Recent Insights into Ecology, Paleoecology, and Evolution. Annual Review of Marine Science, 7(1), 571–596. *https://doi.org/10.1146/annurev-marine-010213-135144.*

Sun, D., Cao, Z., Huang, C., Wu, K., de Schutter, G., & Zhang, L. (2022). Degradation of concrete in marine environment under coupled chloride and sulfate attack: A numerical and experimental study. Case Studies in Construction Materials, 17, e01218. *https://doi.org/10.1016/j.cscm.2022.e01218.*

Tucker, J. P., Vercoe, B., Santos, I. R., Dujmovic, M., & Butcher, P. A. (2019). Whale carcass scavenging by sharks. Global Ecology and Conservation, 19, e00655. *https://doi.org/10.1016/j.gecco.2019.e00655.*

United States National Marine Fisheries Service (NMFS) Office of Protected Resources—Manley, S., Onens, P., Wilkin, S., Fauquier, D., Hall, L., Rowles, T., ... & Damon-Randall, K. (2022). Programmatic Environmental Impact Statement for the Marine Mammal Health and Stranding Response Program: Final Programmatic Environmental Impact Statement. Retrieved from *https://repository.library.noaa.gov/view/noaa/47576.*

United States National Marine Fisheries Service (NMFS) Office of Protected Resources—Onens, P., Wilkin, S., Fauquier, D., Spradlin, T., Manley, S., Wong, A., ... & Davis, N. (2024). 2020 and 2021 Combined Report of Marine Mammal Strandings in the United States. Retrieved from *https://repository.library.noaa.gov/view/noaa/60580.*

Unsworth, R. K. F., Bertelli, C. M., Cullen-Unsworth, L. C., Esteban, N., Jones, B. L., Lilley, R., Lowe, C., Nuuttila, H. K., & Rees, S. C. (2019). Sowing the Seeds of Seagrass Recovery Using Hessian Bags. Frontiers in Ecology and Evolution, 7. *https://doi.org/10.3389/fevo.2019.00311.*

Wang, Y., Zhou, C., Xu, L., Wan, R., Shi, J., Wang, X., Tang, H., Wang, L., Yu, W., & Wang, K. (2021). Degradability evaluation for natural material fibre used on fish aggregation devices (FADs) in tuna purse seine fishery. Aquaculture and Fisheries, 6(4), 376–381. *https://doi.org/10.1016/j.aaf.2020.06.014.*

Whitehead, H., & Reeves, R. (2005). Killer whales and whaling: the scavenging hypothesis. Biology Letters, 1(4), 415–418. *https://doi.org/10.1098/rsbl.2005.0348.*

Zhang, P.-D., Fang, C., Liu, J., Xu, Q., Li, W.-T., & Liu, Y.-S. (2015). An effective seed protection method for planting Zostera marina (eelgrass) seeds: Implications for their large-scale restoration. Marine Pollution Bulletin, 95(1), 89–99. *https://*

doi.org/10.1016/j.marpolbul.2015.04.036.

Stacey M. Jensen,

Director, Oceans, Wetlands, and Communities Division.

For the reasons stated above, the EPA re-issues the general permit for the transportation and ocean disposal of marine mammal and sea turtle carcasses as follows:

General Permit for the Transportation and Ocean Disposal of Marine Mammal and Sea Turtle Carcasses

A. General Requirements for Governmental Entities and Stranding Agreement Holders

Except as provided in Sections B and C below, any officer, employee, agent, department, agency, or instrumentality of Tribal, Federal, State, or local unit of government, any Marine Mammal Health and Stranding Response Program Stranding Agreement Holder, and any authorized member of the Sea Turtle Stranding and Salvage Network who already may take a marine mammal or sea turtle under the Endangered Species Act or Marine Mammal Protection Act, is hereby granted a general permit to transport for the purpose of disposal and dispose of marine mammal and sea turtle carcasses in ocean waters subject to the following conditions:

1. The permittee shall consult with a Stranding Agreement Holder of the National Marine Fisheries Service or an authorized member of the Sea Turtle Stranding and Salvage Network prior to initiating any disposal activities, unless the permittee is an Agreement Holder or Network member, respectively. Points of contact for Stranding Agreement Holders and members of the Sea Turtle Stranding and Salvage Network are available at *https://www.epa.gov/marine-protection-permitting/ocean-disposal-marine-mammal-and-sea-turtle-carcasses.*

2. The permittee shall consult with and obtain written concurrence (via email or letter) from the applicable EPA Regional Office on ocean disposal site selection. A disposal site must be at a location three miles seaward of the mean lower low water line (ordinary low water mark) along the coast or ''closing lines'' across river mouths and openings of bays as demarcated on nautical charts. Disposal sites in the ocean waters of Puget Sound are not subject to the distance-from-shore restrictions, however permittees would need to consult with and obtain concurrence from EPA Region 10 on selection of the site. Because the presence of a marine mammal or sea turtle carcass near human habitation or recreation areas may pose a time-critical public safety issue, the permittee may obtain concurrence via telephone from the applicable EPA Regional Office provided that the permittee subsequently obtains written concurrence (via email or letter). Points of contact at the EPA are available at *https://www.epa.gov/marine-protection-permitting/ocean-disposal-marine-mammal-and-sea-turtle-carcasses.*

3. If a determination is made that the carcass must be sunk, rather than released at the disposal site, the transportation and disposal of materials necessary to ensure the sinking of the carcass are also authorized for ocean dumping under this general permit. When materials are to be used to sink the carcass, the permittee must first consult with and obtain written concurrence (via email or letter) from the applicable EPA Regional Office on the selection of materials. Any materials described in 40 CFR 227.5 (prohibited materials) or 40 CFR 227.6 (constituents prohibited as other than trace amounts) shall not be used. The transportation and dumping of any materials other than the materials necessary to ensure the sinking of the carcass are not authorized under this general permit and constitute a violation of the MPRSA. Because the presence of a marine mammal or sea turtle carcass near human habitation or recreation areas may pose a time-critical public safety issue, the permittee may obtain concurrence via telephone from the applicable EPA Regional Office provided that the permittee subsequently obtains written concurrence (via email or letter).

4. The permittee shall submit a report on the ocean disposal activities authorized by this general permit to the applicable EPA Regional Office within 30 days after carcass disposal. This report shall include:

a. A description of the carcass(es) disposed (*e.g.,* species, approximate length, general condition, floating or not);

b. The date and time of the disposal, the latitude and longitude of the ocean disposal site, and the geodetic datum associated with the coordinates of the disposal site. Latitude and longitude of the disposal site shall be reported at the highest degree of accuracy available on board the vessel that transported the carcass (*e.g.,* onboard geographic position system technology);

c. The name, title, affiliation, and contact information of the person in charge of the disposal operation and the person in charge of the vessel or vehicle that transported the carcass (if different than the person in charge of the disposal); and

d. A statement of need and rationale for selecting ocean disposal rather than other disposal options.

5. The permittee shall immediately notify the EPA of any violation of any condition of this general permit.

6. Additional permit conditions as required by the Port Gamble S'Klallam Tribe's Clean Water Act Section 401 certification for transportation and disposal of marine mammal and sea turtle carcasses waters within the boundaries of the Port Gamble S'Klallam Reservation and trust lands:

a. Entities covered under this general permit shall use best management practices for sediment and turbidity control.

b. No discharge covered under the general permit shall cause exceedances of port Gamble S'Klallam Surface Water Quality Standards narrative or number criteria.

c. No carcasses shall be disposed of near shellfish beds used by Tribal fishers.

d. No activities under this general permit may negatively impact Tribal resources.

e. The Natural Resources Department shall be notified within 24 hours of any accidents, equipment failures, or unexpected impacts resulting from activities associated with this general permit.

B. Requirements for Any Alaska Native Engaged in Subsistence Uses

Notwithstanding Section A, any Alaska Native engaged in subsistence uses is hereby granted a general permit to transport for the purpose of disposal and dispose of marine mammal carcasses in ocean waters subject to the following conditions:

1. The permittee shall submit a report (via email or letter) on all disposal activities authorized by this general permit that the permittee has conducted in the prior calendar year. Reports shall be submitted to EPA Region 10 within 30 days of the end of the calendar year. Contact information for EPA Region 10 is available at *https://www.epa.gov/marine-protection-permitting/ocean-disposal-marine-mammal-and-sea-turtle-carcasses.* This report shall include:

a. The number and type of carcasses disposed;

b. A description of the general vicinity in which the carcasses were disposed; and

c. The name and contact information of the permittee.

2. Where ocean disposal is the selected approach, marine mammal

carcasses must be towed or otherwise transported to a site offshore where, based on available information, which may include local or traditional knowledge, currents and winds are not expected to return the carcass to shore and the carcass is not expected to pose a hazard to navigation.

C. Requirements for Any Member of the Makah Indian Tribe Engaged in Subsistence Uses

Notwithstanding Section A, any member of the Makah Indian Tribe who already may take a marine mammal under the Endangered Species Act and the Marine Mammal Protection Act is hereby granted a general permit to transport for the purpose of disposal and dispose of marine mammal carcasses in ocean waters subject to the following conditions:

1. The permittee shall consult with and obtain written concurrence (via email or letter) from the EPA Region 10 Office on ocean disposal site selection. A disposal site must be at a location three miles seaward of the mean lower low water line (ordinary low water mark) along the coast or ''closing lines'' across river mouths and openings of bays as demarcated on nautical charts. Disposal sites in the ocean waters of Puget Sound are not subject to the distance-from-shore restrictions, however permittees would need to consult with and obtain concurrence from EPA Region 10 on selection of the site. The permittee may obtain concurrence via telephone from the EPA Region 10 Office provided that the permittee subsequently obtains written concurrence (via email or letter). Points of contact at the EPA are available at *https://www.epa.gov/marine-protection-permitting/ocean-disposal-marine-mammal-and-sea-turtle-carcasses.*

2. If a determination is made that the carcass must be sunk, rather than released at the disposal site, the transportation and disposal of materials necessary to ensure the sinking of the carcass are also authorized for ocean dumping under this general permit. When materials are to be used to sink the carcass, the permittee must first consult with and obtain written concurrence (via email or letter) from the EPA Region 10 Office on the selection of materials. Any materials described in 40 CFR 227.5 (prohibited materials) or 40 CFR 227.6 (constituents prohibited as other than trace amounts) shall not be used. The transportation and dumping of any materials other than the materials necessary to ensure the sinking of the carcass are not authorized under this general permit and constitute a violation of the MPRSA. The permittee may obtain concurrence via telephone from the EPA Region 10 Office provided that the permittee subsequently obtains written concurrence (via email or letter).

3. The permittee shall submit a report on the ocean disposal activities authorized by this general permit to the EPA Region 10 Office within 30 days after carcass disposal. This report shall include:

a. A description of the carcass(es) disposed (*e.g.,* species, approximate length, general condition, floating or not);

b. The date and time of the disposal, the latitude and longitude of the ocean disposal site, and the geodetic datum associated with the coordinates of the disposal site. Latitude and longitude of the disposal site shall be reported at the highest degree of accuracy available on board the vessel that transported the carcass (*e.g.,* onboard geographic position system technology);

c. The name, title, affiliation, and contact information of the person in charge of the disposal operation and the person in charge of the vessel or vehicle that transported the carcass (if different than the person in charge of the disposal); and

d. A statement of need and rationale for selecting ocean disposal rather than other disposal options.

4. The permittee shall immediately notify the EPA of any violation of any condition of this general permit.

5. Additional permit conditions as required by the Port Gamble S'Klallam Tribe's Clean Water Act Section 401 certification for transportation and disposal of marine mammal and sea turtle carcasses waters within the boundaries of the Port Gamble S'Klallam Reservation and trust lands:

a. Entities covered under this general permit shall use best management practices for sediment and turbidity control.

b. No discharge covered under the general permit shall cause exceedances of port Gamble S'Klallam Surface Water Quality Standards narrative or number criteria.

c. No carcasses shall be disposed of near shellfish beds used by Tribal fishers.

d. No activities under this general permit may negatively impact Tribal resources.

e. The Natural Resources Department shall be notified within 24 hours of any accidents, equipment failures, or unexpected impacts resulting from activities associated with this general permit.

[FR Doc. 2025–13268 Filed 7–15–25; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting on Tuesday August 5, 2025 in the Commission Meeting Room and available to the public via the internet at *http://www.fcc.gov/live,* from 10:00 a.m. to 12:30 p.m.

DATES: Tuesday, August 5, 2025.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Martin Doczkat, Chief, Electromagnetic Compatibility Division 202–418–2435; *martin.doczkat@fcc.gov.*

SUPPLEMENTARY INFORMATION: At the August 5th meeting, the TAC will consider and advise the Commission on topics such as continued efforts at looking beyond 5G advanced as 6G begins to develop so as to facilitate U.S. leadership; studying advanced spectrum sharing techniques, including the implementation of artificial intelligence and machine learning to improve the utilization and administration of spectrum; and other emerging technologies. This agenda may be modified at the discretion of the TAC Chair and the Designated Federal Officer (DFO).

Meetings are broadcast live with open captioning over the internet from the FCC Live web page at *http://www.fcc.gov/live/.* The public may submit written comments before the meeting to Martin Doczkat, the FCC's Designated Federal Officer for Technological Advisory Council by email: *martin.doczkat@fcc.gov* or U.S. Postal Service Mail (Martin Doczkat, Federal Communications Commission, 45 L Street NE, Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Office of Engineering and Technology at 202–418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation

needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted but may not be possible to fill.

Federal Communications Commission.

Ira Keltz,

Acting Chief, Office of Engineering and Technology.

[FR Doc. 2025–13262 Filed 7–15–25; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Intermittent Survey of Businesses (FR 1374; OMB No. 7100–0302).

DATES: Comments must be submitted on or before September 15, 2025.

ADDRESSES: You may submit comments, identified by FR 1374, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments, including attachments. *Preferred method.*
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.
- *Hand Delivery/Courier:* Same as mailing address.
- *Other Means: publiccomments@frb.gov.* You must include the OMB number or the FR number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at *https://www.federalreserve.gov/apps/proposals/* without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would be not appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportingforms/review* or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR 1374. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection Title: Intermittent Survey of Businesses.

Collection Identifier: FR 1374.

OMB Control Number: 7100–0302.

General description of collection: The FR 1374 survey data are used to gather information to enable the Federal Reserve System to carry out its policy and operational responsibilities. Under the guidance of the Board, Reserve Banks survey business contacts as economic developments warrant. Usually, these voluntary surveys are conducted using an online survey tool, such as Qualtrics, to collect responses by purchasing managers, economists, or other knowledgeable individuals at selected, relevant businesses and occasionally state and local governments. Occasionally, the survey will be conducted via telephone or email as needed. The frequency and content of the questions, as well as the entities contacted, vary depending on developments in the economy. These surveys are conducted to provide Board members and Reserve Bank presidents real-time insights into economic conditions. The Board tailors these survey questions to match current concerns and interests, but they are not meant to supplant the more rigorous, existing economic reporting. The Board collects aggregate responses from the Reserve Banks and then distributes the information to Board members and Reserve Bank presidents.

Frequency: Annual, but it may be conducted up to three times a year depending on developments in the economy.

Respondents: Businesses, and as warranted by economic conditions, state and local governments.

Total estimated number of respondents: 1,500.

Total estimated annual burden hours: 1,125.

Board of Governors of the Federal Reserve System, July 12, 2025.

Benjamin W. McDonough,

Deputy Secretary and Ombuds of the Board.

[FR Doc. 2025–13275 Filed 7–15–25; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 15, 2025.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*.

1. *F&M Bancshares, Inc., Trezevant, Tennessee;* to merge with WestTenn Bancorp, Inc., and thereby indirectly acquire The Bank of Jackson, both of Jackson, Tennessee.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–13314 Filed 7–15–25; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Applications for Employment with the Board of Governors of the Federal Reserve System (FR 28; OMB No. 7100–0181).

DATES: Comments must be submitted on or before September 15, 2025.

ADDRESSES: You may submit comments, identified by FR 28, by any of the following methods:

- *Agency website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments, including attachments. *Preferred method.*
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.
- *Hand Delivery/Courier:* Same as mailing address.
- *Other Means: publiccomments@frb.gov.* You must include the OMB number or the FR number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at *https://www.federalreserve.gov/apps/proposals/* without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportingforms/review* or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR 28. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposals

The Board invites public comment on the following information collections, which are being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collections of information are necessary for the

proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collections, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collections

Collection title: Applications for Employment with the Board of Governors of the Federal Reserve System.

Collection identifier: FR 28.

OMB control number: 7100–0181.

General description of collection: The forms that comprise the FR 28 are used to manage the Board's hiring process by collecting needed information on candidates. The FR 28a (Application for Employment), is used to examine, rate, or assess the applicant's qualifications, and to contact the applicant to arrange an interview. The FR 28a can be completed either online in two parts (the Initial Application portion and, if selected for an interview, the Interview Selection portion) or in its entirety as a PDF. The FR 28s (Applicant's Voluntary Self-Identification) is used for equal employment opportunity (EEO) recordkeeping, reporting, and self-evaluation of hiring practices. The FR 28i (Research Assistant Application) is a supplement to the FR 28a and is used to collect contact information for an application for employment as a Research Assistant (RA), including to help match an RA candidate's interests with the different research areas at the Board and determine the applicants' data analysis and programming experience. The FR 28c (Pre-Hire Conflict of Interest Screening Form) is used to ensure advance knowledge of a prospective employee's potential conflicts of interest.

Proposed revisions: The Board proposes to revise the FR 28a by removing one data field. The Board proposes to revise the FR 28s by changing one data field. The Board proposes to revise the FR 28i by adding eight new data fields and removing one data field, and to revise the FR 28c by adding a new section to the form and updating the language of several of the questions for readability and to include questions about financial assets not previously contemplated due to technological changes that have occurred. Lastly, the Board proposes to revise the FR 28 clearance to include a new Reference Check Form (FR 28r).

Frequency: Event-generated.

Respondents: Individuals seeking employment with the Board.

Total estimated number of respondents: FR 28a (Initial Application), 32,600; FR 28a (Interview Selection), 1,769; FR 28a (PDF), 238; FR 28s, 32,838; FR 28i, 330; FR 28c, 2007; FR 28r, 650.

Estimated average hours per response: FR 28a (Initial Application), 0.48; FR 28a (Interview Selection), 1.51; FR 28a (PDF), 1.69; FR 28s, 0.02; FR 28i, 0.91; FR 28c, 0.62; FR 28r, 0.34.

Total estimated change in burden: −62.

Total estimated annual burden hours: 21,143.

Board of Governors of the Federal Reserve System, July 12, 2025.

Benjamin W. McDonough,

Deputy Secretary and Ombuds of the Board.

[FR Doc. 2025–13276 Filed 7–15–25; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice-MA–2025–17; Docket No. 2025–0002; Sequence No. 15]

Federal Management Regulation (FMR); Rescinding and/or Removing FMR Bulletins

AGENCY: Office of Government-wide Policy (OGP), U.S. General Services Administration (GSA).

ACTION: Notice to rescind and/or remove FMR Bulletins.

SUMMARY: GSA is rescinding and/or removing 41 bulletins due to their being outdated, unnecessary, expired, or inconsistent with Administration policy.

DATES: *Applicability Date:* July 16, 2025.

FOR FURTHER INFORMATION CONTACT: Mr. Alexander Kurien, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–495–9628 or by email at *alexander.kurien@gsa.gov.* Please cite Notice to rescind and/or remove FMR bulletins (MA–2025–17).

SUPPLEMENTARY INFORMATION:

Background

Due to issuance of the Executive Order (E.O.) 14192, *Unleashing Prosperity Through Deregulation,* dated January 31, 2025, GSA is rescinding and/or removing 41 Federal Management Regulation (FMR) Bulletins from GSA's website.

The following bulletins are rescinded and removed from GSA's website because the content is outdated, expired, unnecessary, or inconsistent with Administration policy:

1. FMR Bulletin C–2023–01: Clarifying the Process For Meeting Federal Space Needs
2. Notice-MA–2016–01: Best Practices in Warehouse Asset Management
3. FMR Bulletin 2012–C1: Accurate Reporting of Data for the Federal Real Property Profile
4. FMR Bulletin 2009 B–23: Federal Asset Sales (eFAS) Reporting Tool
5. FMR Bulletin 2008–B7: Federal Real Property Report
6. FMR Bulletin 2008–B2: Real Property Federal Asset Sales
7. FMR Bulletin 2008–B1: Delegations of Lease Acquisition Authority—Notification, Usage, and Reporting Requirements for General Purpose, Categorical, and Special Purpose Space Delegations
8. FMR Bulletin 2007–B3: Assessment of fees and recovery of costs for antennas of Federal agencies and public service organizations
9. FMR Bulletin 2007–B2: Placement of Commercial Antennas
10. FMR Bulletin 2007–B1: Information Technology and Telecommunications Guidelines for Federal Telework and Other Alternative Workplace Arrangement Programs
11. FMR Bulletin 2006–B4: Federal Real Property Profile Summary Report
12. FMR Bulletin 2006–B3: Guidelines for Alternative Workplace Arrangements
13. FMR Bulletin 2005–B2: Federal Real Property Profile Summary Report
14. FMR Bulletin 2005–B1: Revised Implementation Requirements of the Delegation of Lease Acquisition Authority
15. FMR Bulletin 2004 B–1: Federal Real Property Profile Summary Report
16. FMR Bulletin B–53: Use of Government-issued Fleet Charge Cards

17. FMR Bulletin B–52: Clarifying the Process For Meeting Federal Space Needs
18. FMR Bulletin B–43: Vehicle Allocation Methodology for Agency Fleets
19. FMR Bulletin B–40: List of Active and Cancelled or Superseded GSA Bulletins Addressing Personal Property
20. FMR Bulletin B–38: Indirect Costs of Motor Vehicle Fleet Operations
21. FMR Bulletin B–35: Home-to-Work Transportation
22. FMR Bulletin B–33: Alternative Fuel Vehicle Guidance for Law Enforcement and Emergency Vehicle Fleets
23. FMR Bulletin B–31: Government Motor Vehicle Fueling During Market Shortages
24. FMR Bulletin B–29: Accurately Reporting Passenger Vehicle Inventory within the Federal Automotive Statistical Tool
25. FMR Bulletin B–28: Federal Employee Transportation and Shuttle Services
26. FMR Bulletin B–19: Increasing the Fuel Efficiency of the Federal Motor Vehicle Fleet
27. FMR Bulletin B–11: U.S. Government License Plate Codes
28. FMR Bulletin 2004–B6: Proceeds from Sale of Agency-Owned Vehicles
29. FMR Bulletin B–3: Use of Tobacco Products in U.S. Government Vehicles
30. FMR Bulletin B–2: Wireless Phone Use in U.S. Government Vehicles
31. FMR Bulletin C–2: Delegations of Lease Acquisition Authority—Notification, Usage, and Reporting Requirements for General Purpose, Categorical, and Special Purpose Space Delegations
32. FMR Bulletin 2003–B1: Locating Federal Facilities in Rural Areas

The following bulletins are rescinded and removed because the bulletins are unnecessary and the subject matter is already adequately addressed by statute or existing regulations (listed in parentheses after the bulletin title in this notice). Rescission and removal of these bulletins is not intended to and does not impact underlying statutory and regulatory requirements.

33. FMR Bulletin 2009–B1: Protecting Federal Employees and the Public From Exposure to Tobacco Smoke in the Federal Workplace (41 CFR 102–74.315 through 102–74.351)
34. FMR Bulletin 2021–1: Persons who are Nursing in Public Buildings (40 U.S.C. 3318 and 29 U.S.C. 218d)
35. FMR Bulletin 2011–B1: Nursing Mothers in the Federal Workplace (40 U.S.C. 3318 and 29 U.S.C. 218d)
36. FMR Bulletin 2008–B6: POW/MIA Flag Display (36 U.S.C. 902)

The following bulletins are removed from GSA's website because they have expired. Expiration and removal of these bulletins do not alter the designation and redesignations set forth therein:

37. FMR Bulletin PBS 2008–B6: Redesignations of Federal Buildings
38. FMR Bulletin PBS 2007–B3: Redesignations of Federal Buildings
39. FMR Bulletin 2006–B1: Designations and Redesignations of Federal Buildings
40. FMR Bulletin 2005–B3: Redesignations of Federal Buildings
41. FMR Bulletin 2004–B3: Re-designations of Federal Buildings

All currently active FMR bulletins can be viewed at *https://www.gsa.gov/policy-regulations/regulations/federal-management-regulation/fmr-and-related-files.*

Larry Allen,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2025–13295 Filed 7–15–25; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Head Start Grant Application (Office of Management and Budget #0970–0207)

AGENCY: Office of Head Start, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Grant Application Instrument and Instructions (Office of Management and Budget (OMB) #0970–0207, expiration June 30, 2025). The updated grant application reduces the amount of documentation required from grant recipients, both in the baseline application and the continuation application, by reducing the number of required documents to support the application and reducing the amount of required information in the program and budget justification narrative. The goal of these changes is to reduce grant recipient burden.

DATES: *Comments due August 15, 2025.* OMB must decide about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: To receive Head Start funding, Head Start grant recipients must apply for such funds through this information collection. The information submitted by applicants assist program and grant officials in determining whether the applicant meets the requirements for funding under the Act including any requirements specified in annual appropriations by Congress. The updated grant application reduces the amount of documentation required from grant recipients, both in the baseline application and the continuation application, by reducing the number of required documents to support the application and reducing the amount of required information in the program and budget justification narrative. The goal of these changes is to reduce grant recipient burden, and the burden estimates below have been updated to reflect this.

Respondents: Head Start grant recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Head Start Grant Application	1,600	2	20	64,000

Authority: 42 U.S.C. 9801 *et seq.*

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–13310 Filed 7–15–25; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Evaluation of the National Human Trafficking Hotline: Understanding Engagement With the Community, Law Enforcement, and Other Hotlines (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families' (ACF) Office of Planning, Research, and Evaluation (OPRE) is proposing a data collection activity as part of the Evaluation of the National Human Trafficking Hotline (NHTH): Understanding Engagement with the Community, Law Enforcement, and other Hotlines. This data collection activity will examine how the NHTH processes contacts, interacts with law enforcement and other hotline providers, and advertises its services to potential contactors.

DATES: Comments due September 15, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The purpose of the proposed data collection activity is to document and examine how the NHTH processes contacts across modes and contactor types as well as how those processes compare to other similar hotlines, how the NHTH interacts with law enforcement and implements criteria for sharing tips with law enforcement, how the NHTH interacts with other national hotlines including service coordination and information sharing, and how the NHTH communicates and advertises its services to potential contactors.

The proposed data collection activity includes one-time, semi-structured interviews with:

1. Staff and leadership at the NHTH. Interviews with NHTH staff and leadership will include questions focused on NHTH processes, NHTH data collection, communication with contactors, and interactions with law enforcement regarding sharing tips and other hotlines.

2. Staff and leadership at other national hotlines that are similar in scope to the NHTH. Interviews will include questions focused on their own internal processes as well as interactions with and perceptions of the NHTH.

3. Service providers who regularly engage with the NHTH as well as those who do not regularly engage with the NHTH. Interviews will include questions focused on their interactions with and perceptions of the NHTH.

4. Law enforcement personnel who regularly engage with the NHTH as well as those who do not regularly engage with the NHTH. Interviews will include questions focused on perceptions of actionability of tips that are shared by the NHTH, comparison with tips shared by other hotlines, and the deconfliction process.

Respondents: NHTH staff, staff at other national hotlines, law enforcement personnel, victims service providers.

Annual Burden Estimates: This information collection is expected to take place over about 2 years. Burden estimates are shown as the total over 2 years divided by two to provide an annual average estimate.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
NHTH Leadership Interview Guide	5	1	1.5	7.5	3.75
NHTH Staff Interview Guide	15	1	1.5	22.5	11.25
Other Hotline Leadership Interview Guide	15	1	1	15	7.5
Other Hotline Staff Interview Guide	15	1	1	15	7.5
Law Enforcement Interview Guide	20	1	1	20	10
Service Provider Interview Guide	15	1	1	15	7.5

Estimated Total Annual Burden Hours: 47.5

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

(Authority: Public Law 106–386 Section 107 [22 U.S.C. 7105].)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–13297 Filed 7–15–25; 8:45 am]

BILLING CODE 4184–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0534]

Proposed Information Collection Activity; American Indian and Alaska Natives Facility Condition, Location, and Ownership Survey

AGENCY: Office of Head Start, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Office of Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing to collect data for the American Indian and Alaska Natives (AIAN) Facility Condition, Location, and Ownership Survey. This survey fulfills a statutory requirement and is conducted every 5 years. The previous survey used for this purpose was approved under Office of Management and Budget (OMB) #: 0970–0534; this request will be submitted under the same OMB number.

DATES: Comments due September 15, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The AIAN Facility Survey is conducted every 5 years in accordance with section 650(b) of the Head Start Act. The most recent survey was approved under OMB #0970–0534 to fulfill the 2020 statutory requirement. This request will be submitted to OMB under the same number as a reinstatement with changes.

The purpose of the survey is to collect current data on the condition, location, and ownership of facilities used by AIAN Head Start programs. The results inform the 2025 Report to Congress and support ongoing policy, funding, and technical assistance decisions. For the 2025 cycle, updates have been made to reflect lessons learned from the 2020 survey and feedback from OHS staff and partners. Changes include more detailed questions on facility safety (*e.g.,* lead testing, pest control, disaster impact), clearer definitions of facility conditions, and expanded items on funding sources and barriers. These revisions aim to strengthen data quality and ensure the survey captures the full scope of infrastructure challenges and needs across AIAN programs.

Respondents: AIAN Early Head Start and Head Start Preschool grantees.

Annual Burden Estimates

Grant recipients will complete the survey for each facility they operate, which based on current grant recipient information is an average of 3.5 responses per respondent. Data collection is expected to take place following OMB approval over a period of about 6 weeks.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
AIAN Facility Condition, Location, and Ownership Survey	155	3.5	0.17	92

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

(Authority: 42 U.S.C. 9846.)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–13294 Filed 7–15–25; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5942]

Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry.'' The draft guidance document provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for hepatitis B surface antigen (HBsAg) to reduce the risk of transfusion-transmitted hepatitis B virus (HBV). The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. The draft guidance, when finalized, is intended to supersede the recommendations regarding testing of all blood donations for HBsAg in the guidance document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus'' dated October 2012 (October 2012 Guidance). The guidance, when finalized, will also supersede information on the same topic that is in the document entitled ''Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)'' dated December 1987 (December 1987 Memorandum).

DATES: Submit either electronic or written comments on the draft guidance by October 14, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–5942 for ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry.'' The draft guidance provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for HBsAg to reduce the risk of transfusion-transmitted HBV. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. Specifically, the guidance recommends that when the donations are tested for HBV Deoxyribonucleic acid (DNA) by nucleic acid tests (NAT) and for antibody to hepatitis B core antigen (anti-HBc) using screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions, testing for hepatitis B surface antigen (HBsAg) is not necessary to reduce adequately and appropriately the risk of transmission of HBV. Because Source Plasma donations are not tested for anti-HBc, the draft guidance recommends the continued testing of Source Plasma donations for HBsAg. The draft guidance, when finalized, is intended to supersede the recommendations with respect to blood donations that are tested for HBV NAT and anti-HBc in the October 2012 Guidance and the information on the same topic in the December 1987 Memorandum. Upon finalization of the new recommendations set forth in this draft guidance, we intend to consolidate all FDA recommendations for testing blood and blood components for HBV to issue one guidance that includes finalized recommendations for testing donations to reduce the risk of transfusion transmission of hepatitis B. Except for conforming changes needed to reflect the new recommendations in this draft guidance, we do not intend to revise existing recommendations for HBV donation testing, quarantine and disposition of reactive units, donor deferral and requalification.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen.'' It does not establish any

rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338 and the collections of information in 21 CFR parts 610 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: July 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13272 Filed 7–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251; Order #02412–014–004–047181.0]

Notice of Plat of Survey, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plat of survey of the following described lands is scheduled to be officially filed 30 days after the date of this notice in the Bureau of Land Management (BLM) NM State Office, Santa Fe, NM. The survey announced in this notice is necessary for the management of lands administered by the U.S. Bureau of Reclamation (BOR).

DATES: If you wish to protest the survey identified in this notice, you must file a written notice of protest with the BLM Chief Cadastral Surveyor for NM by August 15, 2025.

ADDRESSES: Submit written protests to the BLM NM State Office, 301 Dinosaur Trail, Santa Fe, NM 87508. You may obtain a copy of the survey record from the public room at this office upon required payment. The plat may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Jacob B. Barowsky, Chief Cadastral Surveyor; (505) 761–8903; *jbarowsky@blm.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Rio Arriba County, NM:

The plat representing the dependent resurvey and survey of land in the Tierra Amarilla Grant, accepted May 20, 2025, for Group No. 1218, NM.

This plat was prepared at the request of the BOR, Albuquerque Area Office.

A person or party who wishes to protest this survey must file a written notice of protest by the date specified in the **DATES** section of this notice with the NM State Director, BLM, at the address listed in the **ADDRESSES** section of this notice.

A written statement of the reasons in support of the protest, if not filed with the notice of protest, must be filed with the BLM State Director for NM within 30 calendar days after the notice of protest is received.

Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. Chap. 3)

Jacob B. Barowsky,

Chief Cadastral Surveyor for NM.

[FR Doc. 2025–13302 Filed 7–15–25; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2025–0035]

Commercial Leasing for Outer Continental Shelf Minerals Offshore American Samoa—Request for Information and Interest; Extension of Comment Period

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Request for information and interest; extension of the comment period.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) announces a 30-day extension of the comment period for the request for information and interest (RFI) for leasing of the Outer Continental Shelf minerals in and around an area offshore American Samoa, referred to as the RFI Area.

DATES: BOEM published the RFI on June 16, 2025, and opened a public comment period through July 16, 2025. BOEM is extending this public comment period to August 15, 2025. BOEM must receive all comments, information, and indications of interest in response to this RFI no later than August 15, 2025.

ADDRESSES: Please submit indications of interest in commercial leasing electronically via email to *Pacific.Region@boem.gov* or by hard copy by mail to the following address: Bureau of Ocean Energy Management, Pacific Region, Office of Strategic Resources, 760 Paseo Camarillo (CM 102), Camarillo, California 93010. If you elect to mail a hard copy, also include an electronic copy on a portable storage device. Do not submit indications of interest via the Federal eRulemaking Portal.

Please submit all other comments and information as discussed in section 6 of the June 16, 2025, RFI entitled, ''Types of Information and Comments Requested,'' by either of the following two methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov*. In the search box at the top of the web page, enter BOEM–2025–0035 and then click ''search.'' Follow the instructions to submit public comments and to view supporting and related materials.

2. *By mail to the following address:* Bureau of Ocean Energy Management, Pacific Region, Office of Strategic Resources, 760 Paseo Camarillo (CM 102), Camarillo, California 93010.

Treatment of confidential information is addressed in section 8 of the June 16, 2025, RFI entitled, ''Protection of

Privileged, Personal, or Confidential Information.'' BOEM will post all comments received on *regulations.gov* unless labeled as confidential and BOEM determines that an exemption from disclosure applies.

FOR FURTHER INFORMATION CONTACT: Jennifer Miller, Bureau of Ocean Energy Management, Pacific Region, Office of Strategic Resources, 760 Paseo Camarillo (CM 102), Camarillo, California 93010, at *Pacific.Region@boem.gov* or (805) 384–6305.

SUPPLEMENTARY INFORMATION: Comments already submitted for the June 16, 2025, RFI do not need to be resubmitted. Please refer to the RFI published in the **Federal Register** (90 FR 25369) on June 16, 2025, for more information.

Authority: 43 U.S.C. 1337(k)(1) and 30 CFR 581.12.

Matthew Giacona,

Principal Deputy Director, Bureau of Ocean Energy Management.

[FR Doc. 2025–13280 Filed 7–15–25; 8:45 am]

BILLING CODE 4340–38–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1145 (Third Review)]

Steel Threaded Rod From China

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on steel threaded rod from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on February 3, 2025 (90 FR 8808) and determined on May 9, 2025, that it would conduct an expedited review (90 FR 22115, May 23, 2025).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on July 14, 2025. The views of the Commission are contained in USITC Publication 5647 (July 2025), entitled *Steel Threaded Rod from China: Investigation No. 731–TA–1145 (Third Review).*

By order of the Commission.

Issued: July 14, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–13340 Filed 7–15–25; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Benson Sergiles, P.A.; Decision and Order

On December 2, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Benson Sergiles, P.A., of Peoria, Arizona (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. MB7529261, alleging that Registrant is ''currently without authority to . . . handle controlled substances in the State of Arizona, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 3.[1] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.'' *Id.* 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 4–5; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, Registrant's Arizona physician assistant license expired on January 2, 2023. RFAAX 2, at 1. Further, according to the OSC, his Arizona physician assistant license specified that he was ''[n]ot certified to prescribe controlled drugs,'' and the prescriptive authority under his license before it expired was only for ''NON–CONTROLLED SUBSTANCES.'' *Id.* at 2. According to Arizona online records, of which the Agency takes official notice,[2] Registrant's Arizona physician assistant license remains expired. Arizona Regulatory Board of Physician Assistants Search, *https://www.azpa.gov/PASearch/PASearch* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice as a physician assistant in Arizona, the state in which he is registered with DEA.[3]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . .

[1] Based on the Government's submissions in its RFAA dated May 6, 2025, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on January 15, 2025, the DI emailed a copy of the OSC to Registrant at his registered email address but received an ''Undeliverable'' email in response stating that Registrant's registered email address was ''disabled.'' RFAAX 3, at 5. On the same date, the DI sent a copy of the OSC to Registrant's registered mailing address via USPS First Class Mail, but it was returned on January 23, 2025. *Id.* at 3. The DI also mailed a copy of the OSC to Registrant's ''mail to address'' and two additional business addresses associated with Registrant. *Id.* at 4. On February 18, 2025, one of the copies was returned to the DI. *Id.* at 5. Here, the Agency finds that the DI's efforts to serve Registrant at his registered email address, registered mailing address, and multiple other mailing addresses were '' 'reasonably calculated, under all the circumstances, to apprise [Registrant] of the pendency of the action.' '' *Jones* v. *Flowers,* 547 U.S. 220, 226 (2006) (quoting *Mullane* v. *Central Hanover Bank & Trust Co.,* 339 U.S. 306, 314 (1950)). Therefore, due process notice requirements have been satisfied.

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[3] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this decision, is not licensed to practice as a physician assistant in Arizona. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov.*

[or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371, 71,372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[4]

According to Arizona statute, ''[e]very person who manufactures, distributes, dispenses, prescribes or uses for scientific purposes any controlled substance within th[e] state or who proposes to engage in the manufacture, distribution, prescribing or dispensing of or using for scientific purposes any controlled substance within th[e] state must first: (1) [o]btain and possess a current license or permit as a medical practitioner as defined in § 32–1901 . . . .'' Ariz. Rev. Stat. Ann. § 36–2522(A)(1) (2025). Section 32–1901 defines a ''[m]edical practitioner'' as ''any medical doctor . . . or other person who is licensed and authorized by law to use and prescribe drugs and devices to treat sick and injured human beings or animals or to diagnose or prevent sickness in human beings or animals in [Arizona] or any state, territory or district of the United States.'' *Id.* § 32–1901(56).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice as a physician assistant in Arizona. As discussed above, only a licensed medical practitioner can dispense controlled substances in Arizona. Thus, because Registrant lacks authority to practice as a physician assistant in Arizona, and therefore is not a licensed medical practitioner, Registrant is not eligible to maintain a DEA registration in Arizona. Accordingly, the Agency will order that Registrant's DEA registration in Arizona be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MB7529261 issued to Benson Sergiles, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Benson Sergiles, P.A., to renew or modify this registration, as well as any other pending application of Benson Sergiles, P.A., for additional registration in Arizona. This Order is effective August 15, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 10, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–13315 Filed 7–15–25; 8:45 am]

BILLING CODE 4410–09–P

[4] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper, M.D.,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton, M.D.,* 43 FR at 27,617.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sasha Melissa Ikramelahai; Decision and Order

On January 22, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Sasha Melissa Ikramelahai of Southern Pines, North Carolina (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 5. The OSC proposed the revocation of Registrant's DEA registration, No. MI8411061, alleging that she currently lacks state authority to handle controlled substances in North Carolina and that she materially falsified her application for registration. *Id.* (citing 21 U.S.C. 824(a)(1), 824(a)(3)).

On March 27, 2025, the Government submitted an RFAA to the Administrator requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 1, 3, 6–7. After carefully reviewing the entire record and conducting the analysis as set forth in detail below, the Agency finds that Registrant is in default, finds that Registrant is without state authority, and finds that Registrant materially falsified her application. Accordingly, the Agency grants the Government's RFAA and revokes Registrant's registration.

I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request ''within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default'' unless ''good cause'' is established for the failure. 21 CFR 1301.43(a), (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is ''deemed to have waived their right to a hearing and to be in default.'' 21 CFR 1301.43(c)(2). Unless excused, a default constitutes ''an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

The OSC notified Registrant of her right to file a written request for hearing and answer, and that if she failed to file such a request and answer, she would be deemed to have waived her right to a hearing and be in default.[1] RFAAX 1,

[1] Based on the Government's submissions in its RFAA dated March 27, 2025, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on January 24, 2025, DIs attempted to serve the OSC on Registrant at her

Continued

at 3–4 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, file an answer, or respond to the OSC in any way. RFAA, at 1–2, 6. Accordingly, Registrant is in default. 21 CFR 1301.43(c)(1); RFAA, at 1, 3, 6.

''A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e). Because Registrant is in default and has not moved to excuse the default, the Agency finds that Registrant has admitted to the factual allegations in the OSC. 21 CFR 1301.43(c)(1), (e), (f)(1).

Further, ''[i]n the event that [a registrant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.'' 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 1, 3, 6; *see also* 21 CFR 1316.67.

II. Lack of State Authority

A. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted, in accordance with the OSC, that on July 9, 2024, the North Carolina Medical Board (NCMB) annulled Registrant's physician assistant license. RFAAX 1, at 3. Specifically, the NCMB annulled Registrant's physician assistant license based on findings that (a) she engaged in immoral or dishonorable conduct; (b) made false statements or representations to the NCMB; (c) engaged in unprofessional conduct by fraudulently obtaining and using the identity, credentials, experience, and licensing information of someone else in false representations and forged documents; and (d) obtained or attempted to obtain a practice, money, or anything of value by false representations. *Id.*

According to North Carolina online records, of which the Agency takes official notice, Registrant's physician assistant license is in an ''Inactive'' status.[2] North Carolina Medical Board License Verification Search, *https://portal.ncmedboard.org/verification/search.aspx* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed as a physician assistant in North Carolina, the state in which she is registered with DEA.[3]

B. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General may suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. [21 U.S.C.] 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371, 71,372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[4]

According to North Carolina statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.'' N.C. Gen. Stat. Ann. § 90–87(8) (West 2025). Further, a ''practitioner'' means a ''physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance so long as such activity is within the normal course of professional practice or research in this State.'' *Id.* at § 90–87(22)(a).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice as a physician assistant in North Carolina. As discussed above, an individual must be a licensed practitioner to dispense a controlled substance in North Carolina. Thus, because Registrant lacks authority to

home address. RFAAX 2, at 1. The DIs were met by Registrant's mother, who told them that Registrant did not live at that address. *Id.* On January 27, 2025, DI attempted to serve the OSC to several email addresses associated with Registrant. *Id.* at 2. Service by email was successful as DI received an email delivery receipt from Registrant's registered email address. *Id.* Additionally, on February 6, 2025, DI attempted to serve the OSC on Registrant by USPS Certified Mail at her registered address, but the mail was returned to sender. *Id.* On February 7, 2025, DI attempted to reach Registrant by phone at her registered employer, but was told by the clinic's CEO that she no longer worked there. *Id.* Based on these multiple attempts at service that were ''reasonably calculated'' to notify her of the OSC, and the fact that DI received an email delivery receipt from Registrant's registered email address, the Agency finds that due process notice requirements have been satisfied. *See Jones* v. *Flowers,* 547 U.S. 220, 226 (2006) (quoting *Mullane* v. *Cent. Hanover Bank & Trust Co.,* 339 U.S. 306, 314 (1950)); *Mohammed S. Aljanaby, M.D.,* 82 FR 34,552, 34,552 (2017) (finding that service by email satisfies due process where the email is not returned as undeliverable and other methods have been unsuccessful); *Emilio Luna, M.D.,* 77 FR 4,829, 4,830 (2012) (concluding that ''the use of email to serve Registrant satisfied due process because service was made to an email address which Registrant provided to the Agency and the Government did not receive back either an error or undeliverable message'').

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[3] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this Decision and Order, is not licensed to practice as a physician assistant in North Carolina. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov*.

[4] This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeats, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Blanton,* 43 FR at 27,617.

practice as a physician assistant in North Carolina and, therefore, is not authorized to handle controlled substances in North Carolina, Registrant is not eligible to maintain a DEA registration in that state. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

III. Material Falsification

A. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted to each of the following facts. On October 27, 2023, Registrant applied for DEA registration as a mid-level practitioner, physician assistant, in Schedules II through V. RFAAX 1, at 2. On October 30, 2023, Registrant was granted DEA registration No. MI8411061. *Id.*

Prior to applying for DEA registration, Registrant fraudulently used the identity and credentials of another physician assistant to obtain her own North Carolina physician assistant license. *Id.* Her North Carolina physician assistant license, which she obtained by fraud, was used as a basis for establishing the required state authority to procure her DEA registration. *Id.* at 2–3.

When Registrant applied for DEA registration, the application requested information regarding the medical/professional school that she attended and the year she graduated. *Id.* at 2. Registrant responded by stating that she graduated in 2014 from the University of New Mexico, facts that were true of the other physician assistant whose identity Registrant had assumed, but not of Registrant. *Id.*

The application also asked: ''Have you graduated, in good standing, from an accredited school of . . . physician assistant . . . in the United States during the 5-year period immediately preceding the date on which you first submitted a registration or renewal and the curriculum included not less than 8 hours of training?'' *Id.* Registrant answered ''yes'' to this question. *Id.*

By signing the application for registration, Registrant represented that the following statement contained on the DEA application was true in regards to her state authority to practice as a physician assistant in North Carolina: ''You must be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate.'' *Id.* at 3.

B. Discussion

A DEA registration may be denied, suspended, or revoked upon a finding that the applicant or registrant materially falsified any application filed pursuant to or required by the Controlled Substances Act (CSA). 21 U.S.C. 824(a)(1).[5] To present a *prima facie* case for material falsification, the Government's record evidence must show (1) the submission of an application, (2) containing a false statement and/or omitting information that the application requires, (3) when the submitter knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure, and (4) the false statement and/or required but omitted information is material, that is, it ''connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] 'shall' consider'' when analyzing ''whether issuing a registration 'would be inconsistent with the public interest.''' *Frank Joseph Stirlacci, M.D.,* 85 FR 45,229, 45,238 (2020) (citing 21 U.S.C. 823 and *Kungys,* 485 U.S. at 771). The Government must establish material falsification with record evidence that is clear, unequivocal, and convincing. *Kungys,* 485 U.S. at 772; *Stirlacci,* 85 FR at 45,230–39.

First, the Government must prove that the applicant or registrant submitted an application for registration pursuant to the CSA. 21 U.S.C. 824(a)(1); *see also* 21 U.S.C. 822 (persons required to register); 21 U.S.C. 823(g)(1) (registration requirements).

Second, the Government must prove that the application contained a false statement or omitted information that the application required, either of which may constitute a material falsity. *See, e.g., Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR 21,719, 21,720 (2023) (applicant falsely answered ''no'' to Liability Question 3 on seventeen applications when the true answer was ''yes''); *Richard J. Settles, D.O.,* 81 FR 64,940, 64,945–46 (2016) (applicant failed to disclose an interim consent agreement restricting his license based on findings that he issued controlled substance prescriptions without federal or state legal authority to do so). In making this assessment, the Agency will examine the entire application, including registrant's ''yes/no'' answers to the liability questions and any follow-up response(s). *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,802, 74,808–09 (2015). To establish an omission, the Government must show both that omitted information existed and that the application required inclusion of that information. *See, e.g., Richard A. Herbert, M.D.,* 76 FR 53,942, 53,956 (2011) (omission of a probation which the application required to be identified); *Michel P. Toret, M.D.,* 82 FR 60,041, 60,042 (2017) (Voluntary Surrender Form alone is insufficient evidence to find material falsification based on registrant's ''no'' answer to the question regarding ''surrender[s] (for cause)'').

Third, the Government must prove that the applicant or registrant knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure. *See John J. Cienki, M.D.,* 63 FR 52,293, 52,295 (1998) (''[I]n finding that there has been a material falsification of an application, it must be determined that the applicant knew or should have known that the response given to the liability question was false.''); *Samuel Arnold, D.D.S.,* 63 FR 8,687, 8,688 (1998) (''It is also undisputed that Respondent knew that his Ohio dental license had previously been suspended.''); *Bobby Watts, M.D.,* 58 FR 46,995, 46,995 (1993) (''Respondent knew that the Tennessee Board of Medical Examiners had suspended his medical license on May 7, 1987, and had placed his state medical license on probation on May 2, 1988.''); *see also Stirlacci,* 85 FR at 45,236–37 & nn.22–23 (collecting cases).

Fourth, the Government must prove that the false statement and/or required but omitted information is ''material.'' *Kungys* holds that a statement is material if it is ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the [Agency's] official decision,'' or stated differently, ''had a natural tendency to influence the decision.'' *Kungys,* 485 U.S. at 771–72. As already discussed, materiality, for the purposes of the CSA, is tied to the factors that the Administrator ''shall'' consider when determining whether issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823; *Kungys,* 485 U.S. at 771–72; *Stirlacci,* 85 FR at 45,234, 45,238.

[5] A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing ''otherwise would mean that all applications would have to be granted only to be revoked the next day . . . .'' *Robert Wayne Locklear, M.D.,* 86 FR 33,738, 33,744–45 (2021) (collecting cases).

The Supreme Court's decision in *Kungys* v. *United States,* 485 U.S. 759 (1988), and its progeny, guide the Agency's implementation of these CSA provisions.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. After evaluating each of the alleged material falsifications, the Agency finds that the Government's record evidence presents a *prima facie* case that Registrant submitted a materially false application. 21 U.S.C. 823, 824(a)(1).

Here, there is no question that Registrant submitted an application for DEA registration and that the application contained multiple falsities. RFAAX 1, at 2–3. Two such falsities were that Registrant, assuming the identity of a properly licensed practitioner, represented that she attended the University of New Mexico for professional school and graduated in 2014. *Id.* at 2. Registrant, through her signature, also represented that she was ''currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which [she was] applying *under the laws of the state or jurisdiction in which* [*she was*] *operating or propos*[*ed*] *to operate.*'' *Id.* at 3.

But Registrant's state authorization to handle controlled substances was not obtained pursuant to law—it was obtained by fraud. Registrant, in assuming someone else's identity, certainly knew or should have known that she had not graduated from the University of New Mexico in 2014 as she represented to the NCMB and to DEA. Indeed, the NCMB later found that Registrant's state physician assistant license had been acquired under false pretenses as a result of Registrant representing herself as someone else. *Id.* Accordingly, the NCMB annulled the license it had issued to Registrant under false pretenses. *Id.* Thus, Registrant falsified her DEA application by representing that she was authorized to handle controlled substances ''under the laws of'' North Carolina when she would not have been granted state authority were it not for her fraud. *Id.*

In addition, the falsification was material. The Agency has consistently held for decades that possessing valid state authority to handle controlled substances is a prerequisite for obtaining a DEA registration.[6] Thus, whether an applicant possesses valid state authority to handle controlled substances in the state for which the applicant seeks registration is a critical factor DEA must consider when reviewing an application.[7]

In *Steven Bernhard, D.O.,* the Agency found that an application was materially false where the applicant falsely represented that he possessed valid state authority to handle controlled substances, when in fact, he did not. 82 FR 23,298, 23,300 (2017). The Agency explained that ''[b]ecause the possession of state authority is a prerequisite to obtaining and maintaining a practitioner's registration, Respondent's false representations that he currently possessed a state license . . . [was] capable of influencing the Agency's decision to grant his . . . application.'' *Id.; see also Thomas G. Easter II, M.D.,* 69 FR 5,579, 5,580 (2004) (finding that applicant materially falsified an application for registration by falsely representing that ''he was 'currently authorized to prescribe' controlled substances 'under the laws of the State or jurisdiction in which [he was] operating or propos[ed] to operate' '').

Thus, Registrant's application representing that she possessed state authorization obtained pursuant to law to handle controlled substances directly affected the statutory analysis that DEA was required to make when it reviewed Registrant's application. 21 U.S.C. 802(21), 823(g)(1), 824(a)(3); *Gonzales,* 546 U.S. at 270; *Stirlacci,* 85 FR at 45,238; *Bernhard,* 82 FR at 23,300; *Easter,* 69 FR at 5,580. Stated differently, Registrant's application led DEA to believe that she possessed valid state authority when, in fact, that state authority was invalid under state law as it had been obtained by fraud. RFAAX 1, at 2–3; *Bernhard,* 82 FR at 23,300; *Easter,* 69 FR at 5,580. Thus, her false representation was material because it was ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Registrant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771.

In sum, the Agency finds clear, unequivocal, and convincing record evidence, and Registrant is deemed to have admitted, that she submitted a materially false application for registration. 21 U.S.C. 824(a)(1); 21 CFR 1301.43(e).

As a result of this established violation, the Agency finds that the Government has established a *prima facie* case for sanction, that Registrant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 824(a)(1).

C. Sanction

Where, as here, the Government has presented a *prima facie* case showing that a registrant submitted a materially false application for registration, the burden shifts to Registrant to show why she can be trusted with a registration. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 181 (D.C. Cir. 2005); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,904 (2018). The issue of trust is a fact-dependent determination based on the circumstances presented by the individual practitioner. *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Historically, the Agency has considered acceptance of responsibility, egregiousness, and deterrence when making this assessment.

Specifically, the Agency requires the practitioner to accept responsibility for his or her violation. *Jones Total Health Care Pharmacy,* 881 F.3d at 833; *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995). Acceptance of responsibility must be unequivocal. *Janet S. Pettyjohn, D.O.,* 89 FR 82,639, 82,641 (2024); *Mohammed Asgar, M.D.,* 83 FR 29,569, 29,573 (2018); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 830–31.

In addition, the Agency considers the egregiousness and extent of the misconduct in determining the appropriate sanction. *Jones Total Health Care Pharmacy,* 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by Registrant and by

[6] *See Joely Keen, A.P.R.N.,* 90 FR 13,882, 13,883 (2025) (''DEA has . . . long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration.''); *Blanton,* 43 FR at 27,617 (holding that ''[s]tate authorization to dispense or otherwise handle controlled substances is a prerequisite to'' obtaining and maintaining a DEA registration).

[7] *See* 21 U.S.C. 802(21) (defining a ''practitioner'' as one who is ''licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices'' to handle controlled substances ''in the course of professional practice''); 21 U.S.C. 823(g)(1) (''The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.''); 21 U.S.C. 824(a)(3) (providing a basis for revoking a registration where the registrant lacks the requisite state authority to dispense controlled substances); *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers'' and explaining registration requirements and the definition of ''practitioner''); *Hatem M. Ataya, M.D.,* 81 FR 8,221, 8,244 (2016) (explaining ''the possession of state authority is a prerequisite for obtaining a registration''); *Hoi Y. Kam, M.D.,* 78 FR 62,694, 62,696 (2013) (''Because possessing authority to dispense controlled substances *under the laws of the State* in which a physician practices medicine is a requirement for holding a DEA registration, . . . a false answer to the state license question is material where an applicant no longer holds authority to practice medicine (regardless of the reason for the State's action) or authority to dispense controlled substances . . . .'') (emphasis added).

future applicants for registration. *Stein,* 84 FR at 46,972–73.

Here, Registrant did not timely request a hearing, or timely or properly answer the allegations, and was therefore deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–4. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to answer the allegations contained in the OSC and has not otherwise availed herself of the opportunity to refute the Government's case. As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding her future compliance with the CSA, and has not made any demonstration that she can be trusted with registration.

Moreover, the evidence presented by the Government shows that Registrant misrepresented her qualifications for registration and used another person's identity in order to fraudulently obtain a state professional license, further demonstrating that Registrant cannot be trusted with the responsibilities of holding a controlled substances registration. To permit Registrant to maintain a registration under these circumstances would send a dangerous message that identity theft and fraud are acceptable means of acquiring a DEA registration and that DEA does not require truthfulness from applicants and registrants. Accordingly, the Agency will order the revocation of Registrant's registration.[8]

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MI8411061 issued to Sasha Melissa Ikramelahai. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Sasha Melissa Ikramelahai to renew or modify this registration, as well as any other pending application of Sasha Melissa Ikramelahai for additional registration in North Carolina. This Order is effective August 15, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 10, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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BILLING CODE 4410–09–P

[8] In this matter there are two separate and distinct grounds by which the Government proposed revocation, Registrant's lack of state authority and her material falsification; each ground, standing alone, supports the Agency's decision to revoke.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Osric Malone Prioleau, N.P.; Decision And Order

On February 13, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Osric Malone Prioleau, N.P., of St. Marys, West Virginia (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 4. The OSC proposed the revocation of Registrant's DEA Certificate of Registration (COR) No. MM2233827, alleging that Registrant is ''currently without authority to . . . handle controlled substances in the State of West Virginia, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).[1]

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2–3 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.[2] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.'' *Id.* at 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. According to the OSC, Registrant's West Virginia registered nurse license and advanced practice registered nurse license were suspended by the West Virginia Board of Registered Nurses on August 22, 2024. RFAAX 2, at 1–2; *see also* RFAAX 3. According to West Virginia online records, of which the Agency takes official notice,[3] Registrant's West Virginia licenses have a status of ''Inactive—Suspension.'' West Virginia Board of Registered Nurses License Lookup, *https://wvrn.boardsofnursing.org/licenselookup/* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed as a practitioner in West Virginia, the state in which he is registered with DEA.[4]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General may suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State

[1] According to the OSC and Agency records, Registrant's DEA registration expired on January 31, 2025, before issuance of the OSC. RFAAX 2, at 1, 3. ''The Agency has previously held that it is within its jurisdiction and prerogative to adjudicate a matter to finality where a registration expired before issuance of the OSC.'' *William Thompson IV, M.D.,* 90 FR 26,610, 26,610 n.1 (2025) (citing *Abdul Naushad, M.D.,* 89 FR 54,059, 54,059–60 (2024)).

[2] Based on the Government's submissions in its RFAA dated March 28, 2025, the Agency finds that service of the OSC on Registrant was proper. The included Government's Notice of Service of the OSC indicates that on February 20, 2025, Registrant was personally served with the OSC and signed a receipt of service. RFAAX 1, at 1–4.

[3] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[4] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this Order, is not licensed as a nurse in West Virginia. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov.*

authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.''

With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371, 71,372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[5]

According to West Virginia statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.'' W. Va. Code § 60A–1–101(i) (West 2025). Further, a ''practitioner'' means ''[a] physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.'' *Id.* at § 60A–1–101(y)(1).[6]

Here, the undisputed evidence in the record is that Registrant is not a currently licensed practitioner in West Virginia. As discussed above, a nurse must be a licensed practitioner to dispense a controlled substance in West Virginia. Thus, because Registrant's nursing licenses are suspended in West Virginia and, therefore, he is not currently authorized to handle controlled substances in West Virginia, Registrant is not eligible to maintain a DEA registration in West Virginia. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MM2233827 issued to Osric Malone Prioleau, N.P. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Osric Malone Prioleau, N.P., to renew or modify this registration, as well as any other pending application of Osric Malone Prioleau, N.P., for additional registration in West Virginia.

This Order is effective August 15, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 10, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–13316 Filed 7–15–25; 8:45 am]

BILLING CODE 4410–09–P

[5] This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper, M.D.,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton, M.D.,* 43 FR at 27,617.

[6] Registrant was specifically licensed to distribute controlled substances in West Virginia as an advanced practice registered nurse pursuant to W. Va. Code § 30–7–15a, which provides explicit authority for advanced practice registered nurses to distribute controlled substances in accordance with the West Virginia Uniform Controlled Substances Act (W. Va. Code § 60A, *et. seq.*).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Diana Clouthier, N.P.; Decision and Order

On February 13, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Diana Clouthier, N.P., of Canon City, Colorado (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 4. The OSC proposed the revocation of Registrant's DEA Certificate of Registration (COR) No. MC5780639, alleging that Registrant is ''currently without authority to . . . handle controlled substances in the State of Colorado, the state in which [she is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of her right to file a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. *Id.* at 2–3 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.[1] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.'' *Id.* at 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c) and (f). RFAA, at 1, 4; *see also* 21 CFR 1316.67.

[1] Based on the Government's submissions in its RFAA dated April 7, 2025, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on February 20, 2025, DI attempted to serve Registrant the OSC at her personal residence and by phone, but both attempts were unsuccessful. RFAAX 2, at 1. Registrant returned the phone call and informed DI that she was not in Colorado and ''would not confirm when she would be returning'' to Colorado. *Id.* On February 24, 2025, DI emailed the OSC to Registrant and Registrant replied acknowledging receipt, but did not request a hearing in her response. *Id.* at 2–4. Accordingly, the Agency finds that the Government's service of the OSC on Registrant was adequate. *See Mohammed S. Aljanaby, M.D.,* 82 FR 34,552, 34,552 (2017) (finding that service by email satisfies due process where the email is not returned as undeliverable and other methods have been unsuccessful); *Emilio Luna, M.D.,* 77 FR 4,829, 4,830 (2012) (same).

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. According to the OSC, Registrant's Colorado registered nursing license, advanced practice nurse license, and nurse practitioner prescriptive authority license were suspended by the Colorado State Board of Nursing on October 21, 2024. RFAAX 1, at 1–2; *see also* RFAAX 4. According to Colorado online records, of which the Agency takes official notice,[2] Registrant's Colorado licenses have a status of ''Suspended.'' Colorado DORA License Search, *https://apps2.colorado.gov/dora/licensing/lookup/licenselookup.aspx* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed as a practitioner in Colorado, the state in which she is registered with DEA.[3]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General may suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371, 71,372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[4]

According to Colorado statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user, patient, or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.'' Colo. Rev. Stat. § 18–18–102(9) (West 2025). Further, a ''practitioner'' means a ''physician . . . or other person licensed, registered, or otherwise permitted, by this state, to distribute, dispense, conduct research with respect to, administer, or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.'' *Id.* § 18–18–102(29).

Here, the undisputed evidence in the record is that Registrant is not a currently licensed practitioner in Colorado. As discussed above, a nurse must be a licensed practitioner to dispense a controlled substance in Colorado. Thus, because Registrant's nursing licenses are suspended in Colorado and, therefore, she is not currently authorized to handle controlled substances in Colorado, Registrant is not eligible to maintain a DEA registration in Colorado. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MC5780639 issued to Diana Clouthier, N.P. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Diana Clouthier, N.P., to renew or modify this registration, as well as any other pending application of Diana Clouthier, N.P., for additional registration in Colorado. This Order is effective August 15, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 10, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–13354 Filed 7–15–25; 8:45 am]

BILLING CODE 4410–09–P

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[3] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this Order, is not licensed as a nurse in Colorado. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov.*

[4] This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he or she is no longer authorized to dispense controlled substances under the laws of the state in which he or she practices. *See, e.g., James L. Hooper, M.D.,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton, M.D.,* 43 FR at 27,617.

DEPARTMENT OF JUSTICE

[A.G. Order No. 6335–2025]

Revised Specification Pursuant to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996

AGENCY: Department of Justice.

ACTION: Order.

SUMMARY: This document contains an Order of the Attorney General issued pursuant to sections 401 and 411 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (''PRWORA'' or the ''Act''). This Order withdraws the Attorney General's January 5, 2001, order issued pursuant to PRWORA.

DATES: The effective date of this Order is August 15, 2025.

FOR FURTHER INFORMATION CONTACT: Christina Greer, Office of Legal Policy, Department of Justice, Room 4254, 950 Pennsylvania Avenue NW, Washington, DC 20530, telephone 202–514–5739, for general information. For information regarding particular programs, contact the Federal agency that administers the program.

SUPPLEMENTARY INFORMATION

I. Background on PRWORA

On August 22, 1996, President Clinton signed the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, currently codified in relevant part at 8 U.S.C. 1611 *et seq.,* as amended. With certain exceptions, PRWORA makes aliens who are not ''qualified alien[s]'' ineligible for any ''Federal public benefit,'' as those terms are defined by PRWORA. 8 U.S.C. 1611(a); *see also id.* 1611(c) (defining ''Federal public benefit''), 1641 (defining ''qualified alien''). PRWORA also restricts, with certain exceptions, all aliens from receiving ''Federal means-tested public benefit[s]'' for a five-year period from their entry into the United States with a status within the meaning of the term ''qualified alien.'' 8 U.S.C. 1613(a). Additionally, PRWORA imposes limits on the receipt of State and local benefits by aliens but permits States to authorize the receipt of State and local benefits by otherwise ineligible aliens through the enactment of a State law postdating PRWORA. *See* 8 U.S.C. 1621(a), (d); *see also id.* 1621(c) (defining ''State or local public benefit''). Finally, PRWORA added section 213A to the Immigration and Nationality Act, which excepts from reimbursement certain benefits provided to a sponsored alien pursuant to an affidavit of support. *Id.* 1183a note.

PRWORA requires the creation of uniform verification requirements to ensure that only ''qualified aliens'' eligible for benefits under PRWORA receive them. 8 U.S.C. 1642. Section 1642(a) requires the Attorney General, who at the time of PRWORA's enactment oversaw the Immigration and Naturalization Service within the Department of Justice (''DOJ''), to promulgate regulations requiring verification that a person applying for a Federal public benefit is a qualified alien and is eligible to receive the benefit. Section 1642(a)(2) requires establishment of fair and nondiscriminatory procedures for a person to provide proof of citizenship. Section 1642(b) requires States to have in effect a verification system that complies with the regulations promulgated under section 1642(a). The Attorney General issued interim guidance about the implementation of these verification requirements in 1997. Interim Guidance on Verification of Citizenship, Qualified Alien Status and Eligibility Under Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 62 FR 61344 (Nov. 17, 1997).

II. Authority To Specify Exceptions to PRWORA's Verification Requirements

Sections 401(b)(1)(D) and 411(b)(4) of PRWORA (codified at 8 U.S.C. 1611(b)(1)(D) and 1621(b)(4)), provide that the Attorney General may, in her ''sole and unreviewable discretion after consultation with appropriate Federal agencies and departments,'' specify as excepted from PRWORA's prohibition on receipt of public benefits by unqualified aliens certain types of programs, services, and assistance that meet all of the following criteria: (1) deliver in-kind services at the community level, including through public or private non-profit agencies; (2) do not condition the provision of assistance, the amount of assistance provided, or the cost of assistance provided on the individual recipient's income or resources; and (3) are necessary for the protection of life or safety.

Shortly after PRWORA was signed into law, the Attorney General issued an order implementing this authority by making a ''provisional specification'' of benefits excepted from PRWORA. Specification of Community Programs Necessary for Protection of Life or Safety Under Welfare Reform Legislation, 61 FR 45985 (Aug. 30, 1996) (''Provisional Order''). Approximately one year later, the Attorney General issued a notice to solicit input from ''federal, state, and local agencies operating programs or providing services or assistance that may be covered by the final Order.'' Request for Comments on the Attorney General's Specification of Community Programs Necessary for the Protection of Life or Safety Under the Welfare Reform Act, 62 FR 48308, 48308 (Sept. 15, 1997). The Attorney General subsequently issued a final order specifying these programs in 2001. Final Specification of Community Programs Necessary for Protection of Life or Safety Under Welfare Reform Legislation, 66 FR 3613 (Jan. 16, 2001) (''Final Order''). In both the Provisional Order and the Final Order—the latter of which was, in substance, unchanged in response to the comments received by DOJ—the Attorney General exercised her authority to except programs, services, or assistance to the fullest extent permitted by law by excepting from PRWORA ''any . . . programs, services, or assistance'' that satisfied all three statutory criteria. 61 FR at 45985 (Provisional Order); 66 FR at 3616 (Final Order); *see also id.* at 3615 (''[the] Attorney General has fully exercised the power delegated to her under §§ 401(b)(1)(D) and 411(b)(4) of [PRWORA]'').

The Attorney General's exercise of discretion to determine whether to except benefits from PRWORA does not require notice-and-comment rulemaking. Because PRWORA commits a decision about exceptions to the Attorney General's ''sole and unreviewable discretion'' after consultation with Federal officials, PRWORA ''renders the formal notice-and-comment rulemaking regime inapplicable'' to this action. *See Make The Rd. New York* v. *Wolf,* 962 F.3d 612, 634 (D.C. Cir. 2020). Moreover, the action is exempt from notice-and-comment procedures because the designation of certain benefits as excepted is a ''matter relating to . . . public property, loans, grants, benefits, or contracts.'' 5 U.S.C. 553(a)(2).

III. Executive Order 14218

On February 19, 2025, the President signed Executive Order 14218, ''Ending Taxpayer Subsidization of Open Borders,'' 90 FR 10581. One purpose of the Executive Order is to confirm agencies are complying with PRWORA in administering Federal programs by ensuring, ''to the maximum extent permitted by law, that no taxpayer-funded benefits go to unqualified aliens.'' *Id.* sec. 2(a). The Executive Order directs agencies to identify ''all federally funded programs administered by the agency that currently permit illegal aliens to obtain any cash or non-cash public benefit, and, consistent with applicable law, take all appropriate actions to align such programs with the purpose of the Executive Order and applicable law, including . . . PRWORA.'' *Id.* sec. 2(a)(i).

IV. Re-Evaluation of the 2001 Specification

A. Review of Reliance on the Final Order

In the discharge of her responsibilities under Executive Order 14218 and PRWORA, the Attorney General has reviewed the Final Order issued in 2001. As required by PRWORA, she has engaged in consultation with appropriate Federal agencies and departments about the propriety of

specifying exceptions to PRWORA, including the extent to which agencies rely on the Final Order to except programs, services, or assistance from PRWORA, in order to determine whether the Final Order should be withdrawn or modified.

Multiple agencies responded that they do not rely on the Final Order at all because they do not confer benefits subject to PRWORA; because they rely only on PRWORA's statutory exceptions; or because they do not except the benefits they provide from PRWORA's eligibility requirements. The fact that a particular program does not fall within the scope of PRWORA does not mean that eligibility requirements imposed by other Federal statutes do not apply to the benefit. Some Federal programs, such as Medicaid, unemployment compensation, educational assistance under Title IV of the Higher Education Act of 1965, and assisted housing programs administered by the Department of Housing and Urban Development (''HUD'') already require, absent a waiver, verification of the immigration status of an alien to ensure the alien meets the eligibility requirements for the program. 62 FR at 61345. To verify recipient status and eligibility, agencies use the Systematic Alien Verification for Entitlements (''SAVE'') system, operated by U.S. Citizenship and Immigration Services. *See id.* Except where specified in the statute, PRWORA does not alter preexisting legal requirements regarding the use of the SAVE system or relieve the administrators of statutorily mandated programs of their obligations to comply with the SAVE program. *Id.* The Attorney General defers to agencies as to the extent to which PRWORA applies to the programs they administer and as to whether authorities other than PRWORA require them to ascertain the immigration status of benefit recipients.

Some agencies purported to rely upon the Final Order to except from PRWORA programs that are likely subject to one of PRWORA's statutory exceptions. For example, the Federal Emergency Management Administration purported to rely on the Final Order as to certain emergency or disaster relief programs. But PRWORA already excepts short-term, in-kind, emergency disaster relief from its eligibility requirements, so the Attorney General's exception authority under PRWORA is not legally necessary to except such programs. *See* 8 U.S.C. 1611(b)(1)(B).

Agencies also purported to rely upon the Final Order to except programs that may fail to meet the requirements of PRWORA because eligibility is conditioned on the income or resources of the recipients. For instance, many of the benefits provided through the Community Development Block Grant (''CDBG'') program, managed by HUD, must be conferred to low- or moderate-income persons by statute. *See* 42 U.S.C. 5301 *et seq.* PRWORA, however, grants the Attorney General authority to except only programs for which eligibility is not conditioned on the resources or income of the recipients. *See, e.g.,* 8 U.S.C. 1611(b)(1)(D)(ii).

Agencies also purported to rely upon the Final Order for programs that may go beyond PRWORA's limitation of benefits to programs that are ''necessary for the protection of life or safety.'' 8 U.S.C. 1611(b)(1)(D)(iii). Neither PRWORA nor the Final Order attempts to define this phrase more precisely. This lack of guidance has led to the exception being used more broadly than Congress intended. PRWORA provides examples of the kinds of assistance that the Attorney General has authority to except from the statute's limitation on eligibility—*i.e.,* ''soup kitchens, crisis counseling and intervention, and short-term shelter.'' But agencies have excepted from PRWORA forms of assistance that are quite unlike these examples. For instance, the Department of Homeland Security (''DHS'') funds ''scientific leadership,'' ''citizenship education and training,'' and law enforcement officer training. Such programs—focused more on career building or personal development than human necessities—are not ''necessary for the protection life or safety'' in the sense the drafters of PRWORA used that phrase. Nor is it clear why unqualified aliens would need to receive benefits from such programs. Similarly, while grants, contracts, and loans are a public benefit under PRWORA, many projects funded by HUD through CDBG to address infrastructure improvements or combat urban blight are too far removed from the circumstances that would make them ''necessary for the protection of life or safety'' in the sense that Congress directed when it enacted PRWORA.

B. Revision of the Final Order

Based on her consultations with the appropriate Federal agencies and departments, the Attorney General has determined that the Final Order has created confusion about what sorts of programs are subject to PRWORA's requirements and is being applied more broadly than the statute permits. As a result, unqualified aliens have been able to receive public benefits for which they are not lawfully eligible. To correct this, the Attorney General, in the exercise of her discretion, has chosen not to except any benefits from PRWORA beyond those excepted by the statute itself.

In making this change, the Attorney General is aware that some aliens may have been able to receive certain types of in-kind public benefits that would otherwise be subject to PRWORA's requirements because of the exceptions detailed in the Final Order. Such aliens will not be eligible for those benefits in the future due to this revised specification. To the extent that aliens may have relied on such benefits, the Attorney General concludes, based on her consultation with Federal agencies and departments and other considerations, that the changes described in this specification are nonetheless warranted. This is so for several reasons. First, as noted earlier, some agencies have been excepting from PRWORA certain benefits based on a misunderstanding of the Attorney General's exception authority and hence have been providing benefits to aliens who were not lawfully eligible to receive them. ''No amount of reliance could ever justify continuing a program'' that an ''agency lacked statutory authority to'' implement in the first place, *see Dep't of Homeland Sec.* v. *Regents of the Univ. of California,* 140 S. Ct. 1891, 1930 (2020) (''*Regents*'') (Thomas, J., concurring in part and dissenting in part), so bringing the Federal Government into compliance with the law is a powerful reason to withdraw the Final Order regardless of any reliance interests. Second, as also noted above, some of the benefits previously provided under the Final Order were not, in fact, necessary for life or safety. The lack of any connection to aliens' immediate welfare necessarily reduces the extent of any reliance interests in these benefits. Third, even as to benefits that the Attorney General has the legal authority (but not the duty) to except from PRWORA, any reliance interests are significantly outweighed by the need to reduce the incentive for aliens to illegally migrate to the United States. *See* 8 U.S.C. 1601(2) (''It continues to be the immigration policy of the United States that . . . the availability of public benefits not constitute an incentive for immigration to the United States.''). Finally, Congress has delegated to the Attorney General the authority to determine the appropriate scope of this specification in her ''sole and unreviewable discretion.'' *E.g.,* 8 U.S.C. 1611(b)(1)(D). This delegation indicates Congress's intent that the scope of this specification not be subject to the sort of arbitrary-and-capricious review that would typically require consideration of

reliance interests. *See Regents,* 140 S. Ct. at 1907, 1913 (assessing an agency's consideration of reliance interests only after concluding that the agency's action was subject to judicial review).

Although the Attorney General has the authority to except certain benefits from PRWORA, the decision to do so is expressly committed to her sole and unreviewable discretion. *See, e.g.,* 8 U.S.C. 1611(b)(1)(D). The Attorney General has concluded, in the exercise of that discretion, that the benefits of creating additional exceptions to PRWORA, beyond those set forth in the statute itself, are outweighed by the risks of creating incentives for unlawful migration by allowing access to such programs to individuals who are not ''qualified aliens'' as defined by PRWORA.

This Order does not purport to define what benefit programs are, and are not, ''public benefits'' subject to PRWORA. This Order also has no effect on other statutory eligibility requirements, including those found in PRWORA itself. *See, e.g.,* 8 U.S.C. 1611(b), 1615, 1621(b)(4). The Attorney General has the right, in her sole and unreviewable discretion, to revisit and amend the specification in the future.

Order Specifying Community Programs Necessary for the Protection of Life or Safety Under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996

By virtue of the authority vested in me as Attorney General by law, including Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (the ''Act''), I hereby specify that:

1. Effective August 15, 2025, the Final Order of the Attorney General dated January 16, 2001, and published at 66 FR 6313, is withdrawn and no longer in force.

2. After undertaking the necessary consultations with appropriate Federal agencies and departments, the Attorney General has concluded, in her sole and unreviewable discretion, not to except any benefits from PRWORA pursuant to her authority to make such exceptions under section 401 and section 411 of PRWORA.

3. I do not construe the Act to preclude aliens from receiving police, fire, ambulance, transportation (including paratransit), sanitation, and other similar services. *See* 8 U.S.C. 1611(c), 1621(c). As a result, I need not specify and am not specifying any such services as being excepted from the Act.

4. It is not the purpose of this Order to define more specifically the scope of the public benefits that Congress intended to include within the scope of the Act, and nothing herein should be construed to do so.

Date: July 11, 2025.

Pamela Bondi,

Attorney General.

[FR Doc. 2025–13318 Filed 7–15–25; 8:45 am]

BILLING CODE 4410–BB–P

DEPARTMENT OF LABOR

Employment and Training Administration

Native American Employment and Training Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Renewal of the Native American Employment and Training Council charter.

SUMMARY: The Secretary of Labor (Department) announces the renewal of the Native American Employment and Training Council (NAETC) charter.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

Section 166(i)(4) of the Workforce Innovation and Opportunity Act (WIOA), 29 U.S.C. 3221(i)(4) requires the Secretary of Labor (Secretary) to establish and maintain the NAETC. The statute, as amended, requires the Secretary, to formally consult at least twice annually with the NAETC on the operation and administration of the WIOA Section 166 Indian and Native American Employment and Training programs. In addition, the NAETC advises the Secretary on matters that promote the employment and training needs of Indians and Native Americans, as well as to enhance the quality of life in accordance with the Indian Self-Determination and Education Assistance Act. The NAETC also provides guidance to the Secretary on how to make Department of Labor discretionary funding and other special initiatives more accessible to federally recognized tribes, Alaska Native entities, and Native Hawaiian organizations.

II. Structure

The Council will be composed of no less than 15 members, but no more than 20, appointed by the Secretary, who are representatives of Indian tribes, tribal organizations, Alaska Native entities, Indian-controlled organizations serving Indians, or Native Hawaiian organizations pursuant to WIOA Section 166(i)(4)(B). The membership of the Council will, to the extent practicable, represent all geographic areas of the United States with a substantial Indian, Alaska Native, or Native Hawaiian population, and will include representatives of tribal governments and of non-reservation Native American organizations that have expertise in the areas of workforce development, secondary and post-secondary education, health care, business and economic development, and other sectors with job growth.

Each NAETC member will be appointed for a two-year term. A vacancy occurring in the Council membership will be filled in the same manner as the original appointment. A member appointed to a vacancy on the Council will serve for the remainder of the term for which the predecessor of that member was appointed. Members of NAETC will serve on a voluntary and generally uncompensated basis, but will be reimbursed for travel expenses to attend NAETC meetings, including per diem in lieu of subsistence, as authorized by the Federal travel regulations. All NAETC members will serve at the pleasure of the Secretary. Members may be appointed, reappointed, or replaced, and their terms may be extended, changed, or terminated at the Secretary's discretion.

FOR FURTHER INFORMATION CONTACT: Kimberly Vitelli, Office of Workforce Investment; (202) 693–3980; *vitelli.kimberly@dol.gov*.

Authority: Pursuant to the Workforce Innovation and Opportunity Act, 29 U.S.C. 3221(i)(4); Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Susan Frazier,

Acting Assistant Secretary for Employment and Training Administration.

[FR Doc. 2025–13305 Filed 7–15–25; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Unemployment Compensation for Ex-Servicemembers Handbook

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995

(PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 15, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The UCX law (5 U.S.C. 8521–8523) requires state workforce agencies (SWAs) to administer the UCX program in accordance with the same terms and conditions of the paying state's unemployment insurance law, which apply to unemployed claimants who worked in the private sector. Each state agency needs to obtain certain military service information on claimants filing for UCX benefits to enable them to determine his/her eligibility for benefits. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 11, 202 (90 FR 11750).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Unemployment Compensation for Ex-Servicemembers Handbook.

OMB Control Number: 1205–0176.

Affected Public: State, Local and Tribal Government.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 1,060.

Total Estimated Annual Time Burden: 88 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2025–13286 Filed 7–15–25; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Annual Report for Multiple Employer Welfare Arrangements

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 15, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Health Insurance Portability and Accountability Act of 1996 (HIPAA), codified as part 7 of title I of the Employee Retirement Security Act of 1974 (ERISA), was enacted to improve the portability and continuity of health care coverage for participants and beneficiaries of group health plans. HIPAA also added section 101(g) to ERISA, providing the Secretary of Labor (Secretary) with authority to require, by regulation, multiple employer welfare arrangements (MEWAs) as defined in section 3(40) of ERISA, that offer or provide coverage for medical benefits but which are not group health plans (non-plan MEWAs), to report annually for the purpose of determining compliance with part 7 requirements. While the statutory authority was directed at non-plan MEWAs, based on the authority in ERISA sections 101(g), 505, and 734, the Department of Labor (Department) in 2003 promulgated a regulation at 29 CFR 2520.101–2 that required the administrators of both plan MEWAs and non-plan MEWAs that offer or provide coverage for medical benefits, as well certain entities that claim not to be a MEWA solely due to the exception in section 3(40)(A)(i) of ERISA (referred to as ''Entities Claiming Exception'' or ''ECEs''), to file the Form M–1 on an annual basis (Form M–1 annual report).

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (these are collectively known as the ''Affordable Care Act'' or ''ACA'') amended section 101(g) of ERISA to require non-plan MEWAs that provide benefits consisting of medical care to register with the Secretary before operating in a State. In 2011, the Department amended the Form M–1 reporting regulations to enact the ACA required provisions by requiring all MEWAs (plan and non-plan MEWAs) that offer or provide coverage for medical benefits and ECEs to register with the Secretary upon occurrence of certain registration events, such as prior to operating in a State, in addition to continued reporting on an annual basis regarding compliance with part 7 of ERISA. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 6, 2025 (90 FR 671).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will

have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Annual Report for Multiple Employer Welfare Arrangements.

OMB Control Number: 1210–0116.

Affected Public: Private sector.

Total Estimated Number of Respondents: 791.

Total Estimated Number of Responses: 791.

Total Estimated Annual Time Burden: 1,536 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2025–13288 Filed 7–15–25; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Employee Retirement Income Security Act of 1974 Investment Manager Electronic Registration

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 15, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 203A(a) of the Investment Advisers Act of 1940 (and the implementing SEC regulations) provides thresholds for when investment advisers must register with the SEC or with one or more states to qualify as investment manager under ERISA, investment advisers that register with a state, rather than with the SEC, must satisfy ERISA's section 3(38) requirement to file a copy of the State registration with the Department by electronically registering through the Investment Adviser Registration Depository (IARD). This is a centralized electronic filing system operated by the SEC in conjunction with State securities regulation authorities. Because the IARD was established by the SEC and the states, and made mandatory for advisers required to file with SEC, and because all States permit filing through IARD even for advisers who do not file with SEC, the Department determined that use of the IARD would eliminate the duplication of filing paper copies of State registration forms with the Department and facilitate creation of a uniform and efficient ''one-stop'' filing system for state-registered filings by advisers who wished to meet the ''investment manager'' definition of ERISA section 3(38). For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 6, 2025 (90 FR 671).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Employee Retirement Income Security Act of 1974 Investment Manager Electronic Registration.

OMB Control Number: 1210–0125.

Affected Public: Private sector.

Total Estimated Number of Respondents: 3.

Total Estimated Number of Responses: 3.

Total Estimated Annual Time Burden: 3 hours.

Total Estimated Annual Other Costs Burden: $230.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2025–13291 Filed 7–15–25; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prohibited Transaction Class Exemption 1988–59, Residential Mortgage Financing Arrangements Involving Employee Benefit Plans

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 15, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Prohibited Transaction Class Exemption (PTE) 88–59, which amended and replaced PTE 82–87, allows employee benefit plans to participate in several different types of residential mortgage financing transactions, provided certain conditions are met. The five categories of transactions permitted under the exemption are: (1) issuance of commitments for the provision of mortgage financing to purchasers of residential dwelling units; (2) receipt by a plan of a fee for the issuance of the commitments; (3) the actual making or purchase of a mortgage loan or participation interest therein pursuant to the commitment; (4) the direct making or purchase of an mortgage loan or participation interest therein without the precondition of a commitment; and (5) the sale, exchange or transfer of a mortgage loan or participation interest therein prior to the maturity date of the instrument, provided that the ownership interest sold, exchanged, or transferred represents the plan's entire interest in such investment.

Among other conditions, the exemption requires a plan to maintain for the duration of any loan made pursuant to this exemption all records necessary to determine whether conditions of the exemption have been met and to make such records available for examination on request by any trustee, investment manager, participant or beneficiary of the plan, or agents of the Department or the IRS. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 6, 2025 (90 FR 671).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Prohibited Transaction Class Exemption 1988–59, Residential Mortgage Financing Arrangements Involving Employee Benefit Plans.

OMB Control Number: 1210–0095.

Affected Public: Private sector.

Total Estimated Number of Respondents: 529.

Total Estimated Number of Responses: 2,645.

Total Estimated Annual Time Burden: 1,543 hours.

Total Estimated Annual Other Costs Burden: $2,804.

(Authority: 44 U.S.C. 3507(a)(1)(D).)

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2025–13285 Filed 7–15–25; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Information Collection Activities; Comment Request

AGENCY: Bureau of Labor Statistics, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the ''National Compensation Survey.'' A copy of the proposed information collection request can be obtained by contacting the individual listed below in the Addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the Addresses section of this notice on or before September 15, 2025.

ADDRESSES: Send comments to Nora Kincaid, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, by email to *BLS_PRA_Public@bls.gov.*

FOR FURTHER INFORMATION CONTACT: Nora Kincaid, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number.) (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The National Compensation Survey (NCS) is a nation-wide survey of private industry establishments and state and local governments that provides comprehensive measures of (1) employer costs for employee

compensation, including wages and salaries, and benefits, (2) compensation trends, and (3) the incidence of employer-sponsored benefits among workers. The NCS also collects data and produces estimates on the provisions of selected employer-sponsored benefit plans. The NCS produces:

- Indexes measuring change over time in labor costs through the Employment Cost Index (ECI), a Principal Federal Economic Indicator (PFEI).
- The level of average costs per hour worked through the Employer Costs for Employee Compensation (ECEC).
- Estimates on the incidence of benefits by the percentage of workers with access to and participating in employer-sponsored benefit plans, as well as details of what those plans provide, in the publication of the Employee Benefits in the United States.
- Details of employer-provided health and retirement plan provisions in the Health and Retirement Plan Provision publications.
- Occupational wage data by work level for use by the President's Pay Agent, meeting the requirements of the Federal Employees Pay Comparability Act of 1990 (FEPCA). This data is produced in collaboration with the BLS' Occupational Employment and Wage Statistics (OEWS) program.

II. Current Action

Office of Management and Budget clearance is being sought for a revision of the NCS.

The NCS is designed to be a national representative survey of private industry and state and local government establishments from all 50 states and the District of Columbia. The NCS private industry sample is on a three-year rotational cycle, with one frozen sample year approximately every ten years for the NCS private industry sample when a new NCS State and local government sample is under collection.

The NCS collects occupational information and wage and benefit data from a sample of employers. Using probability sampling, the NCS selects up to eight jobs at an establishment and collects job information, including job duties and work level characteristics, and wages and benefit information. Benefit information includes the incidence, costs, and provisions of the employer-provided benefits. The BLS updates the wage and benefit cost data quarterly. Updating this information allows for the publication of change in the cost of wages, benefits, and total compensation on a quarterly basis as a measure of labor market inflation.

The NCS employs various methods to collect data from establishments. NCS policy is to collect the data in whichever form is easiest for the respondents to provide. Respondents may choose to send the data on forms that the BLS provides. The respondents may respond through email, fax, mail, telephone, or a secure BLS website.

The BLS is planning to eliminate several NCS data elements to reduce the annual costs and burden of the survey. The data elements are not considered to be heavily used or in public demand based on metrics from public database hits and customer service inquiries. The collection and review of these elements are resource intensive. The elements planned for removal capture:

- The presence of and plan details for sick leave carry over.
- The presence of retiree life.
- The presence of third-party plan administration and stop loss protection for health insurance.
- Employee non-medical premiums.
- Employer non-medical premiums when expenditures are collected or costs are unknown.
- Plan details for Defined Benefit Frozen Plans.
- The presence of Other Benefits plans or provisions of plans.

The BLS is planning to discontinue the collection of Worker's Compensation Insurance due to the BLS's inability to improve the currently low response rate for this benefit. Further response efforts could potentially lead to lower response rates for other benefits, which make up a larger proportion of total compensation.

The BLS is also planning a re-weight of the ECI to update employment counts as was done multiple times in the past.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Title of Collection: National Compensation Survey.

OMB Number: 1220–0164.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profit; not-for-profit institutions; and State, local, and tribal governments.

Annual Number of Respondents: 17,194

All figures are based on a three-year average.

	Annual number of respondents	Average number of responses per year	Total annual responses	Average annual burden (minutes)	Estimated total burden (hours)
Totals	17,194	3.1603	54,339	42.3917	38,392

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed on July 11, 2025.

Eric Molina,

Chief, Division of Management Systems, Branch of Policy Analysis.

[FR Doc. 2025–13287 Filed 7–15–25; 8:45 am]

BILLING CODE 4510–24–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2024–406; MC2025–1570 and K2025–1563; MC2025–1572 and K2025–1565; MC2025–1573 and K2025–1566]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 21, 2025.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Public Proceeding(s)
III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)-(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* CP2025–406; *Filing Title:* USPS Request Concerning Amendment One to Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 137, with Materials Filed Under Seal; *Filing Acceptance Date:* July 11, 2025; *Filing Authority:* 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative:* Arif Hafiz; *Comments Due:* July 21, 2025.

2. *Docket No(s).:* MC2025–1570 and K2025–1563; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package Service Contract 76 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 11, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* July 21, 2025.

3. *Docket No(s).:* MC2025–1572 and K2025–1565; *Filing Title:* USPS Request to Add Priority Mail Contract 907 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 11, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Arif Hafiz; *Comments Due:* July 21, 2025.

4. *Docket No(s).:* MC2025–1573 and K2025–1566; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 800 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 11, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* July 21, 2025.

III. Summary Proceeding(s)

None. See Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2025–13334 Filed 7–15–25; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage Negotiated Service Agreements; Priority Mail, and USPS Ground Advantage Negotiated Service Agreements; Priority Mail Negotiated Service Agreements

AGENCY: Postal Service.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: Date of required notice: July 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), it filed with the Postal Regulatory Commission the following requests:

Date filed with postal regulatory commission	Negotiated service agreement product category and No.	MC docket number	K docket number
06/27/25	PM–GA 794	MC2025–1549	K2025–1543
06/30/25	PM–900	MC2025–1550	K2025–1544
07/01/25	PM–GA 795	MC2025–1551	K2025–1545
07/01/25	PME–PM–GA 1383	MC2025–1552	K2025–1546
07/01/25	PME–PM–GA–1384	MC2025–1553	K2025–1547
07/01/25	PM–GA 796	MC2025–1554	K2025–1548
07/02/25	PM 901	MC2025–1555	K2025–1549
07/03/25	PME–PM–GA 1385	MC2025–1556	K2025–1550
07/03/25	PM 902	MC2025–1557	K2025–1551
07/03/25	PM–GA 797	MC2025–1558	K2025–1552
07/03/25	PM–GA 798	MC2025–1559	K2025–1553
07/07/25	PM–GA 799	MC2025–1560	K2025–1554
07/08/25	PME–PM–GA 1386	MC2025–1561	K2025–1555
07/08/25	PME–PM–GA 1387	MC2025–1562	K2025–1556
07/08/25	PM 903	MC2025–1563	K2025–1557
07/09/25	PM 904	MC2025–1564	K2025–1558
07/09/25	PM 906	MC2025–1567	K2025–1560
07/10/25	PME–PM–GA 1388	MC2025–1568	K2025–1561
07/10/25	PME–PM–GA 1389	MC2025–1569	K2025–1562
07/10/25	PME–PM–GA 1390	MC2025–1571	K2025–1564
07/11/25	PM 907	MC2025–1572	K2025–1565
07/11/25	PM–GA 800	MC2025–1573	K2025–1566

Documents are available at *www.prc.gov*.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–13266 Filed 7–15–25; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103435; File No. SR–FINRA–2025–011]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rules 6380A and 6380B (Transaction Reporting) To Extend the Trade Reporting Facilities Operating Hours

July 11, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 8, 2025, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rules 6380A and 6380B regarding the operation of the FINRA/NYSE Trade Reporting Facility, the FINRA/Nasdaq Trade Reporting Facility Carteret, and the FINRA/Nasdaq Trade Reporting Facility Chicago (the ''Trade Reporting Facilities'' or ''TRFs'') to extend TRF operating hours from opening at 8 a.m. Eastern Time (''E.T.'') to opening at 4 a.m. E.T.[4]

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The TRFs are facilities of FINRA that are operated by NYSE Market (DE), Inc. (in the case of the FINRA/NYSE TRF) and Nasdaq, Inc. (in the case of the FINRA/Nasdaq TRF Carteret and the FINRA/Nasdaq TRF Chicago). Along with the Alternative Display Facility (''ADF''),[5] the TRFs provide FINRA members with a mechanism for the reporting of over-the-counter (''OTC'') trades in NMS stocks. While members are required to report all OTC trades in NMS stocks to FINRA, they may choose which FINRA facility (or facilities) to use to satisfy their trade reporting obligations.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] Unless otherwise specified, all times referred to in the proposed rule change are E.T.

[5] Collectively, the TRFs and the ADF are referred to as the ''FINRA facilities.'' The ADF is a display-only facility operated by FINRA that provides members with a facility for the display of quotations, the reporting of trades, and the comparison of trades in NMS stocks. Currently, there are no active quoting ADF participants, and only one Trade Reporting Only participant utilizing the ADF as a back-up trade reporting facility. The ADF operating hours are 8 a.m. to 6:30 p.m. for both quotation display and trade reporting. Separately, FINRA operates the OTC Reporting Facility (''ORF''), a facility for the reporting of trades in OTC Equity Securities. The ORF operating hours are 8 a.m. to 8 p.m. The instant proposed rule change is limited to the TRFs and FINRA is not at this time proposing any changes to the operational hours of either the ADF or the ORF.

Currently, the operating hours of the TRFs are 8 a.m. to 8 p.m. each business day. These operating hours are reflected in the transaction reporting rules for the FINRA/Nasdaq TRFs (FINRA Rule 6380A (Transaction Reporting)) and the FINRA/NYSE TRF (FINRA Rule 6380B (Transaction Reporting)). Under these reporting rules, transactions executed during normal market hours, *i.e.,* 9:30 a.m. to 4 p.m.,[6] must be reported as soon as practicable but no later than 10 seconds after execution. Transactions executed outside normal market hours must be reported as follows:

- For transactions executed between 8 a.m. and 9:30 a.m., as soon as practicable but no later than 10 seconds after execution, with a unique trade report modifier to denote execution outside normal market hours;
- For transactions executed between 4 p.m. and 8 p.m., as soon as practicable but no later than 10 seconds after execution, with a unique trade report modifier to denote execution outside normal market hours;
- For transactions executed between midnight and 8 a.m., by 8:15 a.m., with a unique trade report modifier to denote execution outside normal market hours; and
- For transactions executed between 8 p.m. and midnight, or on any non-business day,[7] by 8:15 a.m. on the following business day, designated ''as/of'' and with a unique trade report modifier to denote execution outside normal market hours.

All trade reports submitted to the TRFs, other than non-tape reports,[8] are reported to and publicly disseminated by the appropriate Securities Information Processor (''SIP'').[9] Currently, the operating hours of the SIPs are 4 a.m. until 8 p.m. on business days.[10] Transactions executed during current TRF operating hours—*i.e.,* between 8 a.m. and 8 p.m. on business days—are reported to the TRFs and publicly disseminated through the SIPs in real time, since both the TRFs and SIPs are operating during those hours. However, because TRF operating hours do not begin until 8 a.m. each business day, OTC transactions in NMS stocks executed when the SIPs are open but the TRFs are still closed (*i.e.,* between 4 a.m. and 8 a.m. on a business day) cannot be reported to a TRF until 8 a.m., and therefore are not publicly disseminated by the SIPs until after 8 a.m. once they are reported to a TRF.

At this time, FINRA is proposing to extend the opening time of the TRFs from 8 a.m. to 4 a.m. each business day, thereby enabling real-time public dissemination of trade reports for OTC transactions in NMS stocks executed between 4 a.m. and 8 a.m.[11] To implement this proposed enhancement to TRF operating hours, the proposed rule change would amend the FINRA TRF reporting rules to reflect the new 4 a.m. opening time, as described in detail below.

Proposed Amendments to TRF Reporting Rules

At this time, FINRA is proposing to amend its TRF reporting rules to provide that the TRF operating hours will now begin at 4 a.m. each business day, rather than the current 8 a.m. opening time. Specifically, the proposed rule change would make amendments to FINRA Rules 6380A (for the FINRA/Nasdaq TRFs) and 6380B (for the FINRA/NYSE TRF) to change the opening time from 8 a.m. to 4 a.m. FINRA also is proposing conforming changes to paragraphs (a)(2)(A), (C), and (D) and (a)(5)(H) of FINRA Rules 6380A and 6380B, which address reporting of transactions executed outside normal hours and the requirement that firms must append a modifier to identify pre-opening and after-hours trades reported more than 10 seconds after execution. Together, the proposed amendments would extend the general requirement to report transactions to the TRFs as soon as practicable but no later than 10 seconds after execution to cover the new four-hour period from 4 a.m. and 8 a.m., and require transactions executed when the TRFs are closed to be reported within 15 minutes after the new opening time of 4 a.m.[12]

Specifically, paragraph (a)(2)(A) of FINRA Rules 6380A and 6380B currently requires members to report transactions executed between 8 a.m. and 9:30 a.m. as soon as practicable but no later than 10 seconds after execution, and that the trade be designated with the unique trader report modifier to denote execution outside normal market hours. FINRA is proposing to amend this paragraph to cover transactions executed between 4 a.m. and 9:30 a.m. Paragraph (a)(2)(C) of FINRA Rules 6380A and 6380B requires members to report transactions executed between midnight and 8 a.m. by 8:15 a.m. on the trade date, and that the trade be designated with the unique trade report modifier to denote execution outside normal market hours. FINRA is amending this paragraph to only cover transactions executed between midnight and 4 a.m. Finally, paragraph (a)(2)(D) of FINRA Rules 6380A and 6380B currently requires members to report transactions executed between 8 p.m. and midnight, or on any non-business day, on the following business day by 8:15 a.m., and further requires that such trades be designated ''as/of'' and carry the unique trade report identifier to denote execution outside normal market hours. FINRA is amending this paragraph to require such transactions to be reported within 15 minutes after the new TRF opening time, *i.e.,* by 4:15

[6] ''Normal market hours'' are defined as 9:30 a.m. to 4 p.m. for purposes of the FINRA TRF rules. *See* [FINRA] Rules 6320A(a)(6) and 6320B(a)(6).

[7] A non-business day means a weekend or holiday. *See* [FINRA] Rules 6380A(a)(2)(D) and 6380B(a)(2)(D).

[8] ''Tape'' or ''media'' reports are those that are submitted to a TRF for public dissemination by the Securities Information Processors. By contrast, ''non-tape'' or ''non-media'' reports are not submitted to a TRF for public dissemination but are submitted for regulatory and/or clearance and settlement purposes. Another term that is often used with respect to ''tape'' or ''media'' reports is ''for publication.'' In certain limited circumstances, trade reports submitted for publication may be suppressed from public dissemination (*e.g.,* transactions in Restricted Equity Securities effected pursuant to Securities Act Rule 144A, as well as T+365 trades and trades executed on a non-business day).

[9] Market data is transmitted to three tapes based on the listing venue of the security: securities listed on New York Stock Exchange are disseminated through Tape A; securities listed on BYX, BZX, EDGA, EDGX, IEX, LTSE, MEMX, MIAX, Nasdaq BX, Nasdaq PSX, NYSE American, NYSE Texas, NYSE National, or NYSE Arca are disseminated through Tape B; and securities listed on Nasdaq are disseminated through Tape C. Tape A and Tape B market data is disseminated pursuant to the Consolidated Tape Association Plan (''CTA Plan'') and the Consolidated Quotation Plan (''CQ Plan''), while Tape C market data is disseminated pursuant to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis (''UTP Plan'').

[10] *See, e.g.,* UTP Plan, Section XI.

[11] As recently announced by the Operating Committees of the CTA Plan, the CQ Plan, and the UTP Plan (the ''SIP Plans''), the SIP Plans' Operating Committees plan to submit proposed amendments to the SIP Plans that would extend the SIP operating hours to run from 8 p.m. Sundays to 8 p.m. Fridays, excluding holidays, with a technical pause beginning at 8 p.m. Monday through Thursday that would be as brief as technically feasible, but not greater than one hour. *See* SIP Plan Operating Committee Press Release, SIPs to Proposed Extended Operating Hours, available at *https://www.prnewswire.com/news-releases/sips-to-propose-extended-operating-hours-302447700.html.* As an initial, incremental step, FINRA is proposing in the instant filing to align the TRF operating hours with the current SIP operating hours. FINRA intends to separately seek to propose additional rule changes as appropriate to further expand TRF operating hours with the goal of ultimately aligning TRF operating hours with any extension of the SIP operating hours, if approved by the SEC.

[12] FINRA has also published guidance and technical documentation relating to TRF reporting, available at *https://www.finra.org/filing-reporting/trade-reporting-facility-trf.* FINRA would make appropriate conforming change to such guidance and technical documentation in connection with implementation of the proposed rule change.

a.m., designated ''as/of'' and carry the unique trade report modifier.

In addition, the proposed rule change would make a conforming change to paragraph (a)(5)(H) of FINRA Rules 6380A and 6380B, which requires members to append the applicable trade report modifier to identify pre-opening trades (currently, trades executed between 8 a.m. and 9:30 a.m.) and after-hours trades (*i.e.,* trades executed between 4 p.m. and 8 p.m.) that are reported more than 10 seconds after execution. FINRA is amending paragraph (a)(5)(H) of FINRA Rules 6380A and 6380B to cover pre-opening trades starting from 4 a.m. instead of 8 a.m. FINRA is not proposing any changes to the definition of ''normal market hours,'' which would remain 9:30 a.m. to 4 p.m., or to the closing time of the TRFs, which would remain 8 p.m.

FINRA believes the proposed rule change would enhance market transparency by facilitating the real-time reporting and public dissemination of information on OTC trades in NMS stocks for additional hours when the SIPs are open and otherwise disseminating real-time market data. In addition, extending the TRF hours would allow firms to report in real time for an additional period of time, which FINRA understands is operationally preferable to queuing trades for bulk reporting during the 15-minute period after the TRFs open.

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date of the proposed rule change will be during the first quarter of 2026. FINRA will announce the specific implementation date of the proposed rule change in a *Regulatory Notice,* which will be published at least 60 days prior to the implementation date.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[13] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

FINRA believes that the proposed rule change is consistent with the Act because it would enhance market transparency by enabling the reporting and real-time public dissemination of OTC transactions in NMS stocks for an additional four-hour period of each business day. As described above, the TRFs currently only accept transaction reports beginning at 8 a.m. each business day, whereas the SIPs are currently operational and able to disseminate real-time market data beginning at 4 a.m. each business day. FINRA believes that extending the TRF hours would improve the timeliness of trade information available to the public with respect to trades executed during the 4 a.m. to 8 a.m. early morning period. Further, FINRA members may also benefit from operational efficiencies and reduced technological burdens by reporting OTC trades in NMS stocks in real time during the early morning period, as they do for the regular trading day, rather than queuing such trade reports for bulk reporting after 8 a.m.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15A(b)(9) of the Act [14] requires that FINRA's rules not impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts of the proposal, including potential costs, benefits, and distributional and competitive effects, relative to the current baseline.

Regulatory Need

As discussed above, FINRA is proposing to extend the opening time of the TRFs from 8 a.m. to 4 a.m. each business day, thereby enabling real-time reporting and public dissemination of OTC transactions in NMS stocks executed between 4 a.m. and 8 a.m. and improving the timeliness of transparency for these transactions.

Economic Baseline

FINRA estimates that, from January 2024 to February 2025, approximately 2.5 percent of OTC trades in NMS stocks were executed outside of TRF operating hours.[15] Table 1 shows the breakdown of the OTC trades in NMS stocks occurring outside of and during TRF operating hours categorized by media and non-media trades, including the breakdown during different periods outside of TRF operating hours.

TABLE 1—NUMBER OF OTC TRADES IN NMS STOCKS REPORTED TO THE TRFS FROM JANUARY 2024 TO FEBRUARY 2025

[By media and non-media trades]

Execution time	Media trades		Non-media trades	
	Number of trade reports	Percentage of all trade reports	Number of trade reports	Percentage of all trade reports
Between midnight and 4 a.m. on business days (excluding 4 a.m.)	20,869,793	0.12	64,826,157	0.38
Between 4 a.m. and 8 a.m. on business days (excluding 8 a.m.)	48,747,658	0.28	194,064,567	1.13
Between 8 p.m. and midnight on business days (excluding 8 p.m. and midnight) or any time on non-business days	30,258,225	0.18	68,706,127	0.40
Total outside of TRF operating hours	99,875,676	0.58	327,596,851	1.91

[13] 15 U.S.C. 78*o*–3(b)(6).

[14] 15 U.S.C. 78*o*–3(b)(9).

[15] The analysis uses FINRA TRF transaction data as of April 16, 2025. The analysis excludes trades that are canceled, declined, rejected, reversed, or with special trade conditions, which account for approximately 0.03% of OTC trade reports in NMS stocks. The analysis includes both media and non-media trades reported to the TRFs. *See supra* note 8.

Media and non-media trades executed outside of TRF operating hours account for approximately 0.6% and 1.9%, respectively, of all OTC trades in NMS stocks reported to the TRFs. Because some trades are reported with a delay, the analysis used all trades reported within ten days after execution. As discussed below, the majority of trades are reported within the timeframe specified under the current reporting requirements.

TABLE 1—NUMBER OF OTC TRADES IN NMS STOCKS REPORTED TO THE TRFS FROM JANUARY 2024 TO FEBRUARY 2025—Continued

[By media and non-media trades]

Execution time	Media trades		Non-media trades	
	Number of trade reports	Percentage of all trade reports	Number of trade reports	Percentage of all trade reports
Total within TRF operating hours	9,031,882,703	52.73	7,669,681,211	44.78
Total outside of and within TRF operating hours	9,131,758,379	53.31	7,997,278,062	46.69
Total number of trade reports	17,129,036,441			

Among the total OTC trades in NMS stocks executed outside of TRF operating hours, approximately 98 percent of trades were reported by 8:15 a.m. on business days,[16] suggesting that the vast majority of trades executed outside of TRF operating hours were ready to be reported to the TRFs when the facilities resumed operations at 8 a.m. on business days.

FINRA estimates that, from January 2024 to February 2025, OTC trades in NMS stocks reported to the TRFs were executed by 375 firms.[17] Of the 375 firms, 217 firms executed OTC trades in NMS stocks exclusively during the TRF operating hours of 8 a.m. to 8 p.m. on business days and did not execute any OTC trades in NMS stocks outside of TRF operating hours. These firms would not be affected by the proposed rule change.

The remaining 158 firms executed at least one OTC trade in NMS stocks between 8 p.m. and 8 a.m. on business days or on non-business days from January 2024 to February 2025. Of the 158 firms, 135 firms executed at least one OTC trade in NMS stocks between 4 a.m. and 8 a.m. on business days from January 2024 to February 2025 and therefore under the proposed rule change would be required to report these trades as soon as practicable but no later than 10 seconds after execution, rather than the current requirement to report by 8:15 a.m. Additionally, from January 2024 to February 2025, almost all of the 158 firms that executed at least one OTC trade in NMS stocks outside of current TRF operating hours also executed at least one OTC trade in NMS stocks during TRF operating hours, which must be reported as soon as practicable but no later than 10 seconds after execution.

Economic Impacts

Anticipated Benefits

FINRA believes that the proposed changes would provide more timely pricing and other transaction information to the market for OTC trades in NMS stocks executed between 4 a.m. and 8 a.m. on business days, which would support more efficient price formation. Specifically, the proposed rule change would require trades executed between 8 p.m. and 4 a.m. to be reported by 4:15 a.m. instead of 8:15 a.m. Thus, information about these trades would become available four hours earlier than under the current rules, thereby providing market participants real-time access to pricing and other information between 4 a.m. to 8 a.m. These proposed changes would serve to reduce information asymmetry and improve price discovery for trades executed during those hours.

Anticipated Costs

Members may incur initial and ongoing costs, such as programming, maintenance, and compliance costs, to implement and maintain a system to report OTC trades in NMS stocks pursuant to the proposed rule change. Furthermore, members that use third-party vendors to report OTC trades in NMS stocks to the TRFs may need to adjust their business relationships to align with the proposed rule change.

The extent of these costs for each member will depend in part on the current activities and reporting systems of each member with respect to OTC trading in NMS stocks. As discussed above, FINRA estimates 158 firms executed at least one OTC trade in NMS stocks between 8 p.m. and 8 a.m. on business days or at any time on non-business days between January 2024 to February 2025. Almost all of the 158 firms also executed at least one OTC trade in NMS stocks between 8 a.m. and 8 p.m. on business days, and therefore these firms would already have systems in place to report trades as soon as practicable but no later than 10 seconds after execution, indicating that the initial fixed costs and variable costs may be relatively or substantially lower for those members.

FINRA identified a very small number of firms executing OTC trades in NMS stocks exclusively outside of current TRF operating hours. To the extent the current trade reporting systems of these firms are not able to report trades as soon as practicable but no later than 10 seconds after execution, such firms would incur costs to upgrade systems or employ a vendor to do so, depending on the time of trade execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on

[16] Approximately 97% of media trades and 98% of non-media trades for OTC trades in NMS stocks executed outside of TRF operating hours were reported within the timeframe required by the rules. Specifically, for OTC trades in NMS stocks, approximately 97% of media trades executed between midnight and 4 a.m. on business days were reported between 8 a.m. and 8:15 a.m. on the same day; approximately 98% of media trades executed between 4 a.m. and 8 a.m. on business days were reported between 8 a.m. and 8:15 a.m. on the same day; and approximately 96% of media trades executed between 8 p.m. and midnight on business days or any time on non-business days were reported between 8 a.m. and 8:15 a.m. on the following business day. In addition, for OTC trades in NMS stocks, approximately 98% of non-media trades executed between midnight and 4 a.m. on business days were reported between 8 a.m. and 8:15 a.m. on the same day; approximately 99% of non-media trades executed between 4 a.m. and 8 a.m. on business days were reported between 8 a.m. and 8:15 a.m. on the same day; and approximately 97% of non-media trades executed between 8 p.m. and midnight on business days or any time on non-business days were reported between 8 a.m. and 8:15 a.m. on the following business day.

[17] The analysis used the Central Registration Depository (CRD) number to identify firms executing trades.

which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[18] and Rule 19b–4(f)(6) thereunder.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2025–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2025–011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–FINRA–2025–011 and should be submitted on or before August 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–13261 Filed 7–15–25; 8:45 am]

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[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103440; File No. SR–NASDAQ–2025–048]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Introduce a New Credit Under Equity 7, Section 118(a)

July 11, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2025, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Equity 7, Section 118(a) to introduce a new credit.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's schedule of credits, at Equity 7, Section 118(a). Specifically, the Exchange proposes to add a new credit of $0.0029 per share executed for stocks in all Tapes for a member that, through one or more of its Nasdaq Market Center MPIDs: (i) adds displayed liquidity in all securities to the Exchange during the month in a volume greater than 0.50% of Consolidated Volume; [3] and (ii) has a combined volume (adding and removing liquidity) of at least 2.50% of Consolidated Volume during the month. The purpose of the new credit is to incentivize activity on the Exchange and liquidity adding activity, in particular. The Exchange believes that if such incentive is effective, then any ensuing increase in liquidity to the Exchange will improve market quality, to the benefit of all participants.[4]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other

[3] Pursuant to Equity 7, Section 118, ''Consolidated Volume'' means ''the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot.''

[4] All references throughout this filing to certain rule sections shall pertain to Nasdaq Equity 7.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Proposal Is Reasonable

The Exchange's proposed change to its schedule of credits ais reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .'' [7]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [8]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange believes that it is reasonable to establish a new credit of $0.0029 for shares executed at or above $1.00 for a member that (i) adds displayed liquidity in all securities to the Exchange during the month in a volume greater than 0.50% of Consolidated Volume; and (ii) has a combined volume (adding and removing liquidity) of at least 2.50% of Consolidated Volume during the month. This proposal is reasonable because it will incentivize activity on the Exchange and liquidity adding activity, in particular. The Exchange believes that if such incentive is effective, then any ensuing increase in liquidity to the Exchange will improve market quality, to the benefit of all participants.

The Proposals Are Equitable Allocations of Credits

The Exchange believes that it is equitable to establish the new credit. To the extent that the Exchange succeeds in increasing the levels of liquidity and activity on the Exchange, the Exchange will experience improvements in its market quality, which stands to benefit all market participants.

Any participant that is dissatisfied with the proposal is free to shift its order flow to competing venues that provide more generous pricing or less stringent qualifying criteria.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that its proposal is not unfairly discriminatory. As an initial matter, the Exchange believes that nothing about its volume-based tiered pricing model is inherently unfair; instead, it is a rational pricing model that is well-established and ubiquitous in today's economy among firms in various industries—from co-branded credit cards to grocery stores to cellular telephone data plans—that use it to reward the loyalty of their best customers that provide high levels of business activity and incent other customers to increase the extent of their business activity. It is also a pricing model that the Exchange and its competitors have long employed with the assent of the Commission. It is fair because it enhances price discovery and improves the overall quality of the equity markets.

The Exchange believes that its proposal to adopt the new credit is not unfairly discriminatory because the changes are not intended to advantage any particular member and will be applied uniformly to all members. Moreover, the proposal stands to improve the overall market quality of the Exchange, to the benefit of all market participants, by incentivizing members to increase the extent of their liquidity adding and overall activity on the Exchange.

Any participant that is dissatisfied with the proposal is free to shift its order flow to competing venues that provide more generous pricing or less stringent qualifying criteria.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that its proposal will place any category of Exchange participant at a competitive disadvantage.

As noted above, the Exchange's proposal to add a new transaction credit is intended to have market-improving effects, to the benefit of all members. Any member may elect to achieve the level of liquidity required to qualify for the new credit.

The Exchange notes that its members are free to trade on other venues to the extent they believe that the Exchange's fee schedule is not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes.

Intermarket Competition

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its credits and fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their credit and own fees in response, and because market

[7] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[8] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

participants may readily adjust their order routing practices, the Exchange believes that the degree to which credit or fee changes in this market may impose any burden on competition is extremely limited.

The proposed new credit is reflective of this competition because, as a threshold issue, even as one of the largest U.S. equities exchanges by volume, the Exchange has less than 15% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to credit and fee changes. This is an addition to free flow of order flow to and among off-exchange venues which at times comprises more than half of industry volume.

The Exchange's proposal to add a new transaction credit is pro-competitive in that the Exchange intends for the credit to increase liquidity addition and overall activity on the Exchange, thereby rendering the Exchange more attractive and vibrant to participants.

In sum, if the change proposed herein is unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2025–048 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2025–048. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2025–048 and should be submitted on or before August 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–13265 Filed 7–15–25; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103443; File No. 4–618]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Between Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc., BOX Exchange LLC, Cboe Exchange, Inc., Cboe C2 Exchange, Inc., NYSE Texas, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., Long-Term Stock Exchange, Inc., MEMX LLC, Nasdaq ISE, LLC, Nasdaq GEMX, LLC, Nasdaq MRX, LLC, Investors Exchange LLC, Miami International Securities Exchange, LLC, MIAX PEARL, LLC, MIAX Emerald, LLC, MIAX Sapphire, LLC, The Nasdaq Stock Market LLC, Nasdaq BX, Inc., Nasdaq PHLX LLC, NYSE National, Inc., New York Stock Exchange LLC, NYSE American LLC, and NYSE Arca, Inc., Long-Term Stock Exchange, Inc., and 24X National Exchange LLC Concerning Covered Regulation NMS and Consolidated Audit Trail Rules

July 11, 2025.

Notice is hereby given that the Securities and Exchange Commission (''Commission'') has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 (''Act''),[1] approving and declaring effective an amendment to the plan for allocating regulatory responsibility (''Plan'') filed on June 25, 2025, pursuant to Rule 17d–2 of the Act,[2] by Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BATS Y''), BOX Exchange LLC (''BOX''), Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), NYSE Texas, Inc. (''Texas''), Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX''), Financial Industry Regulatory Authority, Inc. (''FINRA''), Long-Term Stock Exchange, Inc. (''LTSE''), MEMX LLC (''MEMX''), Nasdaq ISE, LLC

[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

(''ISE''), Nasdaq GEMX, LLC (''GEMX''), Nasdaq MRX, LLC (''MRX''), Investors Exchange LLC (''IEX''), Miami International Securities Exchange, LLC (''MIAX''), MIAX PEARL, LLC (''MIAX PEARL''), MIAX Emerald, LLC (''MIAX Emerald''), MIAX Sapphire, LLC (''MIAX Sapphire''), The Nasdaq Stock Market LLC (''Nasdaq''), Nasdaq BX, Inc. (''BX''), Nasdaq PHLX LLC (''PHLX''), NYSE National, Inc. (''NYSE National''), New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), and NYSE Arca, Inc. (''NYSE Arca''), and 24X National Exchange LLC (''24X'') (each, a ''Participating Organization,'' and, together, the ''Participating Organizations'' or the ''Parties''). This Agreement amends and restates the agreement by and among the Participating Organizations approved by the Commission on August 1, 2024.[3]

I. Introduction

Section 19(g)(1) of the Act,[4] among other things, requires every self-regulatory organization (''SRO'') registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.[5] Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (''common members''). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[6] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[7] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[8] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (''DEA'') to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[9] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[10] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On December 3, 2010, the Commission approved the SRO participants' plan for allocating regulatory responsibilities pursuant to Rule 17d–2.[11] On October 29, 2015, the Commission approved an amended plan that added Regulation NMS Rules 606, 607, and 611(c) and (d) and added additional Participating Organizations that are options markets to the Plan.[12] On August 11, 2016, the Commission approved an amended plan that added IEX and ISE Mercury as Participating Organizations.[13] On February 2, 2017, the Commission approved an amended plan that added MIAX PEARL as a Participating Organization.[14] On February 4, 2019, the Commission approved an amended plan that added MIAX Emerald as a Participating Organization and reflected name changes of certain Participating Organizations.[15] On July 25, 2019, the Commission approved an amended plan that added LTSE as a Participating Organization and reflected name changes of certain Participating Organizations.[16] On March 12, 2020, the Commission approved an amended plan that added Rule 613 under the Act and the rules of each Participating Organization related to Rule 613 listed on Exhibit A to the Plan, and reflected the name change of Nasdaq PHLX, Inc. to Nasdaq PHLX LLC.[17] On June 10, 2020, the Commission approved a proposed amendment to the Plan to add MEMX as a Participant to the Plan.[18] On September 23, 2023, the Commission approved a proposed amendment to the Plan to add MIAX PEARL as a Participant to the Plan.[19]

The proposed 17d–2 Plan is intended to reduce regulatory duplication for firms that are members of more than one Participating Organization.[20] The Plan provides for the allocation of regulatory responsibility according to whether the covered rule pertains to NMS stocks or NMS securities. For covered rules that pertain to NMS stocks (*i.e.,* Rules 607, 611, and 612), FINRA serves as the ''Designated Regulation NMS Examining Authority'' (''DREA'') for common members that are members of FINRA

[3] *See* Securities Exchange Act Release No. 100636, 89 FR 64517 (Aug. 7, 2024).

[4] 15 U.S.C. 78s(g)(1).

[5] 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

[6] 15 U.S.C. 78q(d)(1).

[7] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[8] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[9] *See* Securities Exchange Act Release No. 12352 (Apr. 20, 1976), 41 FR 18808 (May 7, 1976).

[10] *See* Securities Exchange Act Release No. 12935 (Oct. 28, 1976), 41 FR 49091 (Nov. 8, 1976).

[11] *See* Securities Exchange Act Release No. 63430, 75 FR 76758 (Dec. 9, 2010).

[12] *See* Securities Exchange Act Release No. 76311, 80 FR 68377 (Nov. 4, 2015).

[13] *See* Securities Exchange Act Release No. 78552, 81 FR 54905 (Aug. 17, 2016).

[14] *See* Securities Exchange Act Release No. 79928, 82 FR 9814 (Feb. 8, 2017).

[15] *See* Securities Exchange Act Release No. 85046, 84 FR 2643 (Feb. 7, 2019).

[16] *See* Securities Exchange Act Release No. 86470, 84 FR 37363 (July 31, 2019).

[17] *See* Securities Exchange Act Release No. 88366, 85 FR 15238 (Mar. 17, 2020).

[18] *See* Securities Exchange Act Release No. 89042, 85 FR 36450 (June 16, 2020).

[19] *See* Securities Exchange Act Release No. 89972, 85 FR 61062 (Sept. 29, 2020).

[20] The proposed 17d–2 Plan refers to these members as ''Common Members.''

and assumes certain examination and enforcement responsibilities for those members with respect to specified Regulation NMS rules. For common members that are not members of FINRA, the member's DEA serves as the DREA and ''Designated CAT Surveillance Authority (''DCSA''), provided that the DEA exchange operates a national securities exchange or facility that trades NMS stocks and the common member is a member of such exchange or facility. Section 2(c) of the Plan contains a list of principles that are applicable to the allocation of common members in cases not specifically addressed in the Plan. An exchange that does not trade NMS stocks would have no regulatory authority for covered Regulation NMS rules pertaining to NMS stocks. For covered rules that pertain to NMS securities, and thus include options (*i.e.,* Rule 606, Rule 613 and the SRO Covered CAT Rules), the Plan provides that the DREA will be the same as the DREA for the rules pertaining to NMS stocks and will serve as the DCSA. For common members that are not members of an exchange that trades NMS stocks, the common member would be allocated according to the principles set forth in Section 2(c) of the Plan.

The text of the Plan delineates the proposed regulatory responsibilities with respect to the Parties. Included in the proposed Plan is an exhibit (the ''Covered Rules'') that lists the federal securities laws, rules, and regulations, for which the applicable DREA would bear examination and enforcement responsibility, and for which the applicable DCSA would bear surveillance, investigation, and enforcement responsibility, under the Plan for common members of the Participating Organization and their associated persons.

Specifically, the applicable DREA assumes examination and enforcement responsibility, and the applicable DCSA assumes surveillance, investigation, and enforcement responsibility, relating to compliance by common members with the Covered Rules. Covered Rules do not include the application of any rule of a Participating Organization, or any rule or regulation under the Act, to the extent that it pertains to violations of insider trading activities, because such matters are covered by a separate multiparty agreement under Rule 17d–2.[21] Under the Plan, Participating Organizations retain full responsibility for surveillance and enforcement with respect to trading activities or practices involving their own marketplace.[22]

III. Proposed Amendment to the Plan

On June 25, 2025, the parties submitted a proposed amendment to the Plan. The primary purpose of the amendment is to add 24X as a Participant to the Plan and to reflect the name change of NYSE Chicago, Inc. to NYSE Texas, Inc.

The text of the proposed amended 17d–2 Plan is as follows (additions are in *italics;* deletions are in [brackets]):

Agreement for the Allocation of Regulatory Responsibility for the Covered Regulation NMS and Consolidated Audit Trail Rules Pursuant to § 17(d) of the Securities Exchange Act of 1934, 15 U.S.C. 78q(d), and Rule 17d–2 Thereunder

This agreement (the ''Agreement'') by and among Cboe BZX Exchange, Inc. (''Cboe BZX''), Cboe BYX Exchange, Inc. (''Cboe BYX''), BOX Exchange LLC (''BOX''), Cboe Exchange, Inc. (''Cboe Options''), Cboe C2 Exchange, Inc. (''Cboe C2''), NYSE [Chicago] *Texas,* Inc. (''[CHX] *NYSE Texas*''), Cboe EDGA Exchange, Inc. (''Cboe EDGA''), Cboe EDGX Exchange, Inc. (''Cboe EDGX''), Financial Industry Regulatory Authority, Inc. (''FINRA''), MEMX LLC (''MEMX''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX''), Nasdaq MRX, LLC (''MRX''), Investors Exchange LLC (''IEX''), Miami International Securities Exchange, LLC (''MIAX''), MIAX PEARL, LLC (''MIAX PEARL''), MIAX Emerald, LLC (''MIAX Emerald''), MIAX Sapphire, LLC (''MIAX Sapphire''), The Nasdaq Stock Market LLC (''Nasdaq''), Nasdaq BX, Inc. (''BX''), Nasdaq PHLX LLC (''PHLX''), NYSE National, Inc. (''NYSE National''), New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), [and] Long-Term Stock Exchange, Inc. (''LTSE'') *and 24X National Exchange LLC (''24X'')* (each, a ''Participating Organization,'' and, together, the ''Participating Organizations''), is made pursuant to § 17(d) of the Securities Exchange Act of 1934 (the ''Act'' or ''SEA''), 15 U.S.C. 78q(d), and Rule 17d–2 thereunder, which allow for plans to allocate regulatory responsibility among self-regulatory organizations (''SROs''). Upon approval by the Securities and Exchange Commission (''Commission'' or ''SEC''), this Agreement shall amend and restate the agreement by and among the Participating Organizations approved by the SEC on [June 10, 2020] *August 1, 2024.*

Whereas, the Participating Organizations desire to: (a) foster cooperation and coordination among the SROs; (b) remove impediments to, and foster the development of, a national market system; (c) strive to protect the interest of investors; (d) eliminate duplication in their examination and enforcement of (i) SEA Rules 606, 607, 611, 612 and 613 (the ''Covered Regulation NMS Rules'') and (ii) rules of each Participating Organization related to SEA Rule 613 listed on Exhibit A hereto (''SRO Covered CAT Rules,'' together with the Covered Regulation NMS Rules, collectively, the ''Covered Rules'') and (e) eliminate duplication in their surveillance, examination, investigation and enforcement of SEA Rule 613 and the SRO Covered CAT Rules;

Whereas, the Participating Organizations are interested in allocating regulatory responsibilities with respect to broker-dealers that are members of more than one Participating Organization (the ''Common Members'') relating to the examination and enforcement of the Covered Rules and the surveillance, examination, investigation and enforcement of SEA Rule 613 and the SRO Covered CAT Rules; and

Whereas, the Participating Organizations will request regulatory allocation of these regulatory responsibilities by executing and filing with the SEC this plan for the above stated purposes pursuant to the provisions of § 17(d) of the Act, and Rule 17d–2 thereunder, as described below.

Now, therefore, in consideration of the mutual covenants contained hereafter, and other valuable consideration to be mutually exchanged, the Participating Organizations hereby agree as follows:

1. Assumption of Surveillance Responsibility. The Designated CAT Surveillance Authority (the ''DCSA'') shall assume surveillance, investigation and enforcement responsibility relating to compliance by Common Members with SEA Rule 613 and the SRO Covered CAT Rules listed on Exhibit A (''Surveillance Responsibility''). Included in the Surveillance Responsibility assumed hereunder the DCSA shall perform investigations and enforcement resulting from reports and metrics concerning potentially non-compliant CAT reporting generated by the Plan Processor for the National Market System Plan Governing the Consolidated Audit Trail and as provided for in the Monitoring CAT

[21] *See* Securities Exchange Act Release No. 103365 (July 1, 2025), 90 FR 29912 (July 7, 2025) (File No. 4–566) (notice of filing and order approving and declaring effective an amendment to the insider trading 17d–2 plan).

[22] *See* paragraph 3 of the Plan.

Reporter Compliance Policy (dated August 13, 2019 and as amended from time to time) relating to Common Members. FINRA shall serve as DCSA for Common Members that are members of FINRA. The DREA allocated below shall serve as DCSA for Common Members that are not members of FINRA.

2. Assumption of Examination Responsibility. The Designated Regulation NMS Examining Authority (the ''DREA'') shall assume examination and enforcement responsibilities relating to compliance by Common Members with the Covered Rules to which the DREA is allocated responsibility (''Examination Responsibility''). A list of the Covered Rules is attached hereto as Exhibit A.

a. For Covered Regulation NMS Rules Pertaining to ''NMS stocks'' (as defined in Regulation NMS) (*i.e.,* Rules 607, 611 and 612): FINRA shall serve as DREA for Common Members that are members of FINRA. The Designated Examining Authority (''DEA'') pursuant to SEA Rule 17d–1 shall serve as DREA (and accordingly as DCSA as provided in paragraph 1 above) for Common Members that are not members of FINRA, provided that the DEA operates a national securities exchange or facility that trades NMS stocks and the Common Member is a member of such exchange or facility. For all other Common Members, the Participating Organizations shall allocate Common Members among the Participating Organizations (other than FINRA) that operate a national securities exchange that trades NMS stocks based on the principles outlined below and the Participating Organization to which such a Common Member is allocated shall serve as the DREA for that Common Member. (A Participating Organization that operates a national securities exchange that does not trade NMS stocks has no regulatory responsibilities related to Covered Regulation NMS Rules pertaining to NMS stocks and will not serve as DREA for such Covered Regulation NMS Rules.)

b. For Covered Regulation NMS Rules Pertaining to ''NMS securities'' (as defined in Regulation NMS) (*i.e.,* Rule 606 and Rule 613) and the SRO Covered CAT Rules listed on Exhibit A hereto, the DREA shall be the same as the DREA for Covered Regulation NMS Rules pertaining to NMS stocks (and shall serve as the DCSA in paragraph 1 above). For Common Members that are not members of a national securities exchange that trades NMS stocks and thus have not been appointed a DREA under paragraph a., the Participating Organizations shall allocate the Common Members among the Participating Organizations (other than FINRA) that operate a national securities exchange that trades NMS securities based on the principles outlined below and the Participating Organization to which such a Common Member is allocated shall serve as the DREA for that Common Member with respect to Covered Regulation NMS Rules pertaining to NMS securities. The allocation of Common Members to DREAs (including FINRA) and accordingly to serve as DCSA in paragraph 1 above for all Covered Rules is provided in Exhibit B.

c. For purposes of this paragraph 2, any allocation of a Common Member to a Participating Organization other than as specified in paragraphs a. and b. above shall be based on the following principles, except to the extent all affected Participating Organizations consent to one or more different principles and any such agreement to different principles would be deemed an amendment to this Agreement as provided in paragraph 24:

i. The Participating Organizations shall not allocate a Common Member to a Participating Organization unless the Common Member is a member of that Participating Organization.

ii. To the extent practicable, Common Members shall be allocated among the Participating Organizations of which they are members in such a manner as to equalize, as nearly as possible, the allocation among such Participating Organizations.

iii. To the extent practicable, the allocation will take into account the amount of NMS stock activity (or NMS security activity, as applicable) conducted by each Common Member in order to most evenly divide the Common Members with the largest amount of activity among the Participating Organizations of which they are a member. The allocation will also take into account similar allocations pursuant to other plans or agreements to which the Participating Organizations are party to maintain consistency in oversight of the Common Members.[1]

iv. The Participating Organizations may reallocate Common Members from time-to-time and in such manner as they deem appropriate consistent with the terms of this Agreement.

v. Whenever a Common Member ceases to be a member of its DREA (including FINRA), the DREA shall promptly inform the Participating Organizations, who shall review the matter and reallocate the Common Member to another Participating Organization.

vi. The DEA or DREA (including FINRA) may request that a Common Member be reallocated to another Participating Organization (including the DEA or DREA (including FINRA)) by giving 30 days written notice to the Participating Organizations. The Participating Organizations shall promptly consider such request and, in their discretion, may approve or disapprove such request and if approved, reallocate the Common Member to such Participating Organization.

vii. All determinations by the Participating Organizations with respect to allocations shall be by the affirmative vote of a majority of the Participating

viii. Organizations that, at the time of such determination, share the applicable Common Member being allocated; a Participating Organization shall not be entitled to vote on any allocation related to a Common Member unless the Common Member is a member of such Participating Organization.

d. The Participating Organizations agree that they shall conduct meetings among them as needed for the purposes of ensuring proper allocation of Common Members and identifying issues or concerns with respect to the regulation of Common Members. To promote consistency in connection with regulation of Common Members, the Participating Organizations further agree to conduct meetings to discuss the overarching principles as to how Covered Rules, in particular SEA Rule 613 and the SRO Covered CAT Rules, should be surveilled, examined, investigated and enforced. On an ongoing basis, the Participating Organizations agree to consult with and solicit input from the Participating Organizations regarding their surveillance, examination, investigation and enforcement programs regarding SEA Rule 613 and the SRO Covered CAT Rules. In particular, FINRA will consult with Participating Organizations prior to finalizing its disposition and sanctions guidelines with respect to violations of SEA Rule 613 and the SRO Covered CAT Rules. Further, in the period preceding the full implementation of CAT for equities and options securities, FINRA will consult with other Participating Organizations prior to finalizing dispositions other

[1] For example, if one Participating Organization was allocated responsibility for a particular Common Member pursuant to a separate Rule 17d–2 Agreement, that Participant Organization would be assigned to be the DREA of that Common Member, unless there is good cause not to make that assignment.

than no further action that involve their Common Members.

e. By signing this Agreement, the Participating Organizations hereby certify that the list of SRO Covered CAT Rules listed on Exhibit A hereto are correct and are identical or substantially similar to each other.

f. Each year following the commencement date of operation of this Agreement, or more frequently if required by changes in any of the SRO Covered CAT Rules, each Participating Organization shall submit an updated list of SRO Covered CAT Rules to FINRA for review which shall (1) add SRO Covered CAT Rules not included in the current list of SRO Covered CAT Rules that are substantially similar to each other; (2) delete SRO Covered CAT Rules included in the current list that are no longer substantially similar; and (3) confirm that the remaining rules on the current list of SRO Covered CAT Rules continue to be substantially similar. FINRA shall review each Participating Organization's annual certification and confirm whether FINRA agrees with the submitted certified and updated list of SRO Covered CAT Rules. The DREA/DCSA shall not have Regulatory Responsibility for any provision in a SRO Covered CAT Rule provision requiring a member of a Participating Organization to provide notice, reports or any other filings directly to a Participating Organization.

3. Scope of Responsibility. Notwithstanding anything herein to the contrary, it is explicitly understood that the terms ''Surveillance Responsibility'' and ''Examination Responsibility'' (collectively referred to herein as the ''Regulatory Responsibility'') do not include any responsibilities beyond those concerning the Covered Rules, and each of the Participating Organizations shall retain full responsibility for, examination, surveillance and enforcement with respect to trading activities or practices involving its own marketplace unless otherwise allocated pursuant to a separate Rule 17d–2 Agreement. The allocation of DCSA Responsibility to a Participating Organization shall not limit another Participating Organization's ability to utilize data from the Consolidated Audit Trail to perform examination, surveillance, investigative, enforcement or other regulatory work concerning potential or identified violations of statutes or rules other than the SRO Covered CAT Rules.

4. No Retention of Regulatory Responsibility. The Participating Organizations do not contemplate the retention of any responsibilities with respect to the regulatory activities being assumed by the DREA/DCSA under the terms of this Agreement. Nothing in this Agreement will be interpreted to prevent a DREA/DCSA from entering into Regulatory Services Agreement(s) to perform its Regulatory Responsibility.

5. No Charge. A DREA/DCSA shall not charge Participating Organizations for performing the Regulatory Responsibility under this Agreement.

6. Applicability of Certain Laws, Rules, Regulations or Orders. Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule, or order is inconsistent with one or more provisions of this Agreement, the statute, rule, or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

7. Customer Complaints. If a Participating Organization receives a copy of a customer complaint relating to a DREA's/DCSA's Regulatory Responsibility as set forth in this Agreement, the Participating Organization shall promptly forward to such DREA/DCSA a copy of such customer complaint. It shall be such DREA's/DCSA's responsibility to review and take appropriate action in respect to such complaint.

8. Parties to Make Personnel Available as Witnesses. Each Participating Organization shall make its personnel available to the DREA/DCSA to serve as testimonial or non-testimonial witnesses as necessary to assist the DREA/DCSA in fulfilling the Regulatory Responsibility allocated under this Agreement. The DREA/DCSA shall provide reasonable advance notice when practicable and shall work with a Participating Organization to accommodate reasonable scheduling conflicts within the context and demands as the entity with ultimate regulatory responsibility. The Participating Organization shall pay all reasonable travel and other expenses incurred by its employees to the extent that the DREA/DCSA requires such employees to serve as witnesses, and provide information or other assistance pursuant to this Agreement.

9. Sharing of Work-Papers, Data and Related Information.

a. Sharing. A Participating Organization shall make available to the DREA/DCSA information necessary to assist the DREA/DCSA in fulfilling the Regulatory Responsibility assumed under the terms of this Agreement. Such information shall include *any* information collected by a Participating Organization in the course of performing its regulatory obligations under the Act, including information relating to an on-going disciplinary investigation or action against a member, the amount of a fine imposed on a member, financial information, or information regarding proprietary trading systems gained in the course of examining a member (''Regulatory Information''). This Regulatory Information shall be used by the DREA/DCSA solely for the purposes of fulfilling the DREA's/DCSA's Regulatory Responsibility.

b. No Waiver of Privilege. The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

10. Special or Cause Examinations and Enforcement Proceedings. Nothing in this Agreement shall restrict or in any way encumber the right of a Participating Organization to conduct special or cause examinations of a Common Member, or take enforcement proceedings against a Common Member as a Participating Organization, in its sole discretion, shall deem appropriate or necessary.

11. Dispute Resolution Under this Agreement.

a. Negotiation. The Participating Organizations will attempt to resolve any disputes through good faith negotiation and discussion, escalating such discussion up through the appropriate management levels until reaching the executive management level. In the event a dispute cannot be settled through these means, the Participating Organizations shall refer the dispute to binding arbitration.

b. Binding Arbitration. All claims, disputes, controversies, and other matters in question between the Participating Organizations to this Agreement arising out of or relating to this Agreement or the breach thereof that cannot be resolved by the Participating Organizations will be resolved through binding arbitration. Unless otherwise agreed by the Participating Organizations, a dispute submitted to binding arbitration pursuant to this paragraph shall be resolved using the following procedures:

(i) The arbitration shall be conducted in a city selected by the DREA/DCSA in which it maintains a principal office or where otherwise agreed to by the Participating Organizations in accordance with the Commercial Arbitration Rules of the American Arbitration Association and judgment upon the award rendered by the

arbitrator may be entered in any court having jurisdiction thereof; and

(ii) There shall be three arbitrators, and the chairperson of the arbitration panel shall be an attorney. The arbitrators shall be appointed in accordance with the Commercial Arbitration Rules of the American Arbitration Association.

12. Limitation of Liability. As between the Participating Organizations, no Participating Organization, including its respective directors, governors, officers, employees and agents, will be liable to any other Participating Organization, or its directors, governors, officers, employees and agents, for any liability, loss or damage resulting from any delays, inaccuracies, errors or omissions with respect to its performing or failing to perform regulatory responsibilities, obligations, or functions, except: (a) as otherwise provided for under the Act; (b) in instances of a Participating Organization's gross negligence, willful misconduct or reckless disregard with respect to another Participating Organization; or (c) in instances of a breach of confidentiality obligations owed to another Participating Organization. The Participating Organizations understand and agree that the regulatory responsibilities are being performed on a good faith and best effort basis and no warranties, express or implied, are made by any Participating Organization to any other Participating Organization with respect to any of the responsibilities to be performed hereunder. This paragraph is not intended to create liability of any Participating Organization to any third party.

13. SEC Approval.

a. The Participating Organizations agree to file promptly this Agreement with the SEC for its review and approval. FINRA shall file this Agreement on behalf, and with the explicit consent, of all Participating Organizations.

b. If approved by the SEC, the Participating Organizations will notify their members of the general terms of the Agreement and of its impact on their members.

14. Subsequent Parties; Limited Relationship. This Agreement shall inure to the benefit of and shall be binding upon the Participating Organizations hereto and their respective legal representatives, successors, and assigns. Nothing in this Agreement, expressed or implied, is intended or shall: (a) confer on any person other than the Participating Organizations hereto, or their respective legal representatives, successors, and assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement, (b) constitute the Participating Organizations hereto partners or participants in a joint venture, or (c) appoint one Participating Organization the agent of the other.

15. Assignment. No Participating Organization may assign this Agreement without the prior written consent of the DREAs/DCSAs performing Regulatory Responsibility on behalf of such Participating Organization, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that any Participating Organization may assign the Agreement to a corporation controlling, controlled by or under common control with the Participating Organization without the prior written consent of such Participating Organization's DREAs/DCSAs. No assignment shall be effective without Commission approval.

16. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

17. Termination. Any Participating Organization may cancel its participation in the Agreement at any time upon the approval of the Commission after 180 days written notice to the other Participating Organizations (or in the case of a change of control in ownership of a Participating Organization, such other notice time period as that Participating Organization may choose). The cancellation of its participation in this Agreement by any Participating Organization shall not terminate this Agreement as to the remaining Participating Organizations.

18. General. The Participating Organizations agree to perform all acts and execute all supplementary instruments or documents that may be reasonably necessary or desirable to carry out the provisions of this Agreement.

19. Written Notice. Any written notice required or permitted to be given under this Agreement shall be deemed given if sent by certified mail, return receipt requested, or by a comparable means of electronic communication to each Participating Organization entitled to receipt thereof, to the attention of the Participating Organization's representative at the Participating Organization's then principal office or by email.

20. Confidentiality. The Participating Organizations agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations under this Agreement, provided, however, that each Participating Organization may disclose such documents or information as may be required to comply with applicable regulatory requirements or requests for information from the SEC. Any Participating Organization disclosing confidential documents or information in compliance with applicable regulatory or oversight requirements will request confidential treatment of such information. No Participating Organization shall assert regulatory or other privileges as against the other with respect to Regulatory Information that is required to be shared pursuant to this Agreement.

21. Regulatory Responsibility. Pursuant to Section 17(d)(1)(A) of the Act, and Rule 17d–2 thereunder, the Participating Organizations request the SEC, upon its approval of this Agreement, to relieve the Participating Organizations which are participants in this Agreement that are not the DREA or DCSA as to a Common Member of any and all responsibilities with respect to the matters allocated to the DREA or DCSA pursuant to this Agreement for purposes of §§ 17(d) and 19(g) of the Act.

22. Governing Law. This Agreement shall be deemed to have been made in the State of New York, and shall be construed and enforced in accordance with the law of the State of New York, without reference to principles of conflicts of laws thereof. Each of the Participating Organizations hereby consents to submit to the jurisdiction of the courts of the State of New York in connection with any action or proceeding relating to this Agreement.

23. Survival of Provisions. Provisions intended by their terms or context to survive and continue notwithstanding delivery of the regulatory services by the DREA/DCSA and any expiration of this Agreement shall survive and continue.

24. Amendment.

a. This Agreement may be amended to add a new Participating Organization, provided that such Participating Organization does not assume regulatory responsibility, by an amendment executed by all applicable DREAs/DCSAs and such new Participating Organization. All other Participating Organizations expressly consent to allow such DREAs/DCSAs to

jointly add new Participating Organizations to the Agreement as provided above. Such DREAs/DCSAs will promptly notify all Participating Organizations of any such amendments to add a new Participating Organization.

b. All other amendments must be approved by each Participating Organization. All amendments, including adding a new Participating Organization but excluding changes to Exhibit B, must be filed with and approved by the Commission before they become effective.

25. Effective Date. The Effective Date of this Agreement will be the date the SEC declares this Agreement to be effective pursuant to authority conferred by § 17(d) of the Act, and Rule 17d–2 thereunder.

26. Counterparts. This Agreement may be executed in any number of counterparts, including facsimile, each of which will be deemed an original, but all of which taken together shall constitute one single agreement among the Participating Organizations.

* * * * *

Exhibit A

Covered Rules

Covered Regulation NMS Rules

SEA Rule 606—Disclosure of Order Routing Information.*
SEA Rule 607—Customer Account Statements.
SEA Rule 611—Order Protection Rule.
SEA Rule 612—Minimum Pricing Increment.
SEA Rule 613(g)(2)—Consolidated Audit Trail *

* Covered Regulation NMS Rules with asterisks (*) pertain to NMS securities. Covered Regulation NMS Rules without asterisks pertain to NMS stocks.

SRO Covered CAT Rules

24X—Rules 4.5—4.16
Cboe BZX—Rules 4.5–4.16
Cboe BYX—Rules 4.5–4.16
BOX—Rules 16020–16095
Cboe Options—Rules 7.20–7.31
Cboe C2—Chapter 7, Section B (only with respect to incorporation of Cboe Rules 7.20–7.31)
Cboe EDGA—Rules 4.5–4.16
Cboe EDGX—Rules 4.5–4.16
FINRA—Rules 6810–6895
IEX—Rules 11.610–11.695
MEMX Rules 4.5–4.16
MIAX—Rules 1701–1712
MIAX PEARL—Rules 1701–1712
MIAX Emerald—Rules 1701–1712
MIAX Sapphire—Rules 1701–1712
Nasdaq—General 7, Sections 1–13
BX Equities Rules—General 7
PHLX—General 7
ISE—General 7
GEMX—General 7
MRX—General 7
NYSE—Rules 6810–6895
NYSE Arca—Rules—11.6810–11.6895
NYSE American—Rules 6810–6895
NYSE *Texas* [Chicago]—Rules 6810–6895
NYSE National—Rules 6.6810–6.6895
LTSE—Rules 11.610–11.695

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number 4–618 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number 4–618. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/other.shtml*). Copies of the plan also will be available for inspection and copying at the principal offices of the Participating Organizations. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number 4–618 and should be submitted on or before August 6, 2025.

V. Discussion

The Commission finds that the Plan, as amended, is consistent with the factors set forth in Section 17(d) of the Act[23] and Rule 17d–2(c) thereunder[24] in that the proposed amended Plan is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. In particular, the Commission believes that the proposed amended Plan should reduce unnecessary regulatory duplication by allocating to the applicable DREA certain examination and enforcement responsibilities, and to the applicable DCSA certain surveillance, investigation, and enforcement responsibilities, for Common Members that would otherwise be performed by multiple Parties. Accordingly, the proposed amended Plan promotes efficiency by reducing costs to Common Members. Furthermore, because the Parties will coordinate their regulatory functions in accordance with the proposed amended Plan, the amended Plan should promote investor protection.

The Commission is hereby declaring effective a plan that allocates regulatory responsibility for certain provisions of the federal securities laws, rules, and regulations as set forth in Exhibit A to the Plan. The Commission notes that any amendment to the Plan must be approved by the relevant Parties as set forth in Paragraph 24 of the Plan and must be filed with and approved by the Commission before it may become effective.[25]

Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. In particular, the purpose of the amendment is to add 24X as a Participating Organization and to reflect the name change of NYSE Chicago, Inc. to NYSE Texas, Inc. The Commission notes that the most recent prior amendment to the Plan was published for comment and the Commission did not receive any comments thereon.[26] The Commission believes that the current amendment to the Plan does not raise any new regulatory issues that the Commission has not previously considered, and therefore believes that the amended Plan should become effective without any undue delay.

[23] 15 U.S.C. 78q(d).

[24] 17 CFR 240.17d–2(c).

[25] *See* Paragraph 24 of the Plan. The Commission notes, however, that changes to Exhibit B to the Plan (the allocation of Common Members to DREAs) are not required to be filed with, and approved by, the Commission before they become effective.

[26] *See* Securities Exchange Act Release No. 100636 (August 1, 2024), 89 FR 64517 (August 7, 2024).

VI. Conclusion

This Order gives effect to the Plan filed with the Commission in File No. 4–618. The Parties shall notify all members affected by the Plan of their rights and obligations under the Plan.

It is therefore ordered, pursuant to Section 17(d) of the Act, that the Plan in File No. 4–618 is hereby approved and declared effective.

It is further ordered that the Parties who are not the DREA or DCSA as to a particular Common Member are relieved of those regulatory responsibilities allocated to the Common Member's DREA or DCSA under the Plan to the extent of such allocation.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–13264 Filed 7–15–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103436; File Nos. SR–OCC–2025–006]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Approval of Proposed Rule Change by The Options Clearing Corporation Concerning the Adoption of the Amended and Restated Participant Exchange Agreement Between OCC and Each of the National Securities Exchanges That List Equity Options

July 11, 2025.

I. Introduction

On May 13, 2025, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–OCC–2025–006, pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4[2] thereunder, to replace the current Restated Participant Exchange Agreement with a new agreement.[3] The proposed rule change was published for public comment in the **Federal Register** on May 29, 2025.[4] The Commission has received no written comments regarding the proposed rule change.[5] For the reasons discussed below, the Commission is approving the proposed rule change (hereinafter defined as ''Proposed Rule Change'').

II. Background

OCC is the sole clearing agency for standardized equity options listed on national securities exchanges registered with the Commission. OCC's relationship with the national securities exchanges that list options (each an ''Exchange,'' and collectively, the ''Exchanges'') is largely governed by an agreement, last updated in 2007, between OCC and the Exchanges. This agreement, the Restated Participant Exchange Agreement (''RPEA'') sets out the terms and conditions under which OCC will provide to the Exchanges clearing services for the options listed on the Exchanges.

OCC proposes to replace the current RPEA with a new RPEA. OCC represents that the differences between the current and new RPEA are designed to: (i) reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, which may address technology or industry changes or developments that necessitate new or updated agreement terms or incorporate adopted best practices for contract terms; (ii) align the agreement with current law and/or OCC's rules; (iii) eliminate provisions that are out of date or update provisions to reflect current industry terminology; (iv) acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement; and (v) improve overall readability of the document through the incorporation of intervening amendments and changes into the agreement.[6]

Such differences are described in more detail below.

A. Operational and Business Practices

As stated above, OCC represents that some of the differences between the current RPEA and the new RPEA are designed to reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges. These operational and business practice changes generally result from technology and industry developments that either necessitate new or updated agreement terms or incorporate into the new RPEA best practices for contract terms that have been implied or adopted in practice but are not reflected in the current RPEA.[7] The specific updates related to developments in operational and business practices are discussed in more detail below.

Section 5 of the new RPEA would set forth conditions the Exchanges will establish before seeking to delist an option. OCC states that this change would reduce the risk that Clearing Members could have open interest in options with no mechanism to close out those positions.[8]

OCC proposes to add a new Section 2(b)[9] that would allow OCC to refuse to clear options that materially impact OCC's risk profile or introduce novel or unique risks to OCC.[10] Proposed section 2(b) requires OCC to work with the Exchange to mitigate any such risk, if feasible, and to otherwise notify an Exchange of a disapproval of a new product. OCC states that this change would address industry changes in terms of risk assessment and management of new products.[11]

OCC proposes to add a new Section 6 to set forth the conditions for options that are listed on only one Exchange. Where OCC deems the price of an option listed on only one Exchange to be inaccurate, unreliable, unavailable, or inappropriate, the new RPEA would require the Exchanges to work with OCC to determine reliable settlement prices and to use commercially reasonable efforts to continue listing a singly listed option until all open interest is closed out at OCC.[12] OCC states that these changes would address a situation in which an underlying price may not be available or accurate.[13]

As a consequence of the substantial growth in the amount and speed of data flow between OCC and the Exchanges since the execution of the current

[27] 17 CFR 200.30–3(a)(34).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Notice of Filing *infra* note 4, at 90 FR 22807.

[4] *See* Securities Exchange Act Release No. 103106 (May 22, 2025), 90 FR 22807 (May 29, 2025) (File No. SR–OCC–2025–006) (''Notice of Filing'').

[5] On June 17, 2025, representatives of BOX Exchange, LLC met with staff in the Commission's Division of Trading and Markets to discuss the proposed rule changes. *See* Memorandum from the Division of Trading and Markets regarding a June 17, 2025 meeting with representatives of BOX Exchange, LLC; available at *https://www.sec.gov/comments/sr-occ-2025-006/srocc2025006-615728-1806735.pdf.*

[6] *See* Notice of Filing, 90 FR at 22808.

[7] *See* Notice of Filing, 90 FR at 22808.

[8] *See* Notice of Filing, 90 FR at 22810.

[9] Section 2 of the new RPEA corresponds to Section 3 of the current RPEA because OCC proposes deleting section 2 of the current RPEA as described below. OCC proposes to make other section number changes as needed. For clarity, references herein are to the proposed section numbers of the new RPEA unless otherwise stated.

[10] New section 2(b) replaces an out of date section related to the obligation to register options for trading.

[11] *See* Notice of Filing, 90 FR at 22809.

[12] If the Exchange could no longer list a singly listed option, it would be required to notify OCC and to permit listing and trading on an alternate Exchange.

[13] *See* Notice of Filing, 90 FR at 22810.

RPEA,[14] OCC proposes to add a new Section 7 governing OCC's use of data provided by the Exchanges.[15] New Section 7 would restrict OCC's use of Exchange Data such that OCC would not be permitted to use Exchange Data in any index calculation or other financial instrument, investment product, or investment strategy without consent.[16] Section 7 also would limit the entities to which OCC would be permitted to redistribute data based on the type of data being provided by the Exchange, and the Exchanges would be permitted to audit OCC's use of Exchange Data for non-compliance with any material provision of this Section 7. Separately, Section 7 would define Derived Data as data derived by OCC from non-real-time Exchange Data, which OCC would be authorized to create and use without restriction.

Section 8 of the RPEA governs trade comparisons. OCC proposes to add a new provision to Section 8 that would require OCC to notify the Exchanges at least 60 days prior to any change to the time by which an Exchange must report trade comparisons. OCC states that this change is designed to give the Exchanges sufficient notice to prepare for the change.[17]

Section 13 of the RPEA limits on OCC's authority. For the avoidance of doubt, and to reflect current practice,[18] OCC proposes to add a provision to Section 13 that would authorize OCC to calculate position limits at the request of the Exchanges even though OCC is generally precluded from establishing or enforcing position limits. OCC states that it began calculating position limits in 2003 at the request of the Exchanges and continues to provide position limits on the OCC website.[19] OCC also proposes adding a parenthetical noting that the general limit precluding OCC from determining when to open or restrict trading would not limit OCC's other rights and obligations under the RPEA.

Section 15 addresses financial requirements for Clearing Members. Currenctly, Exchanges are required both to notify OCC when a Clearing Member is not in compliance with OCC's financial responsibility standards[20] and notify OCC of any financial condition that would be reported any resolution authority.[21] In an effort to incorporate into the RPEA best practices for contract terms that have already been adopted and are in use by the industry, OCC proposes to remove the requirement to notify OCC when a Clearing Member is not in compliance with OCC's financial responsibility standards.[22] OCC also proposes to change the time requirement for submission of material from 2 p.m. Central Time to 3 p.m. Central Time, and to require such reporting ''promptly'' rather than ''immediately.''

Currently, Section 17, which addresses operations, requires OCC to use its best efforts to maintain sufficient operational capacity to clear new options on behalf of the Exchanges. OCC proposes to replace this language with a requirement to use commercially reasonable efforts, which OCC asserts would allow it to conduct its operations in a manner that is economically justified and in accordance with commonly accepted commercial practices.[23] Relatedly, OCC proposes to replace the current requirement to act ''as expeditiously as possible'' with a requirement to act ''as soon as reasonably practicable.'' Additionally, the new RPEA would require the Exchanges to comply with OCC's operational specification for new products and to provide 60 days notice in advance of operational changes such as trading hour changes. OCC asserts that such changes incorporate best practices for contract terms.[24]

OCC proposes to add a new Section 18 governing financial reporting from the Exchanges, including obligations relating to annual financials, quarterly financials, and losses. For example, an Exhange would be obligated to provide quarterly unaudited financials for three years after becoming a party to the new RPEA (if not a party to the current RPEA). An Exchange would also be required to provide quarterly financials following losses over certain thresholds. Under the proposed terms, OCC would be obligated to maintain the confidentiality of such financials to the extent they are not publicly available.[25] OCC states that the purpose of this new section is to allow OCC to monitor for going concern risk.[26]

OCC proposes to add Section 19 in the new RPEA, which addresses information technology and security. Section 19 requires Exchanges and OCC to provide each other with contact information for personnel relating to operational, technology and information security matters. OCC and the Exchanges would be required to provide notice if either party has an incident that could impact their ability to provide or receive services[27] and to take commercially reasonable efforts to comply with relevant cybersecurity regulations. The Exchanges would further agree to accommodate OCC's connectivity requirements. OCC proposes these changes to to strengthen information security given widespread use of ever evolving and improving electronic systems, along with related security concerns since the time the current RPEA became effective.[28]

OCC proposes changes to Section 24, which governs the services, programs and projects OCC provides to and for Exchanges. The changes would provide OCC sole and absolute discretion with regard to taking on projects for an Exchange. The proposed changes would also make it clear that (i) services OCC develops for any Clearing Member or group of Clearing Members and (ii) programs or projects developed at OCC's own cost will be offered to all Clearing Members on the same terms and cost.

OCC proposes to revise Section 29, which covers miscellaneous items, to state that the RPEA may not be assigned by the Exchange without written consent of OCC, and that the RPEA cannot be assigned by OCC without the consent of all Exchanges.[29] OCC also proposes to add a new provision related to the use of the parties' names,

[14] *See* Notice of Filing, 90 FR at 22810.

[15] The Exchanges would provide daily values of underlying interest and options. *See* Notice of Filing, 90 FR at 22811.

[16] The Exchanges would be required to use commercially reasonable efforts to provide OCC with at least 60 days' notice of material modifications, additions, or deletions to Exchange Data.

[17] *See* Notice of Filing, 90 FR at 22811. To reflect current industry terminology, OCC would also add language stating that the term Trading Day is any day the Exchange is trading. *See id.*

[18] *See* Notice of Filing, 90 FR at 22812.

[19] *See* Notice of Filing, 90 FR at 22812.

[20] Exchanges have indicated that they do not incorporate OCC's financial responsibility standards into their Exchange monitoring processes. *See* Notice of Filing, 90 FR at 22812.

[21] The current RPEA already ready requires notification of such reporting to the Securities Investor Protection Corporation. *See* Notice of Filing, 90 FR at 22812.

[22] *See* Notice of Filing, 90 FR at 22812. This is part of a general set of changes to to remove details related to interactions regarding lack of operational capacity to clear a new underlying.

[23] *See* Notice of Filing, 90 FR at 22812.

[24] *See* Notice of Filing, 90 FR at 22813.

[25] Relatedly, OCC proposes to add language to Section 25, which addresses access to books and records of OCC, to state that an Exchange will not have a right to view another Exchange's Confidential Information.

[26] *See* Notice of Filing, 90 FR at 22813.

[27] The proposed terms would permit OCC to take steps in response to the reporting of an incident, such as suspending its obligations to an Exchange under the RPEA. To suspend obligations to the Exchanges, OCC proposes to add a requirement that the OCC CEO, or the COO if the CEO is unavailable, must approve a suspension of obligations to the Exchange. If neither the OCC CEO and OCC COO are available, the Chief Security Officer has the authority to suspend services to the Exchange.

[28] *See* Notice of Filing, 90 FR at 22813.

[29] The RPEA would allow assignment without written consent in the event of a corporate reorganization or the sale of OCC.

tradenames, logos, and trademarks (collectively, ''Marks''). More specifically, OCC proposes to add language where each Exchange grants OCC license to use each party's respective name, tradename, logos, and trademarks in connection with OCC's activities such as issuance, clearance, settlement, and investor education services. OCC states that these changes are intended to reflect either current or implied business practices between OCC and the Exchanges and to incorporate adopted best practices for contract terms.[30]

Section 31 addresses the options disclosure document (''ODD''). OCC proposes to add a subparagraph addressing indemnification. Specifically, OCC proposes to incorporate language from Section 2(g) of the current RPEA, which is being deleted. The proposed text would indicate that OCC agrees to indemnify each Exchange from claims relating to any untrue statement or alleged untrue statement of a material fact contained in the ODD, and the Exchanges agree to indemnify OCC from damages relating to any untrue statement of a material fact contained in information from the ODD. The new text regarding indemnification would also detail the notice requirements related to indemnification (*e.g.,* notification of claim made against an indemnified party).

OCC also proposes to add a new Section 32 that addresses confidential information. OCC proposes to define ''Confidential Information'' to include information that relates to a disclosing party's products and services, operations, customers, members, prospects, know-how, design rights, trade secrets, market information, business affairs, and information provided to the receiving party. OCC would not be permitted to disclose Exchange Data that identifies an Exchange member except when the Exchange consents, when allowed by OCC By-Laws and Rules or required by law, regulation, or government rule, or as post-trade information given to clearing members. OCC states that these changes are intended to reflect current business practices between OCC and the Exchanges and to adopt best practices for contract terms.[31]

B. Current Law and OCC Rules

As stated above, OCC represents that some of the differences between the current RPEA and the new RPEA are designed to align the agreement with current law and/or OCC's rules.[32] General changes throughout the new RPEA include replacing references from ''the Corporation'' to ''OCC.'' In Section 1, OCC proposes to add a requirement for both OCC and the Exchanges that both parties will remain in compliance with the Exchange Act and its own Exchange rules and to require that each party will use reasonable efforts to come back into compliance in the event a party can no longer make the representation. The proposed language of Section 26, which addresses indemnification, would add ''or noteholder agreement'' where the current RPEA references the ''stockholders agreement'' because certain exchanges are subject to the shareholders agreement while other are subject to the noteholders agreement. OCC also proposes to add references to OCC Rules and references.

C. Out of Date Provisions

As stated above, OCC represents that some of the differences between the current RPEA and the new RPEA are designed to eliminate provisions that are out of date or update provisions to reflect current industry terminology.[33] For example, OCC proposes to replace the term ''Participating Exchange'' with ''Exchange'' throughout the agreement. In the introductory paragraph, the new RPEA would note that the current agreement supercedes the old agreement and would reflect the date of the new agreement. OCC proposes to change Section 1 so that national securities associations cannot become parties to the agreement.[34]

OCC proposes to delete Section 2 of the current RPEA, which relates to the registration of options, because the registration of standardized options is no longer required.[35] OCC also proposes changes to Section 2 of the new RPEA (section 3 of the current RPEA), which addresses selection of underlying interests. OCC proposes changes regarding the products it clears, incuding (i) defining the term ''Underlying Interests''; (ii) requiring that an underlying interest must be permitted on a national securities exchange; and (iii) changing the set of Underlying Interests explicitly listed in the RPEA.[36] OCC also proposes to remove a subsection of what would be Section 2 of the new RPEA that is now out of date as it relates to OCC's former obligation to register options for trading. OCC proposes to remove similar references to its former obligation to register options for trading from Section 31 of the new RPEA as well.

OCC proposes to amend Section 3, which addresses expiration dates, exercise prices, and units of trading, to remove time requirements for new series of options for trading. OCC states that such timeframes were necessary decades prior when adding new series and notifying other exchanges of newly added series was a more manual process but are now no longer needed.[37] OCC proposes further to assign the responsibility for determining units of trading to the Exchanges instead of the Securities Committee because the change reflects current business practices.[38]

OCC proposes to amend Section 4, which addresses the listing of option, by replacing a reference to ''expiration months'' with a reference to ''expiration dates'' because expirations have expanded outside of the standard monthly expiration cycle that was prevalent when the RPEA was first executed. OCC also propose to remove the phrase ''in reasonable quantities'' that currently is used in reference to making the list of options available to members because such lists are now provided electronically.

OCC proposes to amend Section 8, which addresses comparison of options transactions, to remove the ability of an Exchange to request a comparison service because OCC has not been retained by the Exchanges to perform such services. OCC also proposes to make ''Matched Trade(s)'' and ''Trading Day'' defined terms. OCC proposes to amend Section 10, which addresses acceptance of options transactions, to remove the payment of options premiums as a perquisite for clearing because OCC accepts all transactions for clearance until a member terminates its membership or is suspended by OCC.

OCC proposes to amend Section 15, which addresses financial requirements for Clearing Members, to add a reference

[30] *See* Notice of Filing, 90 FR at 22814.

[31] *See* Notice of Filing, 90 FR at 22815.

[32] *See* Notice of Filing, 90 FR at 22808.

[33] *See* Notice of Filing, 90 FR at 22808.

[34] OCC states that no parties to the Existing RPEA are national securities associations and the parties do not anticipate that any such entity will become a party to the agreement in the future. *See* Notice of Filing, 90 FR at 22809.

[35] *See* 17 CFR 230.238.

[36] For example, OCC proposes to remove U.S. Treasury bonds, notes, or bills because they do not underlie listed options that OCC clears and do not align with the interest types OCC is prepared to clear. *See* Notice of Filing, 90 FR at 22809. OCC proposes to add, among other things exchange trades funds and exchange traded notes because they did not exist at the time the current RPEA was first executed. *See id.*

[37] *See* Notice of Filing, 90 FR at 22810.

[38] This reflects a rule change OCC implemented in 2018 that transferred the authority to make contract adjustment determinations from panels of the Securities Committee to OCC. *See* Notice of Filing, 90 FR at 22810.

to ''Regulatory Services Agreement'' because some Exchanges outsource member surveillance. OCC also proposes to remove requirements for in-person delivery of documents and telephone calls. Finally, OCC proposes to replace reference to OCC's Chairman or any Vice President with reference to a ''Financial Risk Management officer'' to reflect OCCs' current designation of authority.

OCC proposes to amend Section 17, which addresses Clearing Member operations, to remove references to systems and response protocols that OCC and the Exchange no longer use. Instead, the new RPEA would require Exchanges to provide OCC with supporting materials to support the Exchange's clearing activities. Exchanges would also be required to make representatives available to OCC to discuss any of OCC's additional information needs, and to comply with OCC operational specifications such as extended trading hours.

OCC proposes to delete Section 16 of the current RPEA because it requires OCC to maintain offices in each city in which an Exchange is located. OCC states that, given the widespread use of electronic communications in financial services, the increase in the number and various locations of Exchanges over time, and the ability of Exchanges and OCC to send and receive information quickly via electronic means, the requirement for OCC to maintain an office in such locations is outdated.[39] Similarly, OCC proposes to amend Section 23, which addresses financial arrangements, to remove a requirement to establish local banking relationships because this is no longer necessary. OCC also proposes to amend Section 28, regarding Notices, to remove references to physical addresses of each party and instead add an option to provide notices by email because the addresses in the current RPEA are out of date and, even if updated, may change over time.

OCC proposes to amend Section 20, which addresses exercise restrictions, to replace references to ''index options'' with references to ''Options that are cash settled'' and to replace references to ''other options'' with references to ''Options that are physically settled'' to ensure consistency with current industry terminology, which generally is broader and more descriptive of the products subject to the provisions. OCC also proposes to add language that allows either an Exchange or OCC to restrict the exercise of Options if doing so would be necessary to comply with any government imposed restriction that would have the effect of restricting the exercise of an option.

OCC proposes to amend Section 31, which addresses options disclosure documents, to reassign the responsibility for chairing the Listed Options Disclosure Committee (''LDOC'') from OCC's Chairman of the Board to a an officer of OCC.[40] The changes would also modify the current provision specifying that the Exchange Directors of OCC's Board will participate on the LDOC to specify that representatives of each Exchange will participate on the LDOC. As new Exchanges have joined OCC over time, not all of them have a representative on the OCC Board. Thus, this change would align the RPEA with current practice and help future proof it in the event that additional Exchanges join OCC in the future. OCC also proposes to require Exchanges to notify OCC of proposed Exchange rule changes that would cause information in the ODD to become inaccurate and to require relevant Exchanges to provide input and feedback when OCC is drafting amendments to the ODD. OCC proposes to remove the requirement that OCC will pay costs associated with the meeting of the LODC. OCC states that this provision is out of date because the LODC does not meet in person.[41]

D. Industry Landscape

As stated above, OCC represents that some of the differences between the current RPEA and the new RPEA are designed to acknowledge and factor into the RPEA the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges.[42]

In Section 2, OCC proposes to add language stating that the underlying interest must be listed in accordance with Options Rules, listed on a national securities exchange, and permitted in the Options Disclosure Document. OCC proposes to add a requirement in Section 2 that Exchanges submit new Options to OCC pursuant to the requirements of the Options Listing Procedures Plan. OCC proposes these changes because because the OLPP serves as the national market plan that establishes the requirements Exchanges must follow when submitting a new option class to OCC.[43]

OCC proposes to amend Section 30, which addresses breach and termination, by adding a provision permitting OCC to suspend its obligations to an Exchange whenever a suspension is necessary to comply with OCC's own rules and outlining which provisions of the RPEA, if breached by an Exchange, would allow OCC to cease providing clearing services. OCC also proposes to add language allowing termination if providing services for the Exchange would cause OCC to be in breach federal securities law. The proposed amendments would also define who at OCC is authorized to approve a suspension and require OCC to notify each Exchange of any suspension. Finally, amended Section 30 would require OCC and the relevant Exchange to work together to minimize a suspension while simultaneously acknowledging that OCC would not be obligated to clear transactions for an Exchange that ceases to (i) be a registered exchange, (ii) abide by the Securities Act of 1933 or the Exchange Act, or (iii) be an OCC noteholder or stockholder.

E. Readability

As stated above, OCC represents that some of the differences between the current RPEA and the new RPEA are designed to improve overall readability of the document through the incorporation of intervening amendments and changes into the agreement.[44] OCC also proposes to replace ''premises'' with ''promises'' in the introduction, and to to remove the language ''The 1975 Agreement is hereby terminated, effective as of the date of this Agreement'' because the 1975 agreement was terminated by the 1983 agreement.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Exchange Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to such organization.[45] Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [46]

The description of a proposed rule change, its purpose and operation, its

[39] *See* Notice of Filing, 90 FR at 22812.

[40] The new RPEA does not specify which officer OCC would designate.

[41] *See* Notice of Filing, 90 FR at 22815.

[42] *See* Notice of Filing, 90 FR at 22808.

[43] *See* Notice of Filing, 90 FR at 22810.

[44] *See* Notice of Filing, 90 FR at 22808.

[45] 15 U.S.C. 78s(b)(2)(C).

[46] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[47] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[48] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify Commission approval of a proposed rule change.[49]

After carefully considering the Proposed Rule Change, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to OCC. More specifically, the Commission finds that the Proposed Rule Change is consistent with and with Section 17A(b)(3)(F) of the Exchange Act,[50] Exchange Act Rules 17ad–222(e)(1),[51] 17ad–222(e)(20),[52] and 17ad–222(e)(21),[53] as described in detail below.

A. Consistency With Section 17A(b)(3)(F) of the Exchange Act

Section 17A(b)(3)(F) of the Exchange Act requires, among other things, that the rules of a clearing agency be designed to foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions.[54] As discussed above, the RPEA sets out the terms and conditions under which OCC will provide clearing services to the Exchanges for the options listed on the Exchanges. Amending the RPEA to better reflect current practices, laws, regulations, and industry terminology as well as general readability, strengthens the RPEA. For example the proposed addition of a section based on singly listed options would require cooperation between OCC and the Exchanges to arrive at a reliable settlement process in the event that the price listed on an exchange is inaccurate. This subparagraph requires both OCC and the exchange to cooperate to determine the correct price. Further, in the selection of new underlying interests, if OCC identifies a risk to a new product, OCC is required to undertake commercially reasonable efforts to address the risk that caused OCC to refuse to issue such option, and the relevant Exchange would be required to reasonably cooperate with those efforts. Both of these provisions require OCC to cooperate with exchanges if there is an inaccurate price or risk posed from the new product. Further, the Proposed Rule Change establishes that an Exchange that makes changes to its Exchange Data will give OCC at least 60 days notice in advance of such change, in most cases. The notice period will provide OCC with the time to prepare for the change, and OCC will cooperate with an Exchange in addressing any such change. Such change, along with those described above, promote cooperation between OCC and the Exchanges because they facilitate, and at times require cooperation between, OCC and the Exchanges.

Accordingly, the Proposed Rule Change is consistent with the requirements of Section 17A(b)(3)(F) of the Exchange Act.[55]

B. Consistency With Rule 17ad–222(e)(1) Under the Exchange Act

Rule 17ad–222(e)(1) under the Exchange Act requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for a well-founded, transparent, and enforceable legal framework for each aspect of its activities in all relevant jurisdictions.[56]

As described above, OCC proposes various changes designed to align the terms of the RPEA with current law and OCC's rules,[57] acknowledge the current legal and regulatory landscape of the options industry,[58] and generally improve the readability of the RPEA.[59] For example, OCC proposes to add multiple representations from both OCC and the Exchanges that OCC and each Exchange is and will remain in compliance with the Exchange Act. In Section 2, OCC proposes to clarify that an Exchange must list options in accordance with the relevant Exchange's rule and submit new products to OCC in accordance with the Options Listing Procedure Plan. These changes are well-founded in that OCC and the exchanges are required to be in compliance with the Exchange Act and create procedures for listing new options and in all aspects of its operations.

As discussed above, in Section 30, OCC proposes to add language permitting OCC to suspend its obligations when necessary to comply with its own rules. OCC also proposes to modify the RPEA to explicitly acknowledge that OCC will not be obligated to clear transactions for an Exchange that cannot abide by the the Exchange Act. These changes help create reasonably designed policies and procedures that allow for a well-founded and enforceable legal framework by ensuring all parties are in compliance with relevant securities laws.

With regard to the ODD, the proposed changes would require that, absent certain exceptions, the Exchanges and OCC indemnify each other for untrue statements or omissions of material fact. Additionally, OCC proposes to update the manner in which the RPEA may be assigned by specifying that an Exchange must have the prior written consent of OCC for assignment and OCC must have prior written consent of all the Exchanges. These changes would help create a more transparent and enforceable legal framework by clarifying both the requirements for effective assignment of the RPEA and when parties are responsible for omissions of material fact by the other party. These changes clarify how the agreement can be assigned and ensure all parties to the RPEA understand the consequences of making or providing untrue statements or omissions of material fact in connection with the ODD.

Accordingly, the Proposed Rule Change is consistent with Rule 17ad–22(e)(1) under the Exchange Act.[60]

C. Consistency With Rule 17ad–22(e)(20) Under the Exchange Act

Rule 17ad–22(e)(20) under the Exchange Act requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to identify, monitor, and manage risks related to any link the covered clearing agency establishes with one or more other clearing agencies, financial market utilities, or trading markets.[61]

As described above, OCC proposes various changes to the RPEA designed to reflect current, enhanced, or implied business practices between OCC and the

[47] *Id.*

[48] *Id.*

[49] *Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 447 (D.C. Cir. 2017).

[50] 15 U.S.C. 78q–1(b)(3)(F).

[51] 17 CFR 240.17ad–222(e)(1).

[52] 17 CFR 240.17ad–222(e)(20).

[53] 17 CFR 240.17ad–222(e)(21).

[54] 15 U.S.C. 78q–1(b)(3)(F).

[55] 15 U.S.C. 78q–1(b)(3)(F).

[56] 17 CFR 240.17ad–222(e)(1).

[57] *See infra* section II.B.

[58] *See infra* section II.D.

[59] *See infra* section II.E.

[60] 17 CFR 240.17ad–22(e)(1).

[61] 17 CFR 240.17ad–22(e)(20).

Exchanges.[62] For example, OCC proposes to add language allowing it to disapprove new options that pose a risk to OCC. OCC also proposes new provisions governing the pricing and listing of options that are listed on only one Exchange, and to add the ability for OCC to calculate position limits at the request of the Exchanges. These changes help decrease the risk to OCC presented by options that are only listed on one exchange by reducing the risk that OCC would be unable to price such options or that members would be unable to trade options for which there is open interest at OCC. It would also help reduce the risk from position limits so that OCC can adjust accordingly if a position grows too large.

As discussed above, the proposed rule would establish financial requirements for Exchanges and allow OCC to monitor for going concern risk. If an Exchange becomes insolvent it could pose a risk to OCC and other financial institutions. Thus, Exchanges would be required to provide certain financial statements to OCC and notify OCC if they experience a certain percentage decrease in shareholder equity or losses exceeding a certain percentage of shareholder equity. At the same time, the proposed changes to the RPEA would create clear obligations for OCC to keep and maintain non-public information submitted to OCC by the Exchanges strictly confidential and would prevent OCC from sharing or disclosing such information outside of limited circumstances. Together, these updates to the RPEA would help OCC manage financial risk from trading markets should an exchange become insolvent, allow OCC to monitor its member Exchanges for signs of financial distress, and help ensure that the Exchnages' sensitive financial information is protected and kept confidential.

The proposed rule change would also require the parties' to take commercially reasonable steps to comply with relevant cybersecurity regulations. As part of this change, OCC would be authorized under the RPEA to take reasonable steps to mitigate any effects from a cybersecurity incident at an Exchange, for example by suspending its obligations for the impacted Exchange. Cyber related incidents have the potential to disrupt financial institutions, including both the Exchanges and OCC. These policy changes would help OCC identify and manage cybersecurity, connectivity, and other operational and technology risks posed to OCC through its connection to the Exchanges and the various trading markets they serve..

The proposed rule would also explain how Confidential Information is defined and provide how it can be shared. It would also outlines the repercussions in the event of a breach of the confidentiality provisions. Given the volume of information produced by both OCC and the Exchanges, it is important to set clear standards to reduce legal risk.

Accordingly, the Proposed Rule Change is consistent with Rule 17ad–22(e)(20) under the Exchange Act.[63]

D. Consistency With Rule 17ad–22(e)(21) Under the Exchange Act

Rule 17ad–22(e)(21) under the Exchange Act requires, in part, that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves, and have the covered clearing agency's management regularly review the efficiency and effectiveness of its (i) scope of products cleared or settled[64] and (ii) use of technology and communication procedures.[65]

As described above, OCC proposes various changes designed to reflect current, enhanced, or implied business practices between OCC and the Exchanges.[66] For example, the proposed rule change addresses how new options will be approved, permits OCC to refuse to issue such option if it identifies a risk in the new option, and requires OCC to undertake commercially reasonable efforts to address the risk that caused OCC to refuse the new option. The Exchange is also required to reasonably cooperate with OCC. The proposed changes also update the Underlying Interests provisions of the RPEA and, more broadly, help establish transparent and consistent procedures for OCC to clear new products and identify and address the specific risks such new products might pose. Such changes will enhance OCC's ability to meet the requirements of its participants and the needs of the market it serves.

As described above, OCC proposes various changes designed to eliminate RPEA provisions that are out of date.[67] For example, the Proposed Rule Change would remove references to specific times for opening new option series and reflect that it is currently the Exchanges, not the Securities Committee, that determine units of trading. Similarly, OCC proposes to remove the requirement that lists of options be provided ''in reasonable quantities'' because such lists are now provided electronically. OCC also proposes to remove references to in-person delivery of documents and telephone calls, requirements for local banking relationships, and the maintenance of offices in certain cities. These updates to remove outdated references to timeframes, quantities, and requirements improve the clarity and effectiveness of OCC's policies and procedures.

Accordingly, the Proposed Rule Change is consistent with Rule 17ad–22(e)(21) under the Exchange Act.[68]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act, and in particular, the requirements of Section 17A of the Exchange Act[69] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[70] that the Proposed Rule Change (SR–OCC–2025–006) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[71]

Sherry R. Haywood,

Assistant Secretary.

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[62] *See infra* section II.A.

[63] 17 CFR 240.17ad–22(e)(20).

[64] 17 CFR 240.17ad–22(e)(21)(ii).

[65] 17 CFR 240.17ad–22(e)(21)(iii).

[66] *See infra* section II.A.

[67] *See infra* section II.C.

[68] 17 CFR 240.17ad–22(e)(21).

[69] In approving the Proposed Rule Change, the Commission has considered the proposed rules' impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[70] 15 U.S.C. 78s(b)(2).

[71] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0733]

Proposed Collection; Comment Request; Extension: Rule 194

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''SEC'' or ''Commission'') is soliciting comments on the proposed collection of

information for Commission Rule of Practice 194, (17 CFR 240.194), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule of Practice 194 provides a process for security-based swap dealers and major security-based swap participants (collectively, ''SBS Entity'') to make an application to the Commission for an order permitting an associated person who is subject to a statutory disqualification to effect or be involved in effecting security-based swaps on behalf of the SBS Entity. Rule of Practice 194 specifies the process for obtaining relief from the statutory prohibition in Exchange Act Section 15F(b)(6), including by setting forth the required showing, the form of application and the items to be addressed with respect to associated persons that are natural persons. An SBS Entity is not required to file an application under Rule of Practice 194 with respect to certain associated persons that are subject to a statutory disqualification, as provided for in paragraph (h) of Rule of Practice 194. To meet those requirements, however, the SBS Entity is required to file a notice with the Commission.

55 SBS Entities in total are currently registered with the Commission.[1] The Commission anticipates that, on an average annual basis, only a small fraction of the natural persons at an SBS Entity would be subject to a statutory disqualification. Accordingly, based on our experience working with Rule of Practice 194, the Commission estimates that, on an average annual basis, the Commission would receive up to one application in accordance with Rule of Practice 194 with respect to associated persons that are natural persons, and up to three notices pursuant to proposed Rule of Practice 194(h) with respect to associated persons that are natural persons.[2] The Commission estimates that the average time necessary for an SBS Entity to research the questions, and complete and file an application under Rule of Practice 194 with respect to associated persons that are natural persons is approximately 30 hours, for a total of approximately 30 burden hours per year for all SBS Entities. The Commission estimates that up to three SBS Entities will provide notices pursuant to Rule of Practice 194(h) for one natural person each on an average annual basis taking approximately 6 hours per notice, for a total of approximately 18 burden hours per year for all SBS Entities providing the notices for an estimated three natural persons. As such, the combined estimated annual hour burden for all SBS Entities to complete applications and notices pursuant to Rule of Practice 194 is approximately 48 hours per year (30 + 18).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to *PaperworkReductionAct@sec.gov* by September 15, 2025. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: July 14, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–13312 Filed 7–15–25; 8:45 am]

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[1] *See* SEC, List of Security-Based Swap Dealers and Major Security-Based Swap Participants, *available at https://www.sec.gov/files/tm-sbsd-msbsp-pax-list-2412.pdf.*

[2] While we previously estimated that we might receive as many as five applications and five notices from SBS Entity respondents in a given year, our experience since making this estimate has led us to revise down this expectation. Since the first registration of an SBS Entity with the Commission on October 27, 2021, the Commission has only received three notices and one application under Rule of Practice 194. *See* SEC, Applications and Notices by Security-Based Swap Dealers or Major Security-Based Swap Participants for Statutorily Disqualified Associated Persons to Effect or Be Involved in Effecting Security-Based Swap Transactions (Rule of Practice 194) (''Rule 194 Approval Orders and Notices Database''), *available at https://www.sec.gov/rule-practice-194-applications-and-notices.* Based on this and related discussions with registered SBS Entities, we do not expect the number of applications and notices to exceed these figures on an annual basis.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103439; File No. SR–MEMX–2025–21]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule Concerning Equities Transaction Pricing

July 11, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on June 30, 2025, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members [3] (the ''Fee Schedule'') pursuant to Exchange Rules 15.1(a) and (c). As is further described below, the Exchange proposes to (i) increase the fee for executions of Retail Orders in securities priced at or above $1.00 per share that remove liquidity from the Exchange and (ii) modify the Liquidity Provision Tiers by reducing the rebate and modifying the required criteria under Liquidity Provision 2 and reducing the rebates under Liquidity Provision Tiers 3, 4, and 5. The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on July 1, 2025. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 1.5(p).

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Fee Schedule to: (i) increase the fee for executions of Retail Orders [4] in securities priced at or above $1.00 per share that remove liquidity from the Exchange (such orders, ''Removed Retail Volume''); and (ii) modify the Liquidity Provision Tiers by reducing the rebate and modifying the required criteria under Liquidity Provision 2 and reducing the rebates under Liquidity Provision Tiers 3, 4, and 5, each as further described below.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 18 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 12.7% of the total market share of executed volume of equities trading.[5] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents approximately 2.2% of the overall market share.[6] The Exchange in particular operates a ''Maker-Taker'' model whereby it provides rebates to Members that add liquidity to the Exchange and charges fees to Members that remove liquidity from the Exchange. The Fee Schedule sets forth the standard rebates and fees applied per share for orders that add and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or lower fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Increase Standard Fee for Removed Retail Volume

Currently, the Exchange charges a standard fee of $0.0028 per share for executions of Removed Retail Volume. The Exchange now proposes to increase the standard fee for executions of Removed Retail Volume to $0.0030 per share.[7] The purpose of increasing the standard fee for executions of Removed Retail Volume is for business and competitive reasons, as the Exchange believes that increasing such fee as proposed would generate additional revenue to offset some of the costs associated with the Exchange's current pricing structure, which provides various rebates for liquidity-adding orders, and the Exchange's operations generally, in a manner that is still consistent with the Exchange's overall pricing philosophy of encouraging added liquidity. The Exchange notes that despite the increase proposed herein, the proposed standard fee for executions of Removed Retail Volume remains in line with the standard fees charged by other exchanges for executions of Retail Orders in securities priced at or above $1.00 per share that remove liquidity.[8]

Liquidity Provision Tiers

The Exchange currently provides a base rebate of $0.0015 per share for executions of displayed orders in securities priced at or above $1.00 per share that add liquidity to the Exchange (such orders, ''Added Displayed Volume'').[9] The Exchange also currently offers Liquidity Provision Tiers 1–5 under which a Member may receive an enhanced rebate for executions of Added Displayed Volume by achieving the corresponding required volume criteria for each such tier. The Exchange now proposes to reduce the rebate and modify the required criteria under Liquidity Provision Tier 2 and reduce the rebates under Liquidity Provision Tiers 3, 4, and 5, as further described below.

First, with respect to Liquidity Provision Tier 2, the Exchange currently provides an enhanced rebate of $0.0032 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving: (1) an ADAV [10] that is equal to or greater than 0.20% of the TCV [11] and an ADV [12] that is equal or greater than 0.50% of the TCV; or (2) an ADAV that is equal to or greater than 0.30% of the TCV. The Exchange now proposes to reduce the rebate for executions of Added Displayed Volume under Liquidity Provision Tier 2 to $0.0031 per share,[13] and to modify the required criteria such that a Member would now qualify for such tier by achieving: (1) an ADAV that is equal to or greater than 0.20% of the TCV and an ADV that is equal to or greater than 0.50% of the TCV; or (2) an ADAV that is equal to or greater than 0.20% of the TCV in securities priced at or above $1.00 per share and a Non-Displayed ADAV that is equal to or greater than 6,000,000 shares. Thus, such proposed change would keep the existing first alternative criteria intact and modify the second alternative criteria to include a reduced ADAV threshold in securities priced at or

[4] A ''Retail Order'' means an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization (''RMO''), provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. *See* Exchange Rule 11.21(a).

[5] Market share percentage calculated as of June 26, 2025. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[6] *Id.*

[7] The proposed standard fee for executions of Removed Retail Volume is referred to by the Exchange on the Fee Schedule under the existing description ''Removed volume from MEMX Book, Retail Order'' with a Fee Code of ''RrA'' on execution reports.

[8] *See, e.g.,* the Cboe EDGX equities fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/*), which reflects a standard fee of $0.0030 per share for executions of Retail orders in securities priced at or above $1.00 per share that remove liquidity; the Cboe BZX equities fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*) which reflects a standard fee of $0.0030 per share for executions of Retail orders in securities priced at or above $1.00 per share that remove liquidity.

[9] The base rebate for executions of Added Displayed Volume is referred to by the Exchange on the Fee Schedule under the existing description ''Added non-displayed volume'' with a Fee Code of ''B'', ''D'' or ''J'', as applicable, on execution reports.

[10] As set forth on the Fee Schedule, ''ADAV'' means the average daily added volume calculated as the number of shares added per day, which is calculated on a monthly basis, and ''Displayed ADAV'' means ADAV with respect to displayed orders.

[11] As set forth on the Fee Schedule, ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[12] As set forth on the Fee Schedule, ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADV is calculated on a monthly basis.

[13] The proposed pricing for Liquidity Provision Tier 2 is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume, Liquidity Provision Tier 2'' with a Fee Code of ''B2'', ''D2'' or ''J2'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

above $1.00 per share and a Non-Displayed ADAV threshold. The Exchange is not proposing to change the rebate for executions of orders in securities priced below $1.00 per share under Liquidity Provision Tier 2.

Second, with respect to Liquidity Provision Tier 3,[14] the Exchange currently provides an enhanced rebate of $0.0030 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving: 1) an ADAV that is equal to or greater than 0.20% of the TCV in securities priced at or above $1.00 per share; or 2) an ADAV that is equal to or greater than 0.175% of the TCV. The Exchange now proposes to reduce the rebate for executions of Added Displayed Volume under Liquidity Provision Tier 3 to $0.0029 per share. The Exchange is not proposing to change the criteria required to qualify for Liquidity Provision Tier 3. The Exchange is also not proposing to change the rebate for executions of orders in securities priced below $1.00 per share under such tier.

Third, with respect to Liquidity Provision Tier 4,[15] the Exchange currently provides an enhanced rebate of $0.0029 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving an ADAV (excluding Retail Orders) that is equal to or greater than 0.09% of the TCV. The Exchange now proposes to reduce the rebate for executions of Added Displayed Volume under Liquidity Provision Tier 4 to $0.0028 per share. The Exchange is not proposing to change the criteria required to qualify for Liquidity Provision Tier 4. The Exchange is also not proposing to change the rebate for executions of orders in securities priced below $1.00 per share under such tier.

Lastly, with respect to Liquidity Provision Tier 5,[16] the Exchange currently provides an enhanced rebate of $0.0025 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving an ADAV that is equal to or greater than 0.06% of the TCV. The Exchange now proposes to reduce the rebate for executions of Added Displayed Volume under Liquidity Provision Tier 5 to $0.0024 per share. The Exchange is not proposing to change the criteria required to qualify for Liquidity Provision Tier 5. The Exchange is also not proposing to change the rebate for executions of orders in securities priced below $1.00 per share under such tier.

The purpose of reducing the rebates for executions of Added Displayed Volume under Liquidity Provision Tiers 2, 3, 4, and 5 as proposed (*i.e.,* by $0.0001 per share), which the Exchange believes is a modest reduction and remains commensurate with the required criteria, is for business and competitive reasons, as the Exchange believes that such reduction would decrease the Exchange's expenditures with respect to its transaction pricing in a manner that is still consistent with the Exchange's overall pricing philosophy of encouraging added liquidity.

The tiered pricing structure for executions of Added Displayed Volume under the Liquidity Provision Tiers provides an incremental incentive for Members to strive for higher volume thresholds to receive higher enhanced rebates for such executions and, as such, is intended to encourage Members to maintain or increase their order flow, primarily in the form of liquidity-adding volume, to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all Members and market participants. The Exchange believes that the Liquidity Provision Tiers, as modified by the proposed changes described above, reflect a reasonable and competitive pricing structure that is right-sized and consistent with the Exchange's overall pricing philosophy of encouraging added and/or displayed liquidity. Specifically, the Exchange believes that, after giving effect to the proposed changes described above, the rebate for executions of Added Displayed Volume provided under each of the Liquidity Provision Tiers 1–5 remains commensurate with the corresponding required criteria under each such tier and is reasonably related to the market quality benefits that each such tier is designed to achieve.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[17] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[18] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [19]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct additional order flow, including displayed liquidity-adding and/or liquidity removing orders to the Exchange, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants.

The Exchange believes that the proposed change to increase the standard fee charged for executions Removed Retail Volume is reasonable because it represents only a modest increase from the current standard fee charged for executions of Removed

[14] The pricing for Liquidity Provision Tier 3 is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume, Liquidity Provision Tier 3'' with a Fee Code of ''B3'', ''D3'' or ''J3'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[15] The pricing for Liquidity Provision Tier 4 is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume, Liquidity Provision Tier 4'' with a Fee Code of ''B4'', ''D4'' or ''J4'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[16] The pricing for Liquidity Provision Tier 5 is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume, Liquidity Provision Tier 5'' with a Fee Code of ''B5'', ''D5'' or ''J5'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[17] 15 U.S.C. 78f.

[18] 15 U.S.C. 78f(b)(4) and (5).

[19] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

Retail Volume and, as noted above, remains in line with the standard fees charged by other executions of Retail orders in securities priced at or above $1.00 per share that remove liquidity.[20] The Exchange also believes the proposed standard fee charged for executions of Removed Retail Volume is equitable and not unfairly discriminatory, as such fee will apply equally to all Members submitting Retail Orders to the Exchange.

The Exchange notes that volume and quoting-based incentives (such as tiers) have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and not unfairly discriminatory because they are open to all members on an equal basis and provide additional benefits that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and the introduction of higher volumes of orders into the price and volume discovery process. The Exchange believes that the Liquidity Provision Tiers 2, 3, 4, and 5, as modified by the proposed changes to the rebates and criteria, as applicable, are reasonable, equitable and not unfairly discriminatory for these same reasons, as such tiers would continue to provide Members with an incremental incentive to achieve certain volume thresholds on the Exchange, are available to all Members on an equal basis, and, as described above, are designed to encourage Members to maintain or increase their order flow, including in the form of displayed, liquidity-adding orders to the Exchange in order to qualify for an enhanced rebate for executions of Added Displayed Volume, thereby contributing to a deeper, more liquid and well balanced market ecosystem on the Exchange to the benefit of all Members and market participants. The Exchange also believes that the proposed changes to such tiers reflect a reasonable and equitable allocation of fees and rebates, because, as noted above, the Exchange believes in each case that the proposed new rebate represents a modest reduction, as applicable, remains commensurate with the corresponding required criteria under such tier, and is reasonably related to the market quality benefits that the tier is designed to achieve, as described above.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act[21] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed additive rebate described herein is appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to incentivize market participants to direct additional order flow to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members and market participants. As a result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [22]

Intramarket Competition

As discussed above, the Exchange believes that the proposal would incentivize Members to submit additional order flow, including displayed, liquidity-adding and/or removing orders to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members, as well as enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The opportunity to qualify for the proposed modified Liquidity Provision Tiers 2, 3, 4, and 5, and thus receive the proposed enhanced rebate for executions of Added Displayed Volume under such tiers, would be available to all Members that meet the associated volume requirements in any month. Additionally, as noted above, the proposed increased standard fee for executions of Removed Retail Volume would continue to apply equally to all Members in the same manner that such standard fees currently do today. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

As noted above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. Members have numerous alternative venues that they may participate on and direct their order flow to, including 17 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 12.7% of the total market share of executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, including with respect to Added Displayed Volume and Removed Retail Volume, and market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed changes represent a competitive proposal through which the Exchange is seeking to generate additional revenue with respect to its transaction pricing and to encourage the submission of additional order flow to the Exchange through volume-based tiers, which have been widely adopted by exchanges, including the Exchange.

[20] *See supra* note 8.

[21] 15 U.S.C. 78f(b)(4) and (5).

[22] *See supra* note 19.

Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar pricing incentives to market participants.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *SEC,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .''.[24] Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [25] and Rule 19b–4(f)(2) [26] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MEMX–2025–21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MEMX–2025–21. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MEMX–2025–21 and should be submitted on or before August 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–13260 Filed 7–15–25; 8:45 am]

BILLING CODE 8011–01–P

[23] *Id.*

[24] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

[25] 15 U.S.C. 78s(b)(3)(A)(ii).

[26] 17 CFR 240.19b–4(f)(2).

[27] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21176 and #21177; TEXAS Disaster Number TX–20058]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Texas (FEMA–4879–DR), dated July 6, 2025.

Incident: Severe Storms, Straight-line Winds, and Flooding.

DATES: Issued on July 10, 2025.

Incident Period: July 2, 2025 and continuing.

Physical Loan Application Deadline Date: September 4, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 6, 2026.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Texas, dated July 6, 2025, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Kendall, Kimble, Menard, San Saba.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–13256 Filed 7–15–25; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21159 and #21160; TENNESSEE Disaster Number TN–20025]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Tennessee

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Tennessee (FEMA–4878–DR), dated June 19, 2025.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

DATES: Issued on July 10, 2025.

Incident Period: April 2, 2025 through April 24, 2025.

Physical Loan Application Deadline Date: August 19, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: March 19, 2026.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Tennessee, dated June 19, 2025, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Carroll, Houston, Wayne.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–13255 Filed 7–15–25; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21176 and #21177; TEXAS Disaster Number TX–20058]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of TEXAS

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of TEXAS (FEMA–4879–DR), dated July 6, 2025.

Incident: Severe Storms, Straight-line Winds, and Flooding.

DATES: Issued on July 13, 2025.

Incident Period: July 2, 2025 and continuing.

Physical Loan Application Deadline Date: September 4, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 6, 2026.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of TEXAS, dated July 6, 2025, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Burnet, Llano, Mason, McCulloch, Tom Green.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–13332 Filed 7–15–25; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21174 and #21175; TEXAS Disaster Number TX–20057]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4879–DR), dated July 6, 2025.

Incident: Severe Storms, Straight-line Winds, and Flooding.

DATES: Issued on July 10, 2025.

Incident Period: July 2, 2025 and continuing.

Physical Loan Application Deadline Date: September 4, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 6, 2026.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated July 6, 2025, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Burnet, San Saba, Tom Green, Travis, Williamson.

Contiguous Counties (Economic Injury Loans Only):

Texas: Bastrop, Bell, Blanco, Brown, Caldwell, Coke, Concho, Hays, Irion, Lampasas, Lee, Llano, Mason, McCulloch, Menard, Milam, Mills, Reagan, Runnels, Schleicher, Sterling.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–13257 Filed 7–15–25; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12774]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: ''Picturing Paris: Monet and the Modern City'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary display in the exhibition ''Picturing Paris: Monet and the Modern City'' at the Allen Memorial Art Museum, Oberlin College, Oberlin, Ohio, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street, NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 574 of March 4, 2025.

Mary C. Miner,

Managing Director for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2025–13347 Filed 7–15–25; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12773]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Abstract Expressionists: The Women'' and ''Krasner and Pollock: Past Continuous'' Exhibitions

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owner or custodian for temporary display in the exhibition ''Abstract Expressionists: The Women'' at the Wichita Art Museum, Wichita, Kansas; the Muscarelle Museum of Art, College of William & Mary, Williamsburg, Virginia; the Speed Art Museum, Louisville, Kentucky; the Grinnell College Museum of Art, Grinnell, Iowa; and the Mobile Museum of Art, Mobile, Alabama; in the exhibition ''Krasner and Pollock: Past Continuous'' at The Metropolitan Museum of Art, New York, New York; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 574 of March 4, 2025.

Mary C. Miner,

Managing Director for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2025–13346 Filed 7–15–25; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2025–0037]

Notice of Intent To Prepare an Environmental Impact Statement in Virginia

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice; correction.

SUMMARY: This Notices corrects the date by which comments must be submitted for the Notice of Intent (NOI) for the Powhite Parkway Project in western Chesterfield County, Virginia.

DATES: Comments on this NOI and the Additional Project Information Document must be received by the FHWA at the addressed below by August 15, 2025.

ADDRESSES: This NOI and Additional Project Information Document is available in the docket referenced above at *http://www.regulations.gov* and on the Project website located at *https://www.vdot.virginia.gov/projects/richmond-district/chesterfield-powhite-parkway-study/.* The NOI and Additional Information Document also will be mailed upon request. Interested parties are invited to submit comments by any of the following methods:

Website: For access to the documents, go to the Federal eRulemaking Portal located at *http://www.regulations.gov* or the Project website located at *https://www.vdot.virginia.gov/projects/richmond-district/chesterfield---powhite-parkway-study/.* The NOI and Additional Project Information Document also will be mailed upon request. Follow the online instructions for submitting comments.

Fax: 804–775–3356.

Mailing address of hand delivery or courier: Federal Highway Administration, 400 North 8th Street, Suite 750, Richmond, Virginia, 23219.

Email address: Amanda.Heath@dot.gov.

All submissions should include the agency name and the docket number that appears in the heading of this Notice. All comments received will be posted without change to *http://www.regulations.gov* or the Project website, *https://www.vdot.virginia.gov/projects/richmond-district/chesterfield---powhite-parkway-study/,* including any personal information provided. A summary of the comments received will be included in the Draft EIS, and all comments received will be included in an appendix to the Draft EIS.

FOR FURTHER INFORMATION CONTACT: FHWA: Amanda Heath, Environmental Protection Specialist, Federal Highway Administration—Virginia Division, 400 North 8th Street, Suite 650, Richmond, VA 23219–4825; email: *Amanda.Heath@dot.gov;* 804–775–3342. VDOT: Heather Staton, NEPA Project Manager/Environmental Division, Virginia Department of Transportation, 1401 East Broad Street, Richmond, VA, 23219; email: *heather.staton@vdot.virginia.gov;* 804–980–5659. Persons interested in receiving Project information can contact *PowhiteParkwayStudy@VDOT.virginia.gov* to be added to the Project mailing list.

SUPPLEMENTARY INFORMATION: On July 11, 2025, at 90 FR 31099, FHWA, in coordination with the Virginia Department of Transportation, published an NOI to solicit comment and advise the public, agencies, and stakeholders that an Environmental Impact Statement will be prepared to evaluate the potential environmental impacts of the proposed transportation improvements for the Powhite Parkway Project in western Chesterfield County, Virginia. That Notice incorrectly stated the comment period end date for this effort. This Notice corrects that error and establishes a comment period end date 30 days from the date of publication of this Notice. Late-filed comments will be considered to the extent practicable.

(Authority: 23 U.S.C. 139; 49 CFR 1.85.)

Daniel Omar Suarez,

Acting Division Administrator, Federal Highway Administration.

[FR Doc. 2025–13348 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0293]

Commercial Driver's License: Application for Exemption; American Public Transportation Association

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; grant in part, and deny in part, application for exemption.

SUMMARY: FMCSA announces its decision to grant, in part, and deny in part, the application from the American Public Transportation Association (APTA), on behalf of public transit agencies and their contractor partners. FMCSA grants the application request to allow State Driver Licensing Agencies (SDLAs) the option to waive the ''under-the-hood'' portion of the pre-trip vehicle inspection skills test requirement for commercial driver's license (CDL) applicants seeking to operate commercial motor vehicles (CMVs) in public transportation. Drivers issued CDLs pursuant to the requested exemption are restricted to intrastate operation of transit buses only. FMCSA denies APTA's application request to allow drivers issued a CDL under this exemption to operate in interstate commerce.

DATES: The exemption is effective July 16, 2025 and expires July 16, 2027.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; 202–366–2722; *richard.clemente@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2024-0293/document* and choose the document to review. To view comments, click this notice, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Privacy

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed under the ''Department Wide System of Records Notices'' at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edit and are searchable by the name of the submitter.

III. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

IV. Background

Current Regulatory Requirements

Under 49 CFR 383.113(a), CDL applicants must possess basic pre-trip vehicle inspection skills for the vehicle class that they operate or expect to operate. Applicants must be able to identify each safety-related part on the test vehicle and explain what needs to be examined during a pre-trip vehicle inspection to ensure the safe operation of the CMV, including the engine compartment.

As prescribed in 49 CFR 383.153(a)(10)(ix), a State may impose restrictions on a CDL or create its own restrictions using additional codes for additional restrictions, as long as each such restriction code is fully explained on the front or back of the CDL document.

Applicant's Request

APTA's application for exemption was described in detail in a **Federal Register** notice published on December 26, 2024, (89 FR 105175) and will not be repeated as the facts have not changed.

V. Public Comments

In response to APTA's application, the Agency received 29 comments;[1] the majority of the comments were from transit-related agencies and associations, such as the Regional Transportation Commission of Southern Nevada, the New York State Metropolitan Transportation Authority, and the Central Ohio Transit Authority. Of the 29 comments, 25 were in support of granting the exemption, three were in opposition, and one comment offered no position either for or against but instead provided general comments.

The three opposing comments were from two individuals and a transit provider. Bryan Martin commented, ''This would call for a separate transit/coach CDL or a restriction to a regular Class B CDL. Currently a bus driver can also drive ANY class B vehicle that they are endorsed for (air brake, tank, HazMat) as well as their bus/coach, but if you take away the small segment of the test for under the hood that would DQ [disqualify] them from traditional commercial trucks.'' Ozark Regional Transit also opposed granting the exemption and posed the following question: ''If you make this change to the CDL, what measures will be in place to prevent a CDL driver to go to another state and start driving a dump truck without knowing the components of

[1] The docket on Regulation.gov lists 30 comments, but one is a duplicate.

under the hood[?]'' Bobby Tyner commented, ''This could be the most unsafe thing that you could do.''

The 25 commenters in support of granting the exemption were primarily transit agencies and associations. Some of the common reasons cited for granting the exemption included: a comparison to the school bus industry's relief from the ''under-the-hood'' skills test; that the ''under-the-hood'' test is unrelated to the driver's job responsibilities; and that the ''under-the-hood'' skills test creates an unnecessary barrier to entry for potential bus operators that further exacerbates the driver shortage. The Community Transportation Association of America commented, ''FMCSA has already exempted the school bus industry from the 'under the hood' CDL testing requirements for many of the same reasons the public transit industry now seeks relief and we urge a similar exemption for all public transit operators.'' The Suburban Mobility Authority for Regional Transportation commented that under current CDL testing requirements, ''public transit workers are compelled to study topics that are not pertinent to their day-to-day responsibilities.'' Latinos in Transit commented, ''we see firsthand how the under-the-hood testing requirement creates unnecessary barriers to entry for potential bus operators, further exacerbating this shortage.''

The Pennsylvania Department of Transportation (PennDOT) was neither for nor against granting the exemption and questioned if APTA wanted an exemption from the original or modernized under-the-hood skills test. PennDOT stated, ''CDL Modernized test exempts applicants from mentioning four fluids (oil, transmission fluid, power steering fluid, and coolant (hydraulic fluid, if applicable)) during their test.'' PennDOT also recommended that FMCSA adopt a single under-the-hood waiver to prevent confusion between CDL restrictions for school and transit bus operators. PennDOT agreed with the applicant's claim that the under-the-hood portion of the test is unnecessary, stating ''Like school bus operators, public transit bus operators have maintenance teams for vehicle servicing, making the under-the-hood portion of the test irrelevant to their job duties. As such, expanding the waiver to eliminate all under-the-hood testing requirements would be practical. This would maintain consistency and allow for interstate driving rather than limiting to intrastate driving only.''

Other commenters, including the American Bus Association and PennDOT, stated that they favored a two-year exemption term and not a five-year exemption as requested by APTA.

VI. FMCSA Decision

FMCSA evaluated APTA's application and public comments and grants the exemption request for a period of two years to permit SDLAs to waive the ''under-the-hood'' portion of the pre-trip vehicle inspection skills test requirement for CDL applicants seeking to operate transit buses in intrastate commerce. FMCSA denies APTA's request to extend the exemption to interstate commerce.

APTA argues that transit agencies are experiencing similar hiring and driver retention challenges as the school bus industry, and the transit industry should receive the same relief granted to the school bus industry, without the intrastate restriction.[2] FMCSA agrees that APTA's request is similar in many respects to the National School Transportation Association's (NSTA) request, and that similar relief is warranted. Like school buses, transit buses travel for relatively short distances and are operated in higher population density areas where mechanics or other qualified personnel are readily available to provide roadside assistance in the event of a vehicle malfunction. Unlike with other CMVs that are often operated for long distances and in remote areas, the risk of a malfunction to a transit bus in a location where only the driver is readily available to perform repairs is low.

Under the exemption, CDL applicants must continue to pass all remaining elements of the pre-trip vehicle inspection components of the skills test, as set forth in 49 CFR 383.113(a)(1)(ii–ix). This exemption is optional for SDLAs, and it may be adopted regardless of which version of the skills test the SDLA administers. All other State or local bus inspection maintenance standards and CDL requirements continue to apply.

FMCSA does not believe that extending the relief beyond the relief granted to the school bus industry, to allow States to issue unrestricted CDLs under the exemption (*i.e.* authorizing interstate operation), would likely achieve an equivalent level of safety. The same reasoning for why FMCSA allowed only intrastate CDLs for school bus drivers under the NSTA exemption applies here as well. The intrastate K restriction required for CDLs issued under the NSTA exemption mitigates concerns about varying State requirements and maintains State authority over driver qualifications for school bus drivers. Allowing interstate operation for drivers issued CDLs under the NSTA exemption would require States that did not adopt the exemption to allow school bus drivers who did not pass the full CDL skills test to operate in their States. In addition, in response to NSTA's request to renew its exemption, the American Association of Motor Vehicle Administrators noted that if a driver received a CDL in a State that adopted the exemption and moved to another jurisdiction that did not adopt the exemption, the new jurisdiction of record would have no way to know that the applicant did not pass the full CDL skills test. FMCSA responded in its decision granting the exemption renewal that requiring States to include ''school bus only'' and K restrictions on CDLs issued under the exemption addressed concerns about drivers moving to a jurisdiction that did not adopt exemption (89 FR 95348, 95351). The reasoning of the NSTA exemption applies here, and FMCSA sees no grounds for granting APTA's request without a similar restriction allowing intrastate operations only.

Further, FMCSA believes that the required restrictions—transit bus only and intrastate only—on CDLs issued under this exemption address the points raised by the commenters who expressed concern about safety and confusion over States' differing rules.

A. Applicability of Exemption

This exemption covers States for the period of two years. Under this exemption, a State may, but is not required to, waive the engine compartment portion of the pre-trip vehicle inspection skills test, set forth in 49 CFR 383.113(a)(1)(i), for CDL applicants seeking the P endorsement and issue them CDLs subject to the K restriction limiting their operation to intrastate commerce and subject to a transit bus only restriction. States issuing CDLs pursuant to this exemption are not subject to the requirement in 49 CFR 383.133(c)(1) that this portion of the pre-trip vehicle inspection test be administered in accordance with an FMCSA pre-approved examiner information manual.

FMCSA intends to closely monitor the safety impacts of the relief granted under this exemption. As necessary, FMCSA may take action to modify the exemption, including scaling back the

[2] On October 27, 2022, FMCSA granted an exemption that allowed States to waive the engine compartment portion of the pre-trip vehicle inspection skills test, set forth in 49 CFR 383.113(a)(1)(i), for CDL applicants seeking the school bus and passenger endorsements, subject to school bus only and K restrictions on their CDLs limiting their operation to intrastate commerce (87 FR 65114). This exemption was renewed on December 2, 2024 (89 FR 95348).

regulatory relief provided, or to terminate the exemption sooner, if conditions warrant.

B. Terms and Conditions

States issuing CDLs pursuant to this exemption must abide by the following terms and conditions:

1. The State Driver Licensing Agency must submit the names and CDL numbers of drivers who are issued a CDL pursuant to the terms of this exemption, as authorized by 49 CFR 383.73(h) and 384.225(e)(2), monthly to *MCPSD@dot.gov.*

2. The CDL credential must conform to the requirements of 49 CFR part 383, subpart J.

3. When issuing a K-restricted CDL with the P endorsement pursuant to this exemption, States must continue to comply with the applicable provisions set forth in 49 CFR 383.73.

4. When issuing a K-restricted CDL with the P endorsement pursuant to this exemption, States must place a transit bus only restriction on the CDL in accordance with 49 CFR 383.153(a)(10)(ix).

5. States must conduct the remaining pre-trip vehicle inspection components of the skills test for drivers subject to this exemption, as set forth in 49 CFR 383.113(a)(1)(ii–ix).

6. This exemption applies only to the intrastate operation by an operator of a public transportation system of public transit buses within the State that issues the CDL. Public transit buses are defined as buses used in ''public transportation,'' as that term is defined in 49 U.S.C. 5302(15). An operator of a public transportation system is defined as any State, local governmental authority, and any other operator of a public transportation system, and its contractor partners, that is subject to the Federal Transit Administration's safety oversight under 49 CFR part 673.

7. States must continue to comply with 49 CFR 383.133(c)(5), including that interpreters are prohibited and neither the applicant nor the examiner may communicate in a language other than English during the skills test.[3]

C. Termination

FMCSA does not believe that drivers issued CDLs under the exemption will experience any deterioration of safety below the level that would be achieved without the exemption. The exemption will be rescinded if: (1) States fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Sue Lawless,

Assistant Administrator.

[FR Doc. 2025–13283 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–EX–P

[3] FMCSA's regulatory guidance provides that a hearing-impaired driver satisfies the English language requirement if the driver is capable of reading and writing in the English language (79 FR 59139).

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0048]

Southern California Regional Rail Authority's Request to Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on July 7, 2025, Southern California Regional Rail Authority (SCAX) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP) and positive train control (PTC) system, seeking FRA's approval to, as a result of updates made to its onboard PTC software, modify its PTC braking algorithm. As this RFA involves a request for FRA's approval of proposed material modifications to an FRA-certified PTC system, FRA is publishing this notice and inviting public comment on SCAX's RFA to its PTCSP.

DATES: FRA will consider comments received by August 5, 2025. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0048. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets.* All comments received will be posted without change to *https://www.regulations.gov*; this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) Section 20157(h) requires FRA to certify that a host railroad's PTC system complies with Title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal or train control system. Accordingly, this notice informs the public that, on July 7, 2025, SCAX submitted an RFA to its PTCSP for its Interoperable Electronic Train Management System, which seeks FRA's approval to modify its PTC braking algorithm. That RFA is available in Docket No. FRA–2010–0048.

Interested parties are invited to comment on SCAX's RFA to its PTCSP by submitting written comments or data. During FRA's review of SCAX's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP, at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov*, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of

regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, D.C.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2025–13330 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0039]

South Florida Regional Transportation Authority's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on July 8, 2025, the South Florida Regional Transportation Authority (SFRV) submitted a request for amendment (RFA) to its FRA-certified Positive Train Control Safety Plan (PTCSP) and positive train control (PTC) system, seeking FRA's approval to temporarily disable its PTC system between Milepost (MP) SX1015.82 and MP SX1022.29 for a planned signal cutover that will last approximately two days and six hours, between September 19, 2025, and September 22, 2025. As this RFA may involve a request for FRA's approval of proposed material modifications to an FRA-certified PTC system, FRA is publishing this notice, and inviting public comment on SFRV's RFA to its PTC system.

DATES: FRA will consider comments received by August 5, 2025. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0039. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) Section 20157(h) requires FRA to certify that a host railroad's PTC system complies with Title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system, or the associated FRA-approved PTC Safety Plan (PTCSP), a host railroad must submit, and obtain FRA's approval of, an RFA to its PTC system or PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal or train control system. Accordingly, this notice informs the public that, on July 8, 2025, SFRV submitted an RFA to its PTCSP for its Interoperable Electronic Train Management System, which seeks FRA's approval to temporarily disable its PTC system for approximately two days and six hours to upgrade end of life wayside signal operating equipment between MP SX1015.82 and MP SX1022.29. That RFA is available in Docket No. FRA–2010–0039.

Interested parties are invited to comment on SFRV's RFA by submitting written comments or data. During FRA's review of SFRV's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, D.C.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2025–13336 Filed 7–15–25; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. OFAC is also publishing updates to the identifying information of 28 persons that are currently included on the SDN List. Finally, OFAC is publishing removal of 518 persons, including blocked property, from the SDN List.

DATES: This action was issued on June 30, 2025. See Supplementary Information for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; Assistant Director for Licensing, 202–622–2480; Assistant Director for Sanctions

Compliance, 202–622–2490 or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Action

On June 30, 2025, the President issued Executive Order (E.O.) 14312 of June 30, 2025, ''Providing for the Revocation of Syria Sanctions'' that removes U.S. sanctions on Syria, effective July 1, 2025. This revocation includes six E.O.s that form the foundation of the Syrian Sanctions Regulations (31 CFR part 542, ''SySR''), and terminates the national emergency underlying those E.O.s, which resulted in the removal of U.S. sanctions on Syria.

A. In line with E.O. 14312, on June 30, 2025, OFAC designated 139 persons who were previously designated pursuant to the SySR. OFAC has determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below. As a result of this designation, OFAC has further updated the listings of these persons, as reflected below.

BILLING CODE 4810–AL–P

Individuals:

1. AL-FREIJ, Fahd Jassem (a.k.a. AL-FREIJ, FAHAD JASSIM; a.k.a. AL-FURAYJ, FAHD JASIM); DOB 01 Jan 1950; POB Hama, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of Executive Order 13894, "Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Syria," as amended by Executive Order 14142, "Taking Additional Steps With Respect to the Situation in Syria," and as further amended by Executive Order 14312, "Providing for the Revocation of Syria Sanctions" ("E.O. 14312") for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
2. ASLAN, Aus (a.k.a. ASLAN, Aous Ali), Syria; DOB 1958; alt. DOB 1960; POB Latakia, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
3. IBRAHIM, Muhammad; DOB 05 Aug 1964; alt. DOB 1958; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
4. LOUKA, Husam Muhammad (Arabic: حسام محمد لوقا) (a.k.a. LOUCA, Housam; a.k.a. LOUCA, Houssam; a.k.a. LOUCA, Husam; a.k.a. LOUCA, Hussam; a.k.a. LOUKA, Hussam (Arabic: حسام لوقا); a.k.a. LUKA, Hussam; a.k.a. LUQA, Husam; a.k.a. LUQA, Hussam), Damascus, Syria; DOB 1964; POB Damascus, Syria; alt. POB Khanasser, Aleppo, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894]
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
5. MAKHLUF, Talal Shafiq (a.k.a. MAKHLOUF, Talal), Syria; DOB 01 Dec 1958; POB Al-Qardaha, Latakia, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
6. MUALLA, Badi (a.k.a. MUALLA, Badi Sulayman), Syria; DOB 1961; alt. DOB 05 Apr 1961; POB Bistuwir, Jablah, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
7. SHIHADAH, Rafiq (a.k.a. SHAHADAH, Rafiq; a.k.a. SHAHADAH, Rafiq Mahmoud; a.k.a. SHEHADEH, Rafik; a.k.a. SHIHADA, Rafiq; a.k.a. SHIHADAH, Wafiq), Syria; DOB 1954; POB Al-Sharasheer, Jableh, Latakia, Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

8. SWEID, Joseph Jurji (a.k.a. SUWAID, Joseph), Syria; DOB 1958; POB Damascus, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
9. AL-HALQI, Wael Nader; DOB 1964; POB Daraa, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
   Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
10. KHADOUR, Tawfiq Muhammad (Arabic: توفيق محمد خضور) (a.k.a. KHADUR, Tawfiq Ahmad), Syria; DOB 1966; POB Hilat Ara, Jablah, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
    Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
11. MAHALLA, Muhammad Mahmud (a.k.a. MAHALA, Muhammad), Syria; DOB 04 Jun 1959; nationality Syria; Gender Male (individual) [PAARSSR-EO13894]
    Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
12. SAATI BIN MOHAMAD NAWZAD, Mohamad Ammar (Arabic:محمد عمار ساعاتي بن محمد نوزاد) (a.k.a. AL-SAATI, Ammar (Arabic: عمار الساعاتي); a.k.a. SAATI, Amar; a.k.a. SAATI, Ammar; a.k.a. SAATI, Mohamed Ammar; a.k.a. SA'ATI, Mohamed Ammar; a.k.a. SAATI, Mohammad Ammar (Arabic: محمد عمار ساعاتي); a.k.a. SA'ATI, Mohammad Ammar; a.k.a. SA'ATI, Mohammed Ammar; a.k.a. SAATI, Mohammed Ammar; a.k.a. SAATI, Muhammed Ammar), Syria; DOB 01 Jan 1967; POB Damascus, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894]..
    Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
13. SALAMEH, Adeeb Namer (Arabic: أديب نمر سلامة) (a.k.a. SALAMAH, Adib Nimr; a.k.a. SALAMEH, Adib), Damascus, Syria; DOB 26 Nov 1953; POB Dahr Al-Maghar, al-Salamiyeh, Hamah, Syria; nationality Syria; Gender Male; Passport 578761 (Syria) (individual) [PAARSSR-EO13894].
    Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
14. BALLUL, Ahmad (a.k.a. BALLUL, Ahmad Muhammad; a.k.a. BALLUL, Ahmed), Syria; DOB 10 Oct 1954; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
    Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
15. DARWISH, Saji Jamil, Syria; DOB 11 Jan 1957; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].

Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

16. RAHMUN, Muhammad Khalid, Syria; DOB 01 Apr 1957; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
17. JABER, Ayman (a.k.a. JABER, Aiman; a.k.a. JABER, Ayman Mehriz; a.k.a. JABER, Ayman Mohriz; a.k.a. JABIR, Ayman; a.k.a. JABIR, Ayman Muhriz); DOB 17 Jan 1967; Passport 003308607 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(A)(1) of E.O. 14312 for being a responsible for or complicit in, or to have directly or indirectly engaged in, or attempted to engage in, actions or policies that further threaten the peace, security, stability, or territorial integrity of Syria.
18. JABER, Mohammad (a.k.a. JA FAR, Abu; a.k.a. JABIR, Mohammad; a.k.a. JABIR, Muhammad; a.k.a. JABIR, Muhammad Mahruz; a.k.a. JABIR, Muhammad Muhraz; a.k.a. JABIR, Muhammad Muhriz; a.k.a. JA'FAR, Abu); DOB 23 Jan 1957; POB Latakia, Syria; Passport N004871560 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(A)(1) of E.O. 14312 for being a responsible for or complicit in, or to have directly or indirectly engaged in, or attempted to engage in, actions or policies that further threaten the peace, security, stability, or territorial integrity of Syria.
19. ADANOV, Munir (a.k.a. ADANOF, Munir; a.k.a. ADNUF, Munir); DOB 1951; Deputy Chief of General Staff of the Syrian Army; Lieutenant General (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
20. AL-SHAAR, Mohammad Ibrahim (a.k.a. AL-CHAAR, Mohammad Ibrahim; a.k.a. AL-SHAAR, Mohammed Ibrahim; a.k.a. AL-SHA'AR, Muhammad Ibrahim; a.k.a. AL-SHAAR, Muhammad Ibrahim); DOB 1950; POB Lattakia Province, Syria; alt. POB Al-Haffa, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
21. AZZAM, Mansour Fadlallah; DOB 1960; POB Sweida, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
22. NAJIB, Atif (a.k.a. NAJEEB, Atef; a.k.a. NAJIB, Atef), Syria; DOB 1960; POB Jablah, Syria; nationality Syria; Gender Male; Former head of the Syrian Political Security Directorate for Dar'a Province (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

23. KHURI, Mudalal (a.k.a. KHOURI, Mudalal; a.k.a. KHOURY, Mudallal; a.k.a. KHURI, Mudalal Mtanyus), Russia; DOB 18 Jun 1957; POB Khoms, Syria; nationality Russia; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(2) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, a former official of the former Assad regime or a person who acted for or on behalf of such an official.
24. MAYALEH, Adib (a.k.a. ANDRE, Miyal; a.k.a. MAYALA, Adib; a.k.a. MAYARD, Andre); DOB 1955; POB Daraa, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
25. 'ABBAS, Yasir (a.k.a. 'ABBAS, Yasir 'Aziz); DOB 22 Aug 1978; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
26. DAVID, Yafi (Arabic: يافي ديفيد) (a.k.a. YAFEE, Daoud), United Arab Emirates; DOB 25 Aug 1969; POB Syria; nationality Ukraine; Gender Male; Passport FE550041 (Ukraine) expires 01 Jun 2026; Identification Number 121619695 (Oman) (individual) [PAARSSR-EO13894] (Linked To: GRAINS MIDDLE EAST TRADING DWC-LLC).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Grains Middle East Trading DWC-LLC, a person whose property and interests in property are blocked pursuant to E.O. 14312.
27. HASSAN, Jamil (a.k.a. HASAN, Jamil); DOB 1953; POB Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
28. KARIM ALI, Ali Abdul (a.k.a. ABD-AL-KARIM ALI, Ali; a.k.a. ABD-AL-KARIM, Ali; a.k.a. ABDULKARIM ALI, Ali; a.k.a. ABDULKARIM, Ali; a.k.a. KARIM ALI, Ali Abdel; a.k.a. KARIM, Ali Abdul); DOB 1953; POB Latakia Governorate, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
29. QUDSIYAH, Abdul Fatah (a.k.a. QUDSIAH, Abdulfatah; a.k.a. QUDSIYAH, Abd-al-Fatah); DOB 1950; alt. DOB 1963; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
30. SHAABAN, Bouthaina (a.k.a. SHAABAN, Buthaina), Rawda Sq. , Damascus, Syria; DOB 1953; POB Homs, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].

Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

31. ZAITOUN, Mohammed Dib (a.k.a. ZAYTUN, Muhammad Dib; a.k.a. ZEITOUN, Mohammed Dib); DOB 1952; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
32. HABIB, Salah (a.k.a. HABIB, Saleh; a.k.a. HABIB, Salih), Villa 43A, al Syniar Street, Jumeirah 3, P.O. Box 127074, Dubai, United Arab Emirates; DOB 05 Jul 1962; POB Ain el-Karm, Syria; nationality Syria; citizen France; alt. citizen Syria; Gender Male; Passport 13AF69606 (France) expires 06 Feb 2023 (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
33. LANG, Jonha (a.k.a. GANGSHAN, Lang), Yuhong District, Shenyang, China; DOB 15 Dec 1978; nationality China; citizen China; Gender Male; Citizen's Card Number 211226197812154256 (China) (individual) [PAARSSR-EO13894] (Linked To: T-RUBBER CO., LTD).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, T-Rubber Co., LTD, a person whose property and interests in property are blocked pursuant to E.O. 14312.
34. JAMALEDDINE, Nazir Ahmad Mohammed (Arabic: نذير احمد محمد جمال الدين) (a.k.a. JAMAL EDDIN, Mohammed Nazer; a.k.a. JAMAL EDDINE, Natheer Ahmed Mohammed; a.k.a. JAMAL EDDINE, Nathier Ahmed Mohammed), Damascus, Syria; DOB 02 Jan 1962; POB Damascus, Syria; nationality Syria; Gender Male; Passport N011612445 (Syria); alt. Passport 002-17-L022286 (Syria); National ID No. 010-30208342 (Syria) (individual) [PAARSSR-EO13894] [SYRIA-CAESAR].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
35. CHIZARI, Mohsen (a.k.a. HANSURI, Muhammad Muhawad); DOB 01 Apr 1959; POB Tehran, Iran; nationality Iran; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).
Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism," as amended by Executive Order 13886, "Modernizing Sanctions To Combat Terrorism" ("E.O. 13224, as amended) for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Islamic Revolutionary Guard Corps (IRGC)-QODS Force, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.
36. ABU ZUREIK, Imad (Arabic: عماد ابو زريق) (a.k.a. ABU ZUREIQ, Imad), Nassib, Syria; DOB 09 Feb 1979; POB Dara', Syria; nationality Syria; Gender Male; National ID No. 12010031783 (Syria) (individual) [PAARSSR-EO13894].

Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.

37. AL-ASSAD, Samer Kamal (Arabic: سامر كمال الأسد) (a.k.a. AL-ASAD, Samer), Syria; DOB 19 May 1973; POB Qardaha, Syria; nationality Syria; Gender Male; Passport 86368 (Syria); National ID No. 06200000449 (Syria) (individual) [PAARSSR-EO13894] [SYRIA-CAESAR].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
38. AL-ASSAD, Wassim (a.k.a. AL-ASSAD, Waseem; a.k.a. AL-ASSAD, Waseem Badi; a.k.a. AL-ASSAD, Wassim Badi' (Arabic: وسيم بديع الأسد)), Syria; DOB 18 Jul 1980; POB Qardaha, Latakia Governorate, Syria; nationality Syria; Gender Male; National ID No. 06200000611 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
39. AL-DJ, Mahmoud Abdulilah (a.k.a. AL-DAJ, Mahmoud Abdul-ilah; a.k.a. AL-DJ, Mahmoud (Arabic: محمد الدج); a.k.a. DAJ, Mahmoud Abdul-ilah; a.k.a. DAJJ, Mahmud Abdulilah), Syria; DOB 26 Jul 1983; POB Tell Rifaat, Aleppo, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
40. AL-KAYALI, Taher (a.k.a. CAIALI, Taer; a.k.a. KAYALI, Taher (Arabic: طاهر كيالي); a.k.a. KAYALI, Taher Abdel Karim), Syria; DOB 11 Jul 1960; POB Aleppo, Syria; nationality Syria; Gender Male; National ID No. 02010229257 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
41. FALHOUT, Raji, Syria; DOB 03 Oct 1985; POB Atil, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
42. HAMIDEH, Abdellatif (Arabic: عبد اللطيف حميده) (a.k.a. HAMID, Abdul Latif), Syria; DOB 12 Jan 1977; POB Aleppo, Syria; nationality Syria; Gender Male; National ID No. 02020194015 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.

43. IIAMIEII, Khaldoun, Syria; DOB 25 Dec 1973; nationality Lebanon; Gender Male; Passport LR1939852 (Lebanon) (individual) [PAARSSR-EO13894] [SYRIA-CAESAR].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
44. QADDOUR, Khalid (a.k.a. QADDOUR, Khaled Nasser (Arabic: خالد ناصر قدور)), Yaafour, Damascus, Syria; DOB 23 Apr 1970; POB Damascus, Syria; nationality Syria; Gender Male; National ID No. 01020097227 (Syria) (individual) [PAARSSR-EO13894] [SYRIA-CAESAR] (Linked To: AL-ASSAD, Maher).
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
45. HABIB, Malik Ali (Arabic: مالک علی حبیب), Palmyra, Syria; DOB 04 Jan 1963; POB Jablah Latakia, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
46. ISMAIL, Ghassan Jaoudat (Arabic: غسان جودت إسماعيل) (a.k.a. ISMAEL, Ghassan Jaoudat; a.k.a. SALAMEH, Ghassan), Aleppo, Syria; DOB 1960; POB Junaynat Ruslan, Darkoush, Drekish, Tartous, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
47. AL-HASSAN, Kamal (a.k.a. HASAN, Kamal 'Ali (Arabic: كمال علي حسن)), Damascus, Syria; DOB 10 Jun 1967; nationality Syria; Gender Male; National ID No. 571778 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
48. AL-DIB, Ahmed (Arabic: احمد الديب) (a.k.a. DEEB, Ahmad; a.k.a. DEEB, Ahmed; a.k.a. DIB, Ahmad; a.k.a. DIB, Ahmed (Arabic: احمد ديب); a.k.a. DIBE, Ahmad; a.k.a. DIBE, Ahmed (Arabic: احمد ديبئ)), Damascus, Syria; DOB 1961; POB Ayn Al-Tineh Village, Latakia, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
49. AL-ALI, Nasr (Arabic: ناصر العلي) (a.k.a. AL-ALI, Naser; a.k.a. AL-ALI, Nasir; a.k.a. AL-ALI, Nasser; a.k.a. ALI, Nasser), Damascus, Syria; DOB 01 Feb 1961; POB Manbij, Aleppo, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
50. DOGAEV, Andrey (a.k.a. DOGAYEV, Andrey; a.k.a. DOGAYEV, Andrey Yuryevich (Cyrillic: ДОГАЕВ, Андрей Юрьевич)); DOB 19 Dec 1955; POB

Russia; nationality Russia; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport 72 9279533 (Russia) issued 27 Aug 2014 expires 27 Aug 2024 (individual) [IRAN-EO13902].
Designated pursuant to section 1(a)(i) of Executive Order 13902, "Imposing Sanctions With Respect to Additional Sectors of Iran," (E.O. 13902) for operating in the petroleum and petrochemical sectors of the Iranian economy.

51. DAIII, Yasin Ahmad, Syria; DOB 1960; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
52. BILAL, Muhammad Nafi (a.k.a. BILAL, Muhammad), Syria; DOB 25 May 1971; alt. DOB 1971; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
53. AL-HASAN, Suhayl Hasan (a.k.a. HASSAN, Suheil), Syria; DOB 1964; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
54. KHIDR, Isa, Syria; DOB 27 Jan 1969; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
55. GHANIM, Ma'n, Syria; DOB 03 May 1970; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
56. 'ALI, Ahmad, Syria; DOB 02 Dec 1969; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
57. AL-HATUM, Yusuf, Syria; DOB 05 Jan 1966; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
58. AIIMAD, Ayman, Syria; DOB 01 Feb 1971; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
59. MAKHLUF, Rami (a.k.a. MAKHLOUF, Rami; a.k.a. MAKHLOUF, Rami Bin Mohammed; a.k.a. MAKIILOUF, Rami Mohammad); DOB 10 Jul 1969; POB Syria; nationality Syria; citizen Syria; Gender Male; Passport 98044 (Syria) (individual) [PAARSSR-EO13894].

Designated pursuant to section 1(a)(i)(A)(1) of E.O. 14312 for being a responsible for or complicit in, or to have directly or indirectly engaged in, or attempted to engage in, actions or policies that further threaten the peace, security, stability, or territorial integrity of Syria.

60. MAKHLUF, Iyad (a.k.a. MAKHLOUF, Eyad; a.k.a. MAKHLOUF, Iyad), Damascus, Syria; DOB 21 Jan 1973; nationality Syria; Gender Male; Passport N001820740 (individual) [PAARSSR-EO13894] (Linked To: MAKHLUF, Rami).
Designated pursuant to section 1(a)(i)(G) of E.O. 14312 for being an adult family member of Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
61. DARWISH, Samir Sakhir, Mezzah, Damascus, Syria; DOB 1971; alt. DOB 1970; alt. DOB 1972; nationality Syria; Gender Male; Head of Al-Bustan Charity (individual) [PAARSSR-EO13894] (Linked To: MAKHLUF, Rami).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
62. ABBAS, Muhammad (a.k.a. ABBAS, Mohammad Hasan; a.k.a. ABBAS, Mohammad Hassan), Damascus, Syria; DOB 01 Sep 1964; POB Al Ladhiqiyah, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894] (Linked To: MAKHLUF, Rami).
Designated pursuant to section 1(a)(i)(E)(3) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
63. HASWANI, George (a.k.a. AL HASAWANI, George; a.k.a. HASAWANI, George; a.k.a. HASWANI, Jurj; a.k.a. HESSWANI, Georges; a.k.a. HESWANI, George; a.k.a. HEWANI, George; a.k.a. KHESOUANI, George; a.k.a. KHESOUANI, Georges), Syria; DOB 26 Sep 1946; POB Yabrud, Syria; nationality Syria; alt. nationality Russia; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
64. ARBASH, Yusuf (a.k.a. ARBASH, Yusef Mikhail), Russia; DOB Oct 1960; nationality Russia; Gender Male (individual) [PAARSSR-EO13894] (Linked To: HESCO ENGINEERING & CONSTRUCTION CO).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Hesco Engineering and Construction Co., a person whose property and interests in property are blocked pursuant to E.O. 14312.
65. KHURI, Imad Mtanyus; DOB 03 Oct 1964; nationality Syria; citizen Russia; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
66. KHAMIS, Imad Mohammad Deeb; DOB 01 Aug 1961; POB near Damascus, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].

Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

67. AL-HASSAN, Bassam (a.k.a. HASAN, Basam; a.k.a. HASAN, Bassam; a.k.a. HASSAN, Bassam); DOB 1961; alt. DOB 1960; alt. DOB 1962; POB Homs, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

68. MASOUTI, Mohammed Hammam Mohammed Adnan (Arabic: محمد همام محمد عدنان مسوتي) (a.k.a. HUMAM, Msuti; a.k.a. MASOUTI BIN MOHAMMED ADNAN, Mohammed Humam (Arabic: محمد همام مسوتي بن محمد عدنان); a.k.a. MASOUTI, Mohammad Humam; a.k.a. MASOUTI, Mohammad Hussam Mohammad Adnan; a.k.a. MASOUTI, Mohammed Hammam; a.k.a. MASOUTI, Mohammed Humam Mohammed Adnan; a.k.a. MSOUTI, Mohammad Humam Mohammad Adnan), Damascus, Syria; DOB 1976; POB Damascus, Syria; nationality Syria; Gender Male (individual) [PAARSSR- EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

69. BALWI, Fadel Ma'ruf (Arabic: فاضل معروف بلوي) (a.k.a. AL-BALAWI, Fadel), Syria; DOB 01 Jan 1983; POB Nubl, Syria; nationality Syria; Gender Male; Passport 2251748 (Syria) (individual) [PAARSSR-EO13894] (Linked To: AL-FADEL EXCHANGE AND MONEY TRANSFER COMPANY).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Al-Fadel Exchange and Money Transfer Company, a person whose property and interests in property are blocked pursuant to E.O. 14312.

70. BALWI, Muhammad Ma'ruf (Arabic: محمد معروف بلوي) (a.k.a. AL-BALAWI, Muhammad; a.k.a. AL-BALWI, Muhammad Ma'ruf), Sayyida Zeynab, Damascus, Syria; DOB 01 Jan 1981; POB Nubl, Syria; nationality Syria; Gender Male; Passport 1982538 (Syria) (individual) [PAARSSR-EO13894] (Linked To: AL-FADEL EXCHANGE AND MONEY TRANSFER COMPANY).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Al-Fadel Exchange and Money Transfer Company, a person whose property and interests in property are blocked pursuant to E.O. 14312.

71. KHITI, Amer Taysir (Arabic: عامر تيسير خيتي) (a.k.a. KHEITI, Amer Tayseer; a.k.a. KHEITI, Amer Taysir), Damascus, Syria; DOB 31 Jul 1980; POB Douma, Syria; nationality Syria; alt. nationality Sudan; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.

72. BALWI, Mut'i Ma'ruf (Arabic: مطيع معروف بلوي) (a.k.a. AL-BALAWI, Mut'i; a.k.a. BALAWI, Mut'i; a.k.a. BALWI, Maarouf; a.k.a. BALWI, Moutee Maarouf), Syria; DOB 01 Jan 1985; POB Nubl, Syria; nationality Syria; Gender

Male; Passport 2488186 (Syria) (individual) [PAARSSR-EO13894] (Linked To: AL-FADEL EXCHANGE AND MONEY TRANSFER COMPANY).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Al-Fadel Exchange and Money Transfer Company, a person whose property and interests in property are blocked pursuant to E.O. 14312.

73. AL-HASOURI, Muhammad Yousef (Arabic: محمد يوسف الحاصوري) (a.k.a. HASOURI, Mohammad Yousef (Arabic: محمد يوسف حاصوري); a.k.a. HASOURI, Muhammad Yousef; a.k.a. HASOURI, Muhammed Yousef), Syria; DOB 1965; POB Talkalakh, Homs, Syria; nationality Syria; Gender Male; Major General (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
74. MIHOUB, Qusay (a.k.a. MAHYUB, Qusay); DOB 1960; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
75. AL-DEKER, Asef (a.k.a. AL-DIKR, Asf; a.k.a. DAKKAR, Asef), Syria; DOB 1965; POB Jableh, Beit Yashout, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
76. KHALIL, Qahtan (Arabic: قحطان خليل), Syria; DOB 1964; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
77. NASSER, Wafiq (Arabic: وفيق ناصر) (a.k.a. NASER, Wafiq; a.k.a. NASSEER, Wafiq), Aleppo, Syria; DOB 10 Jul 1964; POB Jableh, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.
78. BIN ALI, Khodr Taher (Arabic: خضر طاهر بن علي) (a.k.a. Al-Jaja; a.k.a. KHODR, Abou Ali; a.k.a. KHODR, Abu Ali (Arabic: ابو علي خضر); a.k.a. TAHER, Khader Ali; a.k.a. TAHER, Kheder Ali; a.k.a. TAHER, Khider Ali; a.k.a. TAHER, Khodr Ali (Arabic: خضر علي طاهر); a.k.a. "AL-KHUDUR, Khudhur Taher"; a.k.a. "JIJEH, Abu Ali"), Damascus, Syria; Tartous, Syria; DOB 1976; POB Safita, Tartous, Syria; nationality Syria; Gender Male (individual) [PAARSSR-EO13894]. Designated pursuant to section 1(a)(i)(c) of E.O. 14312 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the illicit production and international illicit proliferation of captagon.
79. FOZ, Amer (a.k.a. FOZ, Amer Zuhair (Arabic: عامر زهير فوز); a.k.a. FOZ, Amer Zuheir), Yenisehir Mahallesi Ataturk Bulvari Yalim Apt. 61/1-A, Iskenderun Hatay, Turkey; United Arab Emirates; DOB 11 Mar 1976; POB Homs, Syria; nationality Syria; citizen Turkey; Gender Male; Passport O6O1O274747 (Syria); alt. Passport U10511291 (Turkey); alt. Passport RE0027453 (Syria); National ID

No. 69736232604 (Turkey); alt. National ID No. 162280535 (United Arab Emirates) (individual) [PAARSSR-EO13894] (Linked To: FOZ, Samer).
Designated pursuant to section 1(a)(i)(G) of E.O. 14312 for being an adult family member of Samer Foz, a person whose property and interests in property are blocked pursuant to E.O. 14312.

80. FOZ, Husen (a.k.a. FOZ, Hasan; a.k.a. FOZ, Hosn Zuhair; a.k.a. FOZ, Hoson; a.k.a. FOZ, Housen; a.k.a. FOZ, Husen Aljibawi; a.k.a. FOZ, Hussen (Arabic: حسن فوز)), Meadows 1, Street 13, Villa 38, Dubai, United Arab Emirates; Adawai Area Rawdet Aleman Bld, 1st Floor, Damascus City, Syria; Yenisehir Mahallesi Ataturk Bulvari Yalim, Apt 61/1-A, Iskenderun Hatay, Turkey; DOB 25 May 1981; POB Lattakia, Syria; nationality Syria; alt. nationality Saint Kitts and Nevis; citizen Turkey; alt. citizen Syria; Gender Female; Passport U08527769 (Turkey); alt. Passport RE0027450 (Syria); National ID No. 06010274768 (Syria); alt. National ID No. 784198164202982 (United Arab Emirates); alt. National ID No. 69727232996 (Turkey) (individual) [PAARSSR-EO13894] (Linked To: FOZ, Samer).
Designated pursuant to section 1(a)(i)(G) of E.O. 14312 for being an adult family member of Samer Foz, a person whose property and interests in property are blocked pursuant to E.O. 14312.
81. FOZ, Samer (a.k.a. AL-FOUZ, Samer; a.k.a. FAWAZ, Samer; a.k.a. FAWZ, Samir; a.k.a. FOUZ, Samer; a.k.a. FOZ, Samer Zuhair; a.k.a. FOZ, Samir), Meadows 2, Street 3, Villa 5, Dubai, United Arab Emirates; DOB 20 May 1973; POB Latakia, Syria; nationality Syria; alt. nationality Turkey; alt. nationality Saint Kitts and Nevis; citizen Saint Kitts and Nevis; Gender Male; National ID No. 784197341865828 (Syria) (individual) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(B) of E.O. 14312 for being a former official of the former regime of Bashar al-Assad or a person who acted for or on behalf of such an official.

Entities:

1. COASTAL REFINERY COMPANY PRIVATE JSC (a.k.a. AL-SAHEL REFINERY COMPANY; a.k.a. COAST REFINERY COMPANY (Arabic: شركة مصافة الساحل)), Tartous, Syria; Organization Established Date 09 Feb 2020; Organization Type: Manufacture of refined petroleum products [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
2. KREMSONT COMMERCIAL INC. (a.k.a. KREMSONT ALLIANCE CORP.), Corner of Eyre Street and Hutson Street, Blake Building, No. 302, Belize City, Belize [PAARSSR-EO13894] (Linked To: KHURI, Mudalal).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Mudalal Khuri, a person whose property and interests in property are blocked pursuant to E.O. 14312.
3. AMAN HOLDING COMPANY (a.k.a. AMAN GROUP; a.k.a. AMAN HOLDING GROUP; a.k.a. AMAN HOLDING PRIVATE JSC), Al Shurafa Building Aman Group, Al Moutanabi Street, Lattika, Syria [PAARSSR-EO13894] (Linked To: FOZ, Samer).

Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Amer Foz and Samer Foz, persons whose property and interests in property are blocked pursuant to E.O. 14312.

4. FOZ FOR TRADING (a.k.a. FOZ TRADING), Syria [PAARSSR-EO13894] (Linked To: AMAN HOLDING COMPANY).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Aman Holding Company, a person whose property and interests in property are blocked pursuant to E.O. 14312.
5. LANA TV, Beirut, Lebanon [PAARSSR-EO13894] (Linked To: FOZ, Samer).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Samer Foz, a person whose property and interests in property are blocked pursuant to E.O. 14312.
6. ORIENT CLUB, Al Najmeh Square - Abou Romaaneh 6737, Damascus, Syria [PAARSSR-EO13894] (Linked To: FOZ, Samer).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Samer Foz, a person whose property and interests in property are blocked pursuant to E.O. 14312.
7. AMAN DAMASCUS JOINT STOCK COMPANY (a.k.a. AMAN DAMASCUS JSC), Damascus, Syria [PAARSSR-EO13894] (Linked To: AMAN HOLDING COMPANY).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Aman Holding Company, a person whose property and interests in property are blocked pursuant to E.O. 14312.
8. TADBIR KISH MEDICAL AND PHARMACEUTICAL COMPANY (a.k.a. TADBIR KISH MEDICAL AND PHARMACEUTICAL CO.; a.k.a. TADBIR TED VA DAROYE KISH), Iran; Unit A103, 1st Floor, Padena Complex, Iran Blvd, Kish, Iran; Unit A301, 1st Floor, Padena Complex, Iran Blvd, Kish, Iran; Unit 301, 3rd Floor, Sadaf Tower, Kish, Iran; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 [SDGT] (Linked To: GLOBAL VISION GROUP).
Designated pursuant to section 1(d)(i) of Executive Order 13224, as amended for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, Global Vision Group, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.
9. JAYSH AL-SHA'BI (a.k.a. AL-SHA'BI COMMITTEES; a.k.a. JAYSH AL-SHAAB; a.k.a. JISH SHAABI; a.k.a. SHA'BI COMMITTEES; a.k.a. SHA'BI FORCE; a.k.a. SYRIAN NATIONAL DEFENSE FORCE; a.k.a. SYRIAN NATIONAL DEFENSE FORCES; a.k.a. "ARMY OF THE PEOPLE"; a.k.a. "PEOPLE'S ARMY"; a.k.a. "POPULAR COMMITTEES"; a.k.a. "POPULAR FORCES"; a.k.a. "SHA'BI"; a.k.a. "THE POPULAR ARMY"), Syria [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.

10. SHABIHA (a.k.a. AL-SHABBIHAH; a.k.a. SHABBIHA; a.k.a. SHABBIHAH; a.k.a. SHABEEHA), Syria [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
11. CHAM WINGS AIRLINES (Arabic: أجنحة الشام للطيران) (a.k.a. AJNEHAT AL SHAM; a.k.a. AL-SHAM WINGS; a.k.a. CHAM WINGS (Arabic: أجنحة الشام); f.k.a. SHAM WING AIRLINES), Al Fardous Street, Damascus, Syria; Saadoon Street, Baghdad, Iraq; 8 March Street, Lattakia, Syria; Hai Al Gharbi-Alraees Street, Kamishli, Syria; P.O. Box 1620 Tal-Kurdi, Adra, Damascus, Syria; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Registration ID 14683 (Syria) [SDGT] (Linked To: SHAMMOUT, Issam).
Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224, as amended for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Issam Shammout, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.
12. GRAINS MIDDLE EAST TRADING DWC-LLC (Arabic: جرينز الشرق الأوسط للتجارة دي دبليو سي ش.ذ.م.م), Building A3 Office 213 Dubai World Central Business Park, Dubai, United Arab Emirates; Office 1705, Lake Central Tower, Business Bay, Dubai, United Arab Emirates; Office 426, A5 Building, Dubai World Central, Dubai, United Arab Emirates; Bahnhofstrasse 29, Zug 6300, Switzerland; Bahnhofstrasse 21, Zug 6300, Switzerland; Website https://grains-middleeast.com; Organization Established Date 18 Jul 2019; alt. Organization Established Date 10 May 2022; Company Number CHE-390.605.414 (Switzerland); Business Registration Number 9245 (United Arab Emirates); Registration Number CH-170.9.002.230-0 (Switzerland); Economic Register Number (CBLS) 11454986 (United Arab Emirates) [PAARSSR-EO13894] (Linked To: LIMITED LIABILITY COMPANY STG LOGISTIC).
Designated pursuant to section 1(a)(i)(E)(3) for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, Limited Liability Company STG Logistic, a person whose property and interests in property are blocked pursuant to E.O. 14312.
13. LIMITED LIABILITY COMPANY STG LOGISTIC (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ СТГ ЛОГИСТИК) (a.k.a. ООО STG LOGISTIK; a.k.a. STG STROYTRANSGAZ LOGISTIC; a.k.a. "STG LOGISTIC"), 12 Universitetsky Ave, Moscow 119330, Russia; Damascus, Syria; Organization Established Date 04 Sep 2009; Tax ID No. 5027148148 (Russia); Registration Number 1095027004236 (Russia) [PAARSSR-EO13894] [SYRIA-CAESAR].

Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
14. T-RUBBER CO., LTD (a.k.a. T-RUBBER COMPANY; a.k.a. T-RUBBER LTD; a.k.a. "T-RUBBER"), Rubber Industrial Zone, Shaling Town, Yuhong District, Shenyang 110144, China; No. 5-1, Shenxi Sandong Road, Economic Technology Development Area, Shenyang, Liaoning 110002, China; Website http://www.t-rubber.com/ [PAARSSR-EO13894].

Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.

15. YONA STAR INTERNATIONAL (a.k.a. UNISTAR COMPANY; a.k.a. YONA HOLDING; a.k.a. YONA STAR; a.k.a. YONA STAR COMPANY; a.k.a. YONA STAR SHIPPING; a.k.a. YONA STAR TRADING INTERNATIONAL CO. LTD.), Damascus Airport Free Zone, Damascus, Syria; Al Maktoum Street, Building MM Office # 7, Deira, Dubai, United Arab Emirates; Website http://www.yonastar.com [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
16. HESCO ENGINEERING & CONSTRUCTION CO (a.k.a. HESCO ENG & CON. CO; a.k.a. HESCO ENGINEERING AND CONSTRUCTION COMPANY LIMITED), Al Horani Building, Abdullah Ben Omer Street, Damascus, Syria; Suite 351, 10 Great Russell Street, London WC1B 3BQ, United Kingdom; Company Number 05527424 (United Kingdom) [PAARSSR-EO13894] (Linked To: HASWANI, George).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, George Haswani, a person whose property and interests in property are blocked pursuant to E.O. 14312.
17. TAMAYOZ LLC (Arabic: شركة تميز المحدودة المسؤولية) (a.k.a. EXCELLENCE LIMITED LIABILITY COMPANY), Damascus, Syria; Organization Type: Real estate activities with own or leased property [PAARSSR-EO13894] [SYRIA-CAESAR].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
18. AL MASHREQ INVESTMENT FUND (a.k.a. AL MASHREK FUND; a.k.a. AL MASHREK HOLDING; a.k.a. AL MASHRIQ HOLDING; a.k.a. AL MASHRIQ INVESTMENT FUND; a.k.a. "MASHRIQ"), Damascus, Syria; Organization Type: Financial and Insurance Activities [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
19. AL-BUSTAN CHARITY (a.k.a. AL JAMAIYAH AL BUSTAN; a.k.a. AL-BUSTAN ASSOCIATION; a.k.a. AL-BUSTAN CHARITY ASSOCIATION; a.k.a. AL-BUSTAN CHARITY FOUNDATION; a.k.a. AL-BUSTAN CHARITY SOCIETY; a.k.a. AL-BUSTAN ORGANIZATION; a.k.a. JAMIAT AL-BUSTAN AL-KHAYRIYAH CHARITY), Mazza, Damascus, Syria [PAARSSR-EO13894] (Linked To: MAKHLUF, Rami).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
20. AL-HISN (a.k.a. AL-HISN FIRM; a.k.a. AL-HISN FIRM FOR SECURITY PROTECTION AND GUARD SERVICES; a.k.a. AL-HUSN), Jurmana, Damascus, Syria [PAARSSR-EO13894] (Linked To: MAKHLUF, Rami).

Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.

21. AL-QASIUN (a.k.a. AL-QASIUN FIRM; a.k.a. AL-QASIUN SECURITY SERVICES LLC; a.k.a. QASIYUN; a.k.a. QASIYUN SECURITY COMPANY), Jurmana, Damascus, Syria [PAARSSR-EO13894] (Linked To: MAKHLUF, Rami).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
22. BARLY OFF-SHORE (a.k.a. BARLY OFF-SHORE S.A.L.), Lebanon; Registration Number 1800204 (Lebanon) [PAARSSR-EO13894] (Linked To: ABBAS, Muhammad).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Muhammad Abbas, a person whose property and interests in property are blocked pursuant to E.O. 14312.
23. BENA PROPERTIES (a.k.a. BANNA PROPERTIES; a.k.a. BENA), Cham Holding Building, Daraa Highway, Sahnaya Area, P.O. Box 9525, Damascus, Syria, Syria [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
24. CHAM HOLDING (a.k.a. AL SHAM COMPANY; a.k.a. AL-SHAM COMPANY; a.k.a. CHAM INVESTMENT GROUP; a.k.a. SHAM HOLDING COMPANY SAL; a.k.a. "CHAM"; a.k.a. "SHAM HOLDING"), Cham Holding Building, Daraa Highway, Sahnaya Area, P.O. Box 9525, Damascus, Syria [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
25. RAMAK DEVELOPMENT AND HUMANITARIAN PROJECTS LLC (Arabic: راماك للمشاريع التنموية و الانسانية) (a.k.a. RAMAK COMPANY FOR DEVELOPMENT AND HUMANITARIAN PROJECTS LLC), Rural Damascus, Syria; Organization Established Date 08 Aug 2011; Organization Type: Real estate activities with own or leased property; alt. Organization Type: Construction of buildings [PAARSSR-EO13894] [SYRIA-CAESAR].
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Rami Makhluf, a person whose property and interests in property are blocked pursuant to E.O. 14312.
26. WINGS PRIVATE JSC (Arabic: شركة الاجنحة المساهمة المغفلة الخاصة) (a.k.a. AL-AJNAHA PRIVATE JOINT STOCK COMPANY; a.k.a. WINGS COMPANY; a.k.a. WINGS PRIVATE JOINT STOCK COMPANY), Rural Damascus, Syria; Organization Type: Real estate activities with own or leased property [PAARSSR-EO13894] [SYRIA-CAESAR]. (Linked To: ABBAS, Muhammad).

Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Muhammad Abbas, a person whose property and interests in property are blocked pursuant to E.O. 14312.

27. AL-TA'IR COMPANY (Arabic: شركة الطير), Damascus, Syria; Organization Established Date 17 Dec 2012; Organization Type: Transportation and storage [PAARSSR-EO13894] (Linked To: AL-DJ, Mahmoud Abdulilah).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Mahmoud Abdulilah Al-Dj, a person whose property and interests in property are blocked pursuant to E.O. 14312.
28. FREEBIRD TRAVEL AND TOURISM (a.k.a. AL-TAIR AL-HUR (Arabic: الطير الحر); a.k.a. FREE BIRD COMPANY), Maysaloon Street, Al Muhandiseen Building Floor No. 12, Damascus, Syria; Hour al-Enz al-Mammzar Center, Second Floor, Office 12, Dubai, United Arab Emirates; Athens, Greece; Organization Established Date 2022; Organization Type: Travel agency activities [PAARSSR-EO13894] (Linked To: AL-DJ, Mahmoud Abdulilah).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Mahmoud Abdulilah Al-Dj, a person whose property and interests in property are blocked pursuant to E.O. 14312.
29. BS COMPANY OFFSHORE (a.k.a. B S COMPANY; a.k.a. B.S. COMPANY OFFSHORE; a.k.a. BS COMPANY SAL OFFSHORE), Salame Building, Beit Mery, Lebanon [IRAN-EO13902].
Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the petroleum and petrochemical sectors of the Iranian economy.
30. PROMSYRIOIMPORT (a.k.a. FEDERAL STATE UNITARY ENTERPRISE FOREIGN ECONOMIC ASSOCIATION PROMSYRIOIMPORT; a.k.a. PROMSYRIOIMPORT FOREIGN ECONOMIC ASSOCIATION S.O.C.; a.k.a. VO PROMSYRIEIMPORT (Cyrillic: ВО ПРОМСЫРЬЕИМПОРТ); a.k.a. VO PROMSYRIEIMPORT FGUP; a.k.a. VO PROMSYRIOIMPORT), d. 13 str. 4, bulvar Novinski, Moscow 121099, Russia; 13 Novinski Boulevard, Moscow 121834, Russia; Novinskiy Boulevard 13, Building 4, Moscow 123995, Russia; Novinsky bld. 13, build 4, Moscow 121099, Russia; Additional Sanctions Information - Subject to Secondary Sanctions; Tax ID No. 7704140399 (Russia); Government Gazette Number 01860331; Registration Number 1027700499903 (Russia) [IRAN-EO13902].
Designated pursuant to section 1(a)(i) of Executive Order 13902 for operating in the petroleum and petrochemical sectors of the Iranian economy.
31. AL ALI AND AL HAMZA LLC (Arabic: شركة العلي والحمزة), Rural Damascus, Syria; Organization Established Date 15 Jan 2019; Organization Type: Wholesale of construction materials, hardware, plumbing and heating equipment and supplies [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
32. CASTLE SECURITY AND PROTECTION LLC (a.k.a. AL-QALAA COMPANY FOR SECURITY SERVICES; a.k.a. AL-QALA'A FOR PROTECTION, GUARDING, AND SECURITY SERVICES (Arabic: شركة القلعة للحماية و الحراسة و الخدمات الامنية); a.k.a. C.S.P. CASTLE PROTECTION,

GUARDING AND SECURITY SERVICES; a.k.a. CASTLE COMPANY FOR PROTECTION, GUARDING AND SECURITY SERVICES; a.k.a. CITADEL FOR PROTECTION, GUARD AND SECURITY SERVICES; a.k.a. "CASTLE SECURITY AND PROTECTION"), Opposite the gas station, enter hospital 601, Sheikh Saad, Mazzeh, West Villas, Damascus, Syria; Aleppo, Syria; Organization Type: Private security activities [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.

33. ELLA MEDIA SERVICES LLC (Arabic: شركة ايلا للخدمات الاعلامية), Damascus, Syria; Organization Established Date 07 Apr 2019; Organization Type: Advertising [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
34. ELLA TOURISM COMPANY (Arabic: شركة ايلا للسياحة) (a.k.a. IYLA FOR TOURISM), Syria; Organization Established Date 16 Aug 2017; Organization Type: Tour operator activities [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
35. EMMA LLC (Arabic: شركة ايما), Damascus, Syria; Organization Established Date 19 Jan 2017; Organization Type: Postal activities; alt. Organization Type: Other financial service activities, except insurance and pension funding activities, n.e.c.; Only locations in Syria [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
36. EMMA TEL LLC (Arabic: ايماتيل) (a.k.a. EMATEL COMMUNICATIONS; a.k.a. EMATEL LLC; a.k.a. EMMATEL; a.k.a. IMATEL FOR COMMUNICATIONS (Arabic: شركة ايماتيل للاتصالات); a.k.a. "EMATEL"), Shaalan, Damascus, Syria; Mazzeh Highway, Damascus, Syria; Behind Revolution Street, al-Lahoudiyeh, Tartous, Syria; New Zahira Highway, Al Zahira, Damascus, Syria; Marjeh, Damascus, Syria; Daraa Highway, Town Center, Damascus, Syria; Eastern Qalamoun, Rural Damascus, Syria; Flowers Street, Tartous, Syria; The Main Circle, Civilization Street, Homs, Syria; Quwatli Street, Homs, Syria; Murabit, Hama, Syria; Al Jamelaiah, Aleppo, Syria; Baghdad Street, Latakia, Syria; Latakia, Syria; March 8th Street, Latakia, Syria; University Highway, Al-Zahira, Latakia, Syria; Amara Street, Jeblah, Syria; Daraa, Syria; Al-Qamashil, Northeastern Region, Syria; Al-Hasakah, Syria; Deir Ezzor, Syria; Organization Type: Wholesale of electronic and telecommunications equipment and parts [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher

bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.

37. EMMA TEL PLUS LLC (Arabic: شركة ايماتيل بلس) (a.k.a. IMATEL PLUS LLC), Damascus, Syria; Organization Established Date 17 Jan 2019; Organization Type: Wholesale of electronic and telecommunications equipment and parts [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.

38. GOLDEN STAR TRADING LLC (Arabic: شركة النجم الذهبي التجارية), Rural Damascus, Syria; Organization Established Date 23 Oct 2019; Organization Type: Wholesale of electronic and telecommunications equipment and parts [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.

39. HAMSHO INTERNATIONAL GROUP (a.k.a. HAMCHO INTERNATIONAL; a.k.a. HAMSHO GROUP; a.k.a. HAMSHO GROUP INTERNATIONAL; a.k.a. HAMSHO INTERNATIONAL), Baghdad Street, Building No. 31, P.O. Box 8254, Damascus, Syria; Hamsho Building, Free Zone Area, P.O. Box 8254, Syria [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Muhammad Hamsho, a person whose property and interests in property are blocked pursuant to E.O. 14312.

40. ARFADA PETROLEUM PRIVATE JOINT STOCK COMPANY (Arabic: شركة أرفادا البترولية المساهمة المغفلة الخاصة) (a.k.a. ARFADA PETROLEUM COMPANY JSC; a.k.a. ARVADA PETROLEUM COMPANY JSC), Mashroua Dummar, Lot No. 13, Building 12/2, Damascus, Syria; Website https://www.arfada.com/; Organization Established Date 24 Apr 2018; Organization Type: Support activities for petroleum and natural gas extraction; Registration Number 18394 (Syria) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.

41. AL-RESAFA REFINERY COMPANY PRIVATE JSC (a.k.a. AL-RUSAFA REFINERY COMPANY (Arabic: شركة مصفاة الرصافة)), Al-Rusafa, Raqqa, Syria; Organization Established Date 09 Feb 2020; Organization Type: Manufacture of refined petroleum products [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.

42. JASMINE CONTRACTING COMPANY (Arabic: شركة الياسمين التعهدات) (a.k.a. AL-YASMEEN CONTRACTING COMPANY; a.k.a. AL-YASMEEN FOR CONTRACTING; a.k.a. AL-YAZMEEN FOR CONTRACTING; a.k.a. YASMIN FOR CONTRACTING), Damascus, Syria; Organization Established Date 14 Dec 2017 [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).

Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.

43. SYRIAN COMPANY FOR METALS AND INVESTMENTS LLC (Arabic: شركة السورية للمعادن و الاستثمار), Damascus, Syria; Organization Established Date 22 Oct 2018; Organization Type: Wholesale of metals and metal ores [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
44. SYRIAN HOTEL MANAGEMENT LLC (Arabic: الشركة السورية للادارة الفندقية), Damascus, Syria; Organization Established Date 02 May 2017; Organization Type: Short term accommodation activities [PAARSSR-EO13894] (Linked To: BIN ALI, Khodr Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khodr Taher bin Ali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
45. NEPTUNUS LLC (a.k.a. NEPTUNUS CO LTD), 653/38 Baghdad Street, Lattakia, Syria; Organization Established Date 2017; Business Registration Number 6068911 (Syria) [PAARSSR-EO13894] (Linked To: AL-KAYALI, Taher).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Taher al-Kayali, a person whose property and interests in property are blocked pursuant to E.O. 14312.
46. SALLIZAR SHIPPING SAL (Arabic: ساليزار شيبينغ ش.م.ل.), 1st Floor, Shuwairi Bldg., Boulevard Saib Salam, al-Masraa, Beirut Corniche, Lebanon; Organization Established Date 12 Apr 2018; Registration Number 1024992 (Lebanon) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
47. MAYA EXCHANGE COMPANY (Arabic: شركة مايا للصرافة) (a.k.a. MAYA FOR EXCHANGE AND INTERNATIONAL HAWALAS), Ground Floor, Property Number 17/9/2230, Baqi Zadeh Building, Fardus Street, Salhiyah, Damascus, Syria; First Real Estate Zone, Property Number 936, Section 2, Ground Floor, Haju Building, Abd al-Hamid al-Durubi Street, Homs, Syria; Tartus Real Estate Zone, Section 8, Property Number 3881, Revolution Street, Al-Baraniyah, Tartus, Syria; Ground Floor, Second Real Estate Zone, Sections 7-9, Property 2533, Aziziyah Falls, Baghdad Station, Aleppo, Syria; Organization Type: Other monetary intermediation [PAARSSR-EO13894] [SYRIA-CAESAR].
Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
48. AL-ADHAM EXCHANGE COMPANY (Arabic: شركة الادهم للصرافة) (a.k.a. AL-ADHAM FOREIGN EXCHANGE), May 29th Street, Saroujah, Damascus, Syria;

Hisham Al-Atassi Street, Al-Salam Building, Ground Floor, Homs, Syria; Al-Assi Square, Al-Quwwatli Street, Hama, Syria; Al-Quds Street, Tartous, Syria; Website https://aladham-exchange.com.sy; Organization Established Date 16 Feb 2009; Commercial Registry Number 15691 (Syria) [PAARSSR-EO13894]. Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.

49. AL-FADEL EXCHANGE AND MONEY TRANSFER COMPANY (Arabic: شركة الفاضل للصرافة والتحويلات المالية) (a.k.a. AL-FADEL EXCHANGE AND INTERNATIONAL TRANSFER COMPANY; a.k.a. AL-FADEL EXCHANGE PRIVATE JOINT STOCK COMPANY; a.k.a. AL-FADEL MONEY TRANSFER AND EXCHANGE PRIVATE JSC), Al-Fardous Street, Damascus, Syria; March 8th Street, Al-Sarraj Building, Ground Floor, Lattakia, Syria; Al-Express Street, Al-Farqan Quarter, Aleppo, Syria; Al-Mazza Highway, Damascus, Syria; Sayyida Zeynab, Damascus, Syria; Main Street, Jeremana, Damascus, Syria; Website https://alfadelex.com [PAARSSR-EO13894]. Designated pursuant to section 1(a)(i)(E)(1) of E.O. 14312 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, the former regime of Bashar al-Assad.
50. LIA COMPANY (Arabic: شركة ليا) (a.k.a. LIA CO L.L.C.; a.k.a. "LEAH COMPANY"), Damascus, Syria; Organization Established Date 30 Jan 2011 [PAARSSR-EO13894] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan)."LEAH COMPANY"), Damascus, Syria; Organization Established Date 30 Jan 2011 [PAARSSR-EO13894] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Mohammed Hammam Mohammed Adnan Masouti, a person whose property and interests in property are blocked pursuant to E.O. 14312.
51. POLYMEDICS LLC (Arabic: شركة الطبيات المتعددة) (a.k.a. "POLYMEDICS COMPANY"), Damascus, Syria; Organization Established Date 19 Oct 2011; Organization Type: Wholesale of other machinery and equipment [PAARSSR-EO13894] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan)."POLYMEDICS COMPANY"), Damascus, Syria; Organization Established Date 19 Oct 2011; Organization Type: Wholesale of other machinery and equipment [PAARSSR-EO13894] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Mohammed Hammam Mohammed Adnan Masouti, a person whose property and interests in property are blocked pursuant to E.O. 14312.
52. SOURAN COMPANY (Arabic: شركة سوران) (a.k.a. SORAN COMPANY), Damascus, Syria; Organization Established Date 03 Sep 2018; Organization Type: Other telecommunications activities; alt. Organization Type: Wholesale of electronic and telecommunications equipment and parts [PAARSSR-EO13894] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Mohammed Hammam Mohammed Adnan Masouti, a person whose property and interests in property are blocked pursuant to E.O. 14312.

53. AL-AMER DEVELOPMENT AND REAL ESTATE INVESTMENT (Arabic: العامر للتطوير والاستثمار العقاري) (a.k.a. AL-AMER DEVELOPMENT & REAL ESTATE INVESTMENT; a.k.a. AL-AMER DEVELOPMENT AND REAL ESTATE INVESTMENT COMPANY; a.k.a. AL-AMER REAL ESTATE DEVELOPMENT AND INVESTMENT LLC; a.k.a. "AL-AMER DEVELOPMENT"), Mezzeh Villas, Damascus, Syria; Organization Established Date 19 Dec 2019; Organization Type: Real estate activities with own or leased property; Registration Number 19096 (Syria) [PAARSSR-EO13894] (Linked To: KHITI, Amer Taysir).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Amer Taysir Khiti, a person whose property and interests in property are blocked pursuant to E.O. 14312.
54. AL-AMER FOR MANUFACTURE OF CONCRETE AND FLAGSTONE (Arabic: العامر لصناعة المجبول البيتوني والبلوك والبلاط) (a.k.a. AL-AMER FOR CONCRETE, BLOCK AND TILE MANUFACTURING LLC; a.k.a. AL-AMER FOR MANUFACTURE OF CONCRETE, FLAGSTONE, LIMITED LIABILITY), Rural Damascus, Syria; Organization Established Date 04 Nov 2019; Organization Type: Manufacture of articles of concrete, cement and plaster; Registration Number 12428 (Syria) [PAARSSR-EO13894].
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Amer Taysir Khiti, a person whose property and interests in property are blocked pursuant to E.O. 14312.
55. AL-AMER FOR MANUFACTURE OF PLASTIC (Arabic: العامر لصناعة البلاستيك) (a.k.a. ALAMER FOR MANUFACTURE OF PLASTIC LIMITED LIABILITY; a.k.a. AL-AMER PLASTIC INDUSTRY LLC), Rural Damascus, Syria; Organization Established Date 04 Nov 2019; Organization Type: Manufacture of plastics products; Registration Number 12427 (Syria) [PAARSSR-EO13894] (Linked To: KHITI, Amer Taysir).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Amer Taysir Khiti, a person whose property and interests in property are blocked pursuant to E.O. 14312.
56. AL-LAYTH ALZAHABE TRANSPORTATION AND SHIPPING SERVICES (Arabic: الليث الذهبي لخدمات النقل والشحن) (a.k.a. ALLAYTH ALZAHABE (Arabic: الليث الذهبي); a.k.a. GOLDEN LAITH FREIGHT FORWARD SERVICES; a.k.a. GOLDEN LEIH TRANSPORTATION & SHIPMENT SERVICES L.L.C.; a.k.a. GOLDEN LEIH TRANSPORTATION AND SHIPMENT SERVICES L.L.C.; a.k.a. GOLDEN LEITH FOR TRANSPORTATION AND SHIPPING SERVICES), Damascus, Syria; Organization Established Date 26 May 2019; Registration Number 12388 (Syria) [PAARSSR-EO13894] (Linked To: KHITI HOLDING GROUP).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Khiti Holding Group, a person whose property and interests in property are blocked pursuant to E.O. 14312.
57. GOOD LAND COMPANY (Arabic: شركة ارض الخير) (a.k.a. ARD AL-KHAIR INTERNATIONAL COMPANY; a.k.a. ARD AL-KHER INTERNATIONAL COMPANY; a.k.a. GOOD LAND INTERNATIONAL COMPANY (Arabic: شركة ارض الخير الدولية); a.k.a. GOOD LAND INTERNATIONAL COMPANY

FOR THE IMPORTING AND EXPORTING OF VEGETABLES AND FRUIT a.k.a. GOOD LAND); شركة ارض الخير الدولية لاستيراد وتصدير الخضار و الفواكة :Arabic(; LIMITED LIABILITY COMPANY), Duma, Syria; Oman; Jordan; Egypt ; Organization Established Date 1995; alt. Organization Established Date 2016 Organization Type: Wholesale of food, beverages and tobacco; Registration .Number 10845 (Syria) [PAARSSR-EO13894] (Linked To: KHITI, Amer Taysir) Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Amer Taysir Khiti, a person whose property and interests in property are blocked pursuant to E.O. 14312.

58. KHITI HOLDING GROUP (Arabic: مجموعة خيتي القابضة) (a.k.a. KHEITI HOLDING GROUP; a.k.a. KHITI HOLDING COMPANY; a.k.a. KHITI HOLDING PRIVATE JSC), Mazzeh Highway, Damascus, Syria; Mashroa Domar, Damascus, Syria; Website www.khaitiholding.com; alt. Website www.khitiholding.com; Organization Established Date 2018; Organization Type: Activities of holding companies [PAARSSR-EO13894] (Linked To: KHITI, Amer Taysir).
Designated pursuant to section 1(a)(i)(F) of E.O. 14312 for being owned or controlled by, or having acted or purported to act for or on behalf of, Amer Taysir Khiti, a person whose property and interests in property are blocked pursuant to E.O. 14312.

B. In line with E.O. 14312, on June 30, 2025, OFAC removed 518 persons, including blocked property, from the SDN List. The names and relevant sanctions authorities are listed below:

MUTAWIJ, Nawar, Syria; DOB 23 Sep 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABD-AL-SAMAD, Muhammad Haytham, Syria; DOB 05 Sep 1947; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-ALI, Adnan (a.k.a. AL ALI, Adnan; a.k.a. AL-'ALI, 'Adnan), Baniyas, Syria; DOB 17 Jun 1968; POB Lattakia, Syria; nationality Syria; Gender Male; Passport 6066827 (Syria) expires 09 Mar 2017 (individual) [SYRIA] (Linked To: ABAR PETROLEUM SERVICE SAL). SABBAGH, Muhammad Nasir, Syria; DOB 26 Nov 1954; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. GHAZALI, Rustum, Syria; DOB circa 1949; nationality Syria; Chief of Syrian Military Intelligence for Lebanon (individual) [SYRIA]. KANAAN, Ghazi, Damascus, Syria; DOB circa 1943; POB Near Qerdaha, Syria; nationality Syria; Minister of Interior, Syria (individual) [SYRIA]. SHAWKAT, Assef, Al-Akkad Street, Damascus, Syria; DOB 1950; POB Tartus, Syria; nationality Syria; Director of Syrian Military Intelligence (individual) [SYRIA]. IKHTIYAR, Hisham (a.k.a. AL IKHTEYAR, Hisham; a.k.a. AL IKHTIYAR, Hisham; a.k.a. AL-IKHTIYAR, Hisham; a.k.a. AL-IKHTIYAR, Hisham Ahmad; a.k.a. BAKHTIAR, Hisham; a.k.a. BAKHTIYAR, Hisham; a.k.a. ICHTIJAR, Hisham; a.k.a. IKHTEYAR, Hisham), Maliki, Damascus, Syria; DOB 1941; Major General; Director, Syria Ba'ath Party Regional Command National Security Bureau (individual) [SYRIA]. KHAYRBIK, Muhammad Nasif (a.k.a. KHAIRBEK, Mohammed Nassif; a.k.a. KHAYR-BAYK, Muhammad Nasif; a.k.a. KHEIR BEIK, Mohamad; a.k.a. KHEIR BEIK, Mohamad Nassif; a.k.a. KHEIRBEK, Mohammad Nasif), Damascus, Syria; DOB 05 Apr 1937; POB Hama,

Syria; Passport D000000483, Diplomatic (Syria); Syrian Deputy Vice President for Security Affairs; Major General (individual) [SYRIA]. SYRIATEL (a.k.a. SYRIATEL MOBILE; a.k.a. SYRIATEL MOBILE TELECOM; a.k.a. SYRIATEL MOBILE TELECOM SA), Doctors Syndicate Building, Al Jalaa Street, Abu Roumaneh Area, PO Box 2900, Damascus, Syria [SYRIA] [HRIT-SY]. RAMAK (a.k.a. RAMAK DUTY FREE; a.k.a. RAMAK DUTY FREE SHOP LTD; a.k.a. RAMAK DUTY FREE SHOPS - SYRIA; a.k.a. RAMAK DUTY FREE SHOPS LTD.; a.k.a. RAMAK FIRM FOR FREE TRADE ZONES), Free Zone Area, Jamarek, PO Box 932, Damascus, Syria; Al Rawda Street, PO Box 932, Damascus, Syria; Abu Ramana Street, Rawda, Damascus, Syria; Damascus Duty Free, Damascus International Airport, Damascus, Syria; Dara'a Duty Free, Naseeb Border Center, Dara'a, Syria; Aleppo Duty Free, Aleppo International Airport, Aleppo, Syria; Jdaideh Duty Free Complex, Jdaideh Yaboos, Damascus, Syria; Bab el Hawa Border Center, Aleppo, Syria; Lattakia Port, Lattakia, Syria; Tartous Port, Tartous, Syria; Website www.ramakdutyfree.net; Email Address dam.d.free@net.sy [SYRIA]. SYRIAN GENERAL INTELLIGENCE DIRECTORATE (a.k.a. IDERAT AL-AMN AL-'AMM), Syria [SYRIA] [HRIT-SY]. AL-SHARA, Farouk (a.k.a. AL SHARAA, Farouk; a.k.a. AL-SHARA, Farouq; a.k.a. AL-SHARAA, Farouk; a.k.a. SHARAA, Farouk); DOB 1938; POB Dar'a, Syria; Vice president (individual) [SYRIA]. SAFAR, Adel (a.k.a. SAFR, Adil); DOB 1953; POB Damascus, Syria; Prime Minister (individual) [SYRIA]. MAHMOUD, Ali Habib (a.k.a. HABIB, Ali; a.k.a. MAHMOUD, Ali Muhammad Habib; a.k.a. MAHMUD, Ali Habib); DOB 1939; POB Tartous, Syria; Lieutenant General, Minister of Defense (individual) [SYRIA]. SYRIAN AIR FORCE INTELLIGENCE (a.k.a. AIR FORCE INTELLIGENCE DIRECTORATE; a.k.a. IDARAT AL-MUKHABARAT AL-JAWIYYA) [SYRIA]. SYRIAN NATIONAL SECURITY BUREAU (a.k.a. BA'ATH PARTY NATIONAL SECURITY BUREAU; a.k.a. MAKTAB AL-AMN AL-QAWMI), Syria [SYRIA]. SYRIAN MILITARY INTELLIGENCE DIRECTORATE (Arabic: شعبة المخابرات العسكرية سوريا) (a.k.a. SHU'BAT AL-MUKHABARAT AL-'ASKARIYYA; a.k.a. SYRIAN MILITARY INTELLIGENCE), Syria; Organization Established Date 1969].SYRIA[POLITICAL SECURITY DIRECTORATE (a.k.a. IDARAT AL-'AMN AL-SIYYASI; a.k.a. POLITICAL SECURITY DEPARTMENT), Damascus, Syria [SYRIA]. COMMERCIAL BANK OF SYRIA, P.O. Box 933, Yousef Azmeh Square, Damascus, Syria; Aleppo Branch, P.O. Box 2, Kastel Hajjarin St., Aleppo, Syria; Damascus Branch, P.O. Box 2231, Moawiya St., Damascus, Syria; SWIFT/BIC CMSYSYDA; all offices worldwide [NPWMD]. SYRIAN LEBANESE COMMERCIAL BANK, Hamra, Makdessi Street, SLCB Building, P.O. Box 113-5127/11-8701, Beirut, Lebanon; Hamra Branch, Hamra St., Darwish and Fakhro Building, P.O. Box 113-5127/11-8701, Beirut, Lebanon; Mar Elias Branch, Mar Elias Street, Fakhani Building, P.O. Box 145 796, Beirut, Lebanon; SWIFT/BIC SYLCLBBE [NPWMD]. GENERAL PETROLEUM CORPORATION (a.k.a. "GPC"), New Sham- Building of Syrian Oil Company, PO Box 60694, Damascus, Syria [SYRIA]. SYRIAN PETROLEUM COMPANY (a.k.a. "SPC"), Dummar Province Expansion Square, Island 19, Building 32, PO Box 3378, Damascus, Syria; Dummar Province Expansion Square, Island 19, Building 32, PO Box 2849, Damascus, Syria; Todmar Project, Damascus, Syria [SYRIA]. SYTROL, Prime Minister Building, 17 Street Nissan, Damascus, Syria [SYRIA] [ISA]. SYRIAN COMPANY FOR OIL TRANSPORT (a.k.a. SYRIAN CRUDE OIL TRANSPORTATION COMPANY; a.k.a. "SCOT"; a.k.a. "SCOTRACO"), Banias Industrial Area, Latakia Entrance Way, P.O. Box 13, Banias, Syria; Website www.scot-syria.com; Email scot50@scn-net.org [SYRIA]. SYRIAN GAS

COMPANY, P.O. Box 4499, Homs, Syria; Agricultural Engineering Syndicate Building, Baab Hood Area, Al Arbeen District, Homs, Syria; Website www.sgc.gov.sy; Email sgcpdit@mail.sy; Email info@sgc.gov.sy [SYRIA]. AL-MOALLEM, Walid (a.k.a. AL-MOUALEM, Walid; a.k.a. AL-MOUALLEM, Walid; a.k.a. AL-MUALEM, Walid; a.k.a. AL-MUALLEM, Walid; a.k.a. MOALLEM, Walid; a.k.a. MUALLEM, Walid; a.k.a. MUHI EDDINE MOALLEM, Walid); DOB 1941; POB Damascus, Syria; Foreign and Expatriates Minister; Minister for Foreign Affairs (individual) [SYRIA]. REAL ESTATE BANK (a.k.a. REAL-ESTATE BANK), P.O. Box 2337, Insurance Bldg., Youssef Alazma Square, Damascus, Syria; Syrian General Insurance Company Building, Youssef Al Azmeh Square, P.O. Box 2337, Damascus, Syria; SWIFT/BIC REBSSYDA [SYRIA]. MILITARY HOUSING ESTABLISHMENT, Mili House, Adra Road, Damascus, Syria [SYRIA]. MAKHLUF, Muhammad (a.k.a. MAKHLOUF, Mohammed); DOB 19 Oct 1932; POB Latakia, Syria (individual) [SYRIA]. GENERAL ORGANIZATION OF RADIO AND TV (a.k.a. GENERAL RADIO AND TELEVISION CORPORATION; a.k.a. RADIO AND TELEVISION CORPORATION; a.k.a. RTV SYRIA; a.k.a. SYRIAN DIRECTORATE GENERAL OF RADIO & TELEVISION EST; a.k.a. "GORT"), Al Oumaween Square, P.O. Box 250, Damascus, Syria [SYRIA]. SYRIAN ARAB AIRLINES (a.k.a. SYRIAN AIR; a.k.a. SYRIANAIR), Syria; Social Insurance Building, Youssef Al Azmeh Square, Down Town, PO Box 417, Damascus, Syria; Additional Sanctions Information - Subject to Secondary Sanctions; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 [SDGT] [SYRIA] [IRGC] [IFSR]. AHMAD AL-ABDULLAH, Subhi; DOB 1951; POB Idleb, Syria; Minister of Agriculture and Agrarian Reform (individual) [SYRIA]. AL-JLEILATI, MOHAMMAD (a.k.a. AL-JILILATI, MOHAMMAD); DOB 1945; POB Damascus, Syria; Minister of Finance (individual) [SYRIA]. YEHYA MOALLA, Mohammad; DOB 1951; POB Lattakia, Syria; Minister of Higher Education (individual) [SYRIA]. AL-WAZZ, Hazwan; DOB 1962; POB Damascus, Syria; Minister of Education (individual) [SYRIA]. ZAFER MIHBEK, Mohammad; DOB 1945; POB Aleppo, Syria; Minister of Economy and Foreign Trade (individual) [SYRIA]. SHUKRI KURDI, Fuad; DOB 1953; POB Aleppo, Syria; Minister of Industry (individual) [SYRIA]. IBRAHIM SAID, Mahmoud; DOB 1953; POB Lattakia, Syria; Minister of Transport (individual) [SYRIA]. AL-ASSAF, Safwan; DOB 1959; POB Hama, Syria; Minister of Housing and Urban Development (individual) [SYRIA]. AL-SIBAEI, Yasser; DOB 1951; POB Homs, Syria; Minister of Public Works (individual) [SYRIA]. MU'ZI HNEIDI, Said; DOB 1954; POB Damascus, Syria; Minister of Oil and Mineral Resources (individual) [SYRIA]. MSHAWEH, Lubanah; DOB 1955; POB Damascus, Syria; Minister of Culture (individual) [SYRIA]. MOHAMMAD ZAKARYA, Jassim; DOB 1968; POB Hasaka, Syria; Minister of Social Affairs and Labor (individual) [SYRIA]. AHED AL-ZOUBI, Omran; DOB 1959; POB Damascus, Syria; Minister of Information (individual) [SYRIA]. HAIDAR, Ali; DOB 1962; POB Hama, Syria; Minister of State for National Reconciliation Affairs (individual) [SYRIA]. FARAH SARKIS, Nazira; DOB 1962; POB Aleppo, Syria; Minister of State for Environment Affairs (individual) [SYRIA]. JAMIL, Qadri (a.k.a. JAMIL, Kadri); DOB 1952; POB Damascus, Syria; Deputy Prime Minister for Economic Affairs; Minister of Internal Trade and Consumer Protection (individual) [SYRIA]. DREX TECHNOLOGIES S.A. (a.k.a. DREX TECHNOLOGIES), Virgin Islands, British; Company Number 394678 (Virgin Islands, British) [SYRIA]. AL-SAYYED, Mohammad Abdul-Sattar; DOB 1958; POB Tartus, Syria; Minister of Religious Endowments (individual) [SYRIA]. HABIB, Radwan; DOB 1962; POB

Aleppo, Syria; Minister of Justice (individual) [SYRIA]. AL-NASSER, Hala Mohammad; DOB 1964; POB Raqqa, Syria; Minister of Tourism (individual) [SYRIA]. HANNA, Bassam; DOB 1954; POB Aleppo, Syria; Minister of Water Resources (individual) [SYRIA]. FARZAT, Hussein Mahmoud; DOB 1957; POB Hama, Syria; Minister of State (individual) [SYRIA]. GHALAWANJI, Omar Ibrahim; DOB 1954; POB Tartous, Syria; Deputy Prime Minister for Services Affairs; Minister of Local Administration (individual) [SYRIA]. SABOUNI, Imad Abdul-Ghani (a.k.a. SABOUNI, Emad Abdul-Ghani); DOB 1964; POB Damascus, Syria; Minister of Communications and Technology (individual) [SYRIA]. AL-SUKHNI, Adnan Abdo; DOB 1961; POB Aleppo, Syria; Minister of Industry (individual) [SYRIA]. AL-AHMAD, Najm Hamad; DOB 1969; POB Aleppo, Syria; Minister of Justice (individual) [SYRIA]. AL-NAYEF, Sa'ad Abdel-Salam; DOB 1959; POB Aleppo, Syria; Minister of Health (individual) [SYRIA]. YK-ANI; Aircraft Construction Number (also called L/N or S/N or F/N) 11406; Aircraft Manufacture Date 1981; Aircraft Model An-26B; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 17311406; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ANG; Aircraft Construction Number (also called L/N or S/N or F/N) 10907; Aircraft Manufacture Date 1981; Aircraft Model An-26B; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 17310907; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AYF; Aircraft Construction Number (also called L/N or S/N or F/N) 6349; Aircraft Manufacture Date 10 Oct 1984; Aircraft Model Tu-134B-3; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 66190; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AYE; Aircraft Construction Number (also called L/N or S/N or F/N) 6348; Aircraft Manufacture Date Sep 1984; Aircraft Model Tu-134B-3; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 66187; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AYB; Aircraft Construction Number (also called L/N or S/N or F/N) 6331; Aircraft Manufacture Date 1982; Aircraft Model Tu-134BK-3; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 63994; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AYA; Aircraft Construction Number (also called L/N or S/N or F/N) 6330; Aircraft Manufacture Date 1982; Aircraft Model Tu-134BK-3; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 63992; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AYD; Aircraft Construction Number (also called L/N or S/N or F/N) 6328; Aircraft Manufacture Date 1982; Aircraft Model Tu-134B-3; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 63990; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AYC; Aircraft Construction Number (also called L/N or S/N or F/N) 6327; Aircraft Manufacture Date 1982; Aircraft Model Tu-134B-3; Aircraft

Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 63989; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AQG; Aircraft Construction Number (also called L/N or S/N or F/N) 5919; Aircraft Model Yak-40K(F); Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 9941959; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AQF; Aircraft Construction Number (also called L/N or S/N or F/N) 5918; Aircraft Model Yak-40; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 9931859; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AQE; Aircraft Construction Number (also called L/N or S/N or F/N) 5802; Aircraft Model Yak-40; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 9830258; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AQD; Aircraft Construction Number (also called L/N or S/N or F/N) 5801; Aircraft Model Yak-40; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 9830158; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AQB; Aircraft Construction Number (also called L/N or S/N or F/N) 4304; Aircraft Model Yak-40; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 9530443; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AQA; Aircraft Construction Number (also called L/N or S/N or F/N) 3219; Aircraft Model Yak-40; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 9341932; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ANF; Aircraft Construction Number (also called L/N or S/N or F/N) 3104; Aircraft Manufacture Date 1975; Aircraft Model An-26; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 57303104; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ANE; Aircraft Construction Number (also called L/N or S/N or F/N) 3103; Aircraft Manufacture Date 1975; Aircraft Model An-26; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 57303103; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AND; Aircraft Construction Number (also called L/N or S/N or F/N) 3008; Aircraft Manufacture Date 1975; Aircraft Model An-26; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 57303008; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ANC; Aircraft Construction Number (also called L/N or S/N or F/N) 3007; Aircraft Manufacture Date 1975; Aircraft Model An-26; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 57303007; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR]

(Linked To: SYRIAN ARAB AIRLINES). YK-ATD; Aircraft Construction Number (also called L/N or S/N or F/N) 2309; Aircraft Manufacture Date 1981; Aircraft Model Il-76T; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 13431915; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ATC; Aircraft Construction Number (also called L/N or S/N or F/N) 2308; Aircraft Manufacture Date 1981; Aircraft Model Il-76T; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 13431911; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AGF; Aircraft Construction Number (also called L/N or S/N or F/N) 1788; Aircraft Manufacture Date 12 Nov 1981; Aircraft Model B.727-269; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 22763; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AGE; Aircraft Construction Number (also called L/N or S/N or F/N) 1716; Aircraft Manufacture Date 06 Feb 1981; Aircraft Model B.727-269; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 22361; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AGD; Aircraft Construction Number (also called L/N or S/N or F/N) 1670; Aircraft Manufacture Date 26 Sep 1980; Aircraft Model B.727-269; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 22360; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ATB; Aircraft Construction Number (also called L/N or S/N or F/N) 1605; Aircraft Manufacture Date 1979; Aircraft Model Il-76T; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 93421619; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-ATA; Aircraft Construction Number (also called L/N or S/N or F/N) 1604; Aircraft Manufacture Date 1979; Aircraft Model Il-76T; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 93421613; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AGC; Aircraft Construction Number (also called L/N or S/N or F/N) 1198; Aircraft Manufacture Date 09 Apr 1976; Aircraft Model B.727-294; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 21205; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AGB; Aircraft Construction Number (also called L/N or S/N or F/N) 1194; Aircraft Manufacture Date 18 Mar 1976; Aircraft Model B.727-294; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 21204; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AGA; Aircraft Construction Number (also called L/N or S/N or F/N) 1188; Aircraft Manufacture Date 20 Feb 1976; Aircraft Model B.727-294; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 21203; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT]

[SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AVA; Aircraft Manufacture Date 07 Oct 2008; Aircraft Model ATR-72-212A; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 836; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AVB; Aircraft Manufacture Date 24 Dec 2008; Aircraft Model ATR-72-212A; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 845; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AIA; Aircraft Manufacture Date Jan 1985; Aircraft Model Tu-154M; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 708; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AIC; Aircraft Manufacture Date Mar 1985; Aircraft Model Tu-154M; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 710; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AKA; Aircraft Manufacture Date 02 Sep 1998; Aircraft Model A320-232; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 886; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AKB; Aircraft Manufacture Date 26 Oct 1998; Aircraft Model A320-232; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 918; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AKC; Aircraft Manufacture Date 26 May 1999; Aircraft Model A320-232; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 1032; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AKD; Aircraft Manufacture Date 17 Aug 1999; Aircraft Model A320-232; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 1076; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AKE; Aircraft Manufacture Date 06 Sep 1999; Aircraft Model A320-232; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 1085; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). YK-AKF; Aircraft Manufacture Date 11 Oct 1999; Aircraft Model A320-232; Aircraft Operator Syrianair; Aircraft Manufacturer's Serial Number (MSN) 1117; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (aircraft) [SDGT] [SYRIA] [IRGC] [IFSR] (Linked To: SYRIAN ARAB AIRLINES). AL-DUNYA TELEVISION (a.k.a. ADDOUNIA TV; a.k.a. AL DOUNIA; a.k.a. AL-DONYA TELEVISION CHANNEL; a.k.a. DUNIA LIMITED LIABILITY COMPANY FOR INFORMATION; a.k.a. DUNIA TELEVISION), Information Free Zone, Damascus, Syria [SYRIA]. ARNOUS, Hussein; DOB 1953; POB Idleb, Syria; Minister of Public Works (individual) [SYRIA]. AL-QADRI, Ahmad; DOB 1956; POB Hasaka, Syria; Minister of Agriculture and Agrarian Reform (individual) [SYRIA]. ISMAEL, Ismael; DOB 1955; Minister of Finance

(individual) [SYRIA]. AL-SHAMMAT, Kinda; DOB 1973; POB Damascus, Syria; Minister of Social Affairs (individual) [SYRIA]. HIJAZI, Hassan; DOB 1964; POB Quneitra, Syria; Minister of Labor (individual) [SYRIA]. TEMPBANK (a.k.a. MAB TEMPBANK OAO; a.k.a. MOSCOW JOINT-STOCK BANK TEMPBANK OPEN JOINT-STOCK COMPANY; a.k.a. OTKRYTOE AKTSIONERNOE OBSHCHESTVO MOSKOVSKI AKTSIONERNY BANK TEMPBANK), 36/50 Lyusinovskaya ul., Moscow 115093, Russia; SWIFT/BIC TMJSRUMM; Website www.tempbank.ru; Email Address info@tempbank.ru; Registration ID 1027739270294 [SYRIA]. GAGLOEV, Mikhail Georgievich (a.k.a. GAGLOEV, Mikhail; a.k.a. GAGLOYEV, Mikhail Georgiyevich); DOB 17 Feb 1966; citizen Russia; Chairman of the Management Committee, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). BANIAS REFINERY COMPANY, Banias Refinery Building, 26 Latkia Main Road, Baniyas, Tartous, Syria; Banias Refinery Building, Latkia Main Road, Banias Industrial Area, Banias, Tartous, Syria; Postal Box 26, Tartous, Syria; P.O. Box 26, Banias, Syria [SYRIA]. HOMS REFINERY COMPANY (a.k.a. GENERAL COMPANY FOR HOMS REFINERY), General Company for Homs Refinery Building, 352 Tripoli Street, Homs, Syria; P.O. Box 352, Trablus (Tripoli) Street, Homs, Syria; Postal Box 352, Homs, Syria [SYRIA]. AGRICULTURAL COOPERATIVE BANK (a.k.a. AL MASRAF AL ZERAEI AL TAWENI; a.k.a. "ACB"), Al Naanaa Garden, Damascus, Syria; Postal Box 4325, Damascus, Syria; Tall, Damascus, Syria; Doma, Doma, Syria; Zabadani, Damascus, Syria; Katana, Damascus, Syria; Al Qatifa, Damascus, Syria; Nabek, Damascus, Syria; Yabrood, Damascus, Syria; Daria, Damascus, Syria; Alksoaa, Damascus, Syria; Al Qounaitra, Syria; Deraa, Syria; Azraa, Syria; Alsnmin, Syria; Gazallah, Syria; Nawa, Syria; Sweida, Syria; Shahba, Sweida, Syria; Salkhad, Sweida, Syria; Algaria, Sweida, Syria; Homs, Syria; Talkah, Homs, Syria; Tadmer, Homs, Syria; Al Rastan, Homs, Syria; Al Qasser, Homs, Syria; Shin, Homs, Syria; Agricultural Cooperative Bank Building, Damascus Tajhez, 4325, Damascus, Syria; Website www.agrobank.gov.sy [SYRIA]. INDUSTRIAL BANK, Dar Al Muhanisen Building, 7th Floor, Maysaloun Street, P.O. Box 7572, Damascus, Syria; P.O. Box 7578, 29 Maysaloun Street, Damascus, Syria; Jamal Abd Al Nasser Street, Al Hasaka, Syria; P.O. Box 50, Masarif Building, Sweida, Syria; Near the Big Mosque, Aleppo, Syria; Hama, Syria; Ibn Kholdoun Street, Homs, Syria; P.O. Box 8, Jules Jamal Street, Deraa, Syria; P.O. Box 2359, 29 Ayaar Street, Damascus, Syria; P.O. Box 25069, Harbaka, Damascus, Syria; P.O. Box 10, Rif Dimashq, Daraya, Damascus, Syria; P.O. Box 82, Rif Dimashq, Yabrood, Damascus, Syria; Website www.industrialbank.gov.sy [SYRIA]. SAVING BANK (f.k.a. THE GENERAL ESTABLISHMENT OF MAIL SAVING FUND; f.k.a. THE POST SAVING FUND; a.k.a. "SAVINGS BANK"), Amous Square, Damascus, Syria; P.O. Box: 5467, Al-Furat St., Merjeh, Damascus, Syria [SYRIA]. POPULAR CREDIT BANK (a.k.a. "PCB"), Dar El-Mohandeseen- Mysaloun St., P.O. Box: 2841, Damascus, Syria; P.O. Box 2841, Maysaloun Street, Damascus, Syria; Dar Al Mouhandseen Building, 6th Floor, Maysaloun Street, Dar Al Mohandessin Area, Damascus 2841, Syria [SYRIA]. RIDA, Batoul; DOB 01 Jun 1982; citizen Syria (individual) [SYRIA]. ORFALI, Khodr (a.k.a. ORPHALI, Khedr; a.k.a. ORPHALY, Khodr; a.k.a. ORPHALY, Khudr; a.k.a. URFALI, Khudr); DOB 1956; POB Deir Ezzor, Syria; Minister of Economy and Foreign Trade (individual) [SYRIA]. TU'MA, Kamal Eddin (a.k.a. TOUMA, Kamal Eddin; a.k.a. TU'MA, Kamal Al-Din); DOB 1959; POB Damascus, Syria; Minister of Industry (individual) [SYRIA]. PIRUSETI ENTERPRISES LTD, 1 Logothetou Street, Nicosia 4034, Cyprus; 118 Anexartisias Street, Suite 202, Limassol 3040, Cyprus; Logothetou 1, Germasogeia, Limassol, Cyprus; Registration

ID C290894; alt. Registration ID IIE 290894 [SYRIA]. FRUMINETI INVESTMENTS LTD., Logothetou, 1, Germasogeia, Limassol 4043, Cyprus; Registration ID HE 291043 [SYRIA]. AL-ZEYDI, Issa (a.k.a. AL-ZAYDI, Issa); DOB 07 Feb 1939; POB Russia; nationality Russia; Passport 63N9437545 (Russia) (individual) [SYRIA]. GENERAL DIRECTORATE OF SYRIAN PORTS (a.k.a. "GENERAL DIRECTORATE OF PORTS"), Algazaer Street, Lattakia, Syria [SYRIA]. LATTAKIA PORT GENERAL COMPANY (a.k.a. LATAKIA PORT GENERAL COMPANY), BP 220, Latakia, Syria; Postal Box 220, Lattakia, Syria; Baghdad Street, Lattakia, Syria [SYRIA]. TARTOUS PORT GENERAL COMPANY, Al Mina Street, Tartous, Syria; Postal Box 86, Tartous, Syria [SYRIA]. SYRIAN GENERAL AUTHORITY FOR MARITIME TRANSPORT (a.k.a. SYRIAMAR; a.k.a. SYRIAN GENERAL ESTABLISHMENT FOR MARINE TRANSPORT; a.k.a. SYRIAN GENERAL ORGANIZATION FOR MARITIME TRANSPORT), BP 28, Bur Sa'id Street, Latakia, Syria; BP 225, Yarmouk Street, Latakia, Syria; BP 915, al-Mina Street, Tartous, Syria; BP 730, Argentine Street, Damascus, Syria; Port Road, Lattakia, Syria [SYRIA]. SYRIAN SHIPPING AGENCIES COMPANY (a.k.a. "SHIPCO"; a.k.a. "SHIPPING AGENCIES CO."), Port Said Street, P.O. Box 28, Lattakia, Syria; Port Street, P.O. Box 3, Tartous, Syria; Joul Jammal Street, P.O. Box 28, Banias, Syria; Brazil Street, P.O. Box 12477, Damascus, Syria [SYRIA]. SYRIAN CHAMBER OF SHIPPING (a.k.a. "SCOS"), Al Jazaeer Street, Farid Hanna Bldg, 8th Fl., P.O. Box 1731, Lattakia, Syria; Al Mina Street, Tartous, Syria [SYRIA]. FINIKIA; Vessel Registration Identification IMO 9385233 (vessel) [SYRIA] (Linked To: SYRIAN GENERAL AUTHORITY FOR MARITIME TRANSPORT). LAODICEA; Vessel Registration Identification IMO 9274343 (vessel) [SYRIA] (Linked To: SYRIAN GENERAL AUTHORITY FOR MARITIME TRANSPORT). SOURIA; Vessel Registration Identification IMO 9274331 (vessel) [SYRIA] (Linked To: SYRIAN GENERAL AUTHORITY FOR MARITIME TRANSPORT). THE EAGLES L.L.C. (a.k.a. THE EAGLES INTERNATIONAL LLC), Plot No. 41, Airport Free Trade Zone, Damascus, Syria [SYRIA] (Linked To: ABDULKARIM, Wael; Linked To: ABDULKARIM GROUP). MORGAN ADDITIVES MANUFACTURING CO. (a.k.a. MORGAN MIDDLE EAST LLC), Office No. 2206, 22nd Floor, Jafza View 19, Sheikh Zayed Road Besides Jafza View 18, Jebel Ali Free Zone Authority, Dubai, United Arab Emirates; Suite 13, First Floor, Oliaji Trade Centre, Francis Rachel Street, Victoria, Mahe, Seychelles; Website www.morganme.com; alt. Website morgan.ae [SYRIA] (Linked To: ABDULKARIM, Wael). MILENYUM ENERGY S.A. (a.k.a. MILENYUM DENIZCILIK GEMI; a.k.a. MILENYUM DENIZCILIK GEMI HIZMETLERI ACENTELIK VE OZEL OGRETIM HIZMETLERI LIMITED SIRKETI; a.k.a. MILENYUM SHIPPING), c/o Milenyum Denizcilik Gemi H., Hizmetleri Ltd. Sti, Nazli Sokak 9, Halilrifatpasa Mah, Sisli, Istanbul 34384, Turkey; Ataturk Mahallesi Gulay Sokak, No. 12/3, Atasehir, Istanbul, Turkey; No. 18 D. 1 Kemankes Mah. Necatibey Cad., Akce Sok., Karakoy, Istanbul, Turkey; Sierra Leone; Avenida Norte Enrique Geenzeier El Cangrejo, Panama 0834-1082, Panama; Website http://www.milenyumshipping.com; Company Number 792313 (Panama) [SYRIA] (Linked To: ABDULKARIM, Wael; Linked To: ABDULKARIM GROUP). EBLA TRADE SERVICES S.A.L./OFF-SHORE, Beirut, Lebanon; Nakhle Center, Property Number: 295/24, Baabda, Furn, Chebbak, Lebanon [SYRIA] (Linked To: MILENYUM ENERGY S.A.; Linked To: BLUE ENERGY TRADE LTD. CO.). KENAR, Ufuk, Turkey; DOB 24 Apr 1980 (individual) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). DUZGOREN, Serkan, Turkey; DOB 28 Jan 1979 (individual) [SYRIA] (Linked To: MILENYUM ENERGY S.A.).

DUZGOREN, Erkan, Turkey; DOB 17 Jun 1980 (individual) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). AYDIN, Mustafa, Turkey; DOB 26 May 1988; Passport U04663595 (Turkey) (individual) [SYRIA] (Linked To: MILENYUM ENERGY S.A.; Linked To: BLUE ENERGY TRADE LTD. CO.; Linked To: ABDULKARIM GROUP). GREEN SHIPPING LTD., c/o Milenyum Denizcilik Gemi Hizmetleri Acentelik ve Ozel Ogretim Hizmetleri Ltd. Sti, Nazli Sokak 9, Halilrifatpasa Mah, Sisli, Istanbul 34384, Turkey; Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro, Marshall Islands; Identification Number IMO 5848165 [SYRIA] (Linked To: MILENYUM ENERGY S.A.). AQUA SHIPPING LTD. (a.k.a. AQUA SHIPPING LTD.-MAI), c/o Milenyum Denizcilik Gemi Hizmetleri Acentelik ve Ozel Ogretim Hizmetleri Ltd. Sti, Nazli Sokak 9, Halilrifatpasa Mah, Sisli, Istanbul 34384, Turkey; Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro, Marshall Islands; Identification Number IMO 5849194 [SYRIA] (Linked To: MILENYUM ENERGY S.A.). TALA Panama flag; Vessel Registration Identification IMO 8012114 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). BLUE DREAM Saint Kitts and Nevis flag; Vessel Registration Identification IMO 8002664 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). BLUE WAY Panama flag; Vessel Registration Identification IMO 8800298 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). BLUEGAS Sierra Leone flag; Vessel Registration Identification IMO 7909839 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). GREEN LIGHT Panama flag; Vessel Registration Identification IMO 8810700 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.; Linked To: GREEN SHIPPING LTD.). AQUA Sierra Leone flag; Vessel Registration Identification IMO 7529641 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.; Linked To: AQUA SHIPPING LTD.). MARIANA Sierra Leone flag; Vessel Registration Identification IMO 8016835 (vessel) [SYRIA] (Linked To: MILENYUM ENERGY S.A.). BLUE ENERGY TRADE LTD. CO., P.O. Box 556, Charlestown, Saint Kitts and Nevis [SYRIA] (Linked To: MILENYUM ENERGY S.A.). HUDSOTRADE LIMITED, 118 Anexartisias Street, Suite 202, Limassol 3040, Cyprus; 14 Gubkina Street, Moscow, Moscow Region 117312, Russia; Website http://www.primax.com.cy; Registration ID C81329 (Cyprus) [SYRIA] (Linked To: KHURI, Mudalal; Linked To: NICOLAOU, Nicos; Linked To: PRIMAX BUSINESS CONSULTANTS LIMITED). EZEGOO INVESTMENTS LTD, 1 Logothetou, Lemesos 4043, Cyprus; National ID No. C310521 (Cyprus) [SYRIA] (Linked To: KHURI, Mudalal; Linked To: NICOLAOU, Nicos; Linked To: PRIMAX BUSINESS CONSULTANTS LIMITED). RUSSIAN FINANCIAL ALLIANCE BANK (a.k.a. OPEN JOINT STOCK COMPANY JOINT STOCK COMMERCIAL BANK 'RUSSIAN FINANCIAL ALLIANCE'; a.k.a. RFA BANK; a.k.a. "AKB RFA, OAO"; a.k.a. "OJSC JSCB RFA"), per. Maly Karetny, d. 11-13, str. 1, Moscow 127051, Russia; SWIFT/BIC MNGRRUMM; Website www.rfabank.ru; all offices worldwide [SYRIA] (Linked To: KHURI, Mudalal; Linked To: ILYUMZHINOV, Kirsan Nikolayevich). TIZINI, Nabil (a.k.a. TAZINI, Nabil); DOB 02 Jun 1968; nationality Syria; Passport N009894266; UAE Identification 784-1968-9720837-5; Position: Financial Manager at Hesco Engineering and Construction Ltd in Moscow (individual) [SYRIA] (Linked To: ARBASH, Yusuf; Linked To: HESCO ENGINEERING & CONSTRUCTION CO). KHOURI, Atiya (a.k.a. AL-KHURI, Attiyah; a.k.a. AL-KHURY, Atiyah; a.k.a. KHOURY, Attiyah; a.k.a. KHURI, Atiyah; a.k.a. KIIURI, Attiyah; a.k.a. KIIURY, Attiyah); DOB 25 Jul 1971; POB Homs, Syria; citizen Syria (individual) [SYRIA] (Linked To: MAKHLUF, Rami; Linked To: SYRIATEL; Linked To: MAYALEH, Adib). ALI, Aous (a.k.a. AL-ALI,

Aous; a.k.a. ALI, Aus; a.k.a. ALI, Aws); DOB 15 Feb 1977; POB Damascus, Syria; citizen Syria (individual) [SYRIA] (Linked To: MAKHLUF, Rami). MONETA TRANSFER AND EXCHANGE (a.k.a. MONETA EXCHANGE COMPANY; a.k.a. MONETA MONEY EXCHANGE; a.k.a. MONETA MONEY TRANSFER & EXCHANGE; a.k.a. MONETA TRANSFER & EXCHANGE), Damascus, Syria [SYRIA] (Linked To: KHOURI, Atiya; Linked To: MAKHLUF, Rami; Linked To: SYRIATEL; Linked To: MAYALEII, Adib). E.K.-ULTRA FINANCIAL GROUP LIMITED, Anexartisias, 118, Floor 1, Flat 101, Limassol 3040, Cyprus; Registration ID HE 242159 [SYRIA] (Linked To: NICOLAOU, Nicos). ARGUS CONSTRUCTION, P.O. Box 556, Main Street, Charlestown, Saint Kitts and Nevis [SYRIA] (Linked To: ABDULKARIM, Wael). SYRIAN ARAB ARMY, Damascus, Syria [SYRIA]. SYRIAN ARAB AIR DEFENSE FORCES, Damascus, Syria [SYRIA]. SYRIAN ARAB NAVY, Damascus, Syria [SYRIA]. SYRIAN ARAB REPUBLICAN GUARD, Damascus, Syria [SYRIA]. SYRIAN AIR FORCE, Damascus, Syria [SYRIA]. HAMDAN, Mamun (a.k.a. HAMDAN, Dr. Maamoun; a.k.a. HAMDAN, Dr. Mamoun); DOB 1958; POB Damascus, Syria; Minister of Finance (individual) [SYRIA]. GHANEM, Ali; DOB 1963; POB Damascus, Syria; Minister of Oil; Minister of Petroleum and Mineral Wealth; Minister of Petroleum and Mineral Resources (individual) [SYRIA]. AL-ZAFIR, Ali (a.k.a. AL-DAFEER, Ali); DOB 1962; POB Tartous, Syria; Minister of Communications and Technology; Minister of Telecommunications and Technology (individual) [SYRIA]. TURJUMAN, Muhammad Ramiz (a.k.a. TARJAMAN, Ramez; a.k.a. TORGAMAN, Mohammed Ramez; a.k.a. TOURJMAN, Mohammed Ramez; a.k.a. TOURJUMAN, Mohamed Ramez; a.k.a. TURGEMAN, Mohammed Ramez); DOB 1966; POB Damascus, Syria; Minister of Information (individual) [SYRIA]. AL-HAMO, Ahmad (a.k.a. AL-HAMU, Ahmad; a.k.a. HAMOU, Ahmed); DOB 1947; Minister of Industry (individual) [SYRIA]. HAMMUD, Ali (a.k.a. HAMMOUD, Ali; a.k.a. HAMOUD, Ali); DOB 1964; POB Tartous, Syria; Minister of Transport (individual) [SYRIA]. MUHANNA, Adib (a.k.a. MHANNA, Adib; a.k.a. MOUHANNA, Adib; a.k.a. MUHANA, Adib); DOB 1983; POB Syria; nationality Syria; Passport 3141732 (Syria) (individual) [SYRIA] (Linked To: MAKHLUF, Rami). APANASENKO, Elena (a.k.a. APANASENKO, Elena Mikhailovna); DOB 19 Sep 1970; Deputy Chairman, Executive Board, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). AKHLOMOV, Nikolay (a.k.a. AKHLOMOV, Nikolay Vasilyevich); DOB 25 Apr 1960; Deputy Chairman, Executive Board, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). KOZHENKOVA, Irina (a.k.a. KOZHENKOVA, Irina Vyacheslavovna); DOB 16 Nov 1973; Deputy Chairman, Executive Board, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). DUBINYAK, Andrey (a.k.a. DUBINYAK, Andrey Grigoryevich); DOB 19 Apr 1948; Chairman of Supervisory Board, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). ZHIROVA, Elena (a.k.a. ZHIROVA, Elena Borisnova); DOB 1963; Supervisory Board Member, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). MITYAEV, Dmitriy (a.k.a. MITYAEV, Dmitriy Arkadyevich); DOB 20 May 1966; Supervisory Board Member, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). RESHETNIKOV, Leonid (a.k.a. RESHETNIKOV, Leonid Petrovich); DOB 06 Feb 1947; Supervisory Board Member, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). SYRISS (a.k.a. GUANGZHOU SYRISS LOGISTICS & SERVICES; a.k.a. SYRISS GROUP LIMITED; a.k.a. SYRISS LOGISTICS AND SERVICE COMPANY), Head Office, Suite 707, Oriental Finance Building, 140 Dong Feng Xi Road, Guangzhou 510000, China; Marine Logistics Office, Suite 912, Nan You Building, 142 Dongfeng Xi Road, Guangzhou, China; Air

Logistics Office, Suite 419, Nan You Building, 142 Dongfeng Xi Road, Guangzhou, China; Marine Warehouse, Baiyun Area, ShiJing Town, 20 Qingfeng Qinglong Road, Guangzhou, China; Baramkeh Free Zone, Damascus, Syria; Jebel Ali Free Zone, W.H. # WF06, Jebel Ali, United Arab Emirates; Ras Al Khor Industrial 3, Warehouse # 2, Al Aweer, United Arab Emirates; Exit 19 Al Manakh area , W.H. # 364, Riyadh, Saudi Arabia [SYRIA] (Linked To: YONA STAR INTERNATIONAL). GAGLOEV, Vladimir (a.k.a. GAGLOEV, Vladimir Georgyevich; a.k.a. GAGLOYEV, Vladimir Georgiyevich); DOB 14 Jan 1974; Supervisory Board Member, Tempbank (individual) [SYRIA] (Linked To: TEMPBANK). HAMDAN, Ahmad, Syria; DOB 15 Mar 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SAFTALI, Ghassan, Syria; DOB 20 Feb 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-HURANI, Haytham Ahmad, Syria; DOB 05 Jan 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-IBRAHIM, Muhammad, Syria; DOB 08 Mar 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HASAN, Bilal, Syria; DOB 01 Jan 1978; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DARWISH, Ali, Syria; DOB 02 Mar 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUHANNA, Siwumar, Syria; DOB 03 Dec 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. RASHID, Badr, Syria; DOB 01 Jan 1987; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ISMA'IL, Ayham, Syria; DOB 20 Jan 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ALYA, Mazin, Syria; DOB 28 Feb 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-FAQIR, Muhammad Samir, Syria; DOB 21 Jan 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-TAWWAKHI, Iman, Syria; DOB 04 Mar 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-JIBAWI, Ridwan 'Ali, Syria; DOB 25 Mar 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JAWISH, Samar Shakir, Syria; DOB 01 May 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JIRJIS, Hiyam, Syria; DOB 07 Oct 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-JABI, Salma, Syria; DOB 02 Apr 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-TAQI, Rim Nadir, Syria; DOB 15 Sep 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'AZBAH, Hana, Syria; DOB 15 Feb 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HASAN, As'ad, Syria; DOB 24 Dec 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-AKHRAS, Safwan, Syria; DOB 27 Jan 1950; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HASAN, Ammar, Syria; DOB 01 Jul 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BABA, Samiya, Syria; DOB 26 Feb 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HUDBAH, Amin, Syria; DOB 09 Nov 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-ATASI, Yumna Marwan al-Sayyid Sulayman, Syria; DOB 07 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-DARWISH, Tamam, Syria; DOB 23 Jul 1969; nationality

Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KHAYMI, Abir 'Abd-al-Karim, Syria; DOB 01 Dec 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-DAWUD, Nariman, Syria; DOB 16 Feb 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ALLUSH, Ridwan Hasan, Syria; DOB 20 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABDALLAH, Sayyar, Syria; DOB 15 May 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUSTAFA, Fayiz, Syria; DOB 01 Jan 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-KHATIB, Ridwan, Syria; DOB 03 Sep 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AYYUBI, Rashid, Syria; DOB 25 Jul 1954; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NASR, Isa, Syria; DOB 20 Apr 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NASIF, Saba, Syria; DOB 12 Sep 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NAJJAR, Wafa', Syria; DOB 01 May 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SHAWWA, Ghayth, Syria; DOB 13 Apr 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HIMSI, Muhammad Riyad, Syria; DOB 08 Nov 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-TABBAL, Saba, Syria; DOB 08 Apr 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABBAS, Rim, Syria; DOB 25 Mar 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALLUM, Muhammad, Syria; DOB 31 Oct 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SASI, Jumanah, Syria; DOB 05 Oct 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-RAYS, Hassan, Syria; DOB 03 Nov 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SA'ID, Nidal, Syria; DOB 18 Apr 1976; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SA'UD, Yunus, Syria; DOB 01 Apr 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SINDID, Sa'id, Syria; DOB 27 Nov 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NASR, Muhammad Sayyah, Syria; DOB 23 Aug 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HUSAYN, 'Ali, Syria; DOB 20 Mar 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KIWAN, Rula, Syria; DOB 10 May 1974; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'AQQAD, Ziyad, Syria; DOB 02 Aug 1950; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MUDALLAL, Muhammad Zuhayr, Syria; DOB 24 May 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-JUBBAH, Adnan, Syria; DOB 11 Apr 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SHAYKH, Diyab, Syria; DOB 11 Dec 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZA'RURAH, Fadiyah, Syria; DOB 26 Jan 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SIRHAN, Hala, Syria; DOB 05 Jan 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-DAGHISTANI, Muzayyin, Syria; DOB 03 Apr 1959;

nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MANSUR, Khalil, Syria; DOB 11 Mar 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. RABAH, Zuhayr, Syria; DOB 07 Jan 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SA'ID, Sa'id, Syria; DOB 11 Dec 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-BURSIIAII, Muhammad Akram, Syria; DOB 30 Aug 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZARIFAH, Ahmad, Syria; DOB 09 Nov 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABD-AL-JALIL, Yahya, Syria; DOB 26 Sep 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'ASALI, Zakariya, Syria; DOB 03 Jun 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. QATTAN, Maysa', Syria; DOB 25 Feb 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DA'UD, Lu'ay, Syria; DOB 13 Oct 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-HUSAYN, Mashhur, Syria; DOB 01 Jan 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-IIAKIM, Muhammad Sa'id, Syria; DOB 01 Apr 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SULAYMAN, Akram, Syria; DOB 14 Apr 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. TALLUJ, Muhammad Ghassan, Syria; DOB 15 Jan 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. QATISH, Firiyal, Syria; DOB 26 Jan 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. YUSUF, Muhammad Hisham Fu'ad, Syria; DOB 29 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. FARMAND, Sa'id, Syria; DOB 10 Oct 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HUSAYN, Muhammad, Syria; DOB 25 Feb 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SUKIIAYTAII, Muhammad Khayr, Syria; DOB 18 May 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BIZRAH, Muhammad, Syria; DOB 12 Mar 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BUZ-AL-JUDDI, Fayiz, Syria; DOB 22 Feb 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KHABIYYAH, Muna, Syria; DOB 01 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. YUSUF, Muhsin, Syria; DOB 17 May 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DAYYUB, Rajab, Syria; DOB 01 Jan 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-DALATI, Ayman, Syria; DOB 20 Aug 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-IIALABI, Basil, Syria; DOB 01 Feb 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZANBU'AH, Mahmud, Syria; DOB 30 Jul 1974; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-RASLAN, Abd-al-Salam, Syria; DOB 17 Nov 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HAWWAT, Muhammad, Syria; DOB 10 Mar 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-ID, Nawras, Syria; DOB 13 Aug 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. RAHHAL, Mahmud,

Syria; DOB 25 Jun 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'ALI, Salih, Syria; DOB 05 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MASRI, Ahd, Syria; DOB 01 May 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MAJRUD, Amin, Syria; DOB 03 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DUMIT, Salim, Syria; DOB 11 Jul 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABDU, Hikmat, Syria; DOB 12 Mar 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DAHIR, Ahmad, Syria; DOB 20 Jun 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALIM, Iyad, Syria; DOB 12 Dec 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ASMAR, Haytham, Syria; DOB 02 Nov 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-HARIRI, Musa, Syria; DOB 19 Jun 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MAHFUD, Farhan, Syria; DOB 11 Sep 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DAYYUB, Tha'ir, Syria; DOB 01 Dec 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ALI, Isma'il, Syria; DOB 20 Jun 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHARBA, Muzhir, Syria; DOB 23 Feb 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MIRDASH, Misbah, Syria; DOB 02 Jan 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BU'AYTI, Faysal, Syria; DOB 01 Jan 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'ALI, Zakariya, Syria; DOB 05 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SULAYMAN, Taysir, Syria; DOB 22 Aug 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. FU'ANI, Lu'ay, Syria; DOB 02 Apr 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HUSAYN, Hanan, Syria; DOB 20 Apr 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JUM'AH, Hamid, Syria; DOB 01 Mar 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-JANAN, Sulsubayla, Syria; DOB 04 Jan 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MA'TUQ, Yusuf, Syria; DOB 30 May 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BUNDUQJI, Rana, Syria; DOB 09 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SAQR, Rana, Syria; DOB 01 Oct 1979; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JALAL, Husam-al-Din, Syria; DOB 01 Aug 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SHA'IR, Samir, Syria; DOB 12 Sep 1978; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SA'ID, Majd, Syria; DOB 25 Nov 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DUWAYR, Ruba, Syria; DOB 19 Apr 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALMAN, Muhammad, Syria; DOB 03 Mar 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUSTAFA, Ayham Hajj, Syria; DOB 16 Aug 1984; nationality Syria;

Scientific Studies and Research Center Employee (individual) [SYRIA]. LAYLA, Susan, Syria; DOB 12 Jul 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MASRI, Rahf, Syria; DOB 05 Oct 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-FAWAKHIRI, Ghusn al-Zuhur, Syria; DOB 01 Jan 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZAYDAN, Mustafa, Syria; DOB 09 Jan 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALMAN, Shadi, Syria; DOB 26 Oct 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-WADI, Anas, Syria; DOB 21 May 1987; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SA'ADAH, Ruwaydah, Syria; DOB 10 Feb 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. FADUL, Farhub, Syria; DOB 15 Jul 1951; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-NA'IMI, Muhammad Iyad, Syria; DOB 29 Oct 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-HARZRURI, Mahmubd, Syria; DOB 19 Nov 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JAZBAII, Ibrahim Sa'd Zayn-al-'Abidin, Syria; DOB 02 Apr 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-NAJJAR, Qasim, Syria; DOB 01 Feb 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DABBAGH, Muhammad Nazmi 'Ulwani, Syria; DOB 01 Jan 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABDU, Abdallah, Syria; DOB 05 Dec 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ASWAD, Ali, Syria; DOB 10 Nov 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. LABABIDI, Sa'dallah 'Atif, Syria; DOB 22 Sep 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHAHT, Jamal Zaydan, Syria; DOB 06 Feb 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IIILALI, Muhammad Jalal, Syria; DOB 10 Nov 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-RAHHAL, Muhammad, Syria; DOB 01 Mar 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUSHRIF, Amir, Syria; DOB 10 Jun 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZIIIAR, Muhammad Nadim Subhi, Syria; DOB 29 Mar 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-BAKKUR, 'Abd-al-'Azim, Syria; DOB 14 Nov 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DAWARAH, Ahmad, Syria; DOB 21 Feb 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BASHA, Imad Isma'il, Syria; DOB 12 May 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BASAL, Abd-al-Rahman, Syria; DOB 03 Mar 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BITAR, Ahd, Syria; DOB 23 Jun 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUHAMMAD, Faysal, Syria; DOB 20 Feb 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ANIS, Samih, Syria; DOB 19 Jul 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NUR-AL-DIN, Imad, Syria; DOB 29 Jul 1955; nationality Syria; Scientific Studies and

Research Center Employee (individual) [SYRIA]. IIIJAZI, Umar, Syria; DOB 01 Jun 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-AQRA', Jamal 'Ali, Syria; DOB 17 Apr 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. LULAH, Ziyad Ramadan, Syria; DOB 01 Jan 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SABUNI, Ahmad, Syria; DOB 23 Dec 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AHMAD, Hasan, Syria; DOB 13 May 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SHAYKH, Muhammad, Syria; DOB 08 Mar 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. QANBAR, Khalid Zaki, Syria; DOB 20 Apr 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALIM, Ahmad, Syria; DOB 29 Aug 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HALLAQ, As'ad 'Adnan, Syria; DOB 08 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHUNATI, Haytham, Syria; DOB 04 Jun 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HUSAYN, Wahid, Syria; DOB 01 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. RABI', Mustafa Dib, Syria; DOB 10 Nov 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KHALUF, Faysal, Syria; DOB 21 May 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JAHHAR, Hannan, Syria; DOB 02 Jan 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUIIAMMAD, 'Ali IIajj, Syria; DOB 05 Mar 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-RAHYAH, Fadi, Syria; DOB 27 Dec 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABDALLAH, Muhammad, Syria; DOB 05 Apr 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. QURJU, Muhammad Mu'ammar, Syria; DOB 02 Aug 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HAMANDUSH, Muhammad, Syria; DOB 09 Jan 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JUNDIYAH, Abdallah, Syria; DOB 01 Nov 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MA'RUF, Abd-al-Salam, Syria; DOB 04 Apr 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SA'DU, Muhammad, Syria; DOB 20 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ASWAD, Ahmad, Syria; DOB 21 Aug 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'AZIZI, Fu'ad, Syria; DOB 28 Mar 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALIM, Muhammad Ayman Nasir-al-Din, Syria; DOB 23 Jun 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HAMSHU, Hudu' Nayif, Syria; DOB 08 Jan 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. QUDAYMATI, Muhammad Ridwan, Syria; DOB 12 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUHAYIRI, Muhammad Nasir, Syria; DOB 29 Nov 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABBUD, Hikmat, Syria; DOB 01 Jan 1966; nationality Syria; Scientific Studies and Research Center Employee (individual)

[SYRIA]. SAQR, Sinan, Syria; DOB 15 Apr 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IBRAHIM, Fu'ad 'Abd-al-Qadir, Syria; DOB 24 Nov 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JAWISH, Husayn Rida, Syria; DOB 07 Apr 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NAJIB, Ahmad, Syria; DOB 04 Oct 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MUHAMMAD, Muhammad, Syria; DOB 02 Feb 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IDRIS, Ibrahim, Syria; DOB 05 Apr 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ARAFAT, Muhammad, Syria; DOB 28 Jul 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DAYRI, Ammar, Syria; DOB 06 Mar 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. WARDAH, Bassam, Syria; DOB 20 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'UBAYSI, Mus'id, Syria; DOB 01 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HAJJI, Muhammad Fawzi, Syria; DOB 25 Jun 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-FAKHURI, Husam 'Adbd-al-Barr, Syria; DOB 10 Feb 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. TABAQ, Qasim, Syria; DOB 01 May 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHI'AR, Muhammad 'Azzam, Syria; DOB 02 Sep 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IIAFIZ, Abdallah, Syria; DOB 27 Jun 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABD-AL-QADIR, Abd-al-'Aziz, Syria; DOB 01 Feb 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ALI, Samir, Syria; DOB 12 May 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-KIIUWAYLID, Ibrahim, Syria; DOB 25 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHURAYQI, 'Abd-al-Salam, Syria; DOB 14 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KHASHAFI, Muhammad al-Khalid, Syria; DOB 21 May 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHURUF, 'Abd-al-Hakim, Syria; DOB 25 Apr 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-ISMA'IL, Zakariya 'Ali, Syria; DOB 14 Aug 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MATAR, 'Abdu Tahir, Syria; DOB 17 Oct 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. DIB, Mashhur, Syria; DOB 20 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-QUTMAII, Akram, Syria; DOB 04 Dec 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. TURAYSI, Muhammad Wa'il, Syria; DOB 14 Feb 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HAMAWI, Ahmad, Syria; DOB 15 Jul 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-YUSUF, Samir al-Ahmad, Syria; DOB 02 May 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ALI, Muhammad, Syria; DOB 01 Aug 1979; nationality Syria; Scientific Studies and Research Center

Employee (individual) [SYRIA]. SIIA'BAN, Basil, Syria; DOB 25 Jan 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NAJJAR, Muhammad Amin, Syria; DOB 08 Nov 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NI'MA, Rashid Rashid, Syria; DOB 01 Dec 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABD-AL-WAHHAB, Ahmad, Syria; DOB 01 Jan 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUSATTIT, Sabir Khayr, Syria; DOB 20 Feb 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-AHMAD, Riyad, Syria; DOB 15 Mar 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-BAYKU, Husayn-Ahmad, Syria; DOB 10 May 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JIJAII, Jalal-al-Din 'Adil, Syria; DOB 20 Jan 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SHUAYHANAH, Hadil, Syria; DOB 20 May 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KARIM, Malik 'Adil, Syria; DOB 16 May 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KIIALALU, Ahmad, Syria; DOB 01 Jan 1978; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ID, Nisrin Bubhi, Syria; DOB 26 May 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HAITANI, Muhammad, Syria; DOB 03 Sep 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. WAFA'I, Diya', Syria; DOB 07 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BAWADUQJI, Nur-al-Din, Syria; DOB 07 Jan 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MALA'IKAH, Usamah Ramadan, Syria; DOB 27 Aug 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUSA, Firas, Syria; DOB 13 Jul 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MAIIMUD, Khalid, Syria; DOB 20 Sep 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MIRKAN, Anas 'Adil, Syria; DOB 01 Jul 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KALALAH, Husam-al-Din Walid, Syria; DOB 04 Jan 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SA'ID, Wasim, Syria; DOB 02 Jan 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. HARIRI, Muhammad, Syria; DOB 27 Aug 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KITU', 'Abd-al-Latif, Syria; DOB 28 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALIM, Firas Hajj, Syria; DOB 10 May 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. TAIIA, IIusam a-Sahykh, Syria; DOB 14 Jan 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. NA'SANI, Jawdat, Syria; DOB 08 Jun 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-BAKUR, Khalid, Syria; DOB 25 Jan 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-HUSAYN, Suhayr, Syria; DOB 17 Feb 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ULAYSHAH, Rana, Syria; DOB 25 Oct 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-FIRAS, Muhsin, Syria;

DOB 20 Jan 1979; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SHURAYQI, Isma'il, Syria; DOB 14 Jul 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IBRAHIM, 'Ali, Syria; DOB 25 Mar 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-ISMA'IL, Ammar Fu'ad, Syria; DOB 25 Sep 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'AWDAII, Nasim, Syria; DOB 19 Feb 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-SILMU, Ahmad al-Hasan, Syria; DOB 28 Jun 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IBRAHIM, Ali, Syria; DOB 28 Feb 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'ABD, Ahmad, Syria; DOB 28 Jan 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JUKHDAR, 'Ala'-al-Din, Syria; DOB 03 Mar 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SA'ADAT, Bashar, Syria; DOB 16 Jul 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AS'AD, Murad, Syria; DOB 28 Jan 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-'AYSII, Khalid al-IIajj Muhammad, Syria; DOB 05 Jun 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JADDU', Ahd, Syria; DOB 22 Apr 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. KHADDUR, Hasan, Syria; DOB 26 Aug 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUKIIAYBIR, Salma, Syria; DOB 21 Jul 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. QURJU, Jihad-al-Din, Syria; DOB 22 Aug 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZAMR, 'Abd-al-Nasir Ibbi, Syria; DOB 01 Jul 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-KHUDAYR, Muhammad 'Arif al-Hasan, Syria; DOB 05 Sep 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. JUMUL, Ali, Syria; DOB 07 Feb 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SALMAN, Wasim, Syria; DOB 05 May 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SULAYMAN, Dayma, Syria; DOB 29 Sep 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. BASIIA, Ahmad Nadir Ibrahim, Syria; DOB 15 Apr 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MUSTAFA, Ibrahim, Syria; DOB 06 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-LAYIQ, Baha', Syria; DOB 31 Aug 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. TAHA, Jamilah, Syria; DOB 09 Oct 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. FARAJ, Hala, Syria; DOB 22 Mar 1987; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. AL-MUKAHHAL, Aminah, Syria; DOB 01 Jan 1988; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. ZAYD, Hasan Muhammad, Syria; DOB 15 Feb 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. MAWAS, Milad, Syria; DOB 25 Dec 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. 'ABUD, Ahmad, Syria; DOB 28 May 1984; nationality Syria;

Scientific Studies and Research Center Employee (individual) [SYRIA]. MAKHLUF, Ihab (a.k.a. MAKHLOUF, Ehab; a.k.a. MAKHLOUF, Iehab; a.k.a. MAKHLOUF, Ihab), Damascus, Syria; DOB 21 Jan 1973; Gender Male; Passport N002848852 (individual) [SYRIA] (Linked To: MAKHLUF, Rami). AL-AJNIHAH (a.k.a. AJJNEHA; a.k.a. AL-AGNEHA COMPANY; a.k.a. AL-AJNIHAH PRIVATE JOINT STOCK CORPORATION), Damascus, Syria [SYRIA] (Linked To: ABBAS, Muhammad). SONEX INVESTMENTS LTD. (a.k.a. SONEX INVESTMENTS LIMITED; a.k.a. SONNEX INVESTMENTS LTD.), P.O. Box 7191, Dubai, United Arab Emirates [SYRIA] (Linked To: SYRIAN COMPANY FOR OIL TRANSPORT). AL-QATIRJI, Muhammad (a.k.a. AL-QATIRJI, Bara'; a.k.a. KATARJI, Bara'; a.k.a. KHATARJI, Bara Ahmad; a.k.a. KHATIRJI, Bara Ahmad; a.k.a. QATARJI, Abu al-Bara'; a.k.a. QATIRJI, Muhammad Bara'; a.k.a. QATIRJI, Muhammad Bara; a.k.a. QATIRJI, Muhammad Bara Ahmad Rushdi; a.k.a. QATRJI, Muhammad Nur al-Din; a.k.a. "Abu Bara"); DOB 10 Nov 1976; POB Raqqah; nationality Syria; Gender Male; National ID No. 11010046398 (Syria); Registration Number 11824466 (Syria) (individual) [SYRIA]. INTERNATIONAL PIPELINE CONSTRUCTION FZE, Fujairah, United Arab Emirates [SYRIA] (Linked To: HESCO ENGINEERING & CONSTRUCTION CO). MENA CRYSTAL SUGAR COMPANY LIMITED (a.k.a. M.E.N.A. CRYSTAL SUGAR COMPANY; a.k.a. M.E.N.A. SUGAR COMPANY; a.k.a. MENA SUGAR COMPANY), Homs, Syria [SYRIA] (Linked To: AMAN HOLDING COMPANY). MAINPHARMA (a.k.a. MEENPHARMA), Syria [SYRIA] (Linked To: AMAN HOLDING COMPANY). AL-MOHAIMEN FOR TRANSPORTING & CONTRACTING (a.k.a. AL MOHAIMEN FOR TRANSPORTATION AND CONTRACTING; a.k.a. AL-MOHAIMEN FOR TRANSPORTING AND CONTRACTING), Lattakia, Syria [SYRIA] (Linked To: AMAN HOLDING COMPANY). FOUR SEASONS DAMASCUS (a.k.a. DAMASCUS FOUR SEASONS; a.k.a. FOUR SEASONS HOTEL DAMASCUS), Shukri Al Quatli Street, P.O. Box 6311, Damascus, Syria [SYRIA] (Linked To: FOZ, Samer). DAMASCUS CHAM HOLDING COMPANY (Arabic: شركة دمشق الشام القابضة) (a.k.a. DAMASCUS CHAM HOLDING PRIVATE JSC; a.k.a. DAMASCUS CHAM PRIVATE JOINT STOCK COMPANY), Marota City, Eastern Villas, Mazeh, Damascus 096311, Syria; Organization Established Date 17 Dec 2016; Business Registration Number 17951 (Syria) [SYRIA]. APEX DEVELOPMENT AND PROJECTS LLC (Arabic: شركة القمة للتطوير والمشاريع المحدودة المسؤولية) (a.k.a. AL 'QIMA DEVELOPMENT AND PROJECTS LLC; a.k.a. SUMMIT DEVELOPMENT AND PROJECTS LLC), Rural Damascus, Syria; Organization Established Date 17 Jan 2018; Organization Type: Real estate activities with own or leased property [SYRIA] [SYRIA-CAESAR]. KALAI INDUSTRIES (Arabic: قلعي للصناعات) (a.k.a. KALAI INDUSTRIES MANAGEMENT; a.k.a. MOHAMMED KALAI), Dara Autostrad (Amman Highway), Kessweh, 500m after the Katakir Bridge, Damascus, Syria; Organization Established Date 1990; Registration Number 38372 (Syria) [SYRIA] (Linked To: KALAI, Nader). GRAND TOWN TOURIST CITY (Arabic: غراند تاون المدينة السياحة) (a.k.a. GRAND TOWN; a.k.a. GRAND TOWN TOURISM PROJECT (Arabic: مشروع غراند تاون السياحي); a.k.a. ZK GRAND TOWN), Airport Road, after the Fourth Bridge, Damascus, Syria; Website www.facebook.com/ZKGrandTown/; Organization Established Date 2017; Organization Type: Real estate activities on a fee or contract basis [SYRIA]. TELEFOCUS SAL OFFSHORE (Arabic: تيليفوكوس ش.م.ل.)اوف شور), Mir Bachir St, Riad El Solh, Beirut, Lebanon; 7th Floor-Riad-Solh Lazarieh Tower, Beirut, Lebanon; 1470 Bachoura - Azaria Building - 7th Floor, Beirut, Lebanon; Registration Number 1802940 (Lebanon) [SYRIA] (Linked To: KALAI, Nader). TELEFOCUS

CONSULTANTS INC (a.k.a. TELEFOCUS CONSULTANTS INC CANADA), 871 Young Ave, Halifax, Nova Scotia B3H 2V8, Canada; Commercial Registry Number 3234614 (Canada) [SYRIA] (Linked To: KALAI, Nader). ZUBAIDI AND QALEI LLC (Arabic: شركة زبيدي وقلعي المحدودة المسؤولية) (a.k.a. ZUBEDI & KALAI; a.k.a. ZUBEDI AND KALAI; a.k.a. "ZK HOLDING"), Airport Road, Damascus, Syria; P.O. Box 6416, Damascus, Syria; Organization Type: Real estate activities on a fee or contract basis [SYRIA]. CASTLE INVESTMENT HOLDING (Arabic: شركة كاسل إنفست هولدنغ ش.م.ل.) (a.k.a. CASTLE INVEST HOLDING COMPANY SAL; a.k.a. CASTLE INVEST HOLDING SAL; a.k.a. CASTLE INVESTMENT HOLDING PRIVATE JSC; a.k.a. "CASTLE HOLDINGS"), West Mazzeh, Damascus, Syria; First Floor, Sami Saleh Avenue, Beirut, Lebanon; Registration Number 1900127 (Lebanon) [SYRIA] (Linked To: KALAI, Nader). EBLA HOTEL (Arabic: فندق إيبلا) (a.k.a. EBLA HOTEL AND OMAYAD PALACE FOR CONFERENCES), Airport Road - 4th Bridge, Damascus, Syria; P.O. Box 6416, Damascus, Syria; Organization Established Date 1989; Organization Type: Short term accommodation activities].SYRIA[KALAI, Nader (Arabic: نادر قلعي) (a.k.a. AL KALAI, Nadir; a.k.a. KALAI, Nader Mohamad; a.k.a. KALAI, Nader Mohammed Wajieh; a.k.a. KALEI, Nader; a.k.a. QALAI, Nader; a.k.a. QALEI, Nader), 871 Young Avenue, Halifax, Nova Scotia B3H 2V8, Canada; Ain El Mraisse, Beirut, Lebanon; Saifi Street, Jemayzeh, Beirut, Lebanon; Capsurville, Dekwaneh, El Metn Jemayzeh, Beirut, Lebanon; Ghrayeb Bldg, Sami Soloh St, Badaro, Beirut, Lebanon; DOB 09 Jul 1965; POB Damascus, Syria; nationality Syria; alt. nationality Canada; Gender Male; Passport N 010170320 (Syria); National ID No. 010-40036453 (Syria); alt. National ID No. 34191608 (Canada) (individual) [SYRIA] [SYRIA-CAESAR]. DAMASCUS CHAM FOR MANAGEMENT LLC (Arabic: دمشق الشام الادارة) (a.k.a. DAMASCUS CHAM MANAGEMENT CO. LTD.; a.k.a. DAMASCUS CHAM MANAGEMENT ONE-PERSON CO. LTD.), Marota City, Eastern Villas, Mazeh, Damascus 096311, Syria; Organization Established Date 2018; Organization Type: Real estate activities with own or leased property [SYRIA] (Linked To: DAMASCUS CHAM HOLDING COMPANY). BUNYAN DAMASCUS PRIVATE JOINT STOCK COMPANY (Arabic: شركة بنيان دمشق المساهمة المغلفة الخاصة) (a.k.a. BUNYAN DAMASCUS), Marota City, Eastern Villas, Mazeh, Damascus 096311, Syria; Organization Established Date Apr 2018; Organization Type: Construction of buildings; alt. Organization Type: Real estate activities with own or leased property [SYRIA] (Linked To: DAMASCUS CHAM HOLDING COMPANY). MIRZA COMPANY (Arabic: شركة ميرزا) (a.k.a. MIRZA CO.), Marota City, Eastern Villas, Mazeh, Damascus 096311, Syria; Organization Established Date 14 Jan 2018; Organization Type: Construction of buildings; alt. Organization Type: Real estate activities with own or leased property [SYRIA] (Linked To: DAMASCUS CHAM HOLDING COMPANY). AL-OLABI, Adel Anwar (Arabic: عادل انور العلبي) (a.k.a. AL-OLABI, Adil Anwar; a.k.a. AL-'ULABI, 'Adel Anwar; a.k.a. EL-OULABI, Adel Anouar), Damascus, Syria; DOB 1976; POB Damascus, Syria; nationality Syria; Gender Male (individual) [SYRIA]. RAWAFED DAMASCUS PRIVATE JOINT STOCK COMPANY (Arabic: شركة روافد دمشق المساهمة المغفلة الخاصة) (a.k.a. RAWAFED DAMASCUS INVESTMENTS COMPANY; a.k.a. RAWAFED DAMASCUS PRIVATE JSC; a.k.a. RAWAFID DAMASCUS PRIVATE JOINT STOCK COMPANY; a.k.a. TRIBUTARIES DAMASCUS PRIVATE JSC), Marota City, Damascus, Syria; Organization Established Date 08 Apr 2018; Organization Type: Real estate activities with own or leased property; alt. Organization Type: Construction of buildings [SYRIA]. AL-AMAR ONE-PERSON LLC (Arabic: شركة العمار ذات الشخص الواحد المحدودة المسؤولية ("), a.k.a. AL-AMMAR LLC ONE PERSON COMPANY; a.k.a. "AL-AMMAR(

Rural Damascus, Syria; Organization Established Date 18 Jan 2017; Organization Type: Real estate activities with own or leased property [SYRIA] [SYRIA-].CAESAR TIMEET TRADING LLC (Arabic: شركة التيميت للتجارة المحدودة المسؤولية) (a.k.a. ULTIMATE TRADING LLC), Rural Damascus, Syria; Organization Type: Real estate activities with own or leased property [SYRIA] [SYRIA-CAESAR]. CASTLE HOLDING GMBH (a.k.a. "CASTLE HOLDING"; a.k.a. "CASTLE HOLDING INVESTMENT"; a.k.a. "CASTLE INVEST"; a.k.a. "CASTLE INVEST HOLDING"), Sieveringerstrasse 164, Vienna 1190, Austria; National ID No. FN292092Y (Austria) [SYRIA] (Linked To: KALAI, Nader). ART HOUSE GMBH, Sieveringerstrasse 164, Vienna 1190, Austria; National ID No. FN292891 y (Austria) [SYRIA] (Linked To: CASTLE HOLDING GMBH). FOURTH DIVISION OF THE SYRIAN ARAB ARMY (Arabic: الفرقة الرابعة في الجيش العربي السوري), Syria [PAARSSR-EO13894]. QASIOUN MALL (Arabic: مول قاسيون) (a.k.a. QASIYUN MALL; a.k.a. QASSIOUN SHOPPING MALL), Barzeh District, Damascus, Syria [SYRIA]. MILITARY CONSTRUCTION ESTABLISHMENT (Arabic: مؤسسة تنفيذ الإنشاءات العسكرية) (a.k.a. MILITARY CONSTRUCTION IMPLEMENTATION CORPORATION; a.k.a. "MATAA" (Arabic: "متاع"); a.k.a. "MCIC"), Kafarsouseh Circle, next to Al-Rafai Mosque, Damascus, Syria; Hama, Syria; Lattakia, Syria; Tartous, Syria; Jableh, Syria; Organization Established Date 1972; Organization Type: Construction of buildings; alt. Organization Type: Construction of roads and railways; alt. Organization Type: Construction of other civil engineering projects [SYRIA]. PRODUCTIVE PROJECTS ADMINISTRATION (Arabic: إدارة المشاريع الإنتاجية) (a.k.a. INTAJIA (Arabic: الانتاجية); a.k.a. INTAJIA PPA), P.O. Box 4703, ; Customs Free Zone, Damascus, Syria; Aleppo, Syria; Website http://intajia.sy Organization Established Date 1973; Organization Type: Manufacture of .pharmaceuticals, medicinal chemical and botanical products [SYRIA] AL-QATTAN, Wassim Anwar (Arabic: وسيم انوار القطان) (a.k.a. AL-KATAN, Wassim Anouar; a.k.a. AL-KATTAN, Waseem; a.k.a. AL-KATTAN, Wasseem; a.k.a. AL-QATAN, Waseem; a.k.a. QATTAN, Waseem; a.k.a. QATTAN, Wasim), Damascus, Syria; DOB 04 Mar 1976; nationality Syria; Gender Male (individual) [SYRIA] [SYRIA-CAESAR]. INTERSECTION LLC (Arabic: شركة نقطة تقاطع), Rural Damascus, Syria; Organization Established Date 11 Mar 2018; Organization Type: Construction of buildings [SYRIA] [SYRIA-CAESAR] (Linked To: AL-QATTAN, Wassim Anwar). AL-JALAA HOTEL (Arabic: فندق الجلاء) (a.k.a. AL-JALA' HOTEL; a.k.a. AL-JALAA), Mazzeh Motorway, Damascus, Syria; Organization Type: Short term accommodation activities [SYRIA]. MASSA PLAZA MALL (a.k.a. AL-MALIKI MALL (Arabic: مول المالكي); a.k.a. MALKI MALL), Malki District, Damascus, Syria [SYRIA]. YALBAGHA COMPLEX (Arabic: مجمع يلبغا) (a.k.a. YALBUGHA COMPLEX; a.k.a. YALBUGHA REAL ESTATE COMPOUND), Damascus, Syria; Organization Type: Short term accommodation activities [SYRIA]. ADAM TRADING AND INVESTMENT LLC (Arabic: شركة ادم التجارة و الاستثمار), Damascus, Syria; Organization Established Date 25 Feb 2018; Organization Type: Real estate activities on a fee or contract basis [SYRIA] [SYRIA-CAESAR] (Linked To: AL-QATTAN, Wassim Anwar). MURUJ CHAM INVESTMENT AND TOURISM GROUP (a.k.a. MUROOJ AL-CHAM INVESTMENT AND TOURISM COMPANY (Arabic: شركة مروج الشام الاستثمار و السياحة); a.k.a. MUROOJ AL-CHAM INVESTMENT AND TOURISM GROUP), 1149 Main Street, Al-Saboura, Damascus, Syria; Organization Established Date 23 Jun 2015; Organization Type: Real estate activities on a fee or contract basis; alt. Organization Type: Construction of buildings [SYRIA] [SYRIA-CAESAR] (Linked To: AL-QATTAN, Wassim Anwar). LAROSA FURNITURE (Arabic: مفروشات

لاروسا) (a.k.a. LAROSA FURNISHING), Damascus, Syria; Organization Type: Manufacture of furniture [SYRIA] (Linked To: AL-QATTAN, Wassim Anwar). WASSIM KATTAN LLC (a.k.a. "TWA LLC" (Arabic: "شركة تي دبلايو ا"); a.k.a. "WK LLC" (Arabic: "شركة دبليو ك")), Rural Damascus, Syria; Organization Established Date 04 Jul 2019; Organization Type: Sale of motor vehicle parts and accessories [SYRIA] (Linked To: AL-QATTAN, Wassim Anwar). FIRST DIVISION OF THE SYRIAN ARAB ARMY (Arabic: الفرقة الأولى الجيش العربي السوري) (a.k.a. "1ST ARMORED DIVISION"; a.k.a. "FIRST ARMORED DIVISION" (Arabic: "الفرقة الأولى المدرعة")), Syria [PAARSSR-EO13894]. AL SHIBL, Luna (Arabic: لونا الشبل) (a.k.a. AL CHEBEL, Luna; a.k.a. AL CHEBIL, Luna; a.k.a. AL SHEBEL, Luna; a.k.a. AL SHEBIL, Luna; a.k.a. AL SHIBIL, Luna; a.k.a. ALSHEBEL, Luna; a.k.a. AL-SHIBL, Luna; a.k.a. CHEBEL, Luna; a.k.a. SHIBL, Luna), Damascus, Syria; DOB 01 Sep 1975; POB Suweida, Syria; alt. POB Damascus, Syria; nationality Syria; Gender Female (individual) [SYRIA]. KARFOUL, Hazem Younes (Arabic: حازم يونس قرفول) (a.k.a. KARFOUL, Hazem (Arabic: حازم قرفول); a.k.a. QARFOUL, Hazem Younes), Damascus, Syria; DOB 09 Jul 1976; POB Tartus, Syria; nationality Syria; Gender Male (individual) [SYRIA]. SYRIAN TRANSPORT AND TOURISM COMPANY (Arabic: الشركة السورية للنقل و السياحة) (a.k.a. SYRIAN TRANSPORT AND TOURISM JSC), Al-Bahsa, Damascus, Syria; Organization Established Date 1952; Organization Type: Tour operator activities; alt. Organization Type: Short term accommodation activities [SYRIA] (Linked To: SYRIAN MINISTRY OF TOURISM). SYRIAN MINISTRY OF TOURISM (Arabic: وزارة السياحة السورية), P.O. Box 6642, Victoria Street, Barada Bank, Damascus, Syria; Kwatli Street, Barada Bank, Damascus 96311, Syria; Website http://www.syriatourism.org; Organization Established Date 1972 [SYRIA]. SYRIAN MINISTRY OF PETROLEUM AND MINERAL RESOURCES (Arabic: وزارة النفط و الثروة المعدنية) (a.k.a. MINISTRY OF OIL AND MINERAL RESERVES), Dummar, P.O. Box 31483, Damascus, Syria; Website http://mopmr.gov.sy/ [SYRIA]. PUBLIC ESTABLISHMENT FOR REFINING AND DISTRIBUTION (Arabic: المؤسسة العامة لتكرير النفط و توزيع المشتقات النفطية) (a.k.a. GENERAL ORGANIZATION FOR REFINING AND DISTRIBUTION OF PETROLEUM PRODUCTS; a.k.a. THE PUBLIC ESTABLISHMENT FOR OIL REFINING AND THE DISTRIBUTION OF OIL DERIVATIVES), Tripoli Road, P.O. Box 342, Homs, Syria; Website http://perd.sy/; Organization Established Date 2009; Organization Type: Support activities for petroleum and natural gas extraction [SYRIA]. NATIONAL DEFENSE FORCES (Arabic: قوات الدفاع الوطني), Damascus, Syria; Organization Established Date 2012 [PAARSSR-EO13894]. AL-KINAYEH, Lina Mohammed Nazir (Arabic: لينا محمد نذير الكناية) (a.k.a. AL-CANAIYA, Leena Muhammad Nathir; a.k.a. AL-KINAYA, Lina Muhammed Nazir; a.k.a. AL-KINAYEH, Leena; a.k.a. AL-KINAYEH, Lina (Arabic: لينا الكناية); a.k.a. AL-KINAYEH, Lina Mohammad Natheer; a.k.a. KINAYEH, Lina (Arabic: لينا كناية); a.k.a. KNAYA, Lina; a.k.a. KNIYA, Lina), Al-Zahiriya, Northern Tripoli, Lebanon; DOB 20 Jan 1980; nationality Lebanon; alt. nationality Syria; Gender Female; National ID No. 000036055655 (Lebanon) (individual) [SYRIA]. CENTRAL BANK OF SYRIA (Arabic: مصرف سوريا المركزي) (a.k.a. BANQUE CENTRALE DE SYRIE; a.k.a. MASRIF SOURIYA AL-MARKAZI), P.O. Box 2254, Altajrida Al Mughrabia Square, Damascus, Syria; Sabaa Bahrat Square, Damascus, Syria; SWIFT/BIC CBSYSYDA; Organization Established Date 28 Mar 1953; alt. Organization Established Date 01 Aug 1956; Organization Type: Central banking [SYRIA]. SYRIAN MILITARY INTELLIGENCE BRANCH 290 - ALEPPO BRANCH (a.k.a. "BRANCH 290"), Aleppo, Syria [SYRIA] (Linked To: SYRIAN MILITARY INTELLIGENCE

DIRECTORATE). SYRIAN MILITARY INTELLIGENCE BRANCH 215 - RAIDS (a.k.a. "BRANCH 215" (Arabic: "215 الفرع"); a.k.a. "BRANCH 215: RAIDS COMPANY" (Arabic: "سرية المداهمة والاقتحام"); a.k.a. "KAFRSOUSA BRANCH"; a.k.a. "RAIDS COMPANY" (Arabic: "فرع سرية المداهمة")), Syria; 6th of May Street, Damascus, Syria [SYRIA] (Linked To: SYRIAN MILITARY INTELLIGENCE DIRECTORATE).. SYRIAN MILITARY INTELLIGENCE BRANCH 216 (Arabic: 216 الفرع) (a.k.a. "BRANCH 216: PATROLS BRANCH" (Arabic: "فرع الدوريات")), Damascus, Syria [SYRIA] (Linked To: SYRIAN MILITARY INTELLIGENCE DIRECTORATE). SYRIAN MILITARY INTELLIGENCE BRANCH 227 - AL MINTAQA BRANCH (Arabic: رع المنطقة) (a.k.a. "AL-MINTAQA"; a.k.a. "AL-MINTAQA BRANCH 227"; a.k.a. "BRANCH 227" (Arabic: "227 الفرع"); a.k.a. "BRANCH 227: DAMASCUS GOVERNORATE BRANCH"), 6th of May Street, Damascus, Syria [SYRIA] (Linked To: SYRIAN MILITARY INTELLIGENCE DIRECTORATE). SYRIAN MILITARY INTELLIGENCE BRANCH 235 - PALESTINE (a.k.a. "BRANCH 235" (Arabic: "235 الفرع"); a.k.a. "BRANCH 235: PALESTINE BRANCH" (Arabic: "فرع فلسطين")), Damascus, Syria [SYRIA] (Linked To: SYRIAN MILITARY INTELLIGENCE DIRECTORATE). SYRIAN MILITARY INTELLIGENCE BRANCH 248 - INVESTIGATION (Arabic: فرع التحقيق; Arabic: 248 فرع) (a.k.a. BRANCH 248 MILITARY INTELLIGENCE (Arabic: فرع التحقيق العسكري)), Al Tawajoh Street, Alsyasi Street, 6th of May Street, Damascus, Syria [SYRIA] (Linked To: SYRIAN MILITARY INTELLIGENCE DIRECTORATE). SYRIAN GENERAL INTELLIGENCE BRANCH 251 - AL-KHATIB (a.k.a. "AL-KHATEEB BRANCH" (Arabic: "فرع الخطيب"); a.k.a. "BRANCH 251" (Arabic: "251 الفرع"); a.k.a. "BRANCH 251-AL-KHATEEB"; a.k.a. "THE INTERIOR BRANCH" (Arabic: "الفرع الداخلي")), al-Khatib area of Baghdad Street, Damascus, Syria [SYRIA] (Linked To: SYRIAN GENERAL INTELLIGENCE DIRECTORATE). AL-MINALA, Muhammad 'Ali, Damascus, Syria; DOB 03 Jun 1985; POB Damascus, Syria; nationality Syria; Gender Male (individual) [SYRIA] (Linked To: CENTRAL BANK OF SYRIA). TOUMEH BIN MOHAMMED, Nabil (Arabic: نبيل طعمة بن محمد) (a.k.a. MOHAMMED TOHMA, Nabil (Arabic: نبيل محمد طعمة); a.k.a. TOUMEH, Nabil; a.k.a. TU'MAH, Nabil; a.k.a. "BIN MOHAMMED TOAMEH, Nabil"; a.k.a. "TOHMA, Nabil" (Arabic: "نبيل طعمة")), Damascus, Syria; DOB 04 Jan 1957; POB Damascus, Syria; nationality Syria; Gender Male (individual) [SYRIA]. CHAM ISLAMIC BANK (a.k.a. AL-CHAM ISLAMIC BANK; a.k.a. CHAM BANK), Al-Najmeh Square, Damascus, Syria; All offices worldwide [SYRIA]. BARQAWI, Ahmad (a.k.a. AL-BARQAWI, Ahmad; a.k.a. BARQAWI, Ahmad Abed Allah; a.k.a. BARQAWI, Ahmad Abedallah; a.k.a. BARQAWI, Ahmed; a.k.a. "BARQAWI, Hamodeh"), Dubai, United Arab Emirates; DOB 1985; POB Damascus, Syria; General Manager, Pangates International Corp. Ltd.; General Manager, Maxima Middle East Trading Co. (individual) [SYRIA] (Linked To: PANGATES INTERNATIONAL CORPORATION LIMITED; Linked To: MAXIMA MIDDLE EAST TRADING CO.). AL-ZUBAIDI, Khaled (Arabic: خالد الزبيدي) (a.k.a. AL-ZUBAIDI, Khaled Bassam; a.k.a. AL-ZUBAIDI, Mohammed Khaled Bassam; a.k.a. ZUBAIDI, Mohammed Khaled; a.k.a. ZUBEDI, Khalid), Syria; Canada; DOB 10 Apr 1976; nationality Syria; alt. nationality Canada; Gender Male; Passport N 006540969 (Syria); alt. Passport HC246053 (Canada) (individual) [SYRIA] [SYRIA-CAESAR]. 'ALI, Muhammad, Syria; DOB 30 Aug 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. SYRIA INTERNATIONAL ISLAMIC BANK (a.k.a. SIIB; a.k.a. SYRIAN INTERNATIONAL ISLAMIC BANK), Syria International Islamic Building , Main Highway Road, Al Mazzeh

Area, P.O. Box 35494, Damascus , Syria; PO Box 35494, Mezza'h Vellat Sharqia'h, beside the Saudi Arabia Consulate , Damascus , Syria; SWIFT/BIC SIIBSYDA; all offices worldwide [NPWMD]. MAKAROV, Aleksey (a.k.a. MAKAROV, Alexey), Russia; DOB 06 Aug 1974; nationality Russia; Gender Male; Passport 753533725 (Russia) expires 03 Aug 2026 (individual) [SYRIA] [SYRIA-CAESAR] (Linked To: CENTRAL BANK OF SYRIA). LETIA COMPANY (Arabic: شركة ليتيا) (a.k.a. LETIA JOINT-STOCK COMPANY L.L.C.; a.k.a. LETIA LIMITED LIABILITY COMPANY; a.k.a. LITIA COMPANY), Damascus, Syria; Organization Established Date 10 Jan 2019; Organization Type: Manufacture of medical and dental instruments and supplies [SYRIA]. PRIMAX BUSINESS CONSULTANTS LIMITED, 118 Anexartisias Street, 2nd Floor, Apt/Office 202, Limassol, Cyprus; Registration ID HE 143062 (Cyprus) [SYRIA] (Linked To: KHURI, Mudalal; Linked To: NICOLAOU, Nicos). IMAD AL-DIN AL-MADANI, Kamal (Arabic: كمال عمد الدين المدني) (a.k.a. AMAD AL-DIN AL-MADANI, Kamal; a.k.a. IMAD AL-DEEN AL-MADANI, Kamal), Beirut, Lebanon; DOB 08 Dec 1980; nationality Lebanon; Gender Male (individual) [SYRIA]. AL-HASAN, Abdallah, Syria; DOB 15 Jun 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA]. IMAD AL-DIN AL-MADANI, Tariq (Arabic: طارق عماد الدين المدني) (a.k.a. AMAD AL-DIN AL-MADANI, Tariq; a.k.a. IMAD AL-DEEN AL-MADANI, Tarek; a.k.a. IMAD AL-DIN AL-MADANI, Tareq), Beirut, Lebanon; DOB 12 Dec 1984; nationality Lebanon; Gender Male (individual) [SYRIA]. NASCO POLYMERS & CHEMICALS CO SAL (OFF-SHORE) (a.k.a. NASCO POLYMERS & CHEMICALS; a.k.a. NASCO POLYMERS AND CHEMICALS), 2nd Floor, Nasco Center, Unesco Street, Unesco Sector, Beirut, Lebanon; Postal Box 1800629, Beirut, Lebanon; 2nd Flr, Unesco Center, Verdun Street, Beirut, Lebanon; Website www.nascopolymers.com; Registration Number 1800629; International Maritime Organization No. (5777731) [SYRIA] (Linked To: SYRIAN COMPANY FOR OIL TRANSPORT). SYNERGY SAL OFFSHORE, Azarieh street - Azarieh building, Beirut, Lebanon [SYRIA]. NASSER, Fadi Nabih (a.k.a. NASSER, Fadi), Nasser Building, Menchieh Area, Bourj Brajneh (Baabda), Lebanon; DOB 19 Nov 1963; nationality Lebanon; Gender Male; Passport RL2432659 (Lebanon) issued 22 Jan 2013 expires 22 Jan 2018; alt. Passport RL1239879 (Lebanon) expires 05 Mar 2013; Chairman of Nasco Polymers & Chemicals Co. Sal (Off-shore) (individual) [SYRIA] (Linked To: NASCO POLYMERS & CHEMICALS CO SAL (OFF-SHORE); Linked To: SYRIAN COMPANY FOR OIL TRANSPORT). ABAR PETROLEUM SERVICE SAL (a.k.a. ABAR PETROLEUM SERVICE SAL (OFFSHORE); a.k.a. ABAR PETROLEUM SERVICES LTD SAL (OFFSIIORE)), Azarieh Building, Block 03, 5th floor, Azarieh Street, Beirut, Lebanon [SYRIA]. DURGHAM, Dureid (a.k.a. DERGHAM, Douraid; a.k.a. DERGHAM, Duraid); DOB 1964; Governor of the Central Bank of Syria (individual) [SYRIA]. ILYUMZHINOV, Kirsan Nikolayevich (a.k.a. ILYUMZHINOV, Kirsan); DOB 05 Apr 1962; POB Elista, Republic of Kalmykia, Russia (individual) [SYRIA] (Linked To: MAYALEH, Adib; Linked To: RIDA, Batoul). ABDULKARIM, Wael (a.k.a. ABDULKARIM, Mohammad Wael), Dubai, United Arab Emirates; DOB 1973; POB Damascus, Syria; nationality Syria; Managing Director, Pangates International Corp. Ltd.; General Manager, Pangates International Corp. Ltd.; Director, Abdulkarim Group (individual) [SYRIA] (Linked To: PANGATES INTERNATIONAL CORPORATION LIMITED; Linked To: ABDULKARIM GROUP). MAXIMA MIDDLE EAST TRADING CO., P.O. Box 122925, Sharjah Airport International Free Zone, SAIF Lounge, Sharjah, United Arab Emirates; Suite 13, First Floor Oliaji Trade Centre, Francis Rachel Street, Victoria, Mahe, Seychelles [SYRIA] (Linked To:

ABDULKARIM GROUP; Linked To: PANGATES INTERNATIONAL CORPORATION LIMITED). TOUMEH INTERNATIONAL GROUP (Arabic: مجموعة طعمة الدولية), Damascus, Syria; Organization Established Date 1975; Organization Type: Activities of holding companies [SYRIA] (Linked To: TOUMEH BIN MOHAMMED, Nabil). ABDULKARIM GROUP (a.k.a. ABD-AL-KARIM GROUP; a.k.a. ALKARIM FOR TRADE & INDUSTRY L.L.C.; a.k.a. ALKARIM FOR TRADE AND INDUSTRY; a.k.a. MOHD. WAEL ABDULKARIM & PARTNERS CO.; a.k.a. WAEL ABDULKARIM AND PARTNERS), Abu Rumaneh, Ibn Al Haytham St., Besides Indian Embassy, Building No. 7, 1st Floor, Office No. 5, Damascus, Syria; Jaber Bin Hayan St. No. 162, Akkad & Sufi Bldg No. 1, 1st Floor, Damascus, Syria; P.O. Box 5797, Damascus, Syria; P.O. Box 30693, Damascus, Syria; Adra-Tal El Kordi Triangle PC, Damascus 30693, Syria; Riyad El Solh Street, Beirut 12347, Lebanon; Website abdulkarimgroup.com [SYRIA] (Linked To: PANGATES INTERNATIONAL CORPORATION LIMITED). PANGATES INTERNATIONAL CORPORATION LIMITED, P.O. Box 8177, Sharjah Airport International Free Zone, Sharjah, United Arab Emirates; Office Y-47, Sharjah Airport International Free Zone, Sharjah, United Arab Emirates; P.O. Box 5797, Damascus, Syria; Website www.pangates-me.com; Email Address info@pangates-me.com; alt. Email Address pangates@emirates.net.ae [SYRIA]. NICOLAOU, Nicos; DOB 06 Apr 1965; POB Cyprus; nationality Cyprus (individual) [SYRIA] (Linked To: PIRUSETI ENTERPRISES LTD; Linked To: KHURI, Mudalal).

C. In line with E.O. 14312, on June 30, 2025, OFAC updated the names of 28 persons who were designated pursuant to the SySR, in addition to other sanctions authorities. While these persons remain on the SDN List pursuant to other sanctions authorities, they are no longer designated pursuant to the SySR and their listings no longer reflect the SYRIA tag. The names and relevant sanctions authorities are listed at the URL below and may be distinguished from persons designated on the same day through the inclusion of a sanctions program tag *other than or in addition to* [PAARSSR–EO13894]: *https://ofac.treasury.gov/recent-actions/20250630.*

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2025–13277 Filed 7–15–25; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on U.S. Individual Income Tax Returns and Related Forms, Schedules, Attachments, and Published Guidance

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Information Collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before September 15, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Include ''OMB Control No. 1545–0074'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: View the latest drafts of the tax forms related to the information collection listed in this notice at *https://www.irs.gov/draft-tax-forms*. Requests for additional information or copies of this collection should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Tax Compliance Burden

Tax compliance burden is defined as the time and money taxpayers spend to comply with their tax filing responsibilities. Time-related activities include recordkeeping, tax planning, gathering tax materials, learning about the law and what you need to do, and completing and submitting the return. Out-of-pocket costs include expenses such as purchasing tax software, paying

a third-party preparer, and printing and postage. Tax compliance burden does not include a taxpayer's tax liability, economic inefficiencies caused by sub-optimal choices related to tax deductions or credits, or psychological costs.

Proposed PRA Submission to OMB

Title: U.S. Individual Income Tax Returns and Related Forms, Schedules, Attachments, and Published Guidance.

OMB Number: 1545–0074.

Form Numbers: Form 1040 and all related forms, schedules, and attachments.

Abstract: IRC sections 6011 & 6012 of the Internal Revenue Code require individuals to prepare and file income tax returns annually. These forms, schedules, and attachments are used by individuals to report their income tax liability. This information collection covers the burden associated with preparing and submitting individual income tax returns and related forms, schedules, and attachments, and complying with published guidance.

Current Actions: There have been changes in regulatory guidance related to various forms approved under this approval package during the past year. There have been additions and removals of forms included in this approval package. It is anticipated that these changes will have an impact on the overall burden and cost estimates requested for this approval package, however these estimates were not finalized at the time of release of this notice. These estimated figures are expected to be available by the release of the 30-day comment notice from Treasury. This approval package is being submitted for renewal purposes.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or Households.

Preliminary Estimated Number of Respondents: 170,100,000.

Preliminary Estimated Time Per Respondent (Hours): 12 hrs. 37 mins.

Preliminary Estimated Total Annual Time (Hours): 2,146,000,000.

Preliminary Estimated Total Annual Monetized Time ($): 47,122,000,000.

Preliminary Estimated Total Out-of-Pockets Costs ($): 50,575,000,000.

Preliminary Estimated Total Monetized Burden ($): 97,697,000,000.

Note: Total Monetized Burden = Out-of-Pocket Costs + Monetized Time

Approved: July 14, 2025.

Ronald J. Durbala,

IRS Tax Analyst.

Appendix–A: Forms and Schedules

INDIVIDUAL TAX FORMS

[View the latest drafts of the tax forms related to the information collection listed in this notice at *https://www.irs.gov/draft-tax-forms.*]

Form No.	Form name	Form No.	Form name
1040	U.S. Individual Income Tax Return	7220	Prevailing Wage and Apprenticeship (PWA) Verification and Corrections.
1040(SP)	U.S Individual Income Tax Return (Spanish version)	8082	Notice of Inconsistent Treatment or Administrative Adjustment Request (AAR).
Schedule 1 (1040)	Additional Income and Adjustments to Income	8275	Disclosure Statement.
Schedule 1(SP) (1040(SP))	Additional Income and Adjustments to Income in Spanish.	8275–R	Regulation Disclosure Statement.
Schedule 2 (1040)	Additional Taxes	8283	Noncash Charitable Contributions.
Schedule 2(SP) (1040(SP))	Additional Taxes (Spanish version)	8332	Release/Revocation of Release of Claim to Exemption for Child by Custodial Parent.
Schedule 3 (1040)	Additional Credits and Payments	8379	Injured Spouse Allocation.
Schedule 3(SP) (1040(SP))	Additional Credits and Payments (Spanish version)	8396	Mortgage Interest Credit.
1040–C	U.S. Departing Alien Income Tax Return	8404	Interest Charge on DISC-Related Deferred Tax Liability.
1040 X	Amended U.S. Individual Income Tax Return	8453	U.S. Individual Income Tax Transmittal for an IRS e-file Return.
1040 NR	U.S. Nonresident Alien Income Tax Return	8453(SP)	U.S. Individual Income Tax Transmittal for an IRS e-file Return (Spanish version).
1040 NR(SP)	U.S. Nonresident Alien Income Tax Return (Spanish Version).	8582	Passive Activity Loss Limitation.
Schedule NEC (1040NR)	Tax on Income Not Effectively Connected with a U.S. Trade or Business.	8582–CR	Passive Activity Credit Limitations.
Schedule NEC(SP) (1040NR(SP)).	Tax on Income Not Effectively Connected with a U.S. Trade or Business (Spanish Version).	8586	Low-Income Housing Credit.
Schedule A (1040NR)	Itemized Deductions	8594	Asset Acquisition Statement Under Section 1060.
Schedule A(SP) (1040NR(SP)).	Itemized Deductions (Spanish Version)	8606	Nondeductible IRAs.
Schedule OI (1040NR)	Other Information	8609–A	Annual Statement for Low-Income Housing Credit.
Schedule OI(SP) (1040NR(SP)).	Other Information (Spanish Version)	8611	Recapture of Low-Income Housing Credit.
Schedule P (1040NR)	Gain or Loss of Foreign Persons from Sale or Exchange of Certain Partnership Interests.	8615	Tax for Certain Children Who Have Unearned Income.
1040–PR	U.S. Self-Employment Tax Return (Including the Additional Child Tax Credit for Bona Fide Residents of Puerto Rico) (Puerto Rico Version).	8621	Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund.
1040–SR	U.S. Tax Return for Seniors	8621–A	Return by a Shareholder Making Certain Late Elections to End Treatment as a Passive Foreign Investment Company.
1040–SR (SP)	Tax Return for Seniors (Spanish version)	8689	Allocation of Individual Income Tax to the U.S. Virgin Islands.
1040–SS	U.S. Self-Employment Tax Return (Including the Additional Child Tax Credit for Bona Fide Residents of Puerto Rico).	8697	Interest Computation Under the Look-Back Method for Completed Long-Term Contracts.
1040–SS (SP)	U.S. Self-Employment Tax Return (Including the Additional Child Tax Credit for Bona Fide Residents of Puerto Rico) (Spanish Version).	8801	Credit for Prior Year Minimum Tax-Individuals, Estates, and Trusts.
Schedule A (1040)	Itemized Deductions	8814	Parents' Election to Report Child's Interest and Dividends.
Schedule B (1040)	Interest and Ordinary Dividends	8815	Exclusion of Interest from Series EE and I U.S. Savings Bonds Issued After 1989.

INDIVIDUAL TAX FORMS—Continued

[View the latest drafts of the tax forms related to the information collection listed in this notice at *https://www.irs.gov/draft-tax-forms.*]

Form No.	Form name	Form No.	Form name
Schedule C (1040)	Profit or Loss from Business	8818	Optional Form to Record Redemption of Series EE and I U.S. Savings Bonds Issued After 1989.
Schedule C(SP) (1040(SP))	Profit or Loss from Business (Spanish Version)	8820	Orphan Drug Credit.
Schedule D (1040)	Capital Gains and Losses	8824	Like-Kind Exchanges.
Schedule E (1040)	Supplemental Income and Loss	8826	Disabled Access Credit.
Schedule EIC (1040)	Earned Income Credit	8828	Recapture of Federal Mortgage Subsidy.
Schedule EIC(SP) (1040(SP)).	Earned Income Credit (Spanish version)	8829	Expenses for Business Use of Your Home.
Schedule F (1040)	Profit or Loss from Farming	8833	Treaty-Based Return Position Disclosure Under Section 6114 or 7701(b).
Schedule F(SP) (1040(SP))	Profit or Loss from Farming (Spanish Version)	8834	Qualified Electric Vehicle Credit.
Schedule H (1040)	Household Employment Taxes	8835	Renewable Electricity, Refined Coal, and Indian Coal Production Credit.
Schedule H(SP) (1040(SP))	Household Employment Taxes (Spanish Version)	8838	Consent to Extend the Time to Assess Tax Under Section 367-Gain Recognition Agreement.
Schedule H(PR) (1040)	Household Employment Taxes (Puerto Rico Version)	8838–P	Consent To Extend the Time To Assess Tax Pursuant to the Gain Deferral Method (Section 721(c)).
Schedule J (1040)	Income Averaging for Farmers and Fishermen	8839	Qualified Adoption Expenses.
Schedule LEP (1040)	Request for Change in Language Preference	8840	Closer Connection Exception Statement for Aliens.
Schedule LEP (SP) (1040(SP)).	Request for Change in Language Preference (Spanish Version).	8843	Statement for Exempt Individuals and Individuals with a Medical Condition.
Schedule R (1040)	Credit for the Elderly or the Disabled	8844	Empowerment Zone Employment Credit.
Schedule SE (1040)	Self-Employment Tax	8845	Indian Employment Credit.
Schedule SE (SP) (1040(SP)).	Self-Employment Tax (Spanish Version)	8846	Credit for Employer Social Security and Medicare Taxes Paid on Certain Employee Tips.
1040 V	Payment Voucher	8853	Archer MSA's and Long-Term Care Insurance Contracts.
1040 ES/OCR	Estimated Tax for Individuals (Optical Character Recognition with Form 1040V).	8854	Initial and Annual Expatriation Statement.
1040 ES	Estimate Tax for Individuals	8858	Information Return of U.S. Persons with Respect to Foreign Disregarded Entities (FDEs) and Foreign Branches (FBs).
1040 ES (NR)	U.S. Estimated Tax for Nonresident Alien Individuals	Schedule M (8858).	Transactions Between Foreign Disregarded Entity (FDE) or Foreign Branch (FB)and the Filer or Other Related Entities.
1040 ES (PR)	Estimated Federal Tax on Self Employment Income and on Household Employees (Residents of Puerto Rico).	8859	Carryforward of the District of Columbia First-Time Homebuyer Credit.
Schedule 8812 (1040)	Credits for Qualifying Children and Other Dependents	8862	Information to Claim Earned Income Credit After Disallowance.
Schedule 8812(SP) (1040(SP)).	Credits for Qualifying Children and Other Dependents (Spanish version).	8862(SP)	Information to Claim Earned Income Credit After Disallowance (Spanish Version).
172	Net Operating Losses (NOLs) for Individuals, Estates, and Trusts.	8863	Education Credits (American Opportunity and Lifetime Learning Credits).
461	Limitation on Business Losses	8864	Biodiesel and Renewable Diesel Fuels Credit.
673	Statement for Claiming Exemption from Withholding on Foreign Earned Income Eligible for the Exclusion(s) Provided by Section 911.	8865	Return of U.S. Persons with Respect to Certain Foreign Partnerships.
926	Return by a U.S. Transferor of Property to a Foreign Corporation.	Schedule K–1 (8865).	Partner's Share of Income, Deductions, Credits, etc..
965–A	Individual Report of Net 965 Tax Liability	Schedule K–2 (8865).	Partners' Distributive Share Items—International.
965–C	Transfer Agreement Under 965(h)(3)	Schedule K–3 (8865).	Partner's Share of Income, Deductions, Credits, etc. International.
970	Application to Use LIFO Inventory Method	Schedule O (8865).	Transfer of Property to a Foreign Partnership (Under section 6038B).
972	Consent of Shareholder to Include Specific Amount in Gross Income.	Schedule P (8865).	Acquisitions, Dispositions, and Changes of Interests in a Foreign Partnership.
982	Reduction of Tax Attributes Due to Discharge of Indebtedness (and Section 1082 Basis Adjustment).	8866	Interest Computation Under the Look-Back Method for Property Depreciated Under the Income Forecast Method.
1045	Application for Tentative Refund	8867	Paid Preparer's Due Diligence Checklist.
1098–F	Fines, Penalties and Other Amounts	8873	Extraterritorial Income Exclusion.
1116	Foreign Tax Credit (Individual, Estate, or Trust)	8874	New Markets Credit.
1127	Application for Extension of Time for Payment of Tax Due to Undue Hardship.	8878	IRS e-file Signature Authorization for Form 4868 or Form 2350.
1128	Application to Adopt, Change or Retain a Tax Year	8878 SP	IRS e-file Signature Authorization for Form 4868 or Form 2350 (Spanish Version).
1310	Statement of Person Claiming Refund Due a Deceased Taxpayer.	8879	IRS e-file Signature Authorization.
2106	Employee Business Expenses	8879 SP	IRS e-file Signature Authorization (Spanish Version).
2120	Multiple Support Declaration	8880	Credit for Qualified Retirement Savings Contributions.
2210	Underpayment of Estimated Tax by Individuals, Estates, and Trusts.	8881	Credit for Small Employer Pension Plan Startup Costs.
2210–F	Underpayment of Estimated Tax by Farmers and Fishermen.	8882	Credit for Employer-Provided Child Care Facilities and Services.
2350	Application for Extension of Time to File U.S. Income Tax Return.	8886	Reportable Transaction Disclosure Statement.
2350 SP	Application for Extension of Time to File U.S. Income Tax Return (Spanish Version).	8888	Allocation of Refund (Including Savings Bond Purchases).
2441	Child and Dependent Care Expenses	8889	Health Savings Accounts (HSAs).

INDIVIDUAL TAX FORMS—Continued

[View the latest drafts of the tax forms related to the information collection listed in this notice at *https://www.irs.gov/draft-tax-forms*.]

Form No.	Form name	Form No.	Form name
2555	Foreign Earned Income	8896	Low Sulfur Diesel Fuel Production Credit.
3115	Application for Change in Accounting Method	8898	Statement for Individuals Who Begin or End Bona Fide Residence in a U.S. Possession.
3468	Investment Credit	8900	Qualified Railroad Track Maintenance Credit.
3520	Annual Return to Report Transactions with Foreign Trusts and Receipt of Certain Foreign Gifts.	8903	Domestic Production Activities Deduction.
3520–A	Annual Information Return of Foreign Trust With a U.S. Owner.	8906	Distilled Spirits Credit.
3800	General Business Credit	8908	Energy Efficient Home Credit.
Schedule A (3800)	Transfer Election Statement	8910	Alternative Motor Vehicle Credit.
3903	Moving Expenses	8911	Alternative Fuel Vehicle Refueling Property Credit.
4070	Employee's Report of Tips to Employer	Schedule A (8911).	Alternative Fuel Vehicle Refueling Property.
4070A	Employee's Daily Record of Tips	8912	Credit to Holders of Tax Credit Bonds.
4136	Credit for Federal Tax Paid on Fuels	8915–C	Qualified 2018 Disaster Retirement Plan Distributions and Repayments.
4137	Social Security and Medicare Tax on Unreported Tip Income.	8915–D	Qualified 2019 Disaster Retirement Plan Distributions and Repayments.
4255	Recapture of Investment Credit	8915–F	Qualified Disaster Retirement Plan Distributions and Repayments.
4361	Application for Exemption from Self-Employment Tax for Use by Ministers, Members of Religious Orders, and Christian Science Practitioners.	8919	Uncollected Social Security and Medicare Tax on Wages.
4562	Depreciation and Amortization (Including Information on Listed Property).	8925	Report of Employer-Owned Life Insurance Contracts.
4563	Exclusion of Income for Bona Fide Residents of American Samoa.	8932	Credit for Employer Differential Wage Payments.
4684	Causalities and Thefts	8933	Carbon Oxide Sequestration Credit.
4797	Sale of Business Property	Schedule A (8933).	Disposal or Enhanced Oil Recovery Owner Certification.
4835	Farm Rental Income and Expenses	Schedule B (8933).	Disposal Operator Certification.
4852	Substitute for Form W–2, Wage and Tax Statement or Form 1099–R, Distributions from Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, etc..	Schedule C (8933).	Enhanced Oil Recovery Operator Certification.
4852(SP)	Substitute for Form W–2, Wage and Tax Statement or Form 1099–R, Distributions from Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, etc. (Spanish Version).	Schedule D (8933).	Recapture Certification.
4868	Application for Automatic Extension of Time to File U.S. Individual Income Tax Return.	Schedule E (8933).	Election Certification.
4868 SP	Application for Automatic Extension of Time to File U.S. Individual Income Tax Return (Spanish Version).	8936	Clean Vehicle Credits.
4952	Investment Interest Expense Deduction	Schedule A (8936).	Clean Vehicle Credit Amount.
4970	Tax on Accumulation Distribution of Trusts	8941	Credit for Small Employer Health Insurance Premiums.
4972	Tax on Lump-Sum Distributions	8949	Sales and other Dispositions of Capital Assets.
5074	Allocation of Individual Income Tax to Guam or the Commonwealth of the Northern Mariana Islands (CNMI).	8958	Allocation of Tax Amounts Between Certain Individuals in Community Property States.
5213	Election to Postpone Determination as to Whether the Presumption Applies that an Activity is Engaged in for Profit.	8962	Premium Tax Credit (PTC).
5329	Additional Taxes on Qualified Plans (Including IRAs) and Other Tax-Favored Accounts.	8993	Section 250 Deduction for Foreign Derived Intangible Income (FDII) and Global Intangible Low-Taxed Income (GILTI).
5405	Repayment of the First-Time Homebuyer Credit	8994	Employer Credit for Paid Family and Medical Leave.
5471	Information Return of U.S. Persons with Respect to Certain Foreign Corporations.	8995	Qualified Business Income Deduction Simplified Computation.
Schedule J (5471)	Accumulated Earnings and Profits (E&P) of Controlled Foreign Corporations.	8995–A	Qualified Business Income Deduction.
Schedule M (5471)	Transactions Between Controlled Foreign Corporation and Shareholders or Other Related Persons.	Schedule A (8995–A).	Specified Service Trades or Businesses.
Schedule O (5471)	Organization or Reorganization of Foreign Corporation, and Acquisitions and Dispositions of its Stock.	Schedule B (8995–A).	Aggregation of Business Operations.
5695	Residential Energy Credits	Schedule C (8995–A).	Loss Netting And Carryforward.
5713	International Boycott Report	Schedule D (8995–A).	Special Rules for Patrons of Agricultural or Horticultural Cooperatives.
Schedule A (5713)	International Boycott Factor (Section 999(c)(1))	9000	Alternative Media Preference.
Schedule B (5713)	Specifically Attributable Taxes and Income (Section 999(c)(2)).	9000(SP)	Alternative Media Preference (Spanish Version).
Schedule C (5713)	Tax Effect of the International Boycott Provisions	9465	Installment Agreement Request.
5884	Work Opportunity Credit	9465 SP	Installment Agreement Request (Spanish Version).
5884–A	Employee Retention Credit	Form T (Timber)	Forest Activities Schedule.
6198	At-Risk Limitations	W–4	Employee's Withholding Certificate.
6251	Alternative Minimum Tax-Individuals	W–4 (SP)	Employee's Withholding Certificate (Spanish Version).
6252	Installment Sale Income	W–4 (KO)	Employee's Withholding Certificate (Korean Version).
6478	Biofuel Producer Credit	W–4 (RU)	Employee's Withholding Certificate (Russian Version).

INDIVIDUAL TAX FORMS—Continued

[View the latest drafts of the tax forms related to the information collection listed in this notice at *https://www.irs.gov/draft-tax-forms.*]

Form No.	Form name	Form No.	Form name
6765	Credit for Increasing Research Activities	W–4 (VIE)	Employee's Withholding Certificate (Vietnamese Version).
6781	Gains and Losses from Section 1256 Contracts and Straddles.	W–4 (ZH–S)	Employee's Withholding Certificate (Chinese-Simple Version).
7203	S Corporation Shareholder Stock and Debt Basis Limitations.	W–4 (ZH–T)	Employee's Withholding Certificate (Chinese-Traditional Version).
7204	Consent to Extend the Time to Assess Tax Related to Contested Foreign Income Taxes-Provisional Foreign Tax Credit Agreement.	W—4 P	Withholding Certificate for Pension or Annuity Payments.
7205	Energy Efficient Commercial Buildings Deduction	W–4 S	Request for Federal Income Tax Withholding from Sick Pay.
7206	Self-Employed Health Insurance Deduction	W–4 V	Voluntary Withholding Request.
7207	Advanced Manufacturing Production Credit	W–4 R	Withholding Certificate for Retirement Payments Other Than Pensions or Annuities.
7210	Clean Hydrogen Production Credit	W–7	Application for IRS Individual Taxpayer Identification Number.
7211	Clean Electricity Production Credit	W–7 A	Application for Taxpayer Identification Number for Pending U.S. Adoptions.
7213	Nuclear Power Production Credit	W–7 (SP)	Application for IRS Individual Taxpayer Identification Number (Spanish Version).
7217	Partner's Report of Property Distributed by a Partnership.	W–7 (COA)	Certificate of Accuracy for IRS Individual Taxpayer Identification Number.
7218	Clean Fuel Production Credit	15620	Section 83(b) Election.

Appendix–B: Guidance Documents

Document	Title	Document	Title
Notice 2006–52	Deduction for Energy Efficient Commercial Buildings	TD 9764	Section 6708 Failure To Maintain List of Advisees With Respect to Reportable Transactions.
Notice 2008–40	Amplification of Notice 2006–52; Deduction for Energy Efficient Commercial Buildings.	TD 9408	Dependent Child of Divorced or Separated Parents or Parents Who Live Apart.
Notice 2023–59	Guidance on Requirements for Home Energy Audits for Purposes of the Energy Efficient Home Improvement Credit under Section 25C.	TD 9902	Guidance Under Sections 951A and 954 Regarding Income Subject to a High Rate of Foreign Tax.
Notice 2024–60	Required Procedures to Claim a Section 45Q Credit for Utilization of Carbon Oxide.	TD 9920	Income Tax Withholding on Certain Periodic Retirement and Annuity Payments Under Section 3405(a).
Publication 972 Tables	Child Tax Credit	TD 9924	Income Tax Withholding from Wages.
Rev. Proc. 2004–12	Section 35.—Health Insurance Costs of Eligible Individuals.	TD 9959	Guidance Related to the Foreign Tax Credit; Clarification of Foreign-Derived Intangible Income.
Rev. Proc. 2019–38	Trade or Business	TD 9993	Transfer of Certain Credits.
Rev. Proc. 2024–09	Changes in accounting periods and in methods of accounting.	TD 9998	Increased Amounts of Credit or Deduction for Satisfying Certain Prevailing Wage and Registered Apprenticeship Requirements.
Rev. Proc. 2024–23	Changes in accounting periods and in methods of accounting.	TD 9999	Statutory Disallowance of Deductions for Certain Qualified Conservation Contributions Made by Partnerships and S Corporations.
TD 8400	Taxation of Gain or Loss from Certain Nonfunctional Currency Transactions (Section 988 Transactions).	TD 10015	Definition of Energy Property and Rules Applicable to the Energy Credit.
TD 8865	Amortization of Intangible Property	TD 10016	Taxable Income or Loss and Currency Gain or Loss With Respect to a Qualified Business Unit.
TD 9207	Assumption of Partner Liabilities	TD 10025	Guidance on Clean Electricity Low-Income Communities Bonus Credit Amount Program.

[FR Doc. 2025–13304 Filed 7–15–25; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Proceeds From Real Estate Transactions.

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Information Collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before September 15, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Control No. 1545–0997'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: View the latest drafts of the tax forms related to the information collection listed in this notice at *https://www.irs.gov/draft-tax-forms.* Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Proceeds From Real Estate Transactions.

OMB Control Number: 1545–0997.

Form Number: 1099–S.

Abstract: Internal Revenue Code section 6045(e) and the regulations there under require persons treated as real estate brokers to submit an information return to the IRS to report the gross proceeds from real estate transactions. Form 1099–S is used for this purpose. The IRS uses the information on the form to verify compliance with the reporting rules regarding real estate transactions.

Current Actions: There are no changes to the form that would affect burden, however the agency has updated the estimated number of responses based on the most recent filing projections.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals or households.

Estimated Number of Responses: 5,450,400.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 872,064.

Dated: July 14, 2025.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2025–13338 Filed 7–15–25; 8:45 am]

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FEDERAL REGISTER

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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 218

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Military Readiness Activities in the Hawaii-California Training and Testing Study Area; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[Docket No. 250708–0120]

RIN 0648–BN44

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Military Readiness Activities in the Hawaii-California Training and Testing Study Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; proposed letters of authorization; request for comments.

SUMMARY: NMFS has received a request from the U.S. Department of the Navy (including the U.S. Navy and the U.S. Marine Corps) (Navy) and on behalf of the U.S. Coast Guard (Coast Guard) and U.S. Army (Army) (hereafter, Navy, Coast Guard, and Army are collectively referred to as the Action Proponents) for Incidental Take Regulations (ITR) and multiple associated Letters of Authorization (LOAs) pursuant to the Marine Mammal Protection Act (MMPA). The requested regulations would govern the authorization of take of marine mammals incidental to training and testing activities, and modernization and sustainment of ranges conducted in the Hawaii-California Training and Testing (HCTT) Study Area over the course of seven years from December 2025 through December 2032. NMFS requests comments on this proposed rule. NMFS will consider public comments prior to making any final decision on the promulgation of the requested ITR and issuance of the LOAs; agency responses to public comments will be summarized in the final rule, if issued. The Action Proponents' activities are considered military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (2004 NDAA) and the NDAA for Fiscal Year 2019 (2019 NDAA).

DATES: Comments and information must be received no later than August 15, 2025.

ADDRESSES: A plain language summary of this proposed rule is available at: *https://www.regulations.gov/docket/NOAA-NMFS-2025-0028.* You may submit comments on this document, identified by NOAA–NMFS–2025–0028, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2025–0028 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Ben Laws, Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225.
- *Fax:* (301) 713–0376; Attn: Ben Laws.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing at: *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

A copy of the Action Proponents' Incidental Take Authorization (ITA) application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Leah Davis, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Regulatory Action

This proposed rule, if promulgated, would provide a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to the Action Proponents' training and testing activities and modernization and sustainment of ranges (which qualify as military readiness activities) involving the use of active sonar and other transducers, air guns, and explosives (also referred to *as* ''in-water detonations''); pile driving and vibratory extraction; land-based missile and target launches; and vessel movement in the HCTT Study Area. The HCTT Study Area includes areas in the north-central Pacific Ocean, from California west to Hawaii and the International Date Line, and including the Hawaii Range Complex (HRC) and Temporary Operating Area (TOA), Southern California (SOCAL) Range Complex, Point Mugu Sea Range (PMSR), Silver Strand Training Complex, areas along the Southern California coastline from approximately Dana Point to Port Hueneme, and the Northern California (NOCAL) Range Complex (see figure 1.1–1 of the rulemaking and LOA application (hereafter referred to as the application)). Please see the Legal Authority for the Proposed Action section for relevant definitions.

Legal Authority for the Proposed Action

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review and the opportunity to submit comment.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking; other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (collectively referred to as ''mitigation''); and requirements pertaining to the monitoring and reporting of the takings. The MMPA defines ''take'' to mean to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal (16 U.S.C. 1362). The Preliminary Analysis and Negligible

Impact Determination section discusses the definition of ''negligible impact.''

The 2004 NDAA (Pub. L. 108–136) amended section 101(a)(5) of the MMPA to remove the ''small numbers'' and ''specified geographical region'' provisions, 16 U.S.C. 1371(a)(5)(F), and amended the definition of ''harassment'' in section 3(18)(B) of the MMPA as applied to a ''military readiness activity'' to read as follows: (1) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A Harassment); or (2) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B Harassment). 16 U.S.C. 1362(18)(B). The 2004 NDAA also amended the MMPA to establish in section 101(a)(5)(A)(iii) that ''[f]or a military readiness activity . . . , a determination of 'least practicable adverse impact' . . . shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.'' 16 U.S.C. 1371(a)(5)(A)(iii). On August 13, 2018, the 2019 NDAA (Pub. L. 115–232) amended the MMPA to allow ITRs for military readiness activities to be issued for up to 7 years. 16 U.S.C. 1371(a)(5)(A)(ii).

Summary of Major Provisions Within the Proposed Rule

The major provisions of this proposed rule are as follows:

- The proposed authorization of take of marine mammals by Level A harassment and/or Level B harassment;
- The proposed authorization of take of marine mammals by mortality or serious injury (M/SI);
- The proposed use of defined powerdown and shutdown zones (based on activity);
- Proposed measures to reduce the likelihood of vessel strikes;
- Proposed activity limitations in certain areas and times that are biologically important (*i.e.,* for foraging, migration, reproduction) for marine mammals;
- The proposed implementation of a Notification and Reporting Plan (for dead, live stranded, or marine mammals struck by any vessel engaged in military readiness activities); and
- The proposed implementation of a robust monitoring plan to improve our understanding of the environmental effects resulting from the Action Proponents' training and testing activities and modernization and sustainment of ranges.

This proposed rule includes an adaptive management component that allows for timely modification of mitigation, monitoring, and/or reporting measures based on new information, when appropriate.

Summary of Request

On September 16, 2024, NMFS received an application from the Action Proponents requesting authorization to take marine mammals, by Level A and Level B harassment, incidental to training, testing, and modernization and sustainment of ranges (characterized as military readiness activities) including the use of sonar and other transducers, explosives, air guns, impact and vibratory pile driving and extraction, and land-based missile and target launches conducted within the HCTT Study Area. The Action Proponents also request authorization to take, by serious injury or mortality, a limited number of marine mammal species incidental to the use of explosives and vessel movement during military readiness activities conducted within the HCTT Study Area. The Action Proponents are requesting multiple 7-year LOAs for Navy training activities, Coast Guard training activities, Army training activities, and Navy testing activities. In response to our comments and following an information exchange, the Action Proponents submitted a revised application, deemed adequate and complete on December 13, 2024. On that same date, we published a notice of receipt of application in the **Federal Register** (89 FR 100982), requesting comments and information related to the Action Proponents' request for 30 days. During the 30-day public comment period on the NOR, we received one public comment from the Center for Biological Diversity. NMFS reviewed and considered all submitted material during the drafting of this proposed rule.

NMFS has previously promulgated ITRs pursuant to the MMPA relating to similar military readiness activities in areas located within the HCTT Study Area. NMFS published the first rule effective from January 5, 2009 through January 5, 2014, (74 FR 1456, January 12, 2009), the second rule effective from December 24, 2013 through December 24, 2018 (78 FR 78106, December 24, 2013), and the third rule effective from December 21, 2018 through December 20, 2023 (83 FR 66846, December 27, 2018), which was subsequently amended, extending the effective date until December 20, 2025 (85 FR 41780, July 10, 2020) pursuant to the 2019 NDAA and later further amended to increase the take of large whales by vessel strike and modify the mitigation, monitoring, and reporting measures to reduce vessel strikes (90 FR 4944, January 16, 2025). For this proposed rulemaking, the Action Proponents propose to conduct substantially similar training and testing activities within the HCTT Study Area that were conducted under previous rules (noting that the Study Area has been expanded, as described in the *Geographic Region* section).

The Action Proponents' application reflects the most up-to-date compilation of training and testing activities, and modernization and sustainment of ranges deemed necessary to accomplish military readiness requirements. The types and numbers of activities included in the proposed rule account for interannual variability in training and testing to meet evolving or emergent military readiness requirements. As explained herein, these proposed regulations also consolidate several actions conducted by the Navy that were previously authorized by NMFS and include some new military readiness activities carried out by the Action Proponents. In particular, these proposed regulations would cover incidental take during military readiness activities in the HCTT Study Area that would occur for a 7-year period following the expiration of the existing MMPA authorization which expires on December 20, 2025 (85 FR 41780, as amended by 90 FR 4944). In addition, this proposed rule includes PMSR activities for which incidental take has previously been authorized under separate authorizations, and, if finalized, this rule would supersede the most recent PMSR regulations (87 FR 40888, July 8, 2022). This proposed rule also includes areas along the Southern California coastline from approximately Dana Point to Port Hueneme and would supersede the incidental harassment authorization (IHA) allowing incidental take of marine mammals during pile driving training activities at Port Hueneme (90 FR 20283, May 13, 2025). In this proposed rule, we have undertaken a comprehensive assessment of the risks/impacts of all military training and testing activities on marine mammals likely to be present within the entire range of the Study Area.

Description of Proposed Activity

Overview

The Action Proponents request authorization to take marine mammals

incidental to conducting military readiness activities. The Action Proponents have determined that acoustic and explosives stressors are likely to result in take of marine mammals in the form of Level A and B harassment, and that a limited number of takes by serious injury or mortality may result from vessel movement and use of explosives (including ship shock trials). Detailed descriptions of these activities are provided in chapter 2 and appendix A of the 2024 HCTT Draft Environmental Impact Statement/ Overseas Environmental Impact Statement (2024 HCTT Draft EIS/OEIS) (*https://www.nepa.navy.mil/hctteis/*) and in the Action Proponents' application (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities*), which are summarized here. Of note, the U.S. Air Force (USAF) is a joint lead agency for the 2024 HCTT Draft EIS/OEIS; USAF activities consist of air combat maneuvers and air-to-air gunnery (a gunnery exercise in which fixed-wing aircraft fire medium caliber guns at air targets). The Action Proponents determined that USAF activities would not result in the take of marine mammals, and therefore these activities are not included in the Action Proponents' application. NMFS concurs that these activities are not anticipated to result in incidental take of marine mammals.

The Navy's statutory mission is to organize, train, equip, and maintain combat-ready naval forces for the peacetime promotion of the national security interests and prosperity of the United States, and for prompt and sustained combat incident to operations essential to the prosecution of a naval campaign. This mission is mandated by Federal law (10 U.S.C. 8062 and 10 U.S.C. 8063), which requires the readiness of the naval forces of the United States. The Navy executes this responsibility by establishing and executing at-sea training and testing, often in designated operating areas (OPAREAs) and testing and training ranges. The Navy must be able to access and utilize these areas and associated sea and air space to develop and maintain skills for conducting naval operations. The Navy's testing activities ensure naval forces are equipped with well-maintained systems that take advantage of the latest technological advances. The Navy's research and acquisition community conducts military readiness activities that involve testing. The Navy tests vessels, aircraft, weapons, combat systems, sensors, and related equipment, and conducts scientific research activities to achieve and maintain military readiness.

The mission of the Coast Guard is to ensure the maritime safety, security, and stewardship of the United States. To advance this mission, the Coast Guard must ensure its personnel can qualify and train jointly with, and independently of, the Navy and other services in the effective and safe operational use of Coast Guard vessels, aircraft, and weapons under realistic conditions. These activities help ensure the Coast Guard can safely assist in the defense of the United States by protecting the United States' maritime safety, security, and natural resources in accordance with its national defense mission (14 U.S.C. 102). Coast Guard training, which accounts for a small portion of overall activities, is summarized below.

The Army is increasingly required to support the naval mission, frequently training in concert with the Navy. Some of this training includes the use of explosives in the marine environment.

Dates and Duration

The specified activities would occur at any time during the 7-year period of validity of the regulations. The proposed number of military readiness activities are described in the Detailed Description of the Specified Activity section (table 2 through table 9).

Geographic Region

The HCTT Study Area includes areas in the north-central Pacific Ocean, from California west to Hawaii and the International Date Line, and including the HRC and TOA, SOCAL Range Complex, PMSR, Silver Strand Training Complex, and the NOCAL Range Complex. The HRC encompasses ocean areas around the Hawaiian Islands, extending from 16 degrees north latitude to 43 degrees north latitude and from 150 degrees west longitude to the International Date Line (figure 1). It also includes pierside locations and port transit channels, bays, harbors, inshore waterways, amphibious approach lanes, and civilian ports where military readiness activities occur as well as transits between homeports and the Hawaii and California Study Areas. The geographic extent of the HRC remains the same and has not changed since the last rulemaking. The SOCAL Range Complex is located between Dana Point, California and San Antonio, Mexico, and extends southwest into the Pacific Ocean. The PMSR is located adjacent to Los Angeles, Ventura, Santa Barbara, and San Luis Obispo Counties along the Pacific Coast of Southern California. The Silver Strand Training Complex is an integrated set of training areas located on and adjacent to the Silver Strand, a narrow, sandy isthmus separating the San Diego Bay from the Pacific Ocean. The NOCAL Range Complex consists of two separate areas located offshore of central and northern California, one northwest of San Francisco and the other southwest of Monterey Bay.

The SOCAL Range Complex expansion, which is new, and incorporation of existing NOCAL Range Complex and the PMSR, are revisions for the HCTT Study Area (formerly HSTT (Hawaii-Southern California Training and Testing) Study Area) in this application (noting that take from activities at PMSR are currently authorized under a separate rule (87 FR 40888, July 8, 2022)).

This proposed rule also incorporates areas along the Southern California coastline from approximately Dana Point to Port Hueneme and includes the new IHA allowing incidental take of marine mammals during pile driving training activities at Port Hueneme (90 FR 20283, May 13, 2025).

Please refer to figure 1.1–1 of the application for a color map of the HCTT Study Area and figure 2–1 through figure 2–17 for additional maps of the range complexes, training and testing ranges, and other notable areas. A summary of the HCTT Study Area Training and Testing Ranges are provided in table 1.

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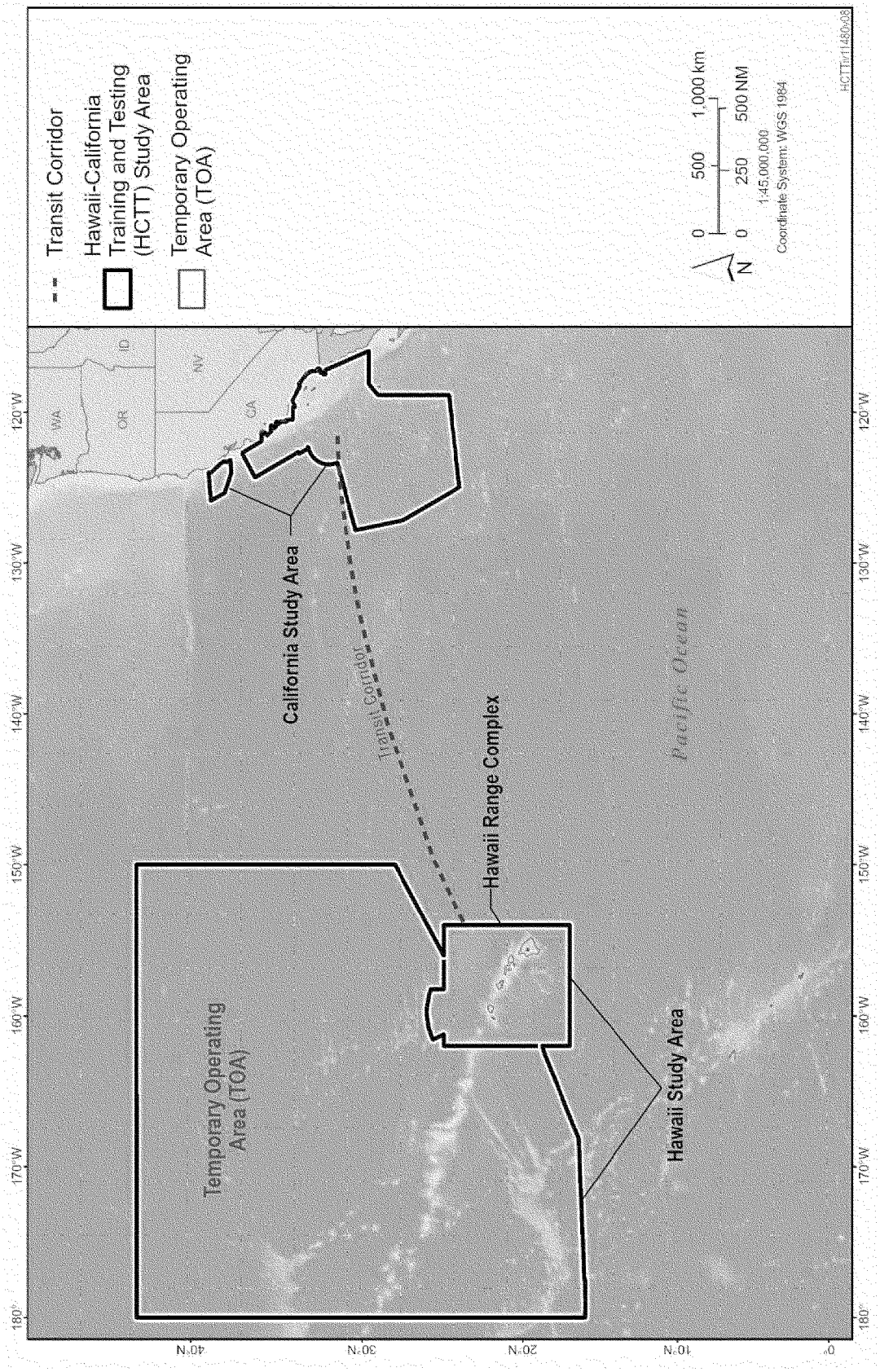

Figure 1 -- Map of the HCTT Study Area

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TABLE 1—HCTT STUDY AREA TRAINING AND TESTING RANGES

Name	Basic location	Spatial extent (air, sea, and undersea space)
Hawaii Range Complex (HRC)	Ocean areas around main Hawaiian islands from 16 degrees north latitude to 43 degrees north latitude and from 150 degrees west longitude to the International Date Line.	235,000 nmi² (80,602,744 ha).
Temporary Operating Area (TOA) ..	North and west from the island of Kaua'i	2,000,000 nmi² (585,980,800 ha).
Southern California Range Complex (SOCAL).	Off San Diego County out to approximately 550 nmi (1,109 km)	217,000 nmi² (74,428,916 ha).
Silver Strand Training Complex	Subset of areas within San Diego Bay and adjacent to ocean out to approximately 4 nmi.	16 nmi² (5,488 ha).
Point Mugu Sea Range (PMSR)	Off Los Angeles and Ventura Counties out to approximately 400 nmi	36,000 nmi² (12,347,654 ha).
Northern California Range Complex (NOCAL).	Two separate areas located offshore of central and northern California, one northwest of San Francisco and the other southwest of Monterey Bay.	16,000 nmi² (5,487,846 ha).

Note: nmi² = square nautical miles, ha = hectares, nmi = nautical miles, km = kilometer. Ports included in HCTT: San Diego Bay, California; Port Hueneme, California; and Pearl Harbor, Hawaii.

Detailed Description of the Specified Activity

The Action Proponents propose to conduct military readiness activities within the HCTT Study Area and have been conducting military readiness activities in the Study Area since the 1940s. The tempo and types of military readiness activities have varied interannually due to the introduction of new technologies, the evolving nature of international events, advances in warfighting doctrine and procedures, and changes in force structure (organization of vessels, weapons, and personnel). Such developments influence the frequency, duration, intensity, and location of required military readiness activities.

Primary Mission Areas

The Navy categorizes their activities into functional warfare areas called primary mission areas, while the Coast Guard categorizes their activities as operational mission programs. For the Navy, these activities generally fall six primary mission areas (Coast Guard mission areas are discussed below). The Navy mission areas with activities that may result in take of marine mammals (and stressors associated with training and testing activities within those mission areas) include the following:

- Amphibious warfare (in-water detonations);
- Anti-submarine warfare (sonar and other transducers, in-water detonations);
- Expeditionary warfare (in-water detonations, pile driving and extraction);
- Mine warfare (sonar and other transducers, in-water detonations);
- Surface warfare (in-water detonations and those occurring at or near the surface); and
- Other (sonar and other transducers, air guns, vessel movement, airborne noise from missile and target launches from San Nicolas Island (SNI) and from shore-to-surface gunnery and missile and aerial target launches from the Pacific Missile Range Facility (PMRF), unmanned systems training, and maintenance of ship and submarine sonar at piers and at-sea).

Most Navy activities conducted in HCTT are categorized under one of these primary mission areas; activities that do not fall within one of these areas are listed as ''other activities.'' In addition, ship shock (underwater detonations) trials, a specific Navy testing activity related to vessel evaluation, would be conducted. The testing community also categorizes most, but not all, of its testing activities under these primary mission areas. The testing community has three additional categories of activities: vessel evaluation (including ship shock trials), unmanned systems (*i.e.,* unmanned surface vehicles (USVs), unmanned underwater vehicles (UUVs)), and acoustic and oceanographic science and technology.

The Action Proponents describe and analyze the effects of their activities within the application (see the 2024 HCTT Draft EIS/OEIS for additional details). In their assessment, the Action Proponents concluded that sonar and other transducers, explosives (in-water detonations and those occurring at or near the surface), air guns, land-based missile and target launches, and pile driving/extraction were the stressors most likely to result in impacts on marine mammals that qualify as harassment (and serious injury or mortality by explosives or vessel strike) as defined under the MMPA. Therefore, the Action Proponents' application provides their assessment of potential effects from these stressors in terms of the primary warfare mission areas in which they would be conducted.

The Coast Guard has four major national defense missions:

- Maritime intercept operations;
- Deployed port operations/security and defense;
- Peacetime engagement; and
- Environmental defense operations (including oil and hazardous substance response).

The Coast Guard manages 6 major operational mission programs with 11 statutory missions, which includes defense readiness. As part of the Coast Guard's defense mission, 14 U.S.C. 1 states the Coast Guard is ''at all times an armed force of the United States.'' As part of the Joint Forces, the Coast Guard maintains its readiness to carry out military operations in support of the policies and objectives of the U.S. government. As an armed force, the Coast Guard trains and operates in the joint military arena at any time and functions as a specialized service under the Navy in time of war or when directed by the President. Coast Guard service members are trained to respond immediately to support military operations and national security. Federal law created the framework for the relationship between the Navy and the Coast Guard (10 U.S.C. 101; 14 U.S.C. 2 (7); 22 U.S.C. 2761; 50 U.S.C. 3004). To meet these statutory requirements and effectively carry out these missions, the Coast Guard's air and surface units train using realistic scenarios, including training with the Navy in their primary mission areas. Every Coast Guard unit is trained to support all statutory missions and, thus, trained to meet all mission requirements, which includes their defense mission requirements. Since all Coast Guard's missions generally entail the deployment of cutters or boats and either fixed-wing or rotary aircraft, the Coast Guard training requirements for one mission generally overlaps with the training requirements of other missions. Thus, when the Coast Guard is training

for its defense mission, the same skill sets are utilized for its other statutory missions.

The Coast Guard's defense mission does not involve use of low- or mid-frequency active sonar (LFAS or MFAS), missiles, in-water detonations, pile driving and vibratory extraction, or air guns that would result in harassment of marine mammals.

The Army's mission is mandated by Federal law (10 U.S.C. 7062), which requires an Army capable of, in conjunction with the other armed forces:

- Preserving the peace and security, and providing for the defense, of the United States, the Commonwealths and possessions, and any areas occupied by the United States;
- Supporting the national policies;
- Implementing the national objectives; and
- Overcoming any nations responsible for aggressive acts that imperil the peace and security of the United States.

In general, the Army includes land combat and service forces, as well as aviation and water transport. It shall be organized, trained, and equipped primarily for prompt and sustained combat incident to operations on land. It is responsible for the preparation of land forces necessary for the effective prosecution of war except as otherwise assigned and, in accordance with integrated joint mobilization plans, for the expansion of the peacetime components of the Army to meet the needs of war.

The Army is increasingly required to operate in the marine environment and with the Navy and, therefore, have an increased requirement to train in the maritime environment. The Army's activities include only the use of explosives, and do not include the use of sonars or other transducers, pile driving and vibratory extraction, or air guns that would result in harassment of marine mammals.

Below, we provide additional detail for each of the applicable primary mission areas.

Amphibious Warfare—

The mission of amphibious warfare is to project military power from the sea to the shore (*i.e.,* attack a threat on land by a military force embarked on ships) through the use of naval firepower and expeditionary landing forces. Amphibious warfare operations include Army, Navy, and Marine Corps small unit reconnaissance or raid missions to large-scale amphibious exercises involving multiple ships and aircraft combined into a strike group.

Amphibious warfare training ranges from individual, crew, and small unit events to large task force exercises. Individual and crew training includes amphibious vehicles and naval gunfire support training. Such training includes shore assaults, boat raids, airfield or port seizures, reconnaissance, and disaster relief. Large-scale amphibious exercises involve ship-to-shore maneuvers, naval fire support such as shore bombardment, air strikes, shore-based missile and artillery firing, and attacks on targets that are near friendly forces. Some amphibious activities include firing at ships from shore in defense of the amphibious objective.

Testing of guns, munitions, aircraft, ships, and amphibious vessels and vehicles used in amphibious warfare are often integrated into training activities and, in most cases, the systems are used in the same manner in which they are used for training activities. Amphibious warfare tests, when integrated with training activities or conducted separately as full operational evaluations on existing amphibious vessels and vehicles following maintenance, repair, or modernization, may be conducted independently or in conjunction with other amphibious ship and aircraft activities. Testing is performed to ensure effective ship-to-shore coordination and transport of personnel, equipment, and supplies. Tests may also be conducted periodically on other systems, vessels, and aircraft intended for amphibious operations to assess operability and to investigate efficacy of new technologies.

Anti-Submarine Warfare—

The mission of anti-submarine warfare is to locate, neutralize, and defeat hostile submarine forces that threaten Navy forces. Anti-submarine warfare is based on the principle that surveillance and attack aircraft, ships, and submarines all search for hostile submarines. These forces operate together or independently to gain early warning and detection and to localize, track, target, and attack submarine threats.

Anti-submarine warfare training addresses basic skills such as detecting and classifying submarines, as well as evaluating sounds to distinguish between enemy submarines and friendly submarines, ships, and marine life. More advanced training integrates the full spectrum of anti-submarine warfare from detecting and tracking a submarine to attacking a target using either exercise torpedoes (*i.e.,* torpedoes that do not contain a warhead) or simulated weapons. These integrated anti-submarine warfare training exercises are conducted in coordinated, at-sea training events involving submarines, ships, and aircraft.

Testing of anti-submarine warfare systems is conducted to develop new technologies and assess weapon performance and operability with new systems and platforms, such as unmanned systems. Testing uses ships, submarines, and aircraft to demonstrate capabilities of torpedoes, missiles, countermeasure systems, and underwater surveillance and communications systems. Tests may be conducted as part of a large-scale fleet training event involving submarines, ships, fixed-wing aircraft, and helicopters. These integrated training events offer opportunities to conduct research and acquisition activities and to train aircrew in the use of new or newly enhanced systems during a large-scale, complex exercise.

Expeditionary Warfare—

The mission of expeditionary warfare is to provide security and surveillance in the littoral (*i.e.,* at the shoreline), riparian (*i.e.,* along a river), or coastal environments. Expeditionary warfare is wide ranging and includes defense of harbors, operation of remotely operated vehicles, clearing obstacles, small boat attack, and boarding/seizure operations.

Expeditionary warfare training activities conducted by the Action Proponents include underwater construction team training, diver propulsion device training and testing, parachute insertion, dive and salvage operations, and insertion/extraction via air, surface, and subsurface platforms, among others (see appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS for a full description of the expeditionary warfare activities).

Mine Warfare—

The mission of mine warfare is to detect, classify, and avoid or neutralize (*i.e.,* disable) mines to protect U.S. ships and submarines, and to maintain free access to ports and shipping lanes. Mine warfare training for the Navy falls into two primary categories: mine detection and classification, and mine countermeasure and neutralization. Mine warfare also includes offensive mine laying to gain control of or deny the enemy access to sea space. Naval mines can be laid by ships, submarines, UUVs, or aircraft.

Mine warfare neutralization training includes exercises in which aircraft, ships, submarines, underwater vehicles, unmanned vehicles, or marine mammal detection systems search for mine shapes. Personnel train to destroy or disable mines by attaching underwater

explosives to or near the mine or using remotely operated vehicles to destroy the mine. Towed influence mine sweep systems mimic a particular ship's magnetic and acoustic signature, which would trigger a real mine causing it to explode.

Testing and development of mine warfare systems is conducted to improve sonar, laser, and magnetic detectors intended to hunt, locate, and record the positions of mines for avoidance or subsequent neutralization. Mine detection and classification testing involves the use of air, surface, and subsurface vessels and uses sonar, including towed and side-scan sonar, and unmanned vehicles to locate and identify objects underwater. Mine detection and classification systems are sometimes used in conjunction with a mine neutralization system. Mine countermeasure and neutralization testing includes the use of air, surface, and subsurface units and uses tracking devices, countermeasure and neutralization systems, and general purpose bombs to evaluate the effectiveness of neutralizing mine threats. Most neutralization tests use mine shapes, or non-explosive practice mines, to accomplish the requirements of the activity. For example, during a mine neutralization test, a previously located mine is destroyed or rendered nonfunctional using a helicopter or manned surface vehicle/USV-based system that may involve the deployment of a towed neutralization system.

A small percentage of mine warfare testing activities require the use of high-explosive mines to evaluate and confirm the ability of the system to neutralize a high-explosive mine under operational conditions. Only a subset of all mine warfare training areas are approved for underwater explosive use (see figures 2–5, 2–11, and 2–12 of the application). The majority of mine warfare systems are deployed by ships, helicopters, and unmanned vehicles. Tests may also be conducted in support of scientific research to support these new technologies (see appendix H (Description of Systems and Ranges) of the 2024 HCTT Draft EIS/OEIS for additional details).

Surface Warfare—

The mission of surface warfare is to obtain control of sea space from which naval forces may operate and entails offensive action against surface and subsurface targets while also defending against enemy forces. In surface warfare, aircraft use guns, air-launched cruise missiles, or other precision-guided munitions; ships employ naval guns and surface-to-surface missiles; and submarines attack surface ships using torpedoes or submarine-launched, anti-ship cruise missiles.

Surface warfare training includes Navy, Coast Guard, and Army surface-to-surface gunnery and missile exercises, air-to-surface gunnery, bombing, and missile exercises, submarine missile or torpedo launch events, other munitions against surface targets, and amphibious operations in a contested environment.

Testing of weapons used in surface warfare is conducted to develop new technologies and to assess weapon performance and operability with new systems and platforms, such as unmanned systems. Tests include various air-to-surface guns and missiles, surface-to-surface guns and missiles, and bombing tests. Testing events may be integrated into training activities to test aircraft or aircraft systems in the delivery of ordnance on a surface target. In most cases the tested systems are used in the same manner in which they are used for training activities.

Other Training Activities—

Other training activities are conducted in the HCTT Study Area that fall outside of the primary mission areas but support overall readiness. These activities include sonar and other transducers, vessel movement, missile and target launch noise from locations on SNI and PMRF, artillery firing noise from shore to surface gunnery at PMRF, unmanned systems training, and maintenance of ship and submarine sonar at piers and at-sea.

Overview of Training Activities Within the Study Area

The Action Proponents routinely train in the HCTT Study Area in preparation for national defense missions. Training activities and exercises covered in this proposed rule are briefly described below and in more detail within appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS. The description, annual number of activities, and location of each training activity are provided by stressor category in table 2 through table 5. Each training activity described meets a requirement that can be traced ultimately to requirements set forth by the National Command Authority.

Within the Navy, a major training exercise (MTE) is comprised of multiple ''unit-level'' range exercises conducted by several units operating together while commanded and controlled by a single commander. These units are collectively referred to as carrier and expeditionary strike groups. These exercises typically employ an exercise scenario developed to train and evaluate the strike group in tactical naval tasks. In a MTE, most of the operations and activities being directed and coordinated by the strike group commander are identical in nature to the operations conducted during individual, crew, and smaller unit-level training events. However, in MTEs, these disparate training tasks are conducted in concert rather than in isolation. Some integrated or coordinated anti-submarine warfare exercises are similar in that they are composed of several unit-level exercises but are generally on a smaller scale than a MTE, are shorter in duration, use fewer assets, and use fewer hours of hull-mounted sonar per exercise. Coordinated training exercises involve multiple units working together to meet unit-level training requirements, whereas integrated training exercises involve multiple units working together in preparation for deployment. Coordinated exercises involving the use of sonar are presented under the category of anti-submarine warfare. The anti-submarine warfare portions of these exercises are considered together in coordinated activities for the sake of acoustic modeling. When other training objectives are being met, those activities are described via unit-level training in each of the relevant primary mission areas.

With a smaller fleet of approximately 250 cutters, Coast Guard activities are not as extensive as Navy activities due to differing mission requirements. However, the Coast Guard does train with the Navy and conducts some of the same training as the Navy. The Coast Guard does not conduct any exercises similar in scale to Navy MTEs/integrated exercises, and the use of mid- or low-frequency sonar, missiles, and underwater detonations are examples of actions that are not a part of the Coast Guard's mission requirements. Coast Guard training generally occurs close to the vessel homeport or close to shore, on established Navy training and testing ranges, or in transit to a scheduled patrol/mission. There are approximately 1,600 Coast Guard vessels (cutters up to 418 feet (ft); 127.4 meters (m) and boats less than 65 ft (19.8 m)), and the largest cutters would be underway for 3–4 months, whereas the smaller cutters would be underway from a few days to 4 weeks. Within California, there are approximately 20 cutters homeported. Cutters are defined as vessels larger than 65 ft (19.8 m). The service has about 1,680 boats nation-wide altogether. These craft include heavy weather response boats, special purpose craft,

aids-to-navigation (ATON) boats, and cutter-based boats. Sizes range from 64 ft (29.5 m) in length down to 12 ft (3.7 m). There are approximately 100 boats in California but the number of boats varies. Within Hawaii, the Coast Guard has eight cutters and an unspecified number of small boats homeported.

The MTEs and integrated/coordinated training activities analyzed for this request are Navy-led exercises in which the Coast Guard may participate and described in table 2. For additional information on these activities see table 1–8 of the application and appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS. Table 3 describes the proposed Navy training activities analyzed within the HCTT Study Area while table 4 describes the proposed Coast Guard training activities analyzed within the HCTT Study Area and table 5 describes the Army training activities analyzed within the HCTT Study Area. In addition to participating in Navy-led exercises, Coast Guard and Army training activities include unit-level activities conducted independently of, and not in coordination with, the Navy.

TABLE 2—MTEs AND INTEGRATED/COORDINATED TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Training type	Exercise group	Description	Scale	Duration	Location (range complex)	Exercise examples	Typical hull-mounted sonar per event (hours)
Major Training Exercise.	Large Integrated ASW.	Larger-scale, longer duration integrated ASW exercises.	Greater than 6 surface ASW units (up to 30 with the largest exercises), 2 or more submarines, multiple ASW aircraft.	Generally greater than 10 days.	SOCAL, PMSR, HRC.	Strike Group COMPUTEX, RIMPAC.	>500
Major Training Exercise.	Medium Integrated ASW.	Medium-scale, medium duration integrated ASW exercises.	Approximately 3–8 surface ASW units, at least 1 submarine, multiple ASW aircraft.	Generally 4–10 days.	SOCAL, PMSR, HRC.	Task Force/ Sustainment Exercise, Multi-Warfare Exercise.	100–500
Integrated/Coordinated Training.	Small Integrated ASW.	Small-scale, short duration integrated ASW exercises.	Approximately 3–6 surface ASW units, 2 dedicated submarines, 2–6 ASW aircraft.	Generally less than 5 days.	SOCAL, HRC	SWATT, NUWTAC ...	50–100
Integrated/Coordinated Training.	Medium Coordinated ASW.	Medium-scale, medium duration, coordinated ASW exercises.	Approximately 2–4 surface ASW units, possibly a submarine, 2–5 ASW aircraft.	Generally 3–10 days.	SOCAL, HRC	SCC, Fleet Battle Problem, TACDEVEX.	<100
Integrated/Coordinated Training.	Small Coordinated ASW.	Small-scale, short duration, coordinated ASW exercises.	Approximately 2–4 surface ASW units, possibly a submarine, 1–2 ASW aircraft.	Generally 2–4 days.	SOCAL, HRC	ID CERTEX	<50

Note: ASW = Anti-Submarine Warfare, HRC = Hawaii Range Complex, ID CERTEX = Independent Deployer Certification Exercise, NUWTAC = Naval Undersea Warfare Training Assessment Course, PMSR = Point Mugu Sea Range Overlap, RIMPAC = Rim of the Pacific, SCC = Submarine Commanders Course, SOCAL = Southern California Range Complex, SWATT = Surface Warfare Advanced Tactical Training, TACDEVEX = Tactical Development Exercise.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Major Training Exercise—Large Integrated ASW.	Composite Training Unit Exercise.	Aircraft carrier and carrier air wing integrates with surface and submarine units in a challenging multi-threat operational environment that certifies them ready to deploy. Duration: 21 days.	LFH, MF to HF, MF1, MFH, MFM.	1–2	11	Hawaii, SOCAL, PMSR, NOCAL.
Acoustic	Major Training Exercise—Large Integrated ASW.	Rim of the Pacific Exercise.	A biennial multinational training exercise in which navies from around the world assemble in Pearl Harbor, Hawaii, to conduct training throughout the Hawaiian Islands in a number of warfare areas. Marine mammal systems may be used during a Rim of the Pacific exercise. Components of a Rim of the Pacific exercise, such as certain mine warfare and amphibious training, may be conducted in the Southern California Range Complex. Duration: 30 days.	HFH, MF1, MFH, MFM.	0–1	4	Hawaii, SOCAL.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Major Training Exercise—Medium Integrated ASW.	Task Force/ Sustainment Exercise.	Aircraft carrier and carrier air wing integrates with surface and submarine units in a challenging multi-threat operational environment to maintain ability to deploy. Duration: 10 days.	LFH, MF to HF, MF1, MFH, MFM.	0–1	3	Hawaii.
Acoustic	Major Training Exercise—Medium Integrated ASW.	Task Force/ Sustainment Exercise.	Aircraft carrier and carrier air wing integrates with surface and submarine units in a challenging multi-threat operational environment to maintain ability to deploy. Duration: 10 days.	LFH, MF to HF, MF1, MFH, MFM.	0–1	3	SOCAL, PMSR, NOCAL.
Acoustic	Integrated/Coordinated ASW.	Composite Training Unit Exercise—Amphibious Ready Group/Marine Expeditionary Unit.	Navy and USMC forces conduct integration training at sea in preparation for deployment. Duration: 3 weeks.	LFH, MF to HF, MF1, MFH, MFM.	1–2	10	Hawaii, SOCAL, PMSR, NOCAL.
Acoustic	Integrated/Coordinated ASW.	Independent Deployer Certification Exercise/ Tailored Surface Warfare Training.	Multiple ships, aircraft, and submarines conduct integrated multi-warfare training with a surface warfare emphasis. Serves as a ready-to-deploy certification for individual surface ships tasked with surface warfare missions. Duration: 2–3 days.	MF to HF, MF1, MFH, MFM.	8–19	89	SOCAL, PMSR, NOCAL.
Acoustic	Integrated/Coordinated ASW.	Medium Coordinated ASW.	Multiple ships, aircraft, and submarines integrate the use of their sensors, including sonobuoys and unmanned systems, to search, detect, and track threat submarines; event may include inert torpedo firings. Duration: 3–10 days.	MF to HF, MF1, MFH, MFM.	12–17	99	Hawaii.
Acoustic	Integrated/Coordinated ASW.	Medium Coordinated ASW.	Multiple ships, aircraft, and submarines integrate the use of their sensors, including sonobuoys and unmanned systems, to search, detect, and track threat submarines; event may include inert torpedo firings. Duration: 3–10 days.	MF to HF, MF1, MFH, MFM.	5–13	59	SOCAL, PMSR, NOCAL.
Acoustic	Integrated/Coordinated ASW.	Small Joint Coordinated ASW.	Typically, a 5-day exercise with multiple ships, aircraft and submarines integrating the use of their sensors, including sonobuoys, to search, detect, and track threat submarines. Duration: 5 days.	LFH, MF to HF, MF1, MFH, MFM.	1	7	Hawaii.
Acoustic	Integrated/Coordinated ASW.	Small Joint Coordinated ASW.	Typically, a 5-day exercise with multiple ships, aircraft and submarines integrating the use of their sensors, including sonobuoys, to search, detect, and track threat submarines. Duration: 5 days.	LFH, MF to HF, MF1, MFH, MFM.	4–9	43	SOCAL, PMSR, NOCAL.
Explosive	Integrated/Coordinated Training—Other.	Large Amphibious Exercise.	The Large Amphibious Exercise utilizes all elements of the Marine Air Ground Task Force (Amphibious) to secure the battlespace (air, land, and sea), maneuver to and seize the objective, and conduct self-sustaining operations ashore with logistic support of the Expeditionary Strike Group. This exercise could include manned and unmanned activities in multiple warfare areas to secure the battlespace (air, land, and sea) and maneuver and secure operations ashore. Duration: 1 week.	E9	0–1	2	Hawaii.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Integrated/Coordinated Training—Other.	Large Amphibious Exercise.	The Large Amphibious Exercise utilizes all elements of the Marine Air Ground Task Force (Amphibious) to secure the battlespace (air, land, and sea), maneuver to and seize the objective, and conduct self-sustaining operations ashore with logistic support of the Expeditionary Strike Group. This exercise could include manned and unmanned activities in multiple warfare areas to secure the battlespace (air, land, and sea) and maneuver and secure operations ashore. Duration: 1 week.	E9	2–4	20	SOCAL, PMSR, NOCAL.
Acoustic and Explosive.	Integrated/Coordinated Training—Other.	Innovation and Demonstration Exercise.	These exercises are conducted to demonstrate or test new capabilities, tactics, techniques, and procedures; and generate standardized, actionable data for evaluation. Duration: 1 week.	E5, HFH, LF to HF, LFH, MF to HF, MF1, MFH, MFM.	0–1	4	Hawaii.
Acoustic and Explosive.	Integrated/Coordinated Training—Other.	Innovation and Demonstration Exercise.	These exercises are conducted to demonstrate or test new capabilities, tactics, techniques, and procedures; and generate standardized, actionable data for evaluation. Duration: 1 week.	E5, HFH, LF to HF, LFH, MF to HF, MF1, MFH, MFM.	3	16	SOCAL.
Acoustic and Explosive.	Integrated/Coordinated Training—Other.	Innovation and Demonstration Exercise.	These exercises are conducted to demonstrate or test new capabilities, tactics, techniques, and procedures; and generate standardized, actionable data for evaluation. Duration: 1 week.	E5, HFH, LF to HF, LFH, MF to HF, MF1, MFH, MFM.	1	7	Transit Corridor.
Acoustic and Explosive.	Integrated/Coordinated Training—Other.	Multi-Warfare Exercise.	Live training events which could involve U.S., Joint, and coalition forces operating across all warfare areas (*e.g.,* amphibious, electronic and cyber, air, surface, sub-surface, special warfare, and expeditionary) with manned and unmanned platforms. Events could be comprised of small units up to and including Carrier and Amphibious Strike Groups. Live-fire events could be ship-to-shore, shore-to-offshore target, and ship-to-ship utilizing live ordnance and laser systems. Duration: 1–5 days.	E5, HFH, LF to HF, LFH, MF to HF, MF1, MFH, MFM.	2	12	Hawaii.
Acoustic and Explosive.	Integrated/Coordinated Training—Other.	Multi-Warfare Exercise.	Live training events which could involve U.S., Joint, and coalition forces operating across all warfare areas (*e.g.,* amphibious, electronic and cyber, air, surface, sub-surface, special warfare, and expeditionary) with manned and unmanned platforms. Events could be comprised of small units up to and including Carrier and Amphibious Strike Groups. Live-fire events could be ship-to-shore, shore-to-offshore target, and ship-to-ship utilizing live ordnance and laser systems. Duration: 1–5 days.	E5, HFH, LF to HF, LFH, MF to HF, MF1, MFH, MFM.	6–7	43	SOCAL, PMSR.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Amphibious Warfare	Amphibious Operations in a Contested Environment.	Navy and Marine Corps forces conduct operations in coastal and offshore waterways against air, surface, and subsurface threats. Duration: 1–2 weeks.	E2	15	105	Hawaii.
Explosive	Amphibious Warfare	Amphibious Operations in a Contested Environment.	Navy and Marine Corps forces conduct operations in coastal and offshore waterways against air, surface, and subsurface threats. Duration: 1–2 weeks.	E2	10	70	SOCAL, SSTC.
Explosive	Amphibious Warfare	Naval Surface Fire Support Exercise-At Sea.	Surface ship crews fire large-caliber guns at a passive acoustic hydrophone scoring system. Duration: 1–2 hours of firing, 8 hours total.	E5	20–25	155	Hawaii.
Explosive	Amphibious Warfare	Shore-to-Surface Artillery Exercise.	Amphibious land-based forces fire artillery guns at surface targets. Duration: 1–2 hours of firing, 8 hours total.	E6	1	7	PMRF.
Explosive	Amphibious Warfare	Shore-to-Surface Artillery Exercise.	Amphibious land-based forces fire artillery guns at surface targets. Duration: 1–2 hours of firing, 8 hours total.	E6	12	84	SCI.
Explosive	Amphibious Warfare	Shore-to-Surface Missile Exercise.	Amphibious land-based forces fire anti-surface missiles, rockets, and loitering munitions at surface targets. Duration: 1–2 hours of firing, 8 hours total.	E9	4	28	PMRF.
Explosive	Amphibious Warfare	Shore-to-Surface Missile Exercise.	Amphibious land-based forces fire anti-surface missiles, rockets, and loitering munitions at surface targets. Duration: 1–2 hours of firing, 8 hours total.	E9	15	105	SCI.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Helicopter.	Helicopter crews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets. Duration: 2–5 hours.	HFH, MFH, MFM.	3–5	27	BARSTUR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Helicopter.	Helicopter crews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets. Duration: 2–5 hours.	HFH, MFH, MFM.	3–5	27	SOAR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Maritime Patrol Aircraft.	Maritime patrol aircraft aircrews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets. Duration: 2–8 hours.	HFH, MFM	20–80	320	BARSTUR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Maritime Patrol Aircraft.	Maritime patrol aircraft aircrews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets. Duration: 2–8 hours.	HFH, MFM	60–80	480	SOAR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Ship.	Surface ship crews search for, track, and detect submarines. Exercise torpedoes are used. Duration: 2–5 hours.	HFH, MF to HF, MF1.	34	238	BARSTUR, BSUR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Ship.	Surface ship crews search for, track, and detect submarines. Exercise torpedoes are used. Duration: 2–5 hours.	HFH, MF to HF, MF1.	104	728	SOAR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Submarine.	Submarine crews search for, track, and detect submarines. Exercise torpedoes are used. Duration: 8 hours.	HFH, LF to HF, MFH.	48	336	BARSTUR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Torpedo Exercise—Submarine.	Submarine crews search for, track, and detect submarines. Exercise torpedoes are used. Duration: 8 hours.	HFH, LF to HF, MFH.	26	182	SOAR.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Helicopter.	Helicopter crews search for, track, and detect submarines. Duration: 2–4 hours.	MFH, MFM	125–130	890	Hawaii.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Helicopter.	Helicopter crews search for, track, and detect submarines. Duration: 2–4 hours.	MFH, MFM	125–130	890	SOCAL, PMSR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Long-Range unmanned Surface Vessel.	Unmanned surface vessels search for, detect, and track a sub-surface target simulating a threat submarine with the goal of determining a firing solution that could be used to launch a torpedo. Duration: 1 day.	MFM	5	35	Hawaii.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Long-Range unmanned Surface Vessel.	Unmanned surface vessels search for, detect, and track a sub-surface target simulating a threat submarine with the goal of determining a firing solution that could be used to launch a torpedo. Duration: 1 day.	MFM	2	14	SOCAL.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Maritime Patrol Aircraft.	Maritime patrol aircraft aircrews search for, track, and detect submarines. Duration: 2–8 hours.	LFH, LFM, MFM.	150–200	1,200	Hawaii.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Maritime Patrol Aircraft.	Maritime patrol aircraft aircrews search for, track, and detect submarines. Duration: 2–8 hours.	LFH, LFM, MFM.	200	1,400	SOCAL, PMSR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Ship.	Surface ship crews search for, track, and detect submarines. Duration: 2–4 hours.	MF to HF, MF1, MFH.	60–119	595	Hawaii.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Ship.	Surface ship crews search for, track, and detect submarines. Duration: 2–4 hours.	MF to HF, MF1, MFH.	240–480	2,400	SOCAL, PMSR.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Submarine.	Submarine crews search for, track, and detect submarines. Duration: 8 hours.	HFH, MFH	200	1,400	Hawaii.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Submarine.	Submarine crews search for, track, and detect submarines. Duration: 8 hours.	HFH, MFH	60	420	SOCAL, PMSR, NOCAL.
Acoustic	Anti-Submarine Warfare.	Anti-Submarine Warfare Tracking Exercise—Submarine.	Submarine crews search for, track, and detect submarines. Duration: 8 hours.	HFH, MFH	9	63	Transit Corridor.
Acoustic and Explosive.	Anti-Submarine Warfare.	Training and End-to-End Mission Capability Verification—Torpedo.	A submarine launches exercise and explosive torpedoes at a suspended target. Duration: 8 hours.	E11, HFH, HFM, MFH.	2	14	BARSTUR.
Acoustic and Explosive.	Anti-Submarine Warfare.	Training and End-to-End Mission Capability Verification—Torpedo.	A submarine launches exercise and explosive torpedoes at a suspended target. Duration: 8 hours.	E11, HFH, HFM, MFH.	1	7	SOAR.
Acoustic	Expeditionary Warfare.	Port Damage Repair	Navy Expeditionary forces train to repair critical port facilities. Duration: 8 hours per day for 5 days.	Pile Driving	12	84	Port Hueneme.
Explosive	Expeditionary Warfare.	Obstacle Clearance	Trains forces to create cleared lanes in simulated enemy obstacle systems to allow friendly forces safe transit from sea to shore. Duration: 8 hours.	E2	40	280	FORACS.
Explosive	Expeditionary Warfare.	Obstacle Clearance	Trains forces to create cleared lanes in simulated enemy obstacle systems to allow friendly forces safe transit from sea to shore. Duration: 8 hours.	E2	10	70	Lima Landing.
Explosive	Expeditionary Warfare.	Obstacle Clearance	Trains forces to create cleared lanes in simulated enemy obstacle systems to allow friendly forces safe transit from sea to shore. Duration: 8 hours.	E2	10	70	Pearl Peninsula.
Explosive	Expeditionary Warfare.	Obstacle Clearance	Trains forces to create cleared lanes in simulated enemy obstacle systems to allow friendly forces safe transit from sea to shore. Duration: 8 hours.	E6	10	70	Pu'uloa.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Expeditionary Warfare.	Obstacle Clearance ..	Trains forces to create cleared lanes in simulated enemy obstacle systems to allow friendly forces safe transit from sea to shore. Duration: 8 hours.	E2	100–150	850	SOCAL.
Explosive	Expeditionary Warfare.	Obstacle Clearance ..	Trains forces to create cleared lanes in simulated enemy obstacle systems to allow friendly forces safe transit from sea to shore. Duration: 8 hours.	E10	6	42	SCI.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Air.	Personnel are inserted into a water objective via fixed-wing aircraft using parachutes or by helicopters via ropes or jumping into the water. Personnel are extracted by helicopters or small boats. Duration: 1 hour.	E1	8	56	FORACS.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Air.	Personnel are inserted into a water objective via fixed-wing aircraft using parachutes or by helicopters via ropes or jumping into the water. Personnel are extracted by helicopters or small boats. Duration: 1 hour.	E1	26	182	Pearl Peninsula.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Air.	Personnel are inserted into a water objective via fixed-wing aircraft using parachutes or by helicopters via ropes or jumping into the water. Personnel are extracted by helicopters or small boats. Duration: 1 hour.	E1	500	3,500	Hawaii.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Air.	Personnel are inserted into a water objective via fixed-wing aircraft using parachutes or by helicopters via ropes or jumping into the water. Personnel are extracted by helicopters or small boats. Duration: 1 hour.	E1	854–954	6,278	SOCAL.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Air.	Personnel are inserted into a water objective via fixed-wing aircraft using parachutes or by helicopters via ropes or jumping into the water. Personnel are extracted by helicopters or small boats. Duration: 1 hour.	E1	500–600	3,800	SSTC.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Surface and subsurface.	Personnel are inserted into and extracted from an objective area by small boats or subsurface platforms. Duration: 2–4 hours.	E1	270–336	2,088	Hawaii.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction—Surface and subsurface.	Personnel are inserted into and extracted from an objective area by small boats or subsurface platforms. Duration: 2–4 hours.	E1	1,049–1,149	7,643	SOCAL.
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction Training—Swimmer/ Diver.	Divers and swimmers infiltrate harbors, beaches, or moored vessels and conduct a variety of tasks. Duration: up to 12 hours.	E1	495	3,465	Hawaii
Explosive	Expeditionary Warfare.	Personnel Insertion/ Extraction Training—Swimmer/ Diver.	Divers and swimmers infiltrate harbors, beaches, or moored vessels and conduct a variety of tasks. Duration: up to 12 hours.	E1	1,080–1,280	8,160	SOCAL.
Explosive	Mine Warfare	Amphibious Breaching Operations.	Amphibious forces use explosive clearing systems to clear simulated mines on beaches, shallow water, and surf zones for potential landing of personnel and vehicles. Duration: 8 hours.	E6	100	700	Hawaii.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Mine Warfare	Amphibious Breaching Operations.	Amphibious forces use explosive clearing systems to clear simulated mines on beaches, shallow water, and surf zones for potential landing of personnel and vehicles. Duration: 8 hours.	E6	275	1,925	SOCAL.
Explosive	Mine Warfare	Amphibious Breaching Operations.	Amphibious forces use explosive clearing systems to clear simulated mines on beaches, shallow water, and surf zones for potential landing of personnel and vehicles. Duration: 8 hours.	E6	315	2,205	SSTC.
Explosive	Mine Warfare	Amphibious Breaching Operations.	Amphibious forces use explosive clearing systems to clear simulated mines on beaches, shallow water, and surf zones for potential landing of personnel and vehicles. Duration: 8 hours.	E6	48–55	357	SWAT 2.
Acoustic and Explosive.	Mine Warfare	Civilian Port Defense–Homeland Security Anti-Terrorism/Force Protection Exercise.	Maritime security personnel train to protect civilian ports against enemy efforts to interfere with access to those ports. Duration: multiple days.	E4, HFH, HFM, MFH.	1–2	10	Hawaii.
Acoustic and Explosive.	Mine Warfare	Civilian Port Defense–Homeland Security Anti-Terrorism/Force Protection Exercise.	Maritime security personnel train to protect civilian ports against enemy efforts to interfere with access to those ports. Duration: multiple days.	E4, HFH, HFM, MFH.	1–2	11	SOCAL.
Acoustic and Explosive.	Mine Warfare	Civilian Port Defense–Homeland Security Anti-Terrorism/Force Protection Exercise.	Maritime security personnel train to protect civilian ports against enemy efforts to interfere with access to those ports. Duration: multiple days.	E4, HFH, HFM, MFH.	1–2	9	PMSR.
Explosive	Mine Warfare	Limpet Mine Neutralization System.	Navy Explosive Ordnance Disposal divers place a small charge on a simulated underwater mine. Duration: 2 hours.	E0, E3	6–8	48	Lima Landing.
Explosive	Mine Warfare	Limpet Mine Neutralization System.	Navy Explosive Ordnance Disposal divers place a small charge on a simulated underwater mine. Duration: 2 hours.	E0, E3	138–150	1,002	SOCAL.
Explosive	Mine Warfare	Limpet Mine Neutralization System.	Navy Explosive Ordnance Disposal divers place a small charge on a simulated underwater mine. Duration: 2 hours.	E0, E3	42–44	300	SSTC.
Acoustic	Mine Warfare	Mine Countermeasure Exercise—Ship Sonar.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	HFH, MF1K	30	210	Hawaii.
Acoustic	Mine Warfare	Mine Countermeasure Exercise—Ship Sonar.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	HFH, MF1K	42	294	Pearl Harbor.
Acoustic	Mine Warfare	Mine Countermeasure Exercise—Ship Sonar.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	HFH, MF1K	92	644	SOCAL.
Acoustic	Mine Warfare	Mine Countermeasure Exercise—Ship Sonar.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	HFH, MF1K	164	1,148	San Diego Bay.
Acoustic and Explosive.	Mine Warfare	Mine Countermeasures Mine Neutralization Remotely Operated Vehicle.	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles. Duration: 1–4 hours.	E4, HFM	7–8	52	Hawaii MTRs.
Acoustic and Explosive.	Mine Warfare	Mine Countermeasures Mine Neutralization Remotely Operated Vehicle.	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles. Duration: 1–4 hours.	E4, HFM	11	74	SOCAL.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic and Explosive.	Mine Warfare	Mine Countermeasures Mine Neutralization Remotely Operated Vehicle.	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles. Duration: 1–4 hours.	E4, HFM	6	42	SSTC.
Acoustic and Explosive.	Mine Warfare	Mine Countermeasures Mine Neutralization Remotely Operated Vehicle.	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles. Duration: 1–4 hours.	E4, HFM	3–6	30	TAR 2.
Acoustic and Explosive.	Mine Warfare	Mine Countermeasures Mine Neutralization Remotely Operated Vehicle.	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles. Duration: 1–4 hours.	E4, HFM	11	74	SCORE.
Explosive	Mine Warfare	Mine Neutralization Explosive Ordnance Disposal.	Personnel disable threat mines using explosive charges. Duration: up to 4 hours.	E6	5–7	41	Hawaii.
Explosive	Mine Warfare	Mine Neutralization Explosive Ordnance Disposal.	Personnel disable threat mines using explosive charges. Duration: up to 4 hours.	E6	203–211	1,445	SOCAL.
Explosive	Mine Warfare	Mine Neutralization Explosive Ordnance Disposal.	Personnel disable threat mines using explosive charges. Duration: up to 4 hours.	E6	17–25	143	SSTC.
Explosive	Mine Warfare	Mine Neutralization Explosive Ordnance Disposal.	Personnel disable threat mines using explosive charges. Duration: up to 4 hours.	E6	0–1	5	SWAT 2.
Acoustic	Mine Warfare	Submarine Mine Counter Measure Exercise.	Submarine crews use active sonar or UUVs, and shore-based personnel operate UUVs to detect and avoid training mine shapes or other underwater hazardous objects. Duration: 6 hours.	HFH, MF to HF, VHFH.	80	560	Hawaii.
Acoustic	Mine Warfare	Submarine Mine Counter Measure Exercise.	Submarine crews use active sonar or UUVs, and shore-based personnel operate UUVs to detect and avoid training mine shapes or other underwater hazardous objects. Duration: 6 hours.	HFH, MF to HF, VHFH.	40	280	SOCAL.
Acoustic	Mine Warfare	Submarine Mobile Mine and Mine Laying Exercise.	Submarine crews and shore-based personnel operating a UUV deploy exercise (inert) mobile mines or mines. Duration: 6 hours.	HFL, HFM, MFM, VHFL.	20	140	Hawaii.
Acoustic	Mine Warfare	Submarine Mobile Mine and Mine Laying Exercise.	Submarine crews and shore-based personnel operating a UUV deploy exercise (inert) mobile mines or mines. Duration: 6 hours.	HFL, HFM, MFM, VHFL.	30	210	SOCAL, PMSR.
Acoustic	Mine Warfare	Surface Ship Object Detection.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	MF1K	30	210	Hawaii.
Acoustic	Mine Warfare	Surface Ship Object Detection.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	MF1K	42	294	Pearl Harbor.
Acoustic	Mine Warfare	Surface Ship Object Detection.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	MF1K	92	644	SOCAL.
Acoustic	Mine Warfare	Surface Ship Object Detection.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar. Duration: up to 15 hours.	MF1K	164	1,148	San Diego Bay.
Explosive	Mine Warfare	Underwater Demolition Qualification and Certification.	Navy divers conduct various levels of training and certification in placing underwater demolition charges. Duration: up to 8 hours.	E5, E6	5	35	Pu'uloa, Ewa Beach, Barbers Point.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Mine Warfare	Underwater Demolition Qualification and Certification.	Navy divers conduct various levels of training and certification in placing underwater demolition charges. Duration: up to 8 hours.	E5, E6	10–20	100	TAR 2.
Explosive	Mine Warfare	Underwater Demolition Qualification and Certification.	Navy divers conduct various levels of training and certification in placing underwater demolition charges. Duration: up to 8 hours.	E5, E6	24	168	SSTC.
Explosive	Mine Warfare	Underwater Demolitions Multiple Charge—Large Area Clearance.	Units deploy large explosive systems from vessels or vehicles to destroy barriers or obstacles over an area large enough to allow amphibious vehicles to access beach areas. Duration: 4 hours.	E13	6	42	TAR 2.
Explosive	Surface Warfare	Bombing Exercise Air-to-Surface.	Fixed-wing aircrews deliver bombs against surface targets. Duration: 1 hour.	E9, E10, E12	194	1,358	Hawaii.
Explosive	Surface Warfare	Bombing Exercise Air-to-Surface.	Fixed-wing aircrews deliver bombs against surface targets. Duration: 1 hour.	E9, E10, E12	653	4,571	SOCAL.
Explosive	Surface Warfare	Bombing Exercise Air-to-Surface.	Fixed-wing aircrews deliver bombs against surface targets. Duration: 1 hour.	E9, E10, E12	10	70	NOCAL.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Boat Medium-Caliber.	Small boat crews fire medium-caliber guns at surface targets. Duration: 1 hour.	E1	10	70	Hawaii.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Boat Medium-Caliber.	Small boat crews fire medium-caliber guns at surface targets. Duration: 1 hour.	E1	14	98	SOCAL.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-Caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3, E5	32	224	Hawaii.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-Caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3, E5	125	875	SOCAL.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-Caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3, E5	14	98	Transit Corridor.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Medium-Caliber.	Surface ship crews fire medium-caliber guns at surface targets. Duration: 2–3 hours.	E1	5–50	170	Hawaii.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Medium-Caliber.	Surface ship crews fire medium-caliber guns at surface targets. Duration: 2–3 hours.	E1	17–180	608	SOCAL.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Medium-Caliber.	Surface ship crews fire medium-caliber guns at surface targets. Duration: 2–3 hours.	E1	6–40	144	Transit Corridor.
Explosive	Surface Warfare	Missile Exercise Air-to-Surface.	Fixed-wing and helicopter aircrews fire air-to-surface missiles at surface targets. Duration: 1 hour.	E6, E7, E8, E9	17–22	134	Hawaii.
Explosive	Surface Warfare	Missile Exercise Air-to-Surface.	Fixed-wing and helicopter aircrews fire air-to-surface missiles at surface targets. Duration: 1 hour.	E6, E7, E8, E9	4–9	43	SOCAL.
Explosive	Surface Warfare	Missile Exercise Air-to-Surface.	Fixed-wing and helicopter aircrews fire air-to-surface missiles at surface targets. Duration: 1 hour.	E6, E7, E8, E9	90	630	PMSR.
Explosive	Surface Warfare	Missile Exercise Air-to-Surface Rocket.	Helicopter aircrews fire both precision-guided and unguided rockets at surface targets. Duration: 1 hour.	E3	109–129	823	Hawaii.
Explosive	Surface Warfare	Missile Exercise Air-to-Surface Rocket.	Helicopter aircrews fire both precision-guided and unguided rockets at surface targets. Duration: 1 hour.	E3	251–271	1,817	SOCAL.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Surface Warfare	Missile Exercise Surface-to-Surface.	Surface ship crews defend against surface threats (ships or small boats) and engage them with missiles. Duration: 2–5 hours.	E9	28–32	208	Hawaii.
Explosive	Surface Warfare	Missile Exercise Surface-to-Surface.	Surface ship crews defend against surface threats (ships or small boats) and engage them with missiles. Duration: 2–5 hours.	E9	10	70	SOCAL.
Explosive	Surface Warfare	Sinking Exercise	Aircraft, ship, and submarine crews deliberately sink a seaborne target, usually a decommissioned ship made environmentally safe for sinking according to U.S. Environmental Protection Agency standards, with a variety of ordnance. Duration: 4–8 hours.	E5, E8, E9, E11, E12.	2–3	17	Hawaii.
Explosive	Surface Warfare	Sinking Exercise	Aircraft, ship, and submarine crews deliberately sink a seaborne target, usually a decommissioned ship made environmentally safe for sinking according to U.S. Environmental Protection Agency standards, with a variety of ordnance. Duration: 4–8 hours.	E5, E8, E9, E11, E12.	0–1	3	SOCAL.
Acoustic	Surface Warfare	Surface Warfare Torpedo Exercise—Submarine.	Submarine crews search for, detect, and track a surface ship simulating a threat surface ship with the goal of determining a firing solution that could be used to launch a torpedo with the intent to simulate destroying the targets. Duration: 8 hours.	HFH	30	210	Hawaii.
Acoustic	Surface Warfare	Surface Warfare Torpedo Exercise—Submarine.	Submarine crews search for, detect, and track a surface ship simulating a threat surface ship with the goal of determining a firing solution that could be used to launch a torpedo with the intent to simulate destroying the targets. Duration: 8 hours.	HFH	10	70	SOCAL.
Explosive	Surface Warfare	Training and End-to-End Mission Capability Verification—Submarine Missile Maritime.	Submarine crews launch missile(s) which may have an explosive warhead at a maritime target simulating an adversary surface ship with the goal of destroying or disabling adversary surface ship. Duration: 8 hours.	E9, E10	2	14	Hawaii.
Explosive	Surface Warfare	Training and End-to-End Mission Capability Verification—Submarine Missile Maritime.	Submarine crews launch missile(s) which may have an explosive warhead at a maritime target simulating an adversary surface ship with the goal of destroying or disabling adversary surface ship. Duration: 8 hours.	E9, E10	3	21	SOCAL.
Acoustic and Explosive.	Other Training Activities.	Multi-Domain Unmanned Autonomous Systems.	Multi-domain (surface, subsurface, and airborne) unmanned autonomous systems are launched from land, ships, and boats, in support of intelligence, surveillance, and reconnaissance operations; and deliver munitions or other non-munition systems to support mission and intelligence requirements. Duration: 4–8 hours.	E5, E7, MF to HF, VHFH.	50–100	500	Hawaii.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic and Explosive.	Other Training Activities.	Multi-Domain Unmanned Autonomous Systems.	Multi-domain (surface, subsurface, and airborne) unmanned autonomous systems are launched from land, ships, and boats, in support of intelligence, surveillance, and reconnaissance operations; and deliver munitions or other non-munition systems to support mission and intelligence requirements. Duration: 4–8 hours.	E5, E7, MF to HF, VHFH.	55–105	535	Pyramid Cove, SWATs.
Acoustic and Explosive.	Other Training Activities.	Multi-Domain Unmanned Autonomous Systems.	Multi-domain (surface, subsurface, and airborne) unmanned autonomous systems are launched from land, ships, and boats, in support of intelligence, surveillance, and reconnaissance operations; and deliver munitions or other non-munition systems to support mission and intelligence requirements. Duration: 4–8 hours.	E5, E7, MF to HF, VHFH.	50–100	500	SOCAL.
Acoustic	Other Training Activities.	Submarine Navigation Exercise.	Submarine crews operate sonar for navigation and object detection while transiting into and out of port during reduced visibility. Duration: 2 hours.	HFH, MFH	220	1,540	Pearl Harbor.
Acoustic	Other Training Activities.	Submarine Navigation Exercise.	Submarine crews operate sonar for navigation and object detection while transiting into and out of port during reduced visibility. Duration: 2 hours.	HFH, MFH	80	560	San Diego Bay.
Acoustic	Other Training Activities.	Submarine Sonar Maintenance and Systems Checks.	Maintenance of submarine sonar systems is conducted pierside or at sea. Duration: 1 hour.	MFH	260	1,820	Hawaii.
Acoustic	Other Training Activities.	Submarine Sonar Maintenance and Systems Checks.	Maintenance of submarine sonar systems is conducted pierside or at sea. Duration: 1 hour.	MFH	260	1,820	Pearl Harbor.
Acoustic	Other Training Activities.	Submarine Sonar Maintenance and Systems Checks.	Maintenance of submarine sonar systems is conducted pierside or at sea. Duration: 1 hour.	MFH	80	560	SOCAL.
Acoustic	Other Training Activities.	Submarine Sonar Maintenance and Systems Checks.	Maintenance of submarine sonar systems is conducted pierside or at sea. Duration: 1 hour.	MFH	13	91	PMSR.
Acoustic	Other Training Activities.	Submarine Sonar Maintenance and Systems Checks.	Maintenance of submarine sonar systems is conducted pierside or at sea. Duration: 1 hour.	MFH	92	644	San Diego Bay.
Acoustic	Other Training Activities.	Submarine Sonar Maintenance and Systems Checks.	Maintenance of submarine sonar systems is conducted pierside or at sea. Duration: 1 hour.	MFH	10	70	Transit Corridor.
Acoustic	Other Training Activities.	Submarine Under Ice Training and Certification.	Submarine crews train to operate under ice. Ice conditions are simulated during training and certification events. Duration: 5 days.	HFH	12	84	Hawaii.
Acoustic	Other Training Activities.	Submarine Under Ice Training and Certification.	Submarine crews train to operate under ice. Ice conditions are simulated during training and certification events. Duration: 5 days.	HFH	6	42	SOCAL.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic and Explosive.	Other Training Activities.	Submarine and UUV Subsea and Seabed Warfare Exercise.	Submarine crews and shore-based operators train to launch or recover and operate all classes of UUVs in the subsea and seabed environment in order to defend deep ocean and seabed infrastructure or take offensive action against a simulated adversary's subsea and seabed infrastructure. Duration: 1 day.	E3, VHFH	20	140	Hawaii.
Acoustic and Explosive.	Other Training Activities.	Submarine and UUV Subsea and Seabed Warfare Exercise.	Submarine crews and shore-based operators train to launch or recover and operate all classes of UUVs in the subsea and seabed environment in order to defend deep ocean and seabed infrastructure or take offensive action against a simulated adversary's subsea and seabed infrastructure. Duration: 1 day.	E3, VHFH	10	70	SOCAL.
Acoustic and Explosive.	Other Training Activities.	Submarine and UUV Subsea and Seabed Warfare Exercise.	Submarine crews and shore-based operators train to launch or recover and operate all classes of UUVs in the subsea and seabed environment in order to defend deep ocean and seabed infrastructure or take offensive action against a simulated adversary's subsea and seabed infrastructure. Duration: 1 day.	E3, VHFH	5	35	PMSR.
Acoustic and Explosive.	Other Training Activities.	Submarine and UUV Subsea and Seabed Warfare Exercise.	Submarine crews and shore-based operators train to launch or recover and operate all classes of UUVs in the subsea and seabed environment in order to defend deep ocean and seabed infrastructure or take offensive action against a simulated adversary's subsea and seabed infrastructure. Duration: 1 day.	E3, VHFH	5	35	NOCAL.
Acoustic	Other Training Activities.	Surface Ship Sonar Maintenance and Systems Checks.	Maintenance of surface ship sonar systems is conducted pierside or at sea. Duration: 4 hours.	HFH, MF1, MF1K, MFH.	75	525	Hawaii.
Acoustic	Other Training Activities.	Surface Ship Sonar Maintenance and Systems Checks.	Maintenance of surface ship sonar systems is conducted pierside or at sea. Duration: 4 hours.	HFH, MF1, MF1K, MFH.	80	560	Pearl Harbor.
Acoustic	Other Training Activities.	Surface Ship Sonar Maintenance and Systems Checks.	Maintenance of surface ship sonar systems is conducted pierside or at sea. Duration: 4 hours.	HFH, MF1, MF1K, MFH.	250	1,750	SOCAL.
Acoustic	Other Training Activities.	Surface Ship Sonar Maintenance and Systems Checks.	Maintenance of surface ship sonar systems is conducted pierside or at sea. Duration: 4 hours.	HFH, MF1, MF1K, MFH.	250	1,750	San Diego Bay.
Acoustic	Other Training Activities.	Surface Ship Sonar Maintenance and Systems Checks.	Maintenance of surface ship sonar systems is conducted pierside or at sea. Duration: 4 hours.	HFH, MF1, MF1K, MFH.	8–12	68	Transit Corridor.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Subsea and Seabed Warfare Kinetic Effectors.	Submarine crews or shore-based operators employ UUV with munitions or non-munition systems on the sea floor or in the water column. Duration: 8 hours.	E3	20	140	Hawaii.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Subsea and Seabed Warfare Kinetic Effectors.	Submarine crews or shore-based operators employ UUV with munitions or non-munition systems on the sea floor or in the water column. Duration: 8 hours.	E3	10	70	SOCAL.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Subsea and Seabed Warfare Kinetic Effectors.	Submarine crews or shore-based operators employ UUV with munitions or non-munition systems on the sea floor or in the water column. Duration: 8 hours.	E3	5	35	PMSR.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Subsea and Seabed Warfare Kinetic Effectors.	Submarine crews or shore-based operators employ UUV with munitions or non-munition systems on the sea floor or in the water column. Duration: 8 hours.	E3	5	35	NOCAL.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Unmanned Aerial Vehicle (UAV).	Submarine crews or shore-based personnel controlling a UUV launch a capsule containing a UAV. The canister is deployed underwater and ascends to a programmed depth. The canister subsequently launches a UAV, and the canister sinks. Duration: 8 hours.	E3	10	70	Hawaii.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Unmanned Aerial Vehicle (UAV).	Submarine crews or shore-based personnel controlling a UUV launch a capsule containing a UAV. The canister is deployed underwater and ascends to a programmed depth. The canister subsequently launches a UAV, and the canister sinks. Duration: 8 hours.	E3	5	35	SOCAL.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Unmanned Aerial Vehicle (UAV).	Submarine crews or shore-based personnel controlling a UUV launch a capsule containing a UAV. The canister is deployed underwater and ascends to a programmed depth. The canister subsequently launches a UAV, and the canister sinks. Duration: 8 hours.	E3	3	21	PMSR.
Explosive	Other Training Activities.	Training and End-to-End Mission Capability Verification—Unmanned Aerial Vehicle (UAV).	Submarine crews or shore-based personnel controlling a UUV launch a capsule containing a UAV. The canister is deployed underwater and ascends to a programmed depth. The canister subsequently launches a UAV, and the canister sinks. Duration: 8 hours.	E3	2	14	NOCAL.
Acoustic	Other Training Activities.	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	82–178	862	Hawaii.
Acoustic	Other Training Activities.	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	284–492	2,612	SOCAL.

TABLE 3—PROPOSED NAVY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Other Training Activities.	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	130–260	1,300	SSTC.
Acoustic	Other Training Activities.	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	18–36	180	China Point.

Note: LF = low-frequency, MF = mid-frequency, HF = high-frequency, dB = decibels, L = low, M= medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count. BARSTUR = Barking Sands Tactical Underwater Range, FORACS = Fleet Operational Readiness Accuracy Check Site, Hawaii = the Hawaii Study Area, MTR = Mine Training Range, NOCAL = Northern California Range Complex, PMRF = Pacific Missile Range Facility, PMSR = Point Mugu Sea Range, SCI = San Clemente Island, SOAR = Southern California Offshore Anti-Submarine Warfare Range, SOCAL = Southern California Range Complex, SSTC = Silver Strand Training Complex, SWAT = Special Warfare Training Area, TAR = Training Area and Range.

TABLE 4—PROPOSED COAST GUARD TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3	5	35	Hawaii.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3	20	140	SOCAL.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3	2	14	PMSR.
Explosive	Surface Warfare	Gunnery Exercise Surface-to-Surface Ship Large-caliber.	Surface ship crews fire large-caliber guns at surface targets. Duration: up to 3 hours.	E3	2	14	NOCAL.
Acoustic	Other Training ..	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	200	1,400	Hawaii.
Acoustic	Other Training ..	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	200	1,400	SOCAL.
Acoustic	Other Training ..	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	100	700	PMSR.

TABLE 4—PROPOSED COAST GUARD TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Other Training ..	Unmanned Underwater Vehicle Training—Certification and Development Exercises.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment. Duration: up to 24 hours.	HFM, MF to HF, VHFH.	10	70	NOCAL.

Note: LF = low-frequency, MF = mid-frequency, HF = high-frequency, dB = decibels, L = low, M = medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count. Hawaii = the Hawaii Study Area, NOCAL = Northern California Range Complex, PMSR = Point Mugu Sea Range, SOCAL = Southern California Range Complex.

TABLE 5—PROPOSED ARMY TRAINING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Amphibious Warfare.	Shore-to-Surface Artillery Exercise.	Amphibious land-based forces fire artillery guns at surface targets. Duration: 1–2 hours of firing, 8 hours total.	E6	2	14	PMRF.
Explosive	Amphibious Warfare.	Shore-to-Surface Missile Exercise.	Amphibious land-based forces fire anti-surface missiles, rockets, and loitering munitions at surface targets. Duration: 1–2 hours of firing, 8 hours total.	E9	18	126	PMRF.

Note: PMRF = Pacific Missile Range Facility.

Overview of Testing Activities Within the Study Area

While this proposed rule includes an evaluation of proposed training activities by the Navy, Coast Guard, and Army, all testing activities evaluated in this proposed rule would only be conducted by the Navy. The Navy's research and acquisition community engages in a broad spectrum of testing activities, some of which ultimately support all Action Proponents. These activities include, but are not limited to, basic and applied scientific research and technology development; testing, evaluation, and maintenance of systems (*e.g.,* missiles, radar, and sonar) and platforms (*e.g.,* surface ships, submarines, and aircraft); and acquisition of systems and platforms to support Navy missions and give a technological edge over adversaries. The individual commands within the research and acquisition community considered in the application are Naval Air Systems Command (NAVAIR), Naval Facilities Engineering and Expeditionary Warfare Center, Naval Sea Systems Command (NAVSEA), Office of Naval Research (ONR), and Naval Information Warfare Systems Command (NAVWAR). Although included in the testing community, proposed Expeditionary Warfare Center activities do not involve sonar and other transducers, underwater detonations, pile driving, airguns, or any other stressors that could result in harassment of marine mammals, and therefore, are not analyzed further in this proposed rule.

The Action Proponents operate in an ever-changing strategic, tactical, financially-constrained, and time-constrained environment. Testing activities occur in response to emerging science or fleet operational needs. For example, future Navy studies to develop a better understanding of ocean currents may be designed based on advancements made by non-government researchers not yet published in the scientific literature. Similarly, future but yet unknown Navy, Coast Guard, and Army operations within a specific geographic area may require development of modified Navy assets to address local conditions. Such modifications must be tested in the field to ensure they meet fleet needs and requirements. Accordingly, generic descriptions of some of these activities are the best that can be articulated in a long-term, comprehensive document.

Some testing activities are similar to training activities conducted by the fleet (*e.g.,* both the fleet and the research and acquisition community fire torpedoes). While the firing of a torpedo might look identical to an observer, the difference is in the purpose of the firing. The fleet might fire the torpedo to practice the procedures for such a firing, whereas the research and acquisition community might be assessing a new torpedo guidance technology or testing it to ensure the torpedo meets performance specifications and operational requirements (see appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS for more detailed descriptions of the activities).

NAVAIR testing activities generally fall in the primary mission areas used by the fleets and include the evaluation of new and in-service aircraft platforms and systems to deliver critical air warfare capabilities to the fleets. To accomplish its mission, NAVAIR conducts anti-submarine warfare tests using fixed-wing and rotary wing aircraft platforms, a suite of passive and active acoustic sonobuoys (to include Lot Acceptance Testing), and dipping sonar systems.

The majority of testing activities conducted by NAVAIR are similar to fleet training activities, and many platforms and systems currently being tested are already being used by the fleet or will ultimately be integrated into fleet training activities. However, some testing activities may be conducted in different locations and in a different manner than similar fleet training activities, and, therefore, the analysis for those events and the potential environmental effects may differ. Table 6 summarizes the proposed testing

activities for NAVAIR analyzed within the HCTT Study Area.

TABLE 6—PROPOSED NAVAIR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Anti-Submarine Warfare.	ASW Torpedo Test—Aircraft.	This event is similar to the training event torpedo exercise. Test evaluates anti-submarine warfare systems onboard rotary-wing and fixed-wing aircraft and the ability to search for, detect, classify, localize, track, and attack a submarine or similar target. Duration: 2–6 hours.	HFH, MFH, MFM.	24–26	174	Hawaii.
Acoustic	Anti-Submarine Warfare.	ASW Torpedo Test—Aircraft.	This event is similar to the training event torpedo exercise. Test evaluates anti-submarine warfare systems onboard rotary-wing and fixed-wing aircraft and the ability to search for, detect, classify, localize, track, and attack a submarine or similar target. Duration: 2–6 hours.	HFH, MFH, MFM.	36–39	259	SOCAL.
Acoustic	Anti-Submarine Warfare.	ASW Torpedo Test—Aircraft.	This event is similar to the training event torpedo exercise. Test evaluates anti-submarine warfare systems onboard rotary-wing and fixed-wing aircraft and the ability to search for, detect, classify, localize, track, and attack a submarine or similar target. Duration: 2–6 hours.	HFH, MFH, MFM.	36–39	259	SCORE.
Acoustic	Anti-Submarine Warfare.	ASW Tracking Test—Fixed-Wing.	The test evaluates the sensors and systems used by maritime patrol aircraft to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements. Duration: 8 hours.	HFM, LFH, LFM, MFM.	61–67	445	Hawaii.
Acoustic	Anti-Submarine Warfare.	ASW Tracking Test—Fixed-Wing.	The test evaluates the sensors and systems used by maritime patrol aircraft to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements. Duration: 8 hours.	HFM, LFH, LFM, MFM.	68–75	497	SOCAL.
Acoustic	Anti-Submarine Warfare.	ASW Tracking Test—Rotary Wing.	The test evaluates the sensors and systems used by helicopters to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements. Duration: 2 hours.	MFH, MFM	66–73	483	Hawaii.
Acoustic	Anti-Submarine Warfare.	ASW Tracking Test—Rotary Wing.	The test evaluates the sensors and systems used by helicopters to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements. Duration: 2 hours.	MFH, MFM	66–73	482	SOCAL.
Acoustic	Anti-Submarine Warfare.	ASW Tracking Test—Rotary Wing.	The test evaluates the sensors and systems used by helicopters to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements. Duration: 2 hours.	MFH, MFM	66–73	482	SCORE.
Acoustic	Anti-Submarine Warfare.	Kilo Dip Test	Functional check of a helicopter-deployed dipping sonar system prior to conducting a testing or training event using the dipping sonar system. Duration: 1–2 hours.	MFH	6–7	45	Hawaii.

TABLE 6—PROPOSED NAVAIR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Anti-Submarine Warfare.	Kilo Dip Test	Functional check of a helicopter-deployed dipping sonar system prior to conducting a testing or training event using the dipping sonar system. Duration: 1–2 hours.	MFH	6–7	45	SOCAL.
Acoustic	Anti-Submarine Warfare.	Sonobuoy Lot Acceptance Test.	Sonobuoys are deployed from surface vessels and aircraft to verify the integrity and performance of a lot or group of sonobuoys in advance of delivery to the fleet for operational use. Duration: 6 hours.	HFM, LFH, LFM, MFM.	32–38	242	Hawaii.
Acoustic	Anti-Submarine Warfare.	Sonobuoy Lot Acceptance Test.	Sonobuoys are deployed from surface vessels and aircraft to verify the integrity and performance of a lot or group of sonobuoys in advance of delivery to the fleet for operational use. Duration: 6 hours.	HFM, LFH, LFM, MFM.	320–352	2,336	SOCAL.
Acoustic	Mine Warfare	Airborne Dipping Sonar Minehunting Test.	A mine-hunting dipping sonar system that is deployed from a helicopter and uses high-frequency sonar for the detection and classification of bottom and moored mines. Duration: 2 hours.	HFH	18–20	132	Hawaii.
Acoustic	Mine Warfare	Airborne Dipping Sonar Minehunting Test.	A mine-hunting dipping sonar system that is deployed from a helicopter and uses high-frequency sonar for the detection and classification of bottom and moored mines. Duration: 2 hours.	HFH	18–20	132	SOCAL.
Explosive	Mine Warfare	Airborne Mine Neutralization System Test.	A test of the airborne mine neutralization system evaluates the system's ability to detect and destroy mines from an airborne mine countermeasures capable helicopter. The Airborne Mine Neutralization System uses up to four unmanned underwater vehicles equipped with high frequency sonar, video cameras, and explosive and non-explosive neutralizers. Duration: 2–3 hours.	E4	36–39	261	Hawaii.
Explosive	Mine Warfare	Airborne Mine Neutralization System Test.	A test of the airborne mine neutralization system evaluates the system's ability to detect and destroy mines from an airborne mine countermeasures capable helicopter. The Airborne Mine Neutralization System uses up to four unmanned underwater vehicles equipped with high frequency sonar, video cameras, and explosive and non-explosive neutralizers. Duration: 2–3 hours.	E4	81–84	576	SOCAL.
Acoustic	Mine Warfare	Airborne Sonobuoy Minehunting Test.	A mine-hunting system made up of sonobuoys deployed from a helicopter. A field of sonobuoys, using high-frequency sonar, is used to detect and classify bottom and moored mines. Duration: 2 hours.	MFM	9–10	66	Hawaii.
Acoustic	Mine Warfare	Airborne Sonobuoy Minehunting Test.	A mine-hunting system made up of sonobuoys deployed from a helicopter. A field of sonobuoys, using high-frequency sonar, is used to detect and classify bottom and moored mines. Duration: 2 hours.	MFM	9–10	66	SOCAL.

TABLE 6—PROPOSED NAVAIR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Surface Warfare	Air-to-Surface Bombing Test.	This event is similar to the training event bombing exercise air-to-surface. Fixed-wing aircraft test the delivery of bombs against surface maritime targets with the goal of evaluating the bomb, the bomb carry and delivery system, and any associated systems that may have been newly developed or enhanced. Duration: 2 hours.	E7, E9	8–9	59	Hawaii.
Explosive	Surface Warfare	Air-to-Surface Bombing Test.	This event is similar to the training event bombing exercise air-to-surface. Fixed-wing aircraft test the delivery of bombs against surface maritime targets with the goal of evaluating the bomb, the bomb carry and delivery system, and any associated systems that may have been newly developed or enhanced. Duration: 2 hours.	E7, E9	14–15	101	SOCAL.
Explosive	Surface Warfare	Air-to-Surface Bombing Test.	This event is similar to the training event bombing exercise air-to-surface. Fixed-wing aircraft test the delivery of bombs against surface maritime targets with the goal of evaluating the bomb, the bomb carry and delivery system, and any associated systems that may have been newly developed or enhanced. Duration: 2 hours.	E7, E9	52	364	PMSR.
Explosive	Surface Warfare	Air-to-Surface Gunnery Test.	This event is similar to the training event gunnery exercise (air to surface). Fixed-wing and rotary-wing aircrews evaluate new or enhanced aircraft guns against surface maritime targets to test that the gun, gun ammunition, or associated systems meet required specifications or to train aircrew in the operation of a new or enhanced weapon system. Duration: 2–3 hours.	E1	6–7	45	Hawaii.
Explosive	Surface Warfare	Air-to-Surface Gunnery Test.	This event is similar to the training event gunnery exercise (air to surface). Fixed-wing and rotary-wing aircrews evaluate new or enhanced aircraft guns against surface maritime targets to test that the gun, gun ammunition, or associated systems meet required specifications or to train aircrew in the operation of a new or enhanced weapon system. Duration: 2–3 hours.	E1	60–66	438	SOCAL.
Explosive	Surface Warfare	Air-to-Surface Gunnery Test.	This event is similar to the training event gunnery exercise (air to surface). Fixed-wing and rotary-wing aircrews evaluate new or enhanced aircraft guns against surface maritime targets to test that the gun, gun ammunition, or associated systems meet required specifications or to train aircrew in the operation of a new or enhanced weapon system. Duration: 2–3 hours.	E1	10	70	PMSR.
Explosive	Surface Warfare	Air-to-Surface Missile Test.	This event is similar to the training event missile exercise air-to-surface. Test may involve both fixed-wing and rotary-wing aircraft launching missiles at surface maritime targets to evaluate the weapons system or as part of another system's integration test. Duration: 2–4 hours.	E6, E7, E8, E9	18–20	132	Hawaii.

TABLE 6—PROPOSED NAVAIR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Explosive	Surface Warfare	Air-to-Surface Missile Test.	This event is similar to the training event missile exercise air-to-surface. Test may involve both fixed-wing and rotary-wing aircraft launching missiles at surface maritime targets to evaluate the weapons system or as part of another system's integration test. Duration: 2–4 hours.	E6, E7, E8, E9	8	56	SOCAL.
Explosive	Surface Warfare	Air-to-Surface Missile Test.	This event is similar to the training event missile exercise air-to-surface. Test may involve both fixed-wing and rotary-wing aircraft launching missiles at surface maritime targets to evaluate the weapons system or as part of another system's integration test. Duration: 2–4 hours.	E6, E7, E8, E9	180–186	1,275	PMSR.
Explosive	Surface Warfare	Rocket Test	Rocket tests evaluate the integration, accuracy, performance, and safe separation of guided and unguided 2.75-inch (7 centimeter (cm)) rockets fired from a hovering or forward flying helicopter. Duration: 1–3 hours.	E3, E9	2	14	Hawaii.
Explosive	Surface Warfare	Rocket Test	Rocket tests evaluate the integration, accuracy, performance, and safe separation of guided and unguided 2.75-inch (7 cm) rockets fired from a hovering or forward flying helicopter. Duration: 1–3 hours.	E3, E9	22–24	160	SOCAL.
Explosive	Surface Warfare	Rocket Test	Rocket tests evaluate the integration, accuracy, performance, and safe separation of guided and unguided 2.75-inch (7 cm) rockets fired from a hovering or forward flying helicopter. Duration: 1–3 hours.	E3, E9	8	56	PMSR.
Explosive	Surface Warfare	Subsurface-to-Surface Missile Test.	Submarines launch missiles at surface maritime targets with the goal of destroying or disabling enemy ships or boats. Duration: 8 hours.	E10	4	28	PMSR.
Explosive	Surface Warfare	Surface-to-Surface Gunnery Test—Large-Caliber.	Evaluates the performance and effectiveness of software and hardware modifications or upgrades of ship-based large-caliber gunnery systems against surface targets. 3 hours.	E3, E5	10	70	PMSR.
Explosive	Surface Warfare	Surface-to-Surface Gunnery Test—Medium-Caliber.	Evaluates the performance and effectiveness of software and hardware modifications or upgrades of ship-based medium-caliber gunnery systems against surface targets. Duration: 3 hours.	E1, E3	26	182	PMSR.
Explosive	Surface Warfare	Surface-to-Surface Missile Test.	Surface ships launch missiles at surface maritime targets. Duration: 2–5 hours.	E9, E10	44	308	PMSR.
Acoustic	Other Testing	Undersea Range System Test.	Post installation node survey and test and periodic testing of range Node transmit functionality. Duration: varies.	MFM	30–33	207	BARSTUR.
Acoustic	Other Testing	Undersea Range System Test.	Post installation node survey and test and periodic testing of range Node transmit functionality. Duration: varies.	MFM	19–21	127	SOCAL.

Note: LF = low-frequency, MF = mid-frequency, HF = high-frequency, dB = decibels, L = low, M = medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count. BARSTUR = Barking Sands Tactical Underwater Range, Hawaii = the Hawaii Study Area, PMSR = Point Mugu Sea Range, SCORE = Southern California Offshore Range, SOAR = Southern California Offshore Anti-Submarine Warfare Range, SOCAL = Southern California Range Complex.

NAVSEA activities are generally aligned with the primary mission areas used by the fleets and include, but are not limited to, new ship construction, life cycle support, and other weapon system development and testing. Testing activities are conducted throughout the life of a Navy ship, from construction through deactivation from the fleet to verification of performance and mission capabilities. Activities include pierside and at-sea testing of ship systems, including sonar, acoustic countermeasures, radars, torpedoes, weapons, unmanned systems, and radio

equipment; tests to determine how the ship performs at sea (sea trials); development and operational test and evaluation programs for new technologies and systems, including ship shock trials to test the survivability of new ships; and testing on all ships and systems that have undergone overhaul or maintenance. Table 7 summarizes the proposed testing activities for NAVSEA analyzed within the HCTT Study Area.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Anti-Submarine Warfare.	ASW Mission Package Testing.	Ships and their supporting platforms (*e.g.,* rotary-wing aircraft, unmanned aerial systems) detect, localize, and prosecute submarines. Duration: 1–2 weeks with 4–8 hours of active sonar use per day.	MF1, MFH	1	7	Hawaii.
Acoustic	Anti-Submarine Warfare.	ASW Mission Package Testing.	Ships and their supporting platforms (*e.g.,* rotary-wing aircraft, unmanned aerial systems) detect, localize, and prosecute submarines. Duration: 1–2 weeks with 4–8 hours of active sonar use per day.	MF1, MFH	1	7	SOCAL.
Acoustic	Anti-Submarine Warfare.	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment. Duration: 4 hours to 11 days.	HFH, HFL, HFM, LF to HF, LF to MF, LFH, LFM, MF to HF, MF1, MF1K, MFH, MFL, MFM.	9–11	70	Hawaii.
Acoustic	Anti-Submarine Warfare.	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment. Duration: 4 hours to 11 days.	HFH, HFL, HFM, LF to HF, LF to MF, LFH, LFM, MF to HF, MF1, MF1K, MFH, MFL, MFM.	16–22	128	SOCAL.
Acoustic	Anti-Submarine Warfare.	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment. Duration: 4 hours to 11 days.	HFH, HFL, HFM, LF to HF, LF to MF, LFH, LFM, MF to HF, MF1, MF1K, MFH, MFL, MFM.	10–20	70	SOAR.
Acoustic	Anti-Submarine Warfare.	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment. Duration: 4 hours to 11 days.	HFH, HFL, HFM, LF to HF, LF to MF, LFH, LFM, MF to HF, MF1, MF1K, MFH, MFL, MFM.	0–1	4	PMRF.
Acoustic	Anti-Submarine Warfare.	Countermeasure Testing.	Countermeasure testing involves the testing of systems that detect, localize, and engage incoming weapons, including marine vessel targets and airborne missiles. Testing includes surface ship torpedo defense systems, marine vessel stopping payloads, and airborne decoys against targets. Duration: 4 hours to 6 days.	HFH, LF to HF, MF to HF, MFH, MFM, VHFH.	3–6	20	Hawaii, Maui Basin, PMRF.
Acoustic	Anti-Submarine Warfare.	Countermeasure Testing.	Countermeasure testing involves the testing of systems that detect, localize, and engage incoming weapons, including marine vessel targets and airborne missiles. Testing includes surface ship torpedo defense systems, marine vessel stopping payloads, and airborne decoys against targets. Duration: 4 hours to 6 days.	HFH, LF to HF, MF to HF, MFH, MFM, VHFH.	7–12	25	SOCAL, SCORE.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Anti-Submarine Warfare.	Pierside Sonar Testing	Pierside testing to ensure systems are fully functional in a controlled pierside environment prior to at-sea test activities and complete any troubleshooting. Duration: up to 3 weeks, with intermittent sonar use.	HFH, HFM, MF to HF, MFH, MFM.	13–25	171	Pearl Harbor.
Acoustic	Anti-Submarine Warfare.	Pierside Sonar Testing	Pierside testing to ensure systems are fully functional in a controlled pierside environment prior to at-sea test activities and complete any troubleshooting. Duration: up to 3 weeks, with intermittent sonar use.	HFH, HFM, MF to HF, MFH, MFM.	44–55	383	San Diego Bay.
Acoustic	Anti-Submarine Warfare.	Pierside Sonar Testing	Pierside testing to ensure systems are fully functional in a controlled pierside environment prior to at-sea test activities and complete any troubleshooting. Duration: up to 3 weeks, with intermittent sonar use.	HFH, HFM, MF to HF, MFH, MFM.	15–20	140	Port Hueneme.
Acoustic	Anti-Submarine Warfare.	Surface Ship Sonar Testing/Maintenance.	Pierside and at-sea testing of ship systems occur periodically following major maintenance periods and for routine maintenance. Duration: up to 3 weeks, with intermittent sonar use.	LFL, MF to HF, MF1, MF1K, MFM.	3	7	Hawaii.
Acoustic	Anti-Submarine Warfare.	Surface Ship Sonar Testing/Maintenance.	Pierside and at-sea testing of ship systems occur periodically following major maintenance periods and for routine maintenance. Duration: up to 3 weeks, with intermittent sonar use.	LFL, MF to HF, MF1, MF1K, MFM.	3	21	Pearl Harbor.
Acoustic	Anti-Submarine Warfare.	Surface Ship Sonar Testing/Maintenance.	Pierside and at-sea testing of ship systems occur periodically following major maintenance periods and for routine maintenance. Duration: up to 3 weeks, with intermittent sonar use.	LFL, MF to HF, MF1, MF1K, MFM.	3	21	SOCAL.
Acoustic	Anti-Submarine Warfare.	Surface Ship Sonar Testing/Maintenance.	Pierside and at-sea testing of ship systems occur periodically following major maintenance periods and for routine maintenance. Duration: up to 3 weeks, with intermittent sonar use.	LFL, MF to HF, MF1, MF1K, MFM.	3	21	San Diego Bay.
Acoustic and Explosive.	Anti-Submarine Warfare.	Torpedo (Explosive) Testing.	Air, surface, or submarine crews employ explosive and non-explosive torpedoes against artificial targets. Duration: 1–2 days, 8–12 hours per day.	E8, E11, HFH, MF to HF, MF1, MFH, MFM.	1–5	17	Hawaii, SOCAL, PMSR.
Acoustic	Anti-Submarine Warfare.	Torpedo (Non-Explosive) Testing.	Air, surface, or submarine crews employ non-explosive torpedoes against submarines, surface vessels, or artificial targets. Duration: up to 2 weeks.	HFH, HFM, LF to HF, MF to HF, MF1, MFH, MFL, MFM, VHFH.	13–17	96	Hawaii, SOCAL, BARSTUR, PMSR.
Explosive	Mine Warfare ...	Mine Countermeasure and Neutralization Testing.	Air, surface, and subsurface vessels neutralize threat mines and mine-like objects. Duration: 1–10 days, with intermittent use of countermeasure systems.	E4	18–45	315	SOCAL.
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	0–1	7	PMRF.
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	16	109	Maui Basin.
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	6	36	CPAAA.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	6	36	SSTC.
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	6	37	Tanner Bank.
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	6	42	Imperial Beach Minefield.
Acoustic and Explosive.	Mine Warfare ...	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations. Duration: 1–2 weeks, with intermittent use of countermeasure systems.	E4, HFM, MFH	1	7	PMSR.
Acoustic	Mine Warfare ...	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects. Duration: up to 24 days, 8–12 hours per day.	HFH	4–8	28	Hawaii.
Acoustic	Mine Warfare ...	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects. Duration: up to 24 days, 8–12 hours per day.	HFH	0–1	4	Imperial Beach Minefield.
Acoustic	Mine Warfare ...	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects. Duration: up to 24 days, 8–12 hours per day.	HFH	2	14	Maui Basin.
Acoustic	Mine Warfare ...	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects. Duration: up to 24 days, 8–12 hours per day.	HFH	2	14	Tanner Bank.
Acoustic	Mine Warfare ...	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects. Duration: up to 24 days, 8–12 hours per day.	HFH	4–8	28	PMSR.
Acoustic	Mine Warfare ...	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects. Duration: up to 24 days, 8–12 hours per day.	HFH	4–9	30	SOCAL.
Acoustic	Unmanned Systems.	Unmanned Underwater Vehicle Testing.	Testing involves the production or upgrade of unmanned underwater vehicles. This may include testing mine detection capabilities, evaluating the basic functions of individual platforms, or conducting complex events with multiple vehicles. Duration: up to 35 days, gliders could operate for multiple months.	HFL, HFM, MF to HF, MFM, VHFH, VHFL.	2	14	Pearl Harbor.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Unmanned Systems.	Unmanned Underwater Vehicle Testing.	Testing involves the production or upgrade of unmanned underwater vehicles. This may include testing mine detection capabilities, evaluating the basic functions of individual platforms, or conducting complex events with multiple vehicles. Duration: up to 35 days, gliders could operate for multiple months.	HFL, HFM, MF to HF, MFM, VHFH, VHFL.	230	1,610	Port Hueneme.
Acoustic	Unmanned Systems.	Unmanned Underwater Vehicle Testing.	Testing involves the production or upgrade of unmanned underwater vehicles. This may include testing mine detection capabilities, evaluating the basic functions of individual platforms, or conducting complex events with multiple vehicles. Duration: up to 35 days, gliders could operate for multiple months.	HFL, HFM, MF to HF, MFM, VHFH, VHFL.	10–15	85	SOCAL.
Acoustic	Unmanned Systems.	Unmanned Underwater Vehicle Testing.	Testing involves the production or upgrade of unmanned underwater vehicles. This may include testing mine detection capabilities, evaluating the basic functions of individual platforms, or conducting complex events with multiple vehicles. Duration: up to 35 days, gliders could operate for multiple months.	HFL, HFM, MF to HF, MFM, VHFH, VHFL.	440	3,080	SOCAL nearshore.
Acoustic	Vessel Evaluation.	In-Port Maintenance Testing.	Each combat system is tested to ensure they are functioning in a technically acceptable manner and are operationally ready to support at-sea testing. Duration: 3 weeks.	MF1	5	30	Pearl Harbor.
Acoustic	Vessel Evaluation.	In-Port Maintenance Testing.	Each combat system is tested to ensure they are functioning in a technically acceptable manner and are operationally ready to support at-sea testing. Duration: 3 weeks.	MF1	5	30	San Diego Bay.
Acoustic	Vessel Evaluation.	In-Port Maintenance Testing.	Each combat system is tested to ensure they are functioning in a technically acceptable manner and are operationally ready to support at-sea testing. Duration: 3 weeks.	MF1	10	70	Port Hueneme.
Acoustic	Vessel Evaluation.	Signature Analysis Operations.	Surface ship and submarine testing of electromagnetic, acoustic, optical, and radar signature measurements. Duration: 1–5 days.	HFM, MFM	2–4	14	Hawaii.
Acoustic	Vessel Evaluation.	Signature Analysis Operations.	Surface ship and submarine testing of electromagnetic, acoustic, optical, and radar signature measurements. Duration: 1–5 days.	HFM, MFM	0–1	1	San Diego Bay.
Explosive	Vessel Evaluation.	Small Ship Shock Trial	Underwater detonations are used to test new ships or major upgrades. Duration: up to 3 weeks.	E16	0–1	1	SOCAL.
Acoustic	Vessel Evaluation.	Submarine Sea Trials—Weapons System Testing.	Submarine weapons and sonar systems are tested at-sea to meet integrated combat system certification requirements. Duration: up to 7 days.	HFH, HFM, LF to HF, MFH, MFL.	2–4	12	Hawaii.
Acoustic	Vessel Evaluation.	Submarine Sea Trials—Weapons System Testing.	Submarine weapons and sonar systems are tested at-sea to meet integrated combat system certification requirements. Duration: up to 7 days.	HFH, HFM, LF to HF, MFH, MFL.	2–4	12	SOCAL.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic and Explosive.	Vessel Evaluation.	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing, and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations). Duration: 7 days.	E3, E5, E6, E7, E8, E9, HFH, MFM.	0–12	48	Hawaii.
Acoustic and Explosive.	Vessel Evaluation.	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing, and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations). Duration: 7 days.	E3, E5, E6, E7, E8, E9, HFH, MFM.	4	35	PMRF.
Acoustic and Explosive.	Vessel Evaluation.	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing, and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations). Duration: 7 days.	E3, E5, E6, E7, E8, E9, HFH, MFM.	3–15	39	SOCAL.
Acoustic and Explosive.	Vessel Evaluation.	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing, and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations). Duration: 7 days.	E3, E5, E6, E7, E8, E9, HFH, MFM.	3–6	30	SOAR.
Acoustic and Explosive.	Vessel Evaluation.	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing, and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations). Duration: 7 days.	E3, E5, E6, E7, E8, E9, HFH, MFM.	4–12	36	SCORE.
Acoustic and Explosive.	Vessel Evaluation.	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing, and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations). Duration: 7 days.	E3, E5, E6, E7, E8, E9, HFH, MFM.	7–20	67	PMSR.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Vessel Evaluation.	Undersea Warfare Testing.	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage undersea targets. Duration: up to 10 days.	HFH, MF1, MFH, MFM.	1–7	26	Hawaii.
Acoustic	Vessel Evaluation.	Undersea Warfare Testing.	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage undersea targets. Duration: up to 10 days.	HFH, MF1, MFH, MFM.	2–3	16	PMRF.
Acoustic	Vessel Evaluation.	Undersea Warfare Testing.	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage undersea targets. Duration: up to 10 days.	HFH, MF1, MFH, MFM.	23–43	154	SOCAL.
Acoustic	Vessel Evaluation.	Undersea Warfare Testing.	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage undersea targets. Duration: up to 10 days.	HFH, MF1, MFH, MFM.	2–14	56	SCORE.
Acoustic and Explosive.	Other Testing ...	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E7, LFM	1	7	Hawaii.
Acoustic and Explosive.	Other Testing ...	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E7, LFM	4–5	31	PMRF.
Acoustic and Explosive.	Other Testing ...	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E7, LFM	2	14	SOCAL.
Acoustic and Explosive.	Other Testing ...	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E7, LFM	0–1	3	PMSR.
Acoustic	Other Testing ...	Insertion/Extraction	Testing of submersibles capable of inserting and extracting personnel and payloads into denied areas from strategic distances. Duration: up to 30 days.	HFM, LF to MF, LFH.	2	14	Hawaii.
Acoustic	Other Testing ...	Insertion/Extraction	Testing of submersibles capable of inserting and extracting personnel and payloads into denied areas from strategic distances. Duration: up to 30 days.	HFM, LF to MF, LFH.	2	14	SOCAL.
Acoustic and Explosive.	Other Testing ...	Semi-Stationary Equipment Testing.	Semi-stationary equipment (*e.g.,* hydrophones) is deployed to determine functionality. Duration: up to 14 days.	E4, HFH	4–8	40	Pearl Harbor.

TABLE 7—PROPOSED NAVSEA TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic and Explosive.	Other Testing ...	Semi-Stationary Equipment Testing.	Semi-stationary equipment (*e.g.,* hydrophones) is deployed to determine functionality. Duration: up to 14 days.	E4, HFH	4–8	40	San Diego Bay.

Note: LF = low-frequency, MF = mid-frequency, HF = high-frequency, dB = decibels, L = low, M = medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count. BARSTUR = Barking Sands Tactical Underwater Range, CPAAA = Camp Pendleton Amphibious Assault Area, Hawaii = the Hawaii Study Area, PMRF = Pacific Missile Range Facility, PMSR = Point Mugu Sea Range, SCORE = Southern California Offshore Range, SOAR = Southern California Offshore Anti-Submarine Range, SOCAL = Southern California Range Complex, SSTC = Silver Strand Training Complex.

NAVWAR is the information warfare systems command for the Navy. The mission of NAVWAR is to identify, develop, deliver, and sustain information warfare capabilities and services that enable naval, joint, coalition, and other national missions operating in warfighting domains from seabed to space; and to perform such other functions and tasks as directed. NAVWAR Systems Center Pacific is the research and development part of NAVWAR focused on developing and transitioning technologies in the area of command, control, communications, computers, intelligence, surveillance, and reconnaissance. Table 8 summarizes the proposed testing activities for NAVWAR analyzed within the HCTT Study Area.

TABLE 8—PROPOSED NAVWAR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic, Oceanographic, and Energy Research.	Testing includes activities utilizing the marine environment for research, and test and evaluation. Tests may involve radar, environmental sensors, magnetic sensors, passive and active acoustic sensors, optical sensors, and lasers. Surface operations utilize a variety of vessels and vehicles for deployment, operation, and testing. Energy research and harvesting would include the development and testing of energy harvesting and storage technologies, maritime charging stations, remote communications, and associated infrastructure. This testing would also include bioacoustics research in support of marine mammal science. Duration: up to 14 days.	HFM, LF to HF, LFM, MF to HF, MFH, MFM.	2	14	Pearl Harbor.
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic, Oceanographic, and Energy Research.	Testing includes activities utilizing the marine environment for research, and test and evaluation. Tests may involve radar, environmental sensors, magnetic sensors, passive and active acoustic sensors, optical sensors, and lasers. Surface operations utilize a variety of vessels and vehicles for deployment, operation, and testing. Energy research and harvesting would include the development and testing of energy harvesting and storage technologies, maritime charging stations, remote communications, and associated infrastructure. This testing would also include bioacoustics research in support of marine mammal science. Duration: up to 14 days.	HFM, LF to HF, LFM, MF to HF, MFH, MFM.	10–16	88	SOCAL.

TABLE 8—PROPOSED NAVWAR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic, Oceanographic, and Energy Research.	Testing includes activities utilizing the marine environment for research, and test and evaluation. Tests may involve radar, environmental sensors, magnetic sensors, passive and active acoustic sensors, optical sensors, and lasers. Surface operations utilize a variety of vessels and vehicles for deployment, operation, and testing. Energy research and harvesting would include the development and testing of energy harvesting and storage technologies, maritime charging stations, remote communications, and associated infrastructure. This testing would also include bioacoustics research in support of marine mammal science. Duration: up to 14 days.	HFM, LF to HF, LFM, MF to HF, MFH, MFM.	133–160	1,012	San Diego Bay.
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic, Oceanographic, and Energy Research.	Testing includes activities utilizing the marine environment for research, and test and evaluation. Tests may involve radar, environmental sensors, magnetic sensors, passive and active acoustic sensors, optical sensors, and lasers. Surface operations utilize a variety of vessels and vehicles for deployment, operation, and testing. Energy research and harvesting would include the development and testing of energy harvesting and storage technologies, maritime charging stations, remote communications, and associated infrastructure. This testing would also include bioacoustics research in support of marine mammal science. Duration: up to 14 days.	HFM, LF to HF, LFM, MF to HF, MFH, MFM.	2–4	20	PMSR.
Acoustic	Other Testing	Communications ..	Testing of maritime communications, underwater network systems with fiber optics cables, laser communications, acoustic modem networks and launching of communication payloads and objects. Durations: typically 5 days for 6–8 hours per day.	LF to MF	1	7	Hawaii.
Acoustic	Other Testing	Communications ..	Testing of maritime communications, underwater network systems with fiber optics cables, laser communications, acoustic modem networks and launching of communication payloads and objects. Durations: typically 5 days for 6–8 hours per day.	LF to MF	4	28	SOCAL.
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	15–17	108	Hawaii.

TABLE 8—PROPOSED NAVWAR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	2	14	Pearl Harbor.
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	83–123	700	SOCAL.
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	5–10	50	CPAAA.
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	8–10	62	San Diego Bay.

TABLE 8—PROPOSED NAVWAR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	11–19	101	SCIUR.
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	38–51	305	SCORE.
Acoustic	Other Testing	Intelligence, Surveillance, Reconnaissance.	Testing deployable autonomous undersea technologies that may include mine detection and classification, detection and classification of targets of interest, sensors on the undersea systems testbed, expansion of the undersea systems testbed with fiber optic cables and nodes, sensor systems to detect mine shapes on ship hulls and pier structures, sensors for swimmer interdiction and other threats, and sensor systems that can detect explosive, radioactive, and other signatures of concern. Duration: up to 30 days.	Air gun, HFL, HFM, LF, LF to HF, LFH, MF to HF, MFH, MFL, MFM, VHFH.	44–62	362	SSTC.
Acoustic	Other Testing	Vehicle Testing	Testing of surface, subsurface and airborne vehicles, sensor systems, payloads, communications, and navigation which may involve remotely operated vehicles, autonomous underwater vehicles, autonomous surface vehicles, and autonomous aerial vehicles. Testing may involve evaluating individual vehicles and payloads or conducting complex events with multiple vehicles. Durations: typically 5 days for 6–8 hours per day.	HFL, HFM, LFH, MFH, MFL, VHFH.	15–22	123	Hawaii.
Acoustic	Other Testing	Vehicle Testing	Testing of surface, subsurface and airborne vehicles, sensor systems, payloads, communications, and navigation which may involve remotely operated vehicles, autonomous underwater vehicles, autonomous surface vehicles, and autonomous aerial vehicles. Testing may involve evaluating individual vehicles and payloads or conducting complex events with multiple vehicles. Durations: typically 5 days for 6–8 hours per day.	HFL, HFM, LFH, MFH, MFL, VHFH.	32–39	245	SOCAL.

TABLE 8—PROPOSED NAVWAR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Other Testing	Vehicle Testing	Testing of surface, subsurface and airborne vehicles, sensor systems, payloads, communications, and navigation which may involve remotely operated vehicles, autonomous underwater vehicles, autonomous surface vehicles, and autonomous aerial vehicles. Testing may involve evaluating individual vehicles and payloads or conducting complex events with multiple vehicles. Durations: typically 5 days for 6–8 hours per day.	HFL, HFM, LFH, MFH, MFL, VHFH.	10–12	76	SCORE.
Acoustic	Other Testing	Vehicle Testing	Testing of surface, subsurface and airborne vehicles, sensor systems, payloads, communications, and navigation which may involve remotely operated vehicles, autonomous underwater vehicles, autonomous surface vehicles, and autonomous aerial vehicles. Testing may involve evaluating individual vehicles and payloads or conducting complex events with multiple vehicles. Durations: typically 5 days for 6–8 hours per day.	HFL, HFM, LFH, MFH, MFL, VHFH.	4–8	40	Transit Corridor.

Note: LF = low-frequency, MF = mid-frequency, HF = high-frequency, dB = decibels, L = low, M = medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count. CPAAA = Camp Pendleton Amphibious Assault Area, Hawaii = the Hawaii Study Area, PMRF = Pacific Missile Range Facility, PMSR = Point Mugu Sea Range, SCIUR = San Clemente Island Underwater Range, SCORE = Southern California Offshore Range, SOCAL = Southern California Range Complex, SSTC = Silver Strand Training Complex.

ONR's mission is to plan, foster, and encourage scientific research in recognition of its paramount importance as related to the maintenance of future naval power, and the preservation of national security. ONR manages the Navy's basic, applied, and advanced research to foster transition from science and technology to higher levels of research, development, test, and evaluation. ONR is also a parent organization for the Naval Research Laboratory, which operates as the Navy's corporate research laboratory and conducts a broad multidisciplinary program of scientific research and advanced technological development. Table 9 summarizes the proposed testing activities for the ONR analyzed within the HCTT Study Area.

TABLE 9—PROPOSED ONR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E1, E3, Air gun and non-explosive impulses, HFH, HFM, LFH, LFM, MFH, MFM, VHFM.	4–5	32	Hawaii.
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E1, E3, Air gun and non-explosive impulses, HFH, HFM, LFH, LFM, MFH, MFM, VHFM.	4–5	32	SOCAL.
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E1, E3, Air gun and non-explosive impulses, HFH, HFM, LFH, LFM, MFH, MFM, VHFM.	1–2	10	Acoustic Research Area.

TABLE 9—PROPOSED ONR TESTING ACTIVITIES ANALYZED WITHIN THE HCTT STUDY AREA—Continued

Stressor category	Activity type	Activity name	Description	Source bin	Number of activities 1-year	Number of activities 7-year	Location
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E1, E3, Air gun and non-explosive impulses, HFH, HFM, LFH, LFM, MFH, MFM, VHFM.	1–2	9	PMSR.
Acoustic	Acoustic and Oceanographic Science and Technology.	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems. Duration: up to 14 days.	E1, E3, Air gun and non-explosive impulses, HFH, HFM, LFH, LFM, MFH, MFM, VHFM.	1–2	14	NOCAL.
Acoustic	Acoustic and Oceanographic Science and Technology.	Long Range Acoustic Communications.	Low-frequency bottom-mounted acoustic source off of the Hawaiian Island of Kaua'i would transmit a variety of acoustic communications sequences. Duration: year-round; active transmissions 200 days a year.	LFM	1–2	11	Hawaii.
Acoustic	Acoustic and Oceanographic Science and Technology.	Mine Countermeasure Technology Research.	Test involves the use of broadband acoustic sources on unmanned underwater vehicles. Duration: up to 30 days.	MFH	1–2	11	Hawaii.
Acoustic	Acoustic and Oceanographic Science and Technology.	Mine Countermeasure Technology Research.	Test involves the use of broadband acoustic sources on unmanned underwater vehicles. Duration: up to 30 days.	MFH	6–8	50	SOCAL.

Note: LF = low-frequency, MF = mid-frequency, HF = high-frequency, dB = decibels, L = low, M = medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count. Hawaii = the Hawaii Study Area, NOCAL = Northern California Range Complex, PMSR = Point Mugu Sea Range, SOCAL = Southern California Range Complex.

Vessel Movement

Vessels used as part of the proposed activities include both surface and subsurface operations of both manned and unmanned vessels (USVs, UUVs). Vessels used as part of the Action Proponents' activities include ships, submarines, unmanned vessels, and boats ranging in size from small, 22 ft (6.7 m) rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft (332.8 m). Unmanned systems may include vehicles ranging from 4–16 ft (1.2–4.9 m) but typical size of USVs is 36–328 ft (11–100 m) while UUVs are 33–98 ft (10–30 m) in length. The Marine Corps operates small boats from 10–50 ft (3–15.2 m) in length and include small unit riverine craft, rigid hull inflatable boats and amphibious combat vehicles. Coast Guard vessels range in size from small boats between 13 and 65 ft (3.9 to 19.8 m) to large cutters with lengths up to 418 ft (127.4 m).

Large Navy ships greater than 350 ft (107 m) generally operate at speeds in the range of 10 to 15 knots (kn; 18.5 to 27.8 kilometers per hour (km/hr)) for fuel conservation. Submarines generally operate at lower speeds in transit and even lower speeds for certain tactical maneuvers. Small craft (considered in this proposed rule to be less than 60 ft (18 m) in length) have much more variable speeds (dependent on the mission). While these speeds for large Navy vessels are representative of most events, some of the Action Proponents' vessels may need to temporarily operate outside of these parameters. For example, to produce the required relative wind speed over the flight deck, an aircraft carrier vessel group engaged in flight operations must adjust its speed through the water accordingly. Additionally, there are specific events including high speed tests of newly constructed vessels. The Navy also anticipates testing large USVs, some of which would be at high speed. Conversely, there are other instances such as launch and recovery of a small rigid hull inflatable boat, vessel boarding, search and seizure training events, or retrieval of a target when vessels would be stopped or moving slowly ahead to maintain steerage. The Coast Guard currently operates approximately 250 cutters. Larger cutters (over 181 ft (55 m) in length) are controlled by Area Commands. The Pacific Area command is located in Alameda, CA. Smaller cutters come under control of district commands. There are four districts in the Pacific Area. Cutters usually carry a motor surf boat and/or a rigid-hulled inflatable boat.

The Coast Guard operates approximately 1,600 boats, defined as any vessel less than 65 ft (20 m) in length. These boats generally operate near shore and on inland waterways. The most common is 25 ft (7.6 m) long, of which the Coast Guard has more than 350; the shortest is 13 ft (4.0 m). Boat training includes small boat crews engaging surface targets with small- and medium-caliber weapons.

The number of vessels used in the HCTT Study Area varies based on military readiness requirements, deployment schedules, annual budgets, and other unpredictable factors. Most military readiness activities involve the use of vessels. These activities could be widely dispersed throughout the HCTT Study Area, but would typically be conducted near naval ports, piers, and range areas. Activities involving vessel movements occur intermittently and are variable in duration, ranging from a few hours to multiple weeks.

Action Proponent vessel traffic would especially be concentrated near San Diego, California and Pearl Harbor, Hawaii. There is no seasonal differentiation in vessel use. Large vessel movement primarily occurs with the majority of the traffic flowing

between the installations and the OPAREAS. Support craft would be more concentrated in the coastal waters in the areas of naval installations, ports, and ranges.

The number of testing activities that include the use of vessels is around 18 percent lower than the number of training activities, but testing activities are more likely to include the use of larger unmanned vessels (although these are expected to transition to training use during the effective period of the rule, if finalized). In addition, testing often occurs jointly with a training event so it is likely that the testing activity would be conducted from a vessel that was also conducting a training activity. Vessel movement in conjunction with testing activities could occur throughout the Study Area, but would typically be conducted near naval ports, piers, and range complexes.

Additionally, a variety of smaller craft would be operated within the HCTT Study Area. Small craft types, sizes, and speeds vary. During military readiness activities, speeds generally range from 10 to 14 kn (18.5 to 25.9 km/hr); however, vessels can and will, on occasion, operate within the entire spectrum of their specific operational capabilities. During modernization and sustainment of ranges activities, vessels would operate more slowly, typically 3 kn (5.6 km/hr) or less. In all cases, the vessels/craft will be operated in a safe manner consistent with the local conditions.

Foreign Navies

In furtherance of national security objectives, foreign militaries may participate in multinational training and testing events in the Study Area. Foreign military activities that are planned by and under the substantial control and responsibility of the Action Proponents are included in the proposed action. These participants could be in various training or testing events described in appendix A of the 2024 HCTT Draft EIS/OEIS, and their effects are analyzed in this proposed rule. However, when foreign military vessels operate independently within the Study Area as sovereign vessels outside the planning, control, and responsibility of the Action Proponents, those activities are not considered part of the specified activity. There are many reasons why foreign military vessels may traverse U.S. waters or come into U.S. port, not all of which are at the behest of any of the Action Proponents. Foreign military vessels and aircraft operate pursuant to their own national authorities and have independent rights under customary international law, embodied in the principle of sovereign immunity, to engage in various activities on the world's oceans and seas. When foreign militaries are participating in a U.S. Navy planned and substantially controlled exercise or event, foreign military use of sonar and explosives, when combined with the U.S. Navy's use of sonar and explosives, would not result in exceedance of the analyzed levels (within each Navy Acoustic Effects Model (NAEMO) modeled sonar and explosive bin) used for estimating predicted impacts, which formed the basis of our acoustic impacts effects analysis that was used to estimate take in this proposed rule.

The most significant joint training event is the Rim of the Pacific (RIMPAC), a multi-national training exercise held every-other-year primarily in the HRC. The participation level of foreign military vessels in U.S. Navy-led training or testing events within the HRC and within SOCAL differs greatly between RIMPAC and non-RIMPAC years. For example, in 2019 (a non-RIMPAC year), there were 0.1 foreign navy surface vessel at-sea days (*i.e.,* 1 day = 24 hours) within HRC and 20 foreign navy at-sea days within SOCAL (Navy 2021). Out of 56 U.S.-led training events in 2019, 4 involved foreign navy vessels, with an average time per event of 8.7 hours. During RIMPAC 2022, foreign vessels operated and/or transited through the HRC for 576 hours (24 days). In 2023 (another non-RIMPAC year), there was no foreign vessel participation within SOCAL. Even in a RIMPAC year, the days at sea for foreign militaries engaged in a Navy-led training or testing activity accounts for a small, but variable, percentage compared to the U.S. Navy activities. For instance, the 2020 foreign military participation (a RIMPAC-year) was 1.5 percent of the U.S. Navy's average days at sea (32 days out of an estimated 2,056 days at sea). During RIMPAC 2024, twenty-five foreign surface vessels participated for a combined 5,000 hours in U.S.-led training events. Therefore, foreign surface vessel activity is estimated to conservatively account for up to 10 percent of the U.S. Navy's annual at sea time in HCTT (205 days out of an estimated 2,056 days at sea).

Please see the Proposed Mitigation Measures section and Proposed Reporting section of this proposed rule for information about mitigation and reporting related to foreign navy activities in the HCTT Study Area.

When foreign militaries are participating in a U.S. Navy-led exercise or event, foreign military use of sonar and explosives, when combined with the U.S. Navy's use of sonar and explosives, would not result in exceedance of the analyzed levels (within each NAEMO modeled sonar and explosive bin) used for estimating predicted impacts, which formed the basis of our acoustic impacts effects analysis that was used to estimate take in this proposed rule. Please see the Proposed Mitigation Measures section and Proposed Reporting section of this proposed rule for information about mitigation and reporting related to foreign navy activities in the HCTT Study Area.

Standard Operating Procedures

For training and testing to be effective, Action Proponent personnel must be able to safely use their sensors, platforms, weapons, and other devices to their optimum capabilities and as intended for use in missions and combat operations. The Action Proponents have developed standard operating procedures through decades of experience to provide for safety and mission success. Because they are essential to safety and mission success, standard operating procedures are part of the Proposed Action and are considered in the environmental analysis for applicable resources (see chapter 3 (Affected Environment and Environmental Consequences) of the 2024 HCTT Draft EIS/OEIS). While standard operating procedures are designed for the safety of personnel and equipment and to ensure the success of training and testing activities, their implementation often yields additional benefits on environmental, socioeconomic, public health and safety, and cultural resources.

Because standard operating procedures are essential to safety and mission success, the Action Proponents consider them to be part of the proposed activities and have included them in the environmental analysis. Standard operating procedures that are recognized as providing a potential secondary benefit on marine mammals during training and testing activities are noted below.

- Vessel safety;
- Weapons firing safety;
- Target deployment safety;
- Towed in-water device safety;
- Pile driving safety; and
- Coastal zones.

Standard operating procedures (which are implemented regardless of their secondary benefits) are different from mitigation measures (which are designed entirely for the purpose of avoiding or reducing impacts). Information on mitigation measures is provided in the Proposed Mitigation Measures section.

Description of Stressors

The Action Proponents use a variety of sensors, platforms, weapons, and other devices. Military readiness activities using these systems may introduce sound and energy into the environment. The proposed military readiness activities were evaluated to identify specific components that would act as stressors by having direct or indirect impacts on marine mammals and their habitat. This analysis included identification of the spatial variation of the identified stressors. The following subsections describe the acoustic and explosive stressors for marine mammals and their habitat within the HCTT Study Area. Each description contains a list of activities that may generate the stressor. Stressor/resource interactions that were determined to have impacts that do not qualify as take under the MMPA (*i.e.,* vessel, aircraft, or weapons noise) were not carried forward for analysis in the application. NMFS reviewed the Action Proponents' analysis and conclusions on de minimis sources (*i.e.,* those that are not likely to result in the take of marine mammals) and finds them complete and supportable (see section 3.7.4 of the technical report ''Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase IV Training and Testing'' (U.S. Department of the Navy, 2024), hereafter referred to as the Acoustic Impacts Technical Report).

Acoustic Stressors

Acoustic stressors include acoustic signals emitted into the water for a specific purpose, such as sonar, other transducers (*i.e.,* devices that convert energy from one form to another—in this case, into sound waves), and air guns, as well as incidental sources of broadband sound produced as a byproduct of vessel movement, aircraft transits, use of weapons or other deployed objects, vibratory pile extraction, and vibratory and impact pile driving. Explosives also produce broadband sound but are characterized separately from other acoustic sources due to their unique hazardous characteristics. Characteristics of each of these sound sources are described in the following sections.

To better organize and facilitate the analysis of approximately 300 sources of underwater sound used for training and testing by the Action Proponents, including sonars and other transducers, air guns, and explosives, a series of source classifications, or source bins, were used. The acoustic source classification bins do not include the broadband noise produced incidental to pile driving, vessel and aircraft transits, weapons firing, and bow shocks. Noise produced from vessels and aircraft are not carried forward because those activities were found to have de minimis or no acoustic impacts, as stated above. Of note, the source bins used in this analysis have been revised from previous (Phase III) acoustic modeling to more efficiently group similar sources and use the parameters of the bin for propagation, making a comparison to previous bins impossible in most cases as some sources are modeled at different propagation parameters. For example, in previous analyses, non-impulsive narrowband sound sources were grouped into bins that were defined by their acoustic properties (*i.e.,* frequency, source level, beam pattern, and duty cycle) or, in some cases, their purpose or application. In the current analysis, these sources are binned based only on their acoustic properties and not on their purpose or application. As such, sources that previously fell into a single ''purpose-based'' bin now, in many cases, fall into multiple bins while sources with similar acoustic parameters that were previously sorted into separate bins due to different purposes now share a bin. Therefore, the acoustic source bins used in the current analysis do not represent a one-for-one replacement with previous bins, making direct comparison not possible in most cases.

The use of source classification bins provides the following benefits:

- Allows new sensors or munitions to be used under existing authorizations as long as those sources fall within the parameters of a ''bin'';
- Improves efficiency of source utilization data collection and reporting requirements anticipated under the MMPA authorizations;
- Ensures that impacts are not underestimated, as all sources within a given class are modeled as the most impactful source (highest source level, longest duty cycle, or largest net explosive weight (NEW)) within that bin;
- Allows analyses to be conducted in a more efficient manner, without any compromise of analytical results; and
- Provides a framework to support the reallocation of source usage (hours/explosives) between different source bins, as long as the total numbers of takes remain within the overall analyzed and authorized limits. This flexibility is required to support evolving training and testing requirements, which are linked to real world events.

Sonar and Other Transducers—

Active sonar and other transducers emit non-impulsive sound waves into the water to detect objects, navigate safely, and communicate. Passive sonars differ from active sound sources in that they do not emit acoustic signals; rather, they only receive acoustic information about the environment (*i.e.,* listen). In this proposed rule, the terms sonar and other transducers will be used to indicate active sound sources unless otherwise specified.

The Action Proponents employ a variety of sonars and other transducers to obtain and transmit information about the undersea environment. Some examples are mid-frequency hull-mounted sonars used to find and track enemy submarines; high-frequency small object detection sonars used to detect mines; high-frequency underwater modems used to transfer data over short ranges; and extremely high-frequency (greater than 200 kilohertz (kHz)) Doppler sonars used for navigation, like those used on commercial and private vessels. The characteristics of these sonars and other transducers, such as source level (SL), beam width, directivity, and frequency, depend on the purpose of the source. Higher frequencies can carry more information or provide more information about objects off which they reflect, but attenuate more rapidly. Lower frequencies attenuate less rapidly, so they may detect objects over a longer distance, but with less detail.

Propagation of sound produced underwater is highly dependent on environmental characteristics such as bathymetry, seafloor type, water depth, temperature, and salinity. The sound received at a particular location will be different than near the source due to the interaction of many factors, including propagation loss; how the sound is reflected, refracted, or scattered; the potential for reverberation; and interference due to multi-path propagation. In addition, absorption greatly affects the distance over which higher-frequency sounds propagate. The effects of these factors are explained in appendix D (Acoustic and Explosive Impacts Supporting Information) of the 2024 HCTT Draft EIS/OEIS. Because of the complexity of analyzing sound propagation in the ocean environment, the Action Proponents rely on acoustic models in their environmental analyses that consider sound source characteristics and varying ocean conditions across the HCTT Study Area. For additional information on how propagation is accounted for, see the Acoustic Impacts Technical Report.

The sound sources and platforms typically used in military readiness activities analyzed in the application are described in appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS. Sonars and other transducers used to obtain and transmit information underwater during military readiness activities generally fall into several categories of use described below.

Anti-Submarine Warfare—

Sonar used during anti-submarine warfare training and testing would impart the greatest amount of acoustic energy of any category of sonar and other transducers analyzed in this proposed rule. Types of sonars used to detect potential enemy vessels include hull-mounted, towed, line array, sonobuoy, helicopter dipping, and torpedo sonars. In addition, acoustic targets and decoys (countermeasures) may be deployed to emulate the sound signatures of vessels or repeat received signals.

Most anti-submarine warfare sonars are mid-frequency (1–10 kHz) because mid-frequency sound balances sufficient resolution to identify targets with distance over which threats can be identified. However, some sources may use higher or lower frequencies. Duty cycles can vary widely, from rarely used to continuously active. Anti-submarine warfare sonars can be wide-ranging in a search mode or highly directional in a track mode.

Most anti-submarine warfare activities involving submarines or submarine targets would occur in waters greater than 600 ft (182.9 m) deep due to safety concerns about running aground at shallower depths. Sonars used for anti-submarine warfare activities would typically be used beyond 12 nmi (22.2 km) from shore. Exceptions include use of dipping sonar by helicopters, pierside testing and maintenance of systems while in port, and system checks while transiting to or from port.

Mine Warfare, Small Object Detection, and Imaging—

Sonars used to locate mines and other small objects, as well as those used in imaging (*e.g.,* for hull inspections or imaging of the seafloor), are typically high-frequency or very high-frequency. Higher frequencies allow for greater resolution and, due to their greater attenuation, are most effective over shorter distances. Mine detection sonar can be deployed (towed or vessel hull-mounted) at variable depths on moving platforms (ships, helicopters, or unmanned vehicles) to sweep a suspected mined area. Hull-mounted anti-submarine sonars can also be used in an object detection mode known as ''Kingfisher'' mode (MF1K) (*e.g.,* used on vessels when transiting to and from port), where pulse length is shorter but pings are much closer together in both time and space, since the vessel goes slower when operating in this mode. Sonars used for imaging are usually used in close proximity to the area of interest, such as pointing downward near the seafloor.

Mine detection sonar use would be concentrated in areas where practice mines are deployed, typically in water depths less than 200 ft (60.9 m), and at established training or testing minefields or temporary minefields close to strategic ports and harbors. Kingfisher mode on vessels is most likely to be used when transiting to and from port. Sound sources used for imaging would be used throughout the HCTT Study Area.

Navigation and Safety—

Similar to commercial and private vessels, the Action Proponents' vessels employ navigational acoustic devices, including speed logs, Doppler sonars for ship positioning, and fathometers. These may be in use at any time for safe vessel operation. These sources are typically highly directional to obtain specific navigational data.

Communication—

Sound sources used to transmit data (*e.g.,* underwater modems), provide location (pingers), or send a single brief release signal to seafloor-mounted devices (acoustic release) may be used throughout the HCTT Study Area. These sources typically have low duty cycles and are usually only used when it is necessary to send a detectable acoustic message.

Classification of Sonar and Other Transducers—

Sonars and other transducers are grouped into bins based on their acoustic properties. Sonars and other transducers are now grouped into bins based on the frequency or bandwidth, source level, duty-cycle, and three-dimensional beam coverage. Unless stated otherwise, a reference distance of 1 microPascal (re 1 µPa) at 1 m (3.3 ft) is used for sonar and other transducers.

- Frequency of the non-impulsive acoustic source:
  - Low-frequency sources operate below 1 kHz;
  - Mid-frequency sources operate at or above 1 kHz, up to and including 10 kHz;
  - High-frequency sources operate above 10 kHz, up to and including 100 kHz; and
  - Very high-frequency sources operate above 100 kHz but below 200 kHz;
- Sound pressure level (SPL):
  - Greater than 160 decibels (dB) re 1 µPa, but less than 185 dB re 1 µPa;
  - Equal to 185 dB re 1 µPa and up to 205 dB re 1 µPa; and
  - Greater than 205 dB re 1 µPa.

Active sonar and other transducer use that was quantitatively analyzed in the Study Area are shown in table 10.

TABLE 10—SONAR AND OTHER TRANSDUCERS QUANTITATIVELY ANALYZED IN THE HCTT STUDY AREA

Source type	Source category	Description	Unit	Training annual	Training 7-year total	Testing annual	Testing 7-year total
Broadband	LF	<205 dB	H			430–570	3,430
Broadband	LF to MF	<205 dB	H			2,801–2,833	19,737
Broadband	LF to HF	<205 dB	C	806–818	5,678	686–859	4,413
Broadband	LF to HF	<205 dB	H			1,662–2,077	11,371
Broadband	MF to HF	<205 dB	H	8,097–11,585	67,142	1,451–1,779	10,483
Low-frequency acoustic	LFL	160 dB to 185 dB	H			12	70
Low-frequency acoustic	LFM	185 dB to 205 dB	C			1,160–1,384	8,792
Low-frequency acoustic	LFM	185 dB to 205 dB	H	468–536	3,480	7,531–8,984	56,955
Low-frequency acoustic	LFH	>205 dB	C	1,498–2,120	12,372	6,046–6,704	44,296
Low-frequency acoustic	LFH	>205 dB	H	14	98	4,050–6,050	34,350
Mid-frequency acoustic	MFL	160 dB to 185 dB	H			12,632–14,982	92,794
Mid-frequency acoustic	MFM	185 dB to 205 dB	C	4,908–6,552	39,400	15,080–16,928	110,737
Mid-frequency acoustic	MFM	185 dB to 205 dB	H	30	210	14,381–16,081	101,064
Mid-frequency acoustic	MFH	>205 dB	H	1,951–3,003	17,010	8,115–10,424	63,221
High-frequency acoustic	HFL	160 dB to 185 dB	H	60	420	21,326–22,076	151,532
High-frequency acoustic	HFM	185 dB to 205 dB	C	9	63	1,800–2,346	14,238

TABLE 10—SONAR AND OTHER TRANSDUCERS QUANTITATIVELY ANALYZED IN THE HCTT STUDY AREA—Continued

Source type	Source category	Description	Unit	Training annual	Training 7-year total	Testing annual	Testing 7-year total
High-frequency acoustic	HFM	185 dB to 205 dB	H	3,907–5,290	31,498	12,409–13,259	89,322
High-frequency acoustic	HFH	>205 dB	C	802–899	5,907	835–1,137	6,351
High-frequency acoustic	HFH	>205 dB	H	2,419–2,498	17,170	1,367–1,920	10,735
Very high-frequency acoustic	VHFL	160 dB to 185 dB	H	30	210	9,160	64,120
Very high-frequency acoustic	VHFM	185 dB to 205 dB	H			96	672
Very high-frequency acoustic	VHFH	>205 dB	C			72–106	580
Very high-frequency acoustic	VHFH	>205 dB	H	5,458–7,862	45,418	12,544–16,824	100,648
Hull-mounted surface ship sonar.	MF1C	Hull-mounted surface ship sonar with duty cycle >80% (previously MF11).	H	796–1,406	7,404	45	314
Hull-mounted surface ship sonar.	MF1K	Hull-mounted surface ship sonar in Kingfisher mode.	H	455	3,183	14	91
Hull-mounted surface ship sonar.	MF1	Hull-mounted surface ship sonar.	H	5,096–8,758	46,828	413–917	4,275

Note: LF = low frequency, MF = mid frequency, HF = high frequency, dB = decibels, L = low, M = medium, H = high (*e.g.,* MFL = mid-frequency low source level), H = hours, C = count.

Air Guns—

Air guns are essentially stainless steel tubes charged with high-pressure air via a compressor. An impulsive sound is generated when the air is almost instantaneously released into the surrounding water. Small air guns with capacities up to 60 cubic inches (in^3; 983 cubic centimeters (cc)) would be used during testing activities in the offshore areas of the California Study Area and in the HRC.

Generated impulses would have short durations, typically a few hundred milliseconds, with dominant frequencies below 1 kHz. The root-mean-square (RMS) SPL and peak pressure (SPL peak) at a distance 1 m (3.3 ft) from the air gun would be approximately 215 dB re 1 µPa and 227 dB re 1 µPa, respectively, if operated at the full capacity of 60 in^3 (983 cc). The size of the air gun chamber can be adjusted, which would result in lower SPLs and sound exposure level (SEL) per shot. The air gun and non-explosive impulsive sources that were quantitatively analyzed in the HCTT Study Area are shown in table 11.

TABLE 11—TRAINING AND TESTING AIR GUN SOURCES QUANTITATIVELY ANALYZED IN THE STUDY AREA

Source class category	Description	Bin	Unit	Training annual	Training 7-year total	Testing annual	Testing 7-year total
Air Guns	Small underwater air guns	AG	C	0	0	30,432–36,780	232,068

Note: AG = air guns, C = count.

Pile Driving—

Impact and vibratory pile driving and extraction would occur during Port Damage Repair training in Port Hueneme, CA. Pile driving would not occur at other locations within the HCTT Study Area. The pile driving method, pile type and size, and assumptions for acoustic impact analysis are presented in table 12. This training activity would occur up to 12 times per year. Each training event consists of up to 7 separate modules, each which could occur up to 3 iterations during a single event (for a maximum of 21 modules). Training events would last a total of 30 days, of which pile driving is only anticipated to occur for a maximum of 14 days. The training would involve the installation and extraction 12- to 20-inch (30.5- to 50.8-cm) steel, timber, or composite round piles, and 27.5- or 18-inch (69.9- or 45.7-cm) steel or FRP Z-shape piles using a vibratory hammer; extraction of 12- to 20-inch (30.5- to 50.8-cm) timber round piles and 12- to 20-inch (30.5- to 50.8 cm) steel H-piles using a vibratory hammer; and installation of 12- to 20-inch (30.5- to 50.8-cm) timber round piles, 12- to 20-inch (30.5- to 50.8-cm) steel H-piles, and 12- to 20-inch (30.5- to 50.8-cm) steel, timber, or composite round piles using an impact hammer table 12.

TABLE 12—PORT DAMAGE REPAIR TRAINING PILES QUANTITATIVELY ANALYZED AND ASSOCIATED UNDERWATER SOUND LEVELS

Method	Pile size and type	Number of piles annual	Number of piles 7-year total	Peak SPL (single strike; dB re 1 µPa)	SEL (single strike; dB re 1 µPa2 ·s)	RMS SPL (single strike; dB re 1 µPa)	Unattenuated SPL (RMS; dB re 1 µPa)	Reference
Impact	12- to 20-inch (30 to 51 cm) timber round.	360	2,520	180	160	170		14-inch (36 cm) round timber piles (Caltrans, 2020).
Impact	12- to 20-inch (30 to 51 cm) steel H.	144	1,008	195	170	180		14-inch (36 cm) steel H-beam piles (Caltrans, 2020).
Impact	12- to 20-inch (30 to 51 cm) steel, timber, or composite round.	360	2,520	203	178	189		24-inch (61 cm) steel pipe piles (Illingworth and Rodkin Inc., 2007).

TABLE 12—PORT DAMAGE REPAIR TRAINING PILES QUANTITATIVELY ANALYZED AND ASSOCIATED UNDERWATER SOUND LEVELS—Continued

Method	Pile size and type	Number of piles annual	Number of piles 7-year total	Peak SPL (single strike; dB re 1 μPa)	SEL (single strike; dB re 1 μPa2 ·s)	RMS SPL (single strike; dB re 1 μPa)	Unattenuated SPL (RMS; dB re 1 μPa)	Reference
Vibratory	12- to 20-inch (30 to 51 cm) timber round.	360	2,520	.....	.....	.....	166	24-inch (61 cm) steel piles (Washington State Department of Transportation, 2010).
Vibratory	12- to 20-inch (30 to 51 cm) steel H.	144	1,008	.....	.....	.....	166	24-inch (61 cm) steel piles (Washington State Department of Transportation, 2010).
Vibratory	12- to 20-inch (30 to 51 cm) steel, timber, or composite round.	1,440	10,080	.....	.....	.....	166	24-inch (61 cm) steel piles (Washington State Department of Transportation, 2010).
Vibratory	18- or 27.5-inch (46- or 70-cm) steel or FRP Z.	2,304	16,128	.....	.....	.....	159	25-inch (64 cm) steel sheet piles (Naval Facilities Engineering Systems Command Southwest, 2020).

Note: Impact method is for installation only.

Only one hammer would be operated at any given point in time; there would not be any instances where multiple piles would be driven simultaneously. All piles and sheets would be extracted using the vibratory hammer.

Impact pile driving would involve the use of an impact hammer with both it and the pile held in place by a crane. When the pile driving starts, the hammer part of the mechanism is raised up and allowed to fall, transferring energy to the top of the pile. The pile is thereby driven into the sediment by a repeated series of these hammer blows. Each blow results in an impulsive sound emanating from the length of the pile into the water column as well as from the bottom of the pile through the sediment. Broadband impulsive signals are produced by impact pile driving methods, with most of the acoustic energy concentrated below 1,000 hertz (Hz) (Hildebrand, 2009). For the purposes of this analysis, the Action Proponents assume the impact pile driver would generally operate on average 60 strikes per pile.

Vibratory installation and extraction would involve the use of a vibratory hammer suspended from the crane and attached to the top of a pile. The pile is then vibrated by hydraulic motors rotating eccentric weights in the mechanism, causing a rapid up and down vibration in the pile, driving the pile into the sediment. During extraction, the vibration causes the sediment particles in contact with the pile to lose frictional grip on the pile. The crane slowly lifts the vibratory driver and pile until the pile is free of the sediment. In some cases, the crane may be able to lift the pile and vibratory driver without vibrations from the driver (*i.e.,* dead pull), in which case no noise would be introduced into the water. Vibratory driving and extraction create broadband, continuous, non-impulsive noise at low source levels, for a short duration with most of the energy dominated by lower frequencies. Port Damage Repair training would occur in shallow water, and sound would be transmitted on direct paths through the water, be reflected at the water surface or bottom, or travel through seafloor substrate. Soft substrates such as sand would absorb or attenuate the sound more readily than hard substrates (*e.g.,* rock), which may reflect the acoustic wave. The predicted sound levels produced by pile driving by method, pile size and type for Port Damage Repair training are presented in table 12.

In addition to underwater noise, the installation and extraction of piles also results in airborne noise in the environment, denoted dBA; dBA is an A-weighted decibel level that represents the relative loudness of sounds as perceived by the human ear. A-weighting gives more value to frequencies in the middle of human hearing and less value to frequencies at the edges as compared to a flat or unweighted decibel level. Impact pile driving creates in-air impulsive sound about 100 dBA re 20 μPa at a range of 15 m for 24-inch (0.61 m) steel piles (Illingworth and Rodkin, 2016). During vibratory extraction, the three aspects that generate airborne noise are the crane, the power plant, and the vibratory extractor. The average sound level recorded in air during vibratory extraction was about 85 dBA re 20 μPa (94 dB re 20 μPa) within a range of 32.8–49.2 ft (10–15 m) (Illingworth and Rodkin, 2015).

Explosive Stressors

This section describes the characteristics of explosions during military readiness activities. The activities analyzed in the application that use explosives are described in appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS, and terminology and metrics used when describing explosives in the application are in appendix D (Acoustic and Explosive Impacts Supporting Information) of the 2024 HCTT Draft EIS/OEIS.

The near-instantaneous rise from ambient to an extremely high peak pressure is what makes an explosive shock wave potentially damaging. Farther from an explosive, the peak pressures decay and the explosive waves propagate as an impulsive, broadband sound. Several parameters influence the effect of an explosive: the weight of the explosive warhead, the type of explosive material, the boundaries and characteristics of the propagation medium, and the detonation depth in water. The NEW, the explosive power of a charge expressed as the equivalent weight of trinitrotoluene (commonly referred to as TNT), accounts for the first two parameters.

Explosions in Water—

Explosive detonations during military readiness activities are associated with high-explosive munitions, including, but not limited to bombs, missiles,

rockets, naval gun shells, torpedoes, mines, demolition charges, and explosive sonobuoys. Explosive detonations during military readiness activities involving the use of high-explosive munitions, including bombs, missiles, and naval gun shells, would occur in the air or near the water's surface. Explosive detonations associated with torpedoes and explosive sonobuoys would occur in the water column; mines and demolition charges would be detonated in the water column or on the ocean floor. The Coast Guard usage of explosives is limited to medium and large-caliber munitions used during gunnery exercises. Most detonations would occur in waters greater than 200 ft (60.9 m) in depth and greater than 3 nmi (5.6 km) from shore, although some mine warfare, demolition, and some testing detonations would occur in shallow water close to shore. The Army usage of explosives is limited to large-caliber projectiles used during shore-to-surface artillery and missile exercises, and all projectiles will impact beyond 3 nmi (5.6 km) from shore.

To better organize and facilitate the analysis of explosives used by the Action Proponents during military readiness activities that would detonate in water or at the water surface, explosive classification bins were developed. The use of explosive classification bins provides the same benefits as described for acoustic source classification bins in the Sonar and Other Transducers section. Explosives detonated in water are binned by NEW. Table 13 shows explosives use that was quantitatively analyzed in the Study Area. A range of annual use indicates that occurrence is anticipated to vary annually, consistent with the variation in the number of annual activities described in chapter 2 (Description of Proposed Action and Alternatives) of the 2024 HCTT Draft EIS/OEIS. The 7-year total takes that variability into account.

TABLE 13—EXPLOSIVE SOURCES QUANTITATIVELY ANALYZED PROPOSED FOR USE UNDERWATER OR AT THE WATER SURFACE

Bin	Net explosive weight (lb.)	Example explosive source	Navy training annual	Navy training 7-year	Coast Guard training annual	Coast Guard training 7-year	Army training annual	Army training 7-year	Navy testing annual	Navy testing 7-year
E1	0.1–0.25	Medium-caliber projectile	1,750–4,303	19,911					7,305–7,430	51,510
E2	>0.25–0.5	Medium-caliber projectile	2,950–3,000	20,800						
E3	>0.5–2.5	2.75-inch (7 cm) rockets	5,438–5,720	38,912	150	1,050			4,744–6,568	36,704
E4	>2.5–5	Mine neutralization charge.	179–190	1,286					1,324–2,624	18,352
E5	>5–10	5-inch (12.7 cm) projectile.	5,059–5,984	38,188					2,024–2,676	16,732
E6	>10–20	Hellfire missile	1,693–1,757	12,043			600	4,200	144–148	1,020
E7	>20–60	Demo block/shaped charge.	115–190	1,030					549–622	2,322
E8	>60–100	Lightweight torpedo	3–5	27					213–234	1,552
E9	>100–250	500 lb. (228 kg) bomb	278–300	2,015			108	756	111–115	789
E10	>250–500	Harpoon missile	89	620					13	91
E11	>500–675	Heavyweight Torpedo	7–11	61					1–2	8
E12	>675–1,000	2,000 lb. (907.2 kg) bomb	17–19	125						
E13	>1,000–1,740	Underwater demolitions—large area clearance.	6	42						
E16	10,000	Ship shock detonation							0–3	3

Note: > = greater than, in. = inch, lb. = pound, kg = kilogram.

Propagation of explosive pressure waves in water is highly dependent on environmental characteristics such as bathymetry, seafloor type, water depth, temperature, and salinity, which affect how the pressure waves are reflected, refracted, or scattered; the potential for reverberation; and interference due to multi-path propagation. In addition, absorption greatly affects the distance over which higher-frequency components of explosive broadband noise can propagate. Appendix D (Acoustic and Explosive Impacts Supporting Information) of the 2024 HCTT Draft EIS/OEIS explains the characteristics of explosive detonations and how the above factors affect the propagation of explosive energy in the water. Because of the complexity of analyzing sound propagation in the ocean environment, the Action Proponents rely on acoustic models in their environmental analyses that consider sound source characteristics and varying ocean conditions across the Study Area.

In-Air Acoustic Stressors

The proposed military readiness activities would generate missile and aerial target launch noise from locations on SNI (California), noise from missile and aerial target launches at the PMRF (Kaua'i, Hawaii), and artillery firing noise from shore to surface gunnery at San Clemente Island and PMRF. Table 14 shows launch noise that was quantitatively analyzed in the HCTT Study Area.

Noise from target and missile launches from land at SNI and PMRF may disturb hauled-out pinnipeds. At SNI, this disturbance has been documented over nearly two decades of monitoring and reporting of those activities (U.S. Department of the Navy, 2020, 2022, 2023).

At PMRF, Hawaiian monk seals are known to haul out on a beach near the missile launch complex. If a seal is hauled out during a missile or aerial target launch, the seal may react to the noise and exhibit a behavioral response that may qualify as harassment (*e.g.,* flushing into the water). (Though, of note, behavioral disturbance of monk seals (*e.g.,* flushing or other disturbance) has not been observed due to these activities.) Currently, if a monk seal is hauled out on the beach (typically within approximately 1,000 ft (304.8 m) of the launch site) prior to a missile launch, the launch is halted or postponed until the seal has left the beach.

TABLE 14—PROPOSED LAUNCHES ANALYZED WITHIN THE HCTT STUDY AREA

Launch type	Location	Navy training annual	Navy training 7-year total	Navy testing annual	Navy testing 7-year total
Missiles and Aerial Targets	SNI (PMSR)	0	0	40	280
Missiles and Aerial Targets	PMRF	22	154	13	91
Artillery	PMRF	900	6,300	0	0

Note: SNI = San Nicolas Island, PMSR = Point Mugu Sea Range, PMRF = Pacific Missile Range Facility.

Vessel Strike

NMFS also considered the likelihood that vessel movement during military readiness activities could result in an incidental, but not intentional, strike of a marine mammal in the HCTT Study Area, which has the potential to result in serious injury or mortality. Vessel strikes are not specific to any specific military readiness activity but rather, a limited, sporadic, and incidental result of the Action Proponents' vessel movement during military readiness activities within the Study Area. Vessel strikes from commercial, recreational, and military vessels are known to seriously injure and occasionally kill cetaceans (Abramson *et al.,* 2011; Berman-Kowalewski *et al.,* 2010; Calambokidis, 2012; Crum *et al.,* 2019; Douglas *et al.,* 2008; Laggner 2009; Van der Hoop *et al.,* 2012; Van der Hoop *et al.,* 2013), although reviews of the literature on vessel strikes mainly involve collisions between commercial vessels and whales (Jensen and Silber, 2003, Laist *et al.,* 2001). Vessel speed, size, and mass are all important factors in determining both the potential likelihood and impacts of a vessel strike to marine mammals (Blondin *et al.* 2025; Conn and Silber, 2013; Garrison *et al.* 2025; Gende *et al.,* 2011; Redfern *et al.,* 2019; Silber *et al.,* 2010; Szesciorka *et al.,* 2019; Vanderlaan and Taggart, 2007; Wiley *et al.,* 2016). For large vessels, speed and angle of approach can influence the severity of a strike.

The Action Proponents' vessels transit at speeds that are optimal for fuel conservation or to meet training and testing requirements. From unpublished Navy data, average speed for large (greater than 350 ft (107 m) Navy ships in Southern California and Hawaii from 2016–2023 varied from 10 to 15 kn (18.5 to 27.8 km/hr) in offshore waters greater than 12 nmi from land and from 5 to 10 kn (9.3 to 18.5 km/hr) closer to the coast (less than 12 nmi; Navy 2021, unpublished data). Small craft (for purposes of this analysis, less than 59 ft (18 m) in length) have much more variable speeds (0 to 50 kn (0 to 92.6 km/hr), dependent on the activity). Submarines generally operate at speeds in the range of 8 to 13 kn (14.8 to 24.1 km per hour). Similar patterns are anticipated in the HCTT Study Area. A full description of the Action Proponents' vessels proposed for use during military readiness activities can be found in Chapter 2 (Description of Proposed Action and Alternatives) of the 2024 HCTT Draft EIS/OEIS.

While these speeds for large Navy vessels are representative of most events, some of the Action Proponents' vessels may need to temporarily operate outside of these parameters. For example, to produce the required relative wind speed over the flight deck, an aircraft carrier engaged in flight operations must adjust its speed through the water accordingly. There are specific events, including high speed tests of newly constructed vessels, where the Action Proponents' vessel would operate at higher speeds. By comparison, there are other instances when the Action Proponents vessel would be stopped or moving slowly ahead to maintain steerage, such as launch and recovery of a small rigid hull inflatable boat; vessel boarding, search, and seizure training events; or retrieval of a target.

Large Navy vessels (>400 ft (121.9 m)) and Coast Guard vessels within the offshore areas of range complexes and testing ranges operate differently from commercial vessels, which may reduce potential vessel strikes of large whales. Surface ships operated by or for the Navy have multiple personnel assigned to stand watch at all times, when a ship or surfaced submarine is moving through the water (underway). A primary duty of personnel standing watch on surface ships is to detect and report all objects and disturbances sighted in the water that may indicate a threat to the vessel and its crew, such as debris, a periscope, surfaced submarine, or surface disturbance. Per vessel safety requirements, personnel standing watch also report any marine mammals sighted in the path of the vessel as a standard collision avoidance procedure. All vessels proceed at a safe speed so they can take proper and effective action to avoid a collision with any sighted object or disturbance, and can stop within a distance appropriate to the prevailing circumstances and conditions. As described in the Standard Operating Procedures section, the Action Proponents utilize Lookouts to avoid collisions, and Lookouts are trained to spot marine mammals so that vessels may change course or take other appropriate action to avoid collisions. Despite the precautions, should a vessel strike occur, NMFS anticipates it would likely result in incidental take in the form of serious injury and/or mortality, though it is possible that it could result in a non-serious injury (Level A harassment). Accordingly, for the purposes of the analysis, NMFS assumes that any vessel strike would result in serious injury or mortality.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation Measures section, Proposed Monitoring section, and Proposed Reporting section).

Description of Marine Mammals and Their Habitat in the Area of Specified Activities

Marine mammal species and their associated stocks that have the potential to occur in the HCTT Study Area are presented in table 15 along with each stock's Endangered Species Act (ESA) and MMPA statuses, abundance estimate and associated coefficient of variation (CV) value, minimum abundance estimate, potential biological removal (PBR), annual M/SI, and potential occurrence in the HCTT Study Area. The Action Proponents request authorization to take individuals of 40 species (79 stocks) by Level A and Level B harassment incidental to military readiness activities from the use of sonar and other transducers, in-water detonations, air guns, missile and target launch noise, pile driving/extraction, and vessel movement in the HCTT Study Area. Currently, the humpback whale (Central America and Mexico Distinct Population Segments (DPSs)), killer whale (Eastern North Southern Resident DPS), false killer whale (Main Hawaiian Islands Insular DPS), and Hawaiian monk seal have critical habitat designated under the ESA in the HCTT Study Area (see *Critical Habitat* section below).

Sections 3 and 4 and appendix B (Marine Mammal Supplemental Information) of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs) (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website at: *https://www.fisheries.noaa.gov/find-species.* Additional information on the general biology and ecology of marine mammals is included in the 2024 HCTT Draft EIS/OEIS. Table 15 incorporates the best available science, including data from the 2023 Pacific and Alaska Marine Mammal Stock Assessment Reports (Carretta *et al.,* 2024; Young *et al.,* 2024) (see *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments),* and 2024 draft SARs, as well as monitoring data from the Navy's marine mammal research efforts.

TABLE 15—MARINE MAMMAL OCCURRENCE WITHIN THE HCTT STUDY AREA [1]

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
Family Eschrichtiidae:						
Gray whale	*Eschrichtius robustus*	Eastern North Pacific	-, -, N	25,960 (0.05, 25,849, 2016).	801	131
Gray whale	*Eschrichtius robustus*	Western North Pacific	E, D, Y	290 (N/A, 271, 2016)	0.12	UNK
Family Balaenopteridae (rorquals):						
Blue whale	*Balaenoptera musculus*	Central North Pacific	E, D, Y	133 (1.09, 63, 2010)	0.1	0
Blue whale	*Balaenoptera musculus*	Eastern North Pacific	E, D, Y	1,898 (0.085, 1,767, 2018)	4.1	≥18.6
Bryde's whale	*Balaenoptera edeni*	Eastern Tropical Pacific	-, -, N	UNK (UNK, UNK, N/A)	UND	UNK
Bryde's whale	*Balaenoptera edeni*	Hawaii	-, -, N	791 (0.29, 623, 2020)	6.2	0
Fin whale	*Balaenoptera physalus*	Hawaii	E, D, Y	203 (0.99, 101, 2017)	0.2	0
Fin whale	*Balaenoptera physalus velifera*	California/Oregon/Washington.	E, D, Y	11,065 (0.405, 7,970, 2018).	80	≥43.4
Humpback whale	*Megaptera novaeangliae*	Central America/Southern Mexico-California-Oregon-Washington [5].	E, D, Y	1,496 (0.171, 1,284, 2021)	3.5	14.9
Humpback whale	*Megaptera novaeangliae*	Mainland Mexico-California-Oregon-Washington [5].	T, D, Y	3,477 (0.101, 3,185, 2018)	43	22
Humpback whale	*Megaptera novaeangliae*	Hawaii	-, -, N	11,278 (0.56, 7,265, 2020)	127	27.09
Minke whale	*Balaenoptera acutorostrata*	Hawaii	-, -, N	438 (1.05, 212, 2017)	2.1	0
Minke whale	*Balaenoptera acutorostrata*	California/Oregon/Washington.	-, -, N	915 (0.792, 509, 2018)	4.1	≥0.19
Sei whale	*Balaenoptera borealis*	Hawaii	E, D, Y	391 (0.9, 204, 2010)	0.4	0.2
Sei whale	*Balaenoptera borealis*	Eastern North Pacific	E, D, Y	864 (0.40, 625, 2014)	1.25	UNK
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Physeteridae:						
Sperm whale	*Physeter macrocephalus*	Hawaii	E, D, Y	5,707 (0.23, 4,486, 2017)	18	0
Sperm whale	*Physeter macrocephalus*	California/Oregon/Washington.	E, D, Y	2,606 (0.135, 2,011, 2018)	4	0.52
Family Kogiidae:						
Dwarf sperm whale	*Kogia sima*	Hawaii	-, -, N	UNK (UNK, UNK, 2017)	UND	0
Dwarf sperm whale	*Kogia sima*	California/Oregon/Washington.	-, -, N	UNK (UNK, UNK, 2014)	UND	0
Pygmy sperm whale	*Kogia breviceps*	Hawaii	-, -, N	42,083 (0.64, 25,695, 2017).	257	0
Pygmy sperm whale	*Kogia breviceps*	California/Oregon/Washington.	-, -, N	4,111 (1.12, 1,924, 2014)	19.2	0
Family Ziphiidae (beaked whales):						
Baird's beaked whale	*Berardius bairdii*	California/Oregon/Washington.	-, -, N	1,363 (0.53, 894, 2018)	8.9	≥0.2
Blainville's beaked whale.	*Mesoplodon densirostris*	Hawaii	-, -, N	1,132 (0.99, 564, 2017)	5.6	0
Goose-beaked whale	*Ziphius cavirostris*	Hawaii	-, -, N	4,431 (0.41, 3,180, 2017)	32	0
Goose-beaked whale	*Ziphius cavirostris*	California/Oregon/Washington.	-, -, N	5,454 (0.27, 4,214, 2016)	42	<0.1
Longman's beaked whale.	*Indopacetus pacificus*	Hawaii	-, -, N	2,550 (0.67, 1,527, 2017)	15	0
Mesoplodont beaked whale.	*Mesoplodon spp.* [6]	California/Oregon/Washington.	-, -, N	3,044 (0.54, 1,967, 2014)	20	0.1
Family Delphinidae:						
False killer whale	*Pseudorca crassidens*	Main Hawaiian Islands Insular.	E, D, Y	167 (0.14, 149, 2015)	0.3	0.1
False killer whale	*Pseudorca crassidens*	Northwest Hawaiian Islands.	-, -, N	477 (1.71, 178, 2017)	1.43	0.16
False killer whale	*Pseudorca crassidens*	Hawaii Pelagic	-, -, Y	5,528 (0.35, 4,152, 2017)	36	47
False killer whale	*Pseudorca crassidens*	Baja California Peninsula Mexico [7].	N/A	2.962 (0.71, N/A, N/A)	N/A	N/A

TABLE 15—MARINE MAMMAL OCCURRENCE WITHIN THE HCTT STUDY AREA [1]—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Killer whale	*Orcinus orca*	Hawaii	-, -, N	161 (1.06, 78, 2017)	0.8	0
Killer whale	*Orcinus orca*	Eastern North Pacific Offshore.	-, -, N	300 (0.1, 276, 2012)	2.8	0
Killer whale	*Orcinus orca*	Eastern North Pacific Southern Resident.	E, D, Y	75 (N/A, 75, 2023)	0.13	0
Killer whale	*Orcinus orca*	West Coast Transient	-, -, N	349 (N/A, 349, 2018)	3.5	0.4
Melon-headed whale	*Peponocephala electra*	Hawaiian Islands	-, -, N	40,647 (0.74, 23,301 [3] 2017).	233	0
Melon-headed whale	*Peponocephala electra*	Kohala Resident (Hawaii)	-, -, N	UNK (UNK, UNK, 2017)	UND	0
Pygmy killer whale	*Feresa attenuata*	Hawaii	-, -, N	10,328 (0.75, 5,885, 2017)	59	0
Pygmy killer whale	*Feresa attenuata*	California-Baja California Peninsula Mexico [7].	N/A	229 (1.11, N/A, N/A)	N/A	N/A
Short-finned pilot whale	*Globicephala macrorhynchus*	Hawaii	-, -, N	19,242 (0.23, 15,894, 2020).	159	0.2
Short-finned pilot whale	*Globicephala macrorhynchus*	California/Oregon/Washington.	-, -, N	836 (0.79, 466, 2014)	4.5	1.2
Bottlenose dolphin	*Tursiops truncatus*	Maui Nui	-, -, N	64 (0.15, 56, 2018)	0.6	UNK
Bottlenose dolphin	*Tursiops truncatus*	Hawaii Island	-, -, N	136 (0.43, 96, 2018)	1	>0.2
Bottlenose dolphin	*Tursiops truncatus*	Hawaii Pelagic	-, -, N	24,669 (0.57, 15,783, 2020).	158	0
Bottlenose dolphin	*Tursiops truncatus*	Kaua'i/Ni'ihau	-, -, N	112 (0.24, 92, 2018)	0.9	UNK
Bottlenose dolphin	*Tursiops truncatus*	O'ahu	-, -, N	112 (0.17, 97, 2017)	1	UNK
Bottlenose dolphin	*Tursiops truncatus*	California Coastal	-, -, N	453 (0.06, 346, 2011)	2.7	≥2.0
Bottlenose dolphin	*Tursiops truncatus*	California/Oregon/Washington Offshore.	-, -, N	3,477 (0.696, 2,048, 2018)	19.7	≥0.82
Fraser's dolphin	*Lagenodelphis hosei*	Hawaii	-, -, N	40,960 (0.7, 24,068, 2017)	241	0
Long-beaked common dolphin.	*Delphinus delphis bairdii*	California	-, -, N	83,379 (0.216, 69,636, 2018).	668	≥29.7
Northern right whale dolphin.	*Lissodelphis borealis*	California/Oregon/Washington.	-, -, N	29,285 (0.72, 17,024, 2018).	163	≥6.6
Pacific white-sided dolphin.	*Lagenorhynchus obliquidens*	California/Oregon/Washington.	-, -, N	34,999 (0.222, 29,090, 2018).	279	7
Pantropical spotted dolphin.	*Stenella attenuata*	Maui Nui	-, -, N	UNK (UNK, UNK, N/A)	UND	UNK
Pantropical spotted dolphin.	*Stenella attenuata*	Hawaii Island	-, -, N	UNK (UNK, UNK, N/A)	UND	UNK
Pantropical spotted dolphin.	*Stenella attenuata*	Hawaii Pelagic	-, -, N	67,313 (0.27, 53,839, 2020).	538	0
Pantropical spotted dolphin.	*Stenella attenuata*	O'ahu	-, -, N	UNK (UNK, UNK, N/A)	UND	UNK
Pantropical spotted dolphin.	*Stenella attenuata*	Baja California Peninsula Mexico [7].	N/A	105,416 (0.46, N/A, N/A)	N/A	N/A
Risso's dolphin	*Grampus griseus*	Hawaii	-, -, N	6,979 (0.29, 5,283, 2020)	53	0
Risso's dolphin	*Grampus griseus*	California/Oregon/Washington.	-, -, N	6,336 (0.32, 4,817, 2014)	46	≥3.7
Rough-toothed dolphin	*Steno bredanensis*	Hawaii	-, -, N	83,915 (0.49, 56,782, 2017).	511	3.2
Short-beaked common dolphin.	*Delphinus delphis*	California/Oregon/Washington.	-, -, N	1,056,308 (0.21, 888,971, 2018).	8,889	≥30.5
Spinner dolphin	*Stenella longirostris*	Hawaii Pelagic	-, -, N	UNK (UNK, UNK, 2010)	UND	0
Spinner dolphin	*Stenella longirostris*	Hawaii Island	-, -, N	665 (0.09, 617, 2012)	6.2	≥1.0
Spinner dolphin	*Stenella longirostris*	Kaua'i/Ni'ihau	-, -, N	N/A (N/A, N/A, 2005)	UND	UNK
Spinner dolphin	*Stenella longirostris*	Midway Atoll/Kure	-, -, N	UNK (UNK, UNK, 2010)	UND	UNK
Spinner dolphin	*Stenella longirostris*	O'ahu/4 Islands Region	-, -, N	N/A (N/A, N/A, 2007)	UND	≥0.4
Spinner dolphin	*Stenella longirostris*	Pearl and Hermes	-, -, N	UNK (UNK, UNK, N/A)	UND	UNK
Spinner dolphin	*Stenella coeruleoalba*	Hawaii Pelagic	-, -, N	64,343 (0.28, 51,055, 2020).	511	0
Spinner dolphin	*Stenella coeruleoalba*	California/Oregon/Washington.	-, -, N	29,988 (0.3, 23,448, 2018)	225	≥4
Family Phocoenidae (porpoises):						
Dall's porpoise	*Phocoenoides dalli*	California/Oregon/Washington.	-, -, N	16,498 (0.61, 10,286, 2018).	99	≥0.66
Harbor porpoise	*Phocoena phocoena*	Monterey Bay	-, -, N	3,760 (0.561, 2,421, 2013)	35	≥0.2
Harbor porpoise	*Phocoena phocoena*	Morro Bay	-, -, N	4,191 (0.56, 2,698, 2012)	65	0
Harbor porpoise	*Phocoena phocoena*	Northern California/Southern Oregon.	-, -, N	15,303 (0.575, 9,759, 2022).	195	0
Harbor porpoise	*Phocoena phocoena*	San Francisco/Russian River.	-, -, N	7,777 (0.62, 4,811, 2017)	73	≥0.4
Order Carnivora—Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California sea lion	*Zalophus californianus*	U.S.	-, -, N	257,606 (N/A, 233,515, 2014).	14,011	>321
Guadalupe fur seal	*Arctocephalus townsendi*	Mexico	T, D, Y	68,850 (N/A, 57,199, 2013)	1,959	≥10.0
Northern fur seal	*Callorhinus ursinus*	Eastern Pacific	-, D, Y	612,765 (0.2, 518,651, 2022).	11,151	296

TABLE 15—MARINE MAMMAL OCCURRENCE WITHIN THE HCTT STUDY AREA [1]—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Northern fur seal	*Callorhinus ursinus*	California	-, -, N	19,634 (N/A, 8,788, 2022)	527	≥1.2
Steller sea lion	*Eumetopias jubatus*	Eastern	-, -, N	36,308 (N/A, 36,308, 2022)	2,178	93
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	California	-, -, N	30,968 (N/A, 27,348, 2012)	1,641	43
Hawaiian monk seal	*Neomonachus schauinslandi*	Hawaii	E, D, Y	1,605 (0.05, 1,508, 2022)	5	≥4.8
Northern elephant seal	*Mirounga angustirostris*	California Breeding	-, -, N	194,907 (N/A, 88,794, 2023).	5,328	11

Note: N/A = Not Applicable, UND = Undetermined, UNK = Unknown. Unless otherwise noted, abundance estimates are from the final 2022 Pacific stock assessment report (Carretta *et al.,* 2024; Carretta *et al.,* 2023b), the draft 2023 Pacific stock assessment report (Carretta *et al.,* 2024), or the Alaska stock assessment reports (Young, 2024).

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/;* Committee on Taxonomy (2022)).

[2] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[5] Humpback whales in the Central America/Southern Mexico-California-Oregon-Washington Stock make up the endangered Central America DPS, and humpback whales in the Mainland Mexico-California-Oregon-Washington Stock are part of the threatened Mexico DPS, along with whales from the Mexico-North Pacific Stock, which do not occur in the Study Area.

[6] Mesoplodont beaked whales are analyzed as a group due to insufficient data available to estimate species-specific densities.

[7] The Baja California Peninsula Mexico and California-Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

Species Not Included in the Analysis

The species carried forward for analysis (and described in table 15) are those likely to be found in the HCTT Study Area based on the most recent data available, and do not include species that may have once inhabited or transited the area but have not been sighted in recent years (*e.g.,* species which were extirpated from factors such as 19th and 20th century commercial exploitation). North Pacific right whale may be present in the northeast Pacific Ocean, but has an extremely low probability of presence in the HCTT Study Area. It is considered extralimital (*i.e.,* not anticipated to occur in the Study Area) and was not included in the analysis.

One species of marine mammal, the southern sea otter, occurs in the HCTT Study Area but is managed by the U.S. Fish and Wildlife Service (U.S. FWS) and thus are not considered further in this analysis.

Below, we consider additional information about the marine mammals in the area of the specified activities that informs our analysis, such as identifying known areas of important habitat or behaviors, or where unusual mortality events have been designated.

Critical Habitat

Currently, the humpback whale (Central America and Mexico DPSs), killer whale (Eastern North Pacific Southern Resident DPS), false killer whale (Main Hawaiian Islands Insular DPS), and Hawaiian monk seal have ESA-designated critical habitat in the HCTT Study Area.

Humpback Whale

On April 21, 2021, NMFS designated critical habitat for the endangered Western North Pacific DPS, the endangered Central America DPS, and the threatened Mexico DPS of humpback whales (86 FR 21082). Areas proposed as critical habitat include specific marine areas located off the coasts of California, Oregon, Washington, and Alaska. Designated critical habitat for the Central America DPS overlaps the NOCAL Range Complex (Units 15, 16, and 17), as well as PMSR and the northern portion of the SOCAL Range Complex (Units 17 and 18). These areas are essential for humpback whale foraging and migration. One of the proposed critical habitat areas, critical habitat Unit 19, would have also overlapped with the SOCAL range in the HSTT Study Area but was excluded after consideration of potential national security and economic impacts of designation.

NMFS, in the final rule designating critical habitat for humpback whales, identified prey species, primarily euphausiids and small pelagic schooling fishes of sufficient quality, abundance, and accessibility within humpback whale feeding areas to support feeding and population growth, as an essential habitat feature. NMFS, through a critical habitat review team (CHRT), also considered inclusion of migratory corridors and passage features, as well as sound and the soundscape, as essential habitat features. NMFS did not include either in the final critical habitat; however, as the CHRT concluded that the best available science did not allow for identification of any consistently used migratory corridors or definition of any physical, essential migratory or passage conditions for whales transiting between or within habitats of the three DPSs. Regardless of whether critical habitat is designated for a particular area, NMFS has considered all applicable information regarding marine mammals and their habitat in the analysis supporting these proposed regulations.

Killer Whale

NMFS designated critical habitat for the Southern Resident killer whale DPS on November 29, 2006 (71 FR 69054) in inland waters of Washington State, and on August 2, 2021, revised the designation by designating six additional coastal critical habitat areas along the U.S. West Coast (86 FR 41668). The HCTT Study Area overlaps two of the three continuous sections off the California coast: the North Central CA Coast Area and the Monterey Bay Area. Based on the natural history of the Southern Resident killer whales and their habitat needs, NMFS identified physical or biological features essential to the conservation of the Southern

Resident killer whale DPS: (1) water quality to support growth and development; (2) prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; and (3) passage conditions to allow for migration, resting, and foraging.

False Killer Whale (Main Hawaiian Island Insular DPS)

Critical habitat for the ESA-listed Main Hawaiian Islands insular false killer whale DPS was finalized in July 2018 (83 FR 35062, July 24, 2018) designating waters from the 45 m depth contour to the 3,200 m depth contour around the main Hawaiian Islands from Niʻihau east to Hawaii. This designation does not include most bays, harbors, or coastal in-water structures. NMFS excluded 14 areas. The total area designated was approximately 45,504 square kilometers (km^2; 13,267 square nautical miles (nmi^2)) of marine habitat. Critical habitat for the main Hawaiian Islands insular DPS of false killer whale entirely overlaps the HRC.

Main Hawaiian Islands insular false killer whales are island-associated whales that rely entirely on the productive submerged habitat of the main Hawaiian Islands to support all of their life-history stages. Island-associated marine habitat for Main Hawaiian Islands insular false killer whale is the only essential feature of the critical habitat. The following characteristics of this habitat support insular false killer whales' ability to travel, forage, communicate, and move freely around and among the waters surrounding the main Hawaiian Islands: (1) adequate space for movement and use within shelf and slope habitat; (2) prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; (3) waters free of pollutants of a type and amount harmful to Main Hawaiian Islands insular false killer whales; and (4) sound levels that would not significantly impair false killer whales' use or occupancy.

Hawaiian Monk Seal

Critical habitat for Hawaiian monk seals was designated in 1986 (51 FR 16047, April 30, 1986) and later revised in 1988 (53 FR 18988, May 26, 1988) and in 2015 (80 FR 50925, August 21, 2015). In the Northwestern Hawaiian Islands Hawaiian monk seal critical habitat includes all beach areas, sand spits and islets, including all beach crest vegetation to its deepest extent inland as well as the seafloor and marine habitat 10 m in height above the seafloor from the shoreline out to the 200 m depth contour around Kure Atoll (Hōlanikū), Midway Atoll (Kuaihelani), Pearl and Hermes Reef (Manawai), Lisianski Island (Kapou), Laysan Island (Kamole), Maro Reef (Kamokuokamohoaliʻi), Gardner Pinnacles (ʻŌnūnui), French Frigate Shoals (Lalo), Necker Island (Mokumanamana) and Nihoa Island. In the main Hawaiian Islands, Hawaiian monk seal critical habitat includes the seafloor and marine habitat to 10 m above the seafloor from the 200 m depth contour through the shoreline and extending into terrestrial habitat 5 m inland from the shoreline between identified boundary points around Kaula Island (includes marine habitat only), Niʻihau (includes marine habitat from 10 m-200 m in depth), Kauaʻi, Oʻahu, Maui Nui (including Kahoʻolawe, Lānaʻi, Maui, and Molokaʻi), and Hawaii Island. A portion of the critical habitat overlaps the HRC.

The essential features of Hawaiian monk seal critical habitat are: (1) terrestrial areas and adjacent shallow, sheltered aquatic areas with characteristics preferred by monk seals for pupping and nursing; (2) marine areas from 0 to 200 m in depth that support adequate prey quality and quantity for juvenile and adult monk seal foraging; and (3) significant areas used by monk seals for hauling out, resting or molting.

Biologically Important Areas

Ferguson *et al.* (2015) identified Biologically Important Areas (BIAs) within U.S. waters of the West Coast (Calambokidis *et al.* 2015) and in Hawaii (Baird *et al.* 2015), which represent areas and times in which cetaceans are known to concentrate in areas of known importance for activities related to reproduction, feeding, and migration, or areas where small and resident populations are known to occur. Unlike ESA critical habitat, these areas are not formally designated pursuant to any statute or law, but are a compilation of the best available science intended to inform impact and mitigation analyses. An interactive map of the BIAs is available at: *https://oceannoise.noaa.gov/biologically-important-areas.* In some cases, additional, or newer, information regarding known feeding, breeding, or migratory areas is available and has been used to update these BIAs (as cited below), and a summary of all of the BIAs is included below.

The West Coast and Hawaii BIAs were updated in 2024 (Calambokidis *et al.*) and 2023 (Kratofil *et al.*), respectively (referred to as BIA II herein). Calambokidis *et al.* (2024) and Kratofil *et al.* (2023) use a new scoring system described here and in Harrison *et al.* (2023). Experts identified an overall Importance Score for each BIA that considers: (1) ''Intensity''—the intensity and characteristics underlying an area's identification as a BIA; and (2) ''Data Support''—the quantity, quality, and type of information, and associated uncertainties, upon which the BIA delineation and scoring depends. Importance Scores range from 1 to 3, with a higher score representing an area of higher intensity and data support. Each BIA identified in BIA II is also scored for boundary uncertainty and spatiotemporal variability (dynamic, ephemeral, or static). Additionally, BIA II includes hierarchical BIAs for some species and stocks where a higher intensity score is appropriate for a smaller core area(s) (child BIA) within a larger BIA unit (parent BIA).

The Hawaii Study Area overlaps BIAs for small and resident populations of the following species: spinner dolphin, short-finned pilot whale, rough-toothed dolphin, pygmy killer whale, pantropical spotted dolphin, melon-headed whale, false killer whale, dwarf sperm whale, goose-beaked whale, common bottlenose dolphin, and Blainville's beaked whale. Further, the Hawaii Study Area overlaps updated BIAs for humpback whale reproduction (Kratofil *et al.* 2023). The California Study Area overlaps feeding BIAs for blue whale, fin whale, and humpback whale in SOCAL. Additionally, it overlaps a reproductive BIA as well as northbound and southbound migratory BIAs for gray whale (Calambokidis *et al.* 2024). Table 16 describes each BIA that overlaps the HCTT Study Area and the scores for the above criteria.

TABLE 16—BIAS OVERLAPPING THE HCTT STUDY AREA

Species	BIA type	Parent/child/non-hierarchical	BIA name	Effective months	BIA area (km^2)	Figure in action proponents' LOA application	Importance score	Intensity score	Data support score	Boundary certainty	Spatiotemporal variability	Transboundary across
Hawaii Study Area (Kratofil *et al.*, 2023)												
Humpback whale	Reproductive	Parent	Main Hawaiian Islands—Parent.	December through May.	23,041	B.1–11	2	2	2	2	Static	None.
Humpback whale	Reproductive	Child	Main Hawaiian Islands—Child.	December through May.	6,676	B.1–11	3	3	3	3	Static	None.
False killer whale	Small and Resident Population.	Parent	Main Hawaiian Islands Insular Stock—Parent.	Year-round	94,217	B.1–7	1	1	3	3	Static	None.
False killer whale	Small and Resident Population.	Child	Main Hawaiian Islands Insular Stock—Child.	Year-round	7,775	B.1–7	3	3	3	3	Static	None.
False killer whale	Small and Resident Population.	Non-hierarchical.	Northwestern Hawaiian Islands Insular Stock.	Year-round	138,001	B.1–7	1	1	2	2	Static	None.
Dwarf sperm whale.	Small and Resident Population.	Parent	Hawaii Island—Parent.	Year-round	1,341	B.1–14	3	3	2	2	Static	None.
Dwarf sperm whale.	Small and Resident Population.	Child	Hawaii Island—Child.	Year-round	457	B.1–14	3	3	2	2	Static	None.
Pygmy killer whale.	Small and Resident Population.	Non-hierarchical.	O'ahu-Maui Nui	Year-round	7,416	B.1–15	3	3	2	2	Static	None.
Pygmy killer whale.	Small and Resident Population.	Non-hierarchical.	Hawaii Island	Year-round	5,201	B.1–15	2	2	2	2	Static	None.
Short-finned pilot whale.	Small and Resident Population.	Parent	Main Hawaiian Islands—Parent.	Year-round	51,280	B.1–16	1	1	3	3	Static	None.
Short-finned pilot whale.	Small and Resident Population.	Child	Main Hawaiian Islands—Child (Western Community Core Range).	Year-round	4,040	B.1–16	3	3	3	3	Static	None.
Short-finned pilot whale.	Small and Resident Population.	Child	Main Hawaiian Islands—Child (Central Community Core Range).	Year-round	2,427	B.1–16	3	3	3	3	Static	None.
Short-finned pilot whale.	Small and Resident Population.	Child	Main Hawaiian Islands—Child (Eastern Community Core Range).	Year-round	2,461	B.1–16	3	3	3	3	Static	None.
Common bottlenose dolphin.	Small and Resident Population.	Parent	Kaua'i/Ni'ihau-O'ahu-Maui Nui.	Year-round	36,634	B.1–18	1	1	3	2	Static	None.
Common bottlenose dolphin.	Small and Resident Population.	Child	Kaua'i/Ni'ihau-O'ahu-Maui Nui-Kaua'i/Ni'ihau).	Year-round	2,772	B.1–18	3	3	3	3	Static	None.
Common bottlenose dolphin.	Small and Resident Population.	Child	Kaua'i/Ni'ihau-O'ahu-Maui Nui—O'ahu.	Year-round	8,486	B.1–18	3	3	2	2	Static	None.
Common bottlenose dolphin.	Small and Resident Population.	Child	Kaua'i/Ni'ihau-O'ahu-Maui Nui—Maui Nui.	Year-round	10,622	B.1–18	2	2	2	2	Static	None.
Common bottlenose dolphin.	Small and Resident Population.	Non-hierarchical.	Hawaii Island	Year-round	8,299	B.1–18	2	2	3	3	Static	None.

TABLE 16—BIAS OVERLAPPING THE HCTT STUDY AREA—Continued

Species	BIA type	Parent/child/non-hierarchical	BIA name	Effective months	BIA area (km^2)	Figure in action proponents' LOA application	Importance score	Intensity score	Data support score	Boundary certainty	Spatiotemporal variability	Transboundary across
Pantropical spotted dolphin.	Small and Resident Population.	Parent	O'ahu-Maui Nui-Hawaii Island—Parent.	Year-round	57,711	B.1–19	1	1	2	2	Static	None.
Pantropical spotted dolphin.	Small and Resident Population.	Child	O'ahu-Maui Nui-Hawaii Island—Child (O'ahu).	Year-round	12,952	B.1–19	1	1	2	2	Static	None.
Pantropical spotted dolphin.	Small and Resident Population.	Child	O'ahu-Maui Nui-Hawaii Island—Child (Maui Nui).	Year-round	6,743	B.1–19	1	1	2	2	Static	None.
Pantropical spotted dolphin.	Small and Resident Population.	Child	O'ahu-Maui Nui-Hawaii Island—Hawaii Island—Child (Hawaii Island).	Year-round	10,768	B.1–19	1	1	2	2	Static	None.
Rough-toothed dolphin.	Small and Resident Population.	Non-hierarchical.	Maui Nui-Hawaii Island.	Year-round	15,112	B.1–21	1	1	2	2	Static	None.
Rough-toothed dolphin.	Small and Resident Population.	Parent	Kaua'i/Ni'ihau-O'ahu—Parent.	Year-round	24,233	B.1–21	1	1	2	2	Static	None.
Rough-toothed dolphin.	Small and Resident Population.	Child	Kaua'i/Ni'ihau-O'ahu—Child (Kaua'i/Ni'ihau).	Year-round	1,149	B.1–21	2	2	2	2	Static	None.
Melon-headed whale.	Small and Resident Population.	Non-hierarchical.	Kohala Residents—Hawaii Island.	Year-round	3,816	B.1–21	2	2	3	3	Static	None.
Spinner dolphin ...	Small and Resident Population.	Non-hierarchical.	Manawai (Pearl and Hermes Reef).	Year-round	2,094	B.1–20	1	2	1	2	Static	None.
Spinner dolphin ...	Small and Resident Population.	Non-hierarchical.	Kuaihelani/Hōlanikū (Midway/Kure Atolls).	Year-round	4,841	B.1–20	1	2	1	2	Static	None.
Spinner dolphin ...	Small and Resident Population.	Non-hierarchical.	Kaua'i and Ni'ihau.	Year-round	7,233	B.1–20	1	1	2	3	Static	None.
Spinner dolphin ...	Small and Resident Population.	Non-hierarchical.	O'ahu and Maui Nui.	Year-round	14,651	B.1–20	1	1	2	3	Static	None.
Spinner dolphin ...	Small and Resident Population.	Non-hierarchical.	Hawaii Island	Year-round	9,477	B.1–20	1	1	3	3	Static	None.
Goose-beaked whale.	Small and Resident Population.	Parent	Hawaii Island	Year-round	37,157	B.1–23	2	2	3	2	Static	None.
Goose-beaked whale.	Small and Resident Population.	Child	Hawaii Island	Year-round	5,400	B.1–23	3	3	3	3	Static	None.
Blainville's beaked whale.	Small and Resident Population.	Parent	O'ahu-Maui Nui-Hawaii Island—Parent.	Year-round	78,714	B.1–24	1	1	3	2	Static	None.
Blainville's beaked whale.	Small and Resident Population.	Child	O'ahu-Maui Nui-Hawaii Island—Child (Hawaii Island).	Year-round	4,214	B.1–24	3	3	3	3	Static	None.
California Study Area (Calambokidis *et al.*, 2024)												
Blue whale	Feeding	Parent	Blue whale West Coast—Parent.	June through November.	173,433	B.1–1	2	2	3	3	Static	None.
Blue whale	Feeding	Child	Blue whale West Coast—Core.	June through November.	54,349	B.1–1	3	3	3	3	Static	None.
Fin whale	Feeding	Parent	Fin whale West Coast—Parent.	June through November.	315,072	B.1–2	1	1	2	2	Static	None.

Fin whale	Feeding	Child	Fin whale West Coast—Core.	June through November.	155,508	B.1–2	2	2	2	Static	None.
Humpback whale	Feeding	Parent	Humpback whale West Coast—Parent.	March through November.	140,303	B.1–5	2	2	3	Static	None.
Humpback whale	Feeding	Child	Humpback whale West Coast—Core.	March through November.	38,052	B.1–5	3	3	3	Static	None.
Gray whale	Migratory	Parent	Gray Whale Migratory Route—Southbound and Northbound.	January through June, November through December.	167,066	B.1–13	1	2	2	Static	GOA.
Gray whale	Migratory	Child	Southbound	November–February.	70,110	B.1–13	2	3	3	Static	None.
Gray whale	Migratory	Child	Northbound Phase A.	January–May	65,047	B.1–13	2	2	3	Static	None.
Gray whale	Migratory	Child	Northbound Phase B.	March–May	51,947	B.1–13	3	3	3	Static	None.
Gray whale	Reproductive	Non-hierarchical.	Gray whale—Cow and Calf Migrants.	March–May	51,947	B.1–13	3	3	3	Static	None.
Harbor porpoise	Small and Resident Population.	Non-hierarchical.	Monterey Bay	Year-round	1,911	B.1–22	2	2	3	Static	None.
Harbor porpoise	Small and Resident Population.	Non-hierarchical.	Morro Bay	Year-round	3,030	B.1–22	1	1	3	Static	None.

National Marine Sanctuaries

Under Title III of the Marine Protection, Research, and Sanctuaries Act of 1972 (also known as the National Marine Sanctuaries Act (NMSA)), NOAA can establish as national marine sanctuaries (NMS) areas of the marine environment with special conservation, recreational, ecological, historical, cultural, archaeological, scientific, educational, or aesthetic qualities. Sanctuary regulations prohibit destroying, causing the loss of, or injuring any sanctuary resource managed under the law or regulations for that sanctuary (15 CFR part 922). NMS are managed on a site-specific basis, and each sanctuary has site-specific regulations. Most, but not all sanctuaries have site-specific regulatory exemptions from the prohibitions for certain military activities. Separately, section 304(d) of the NMSA requires Federal agencies to consult with the Office of National Marine Sanctuaries (ONMS) whenever their Proposed Activities are likely to destroy, cause the loss of, or injure a sanctuary resource. There are seven designated NMSs and one proposed NMS within the HCTT Study Area (see section 6 of the 2024 HCTT Draft EIS/OEIS):

- Channel Islands NMS
- Chumash Heritage NMS;
- Cordell Bank NMS;
- Greater Farallones NMS;
- Monterey Bay NMS;
- Hawaiian Islands Humpback Whale NMS
- Pacific Remote Islands NMS (in designation); and
- Papahānaumokuākea NMS.

Channel Islands NMS is an ecosystem-based managed sanctuary consisting of an area of 1,109 nmi^2 (3,803 km^2) around Anacapa Island, Santa Cruz Island, Santa Rosa Island, San Miguel Island, and Santa Barbara Island to the south. It encompasses sensitive habitats (*e.g.,* kelp forest habitat, deep benthic habitat) and includes various shipwrecks and maritime heritage artifacts. Channel Islands NMS waters and its remote, isolated position at the confluence of two major ocean currents support significant biodiversity of marine mammals, fish, and invertebrates. At least 33 species of cetaceans have been reported in the Channel Islands NMS region with common species, including: Long-beaked common dolphin, short-beaked common dolphin, Bottlenose dolphin, Pacific white-sided dolphin, Northern right whale dolphin, Risso's dolphin, California gray whale, Blue whale, and Humpback whale. The three species of pinnipeds that are commonly found throughout or in part of the Channel Islands NMS include: California sea lion, Northern elephant seal, and Pacific harbor seal.

Chumash Heritage NMS encompasses 3,430 nmi^2 (11,766 km^2) of coastal and ocean waters offshore Central California stretching nearly 52 nmi (96.6 km) from shore and down to a maximum depth of 11,580 ft (3,530 m). The sanctuary protects and collaboratively manages natural and cultural resources, maritime historical resources, and Indigenous cultural history along 100 nmi (186.9 km) of coastline. Chumash Heritage NMS contains marine biodiversity, productive ecosystems, and sensitive species and habitats, with special geologic features like Rodriguez Seamount and Santa Lucia Bank, along with an important biogeographic transition zone and upwelling along the California Current, which drives biological productivity and creates ecological conditions in the area that supports a high abundance of marine mammals. Different types of ecological habitats found within the sanctuary include kelp forests, rocky reefs, deep-sea coral gardens, and sandy beaches.

Cordell Bank NMS is an extremely productive marine area off the West Coast in northern California, just north of the Gulf of the Farallones. With its southern-most boundary located 36.5 nmi (67.6 km) north of San Francisco, the sanctuary is entirely offshore, with the eastern boundary 5.2 nmi (9.7 km) from shore and the western boundary 26.1 nmi (48.3 km) offshore. In total, the sanctuary protects an area of 971 nmi^2 (3,330 km^2). The centerpiece of the sanctuary is Cordell Bank, a 3.9 nmi by 8.3 nmi (7.2 km by 15.3 km) rocky undersea feature. The combination of ocean conditions and undersea topography creates a rich and diverse marine community in the sanctuary. The prevailing California Current flows southward along the coast, and the annual upwelling of nutrient-rich deep ocean water supports the sanctuary's rich biological community, including marine mammals.

Greater Farallon NMS encompasses 2,488 nmi^2 (8,534 km^2) just north and west of San Francisco Bay, CA, within the California Current ecosystem. Due to a high degree of wind-driven upwelling, there is a ready supply of nutrients to surface waters and the California Current ecosystem is one of the most biologically productive regions in the world. Greater Farallones NMS provides breeding and feeding grounds for at least 25 endangered or threatened species; 36 marine mammal species, including blue, gray, and humpback whales, harbor seals, elephant seals, Pacific white-sided dolphins, and one of the southernmost U.S. populations of threatened Steller sea lion.

Monterey Bay NMS is an ecosystem-based managed sanctuary consisting of an area of 4,601 nmi^2 (15,781 km^2) stretching from Marin to Cambria and extending an average of 26.1 nmi (48.3 km) from shore. Monterey Bay NMS contains extensive kelp forests and one of North America's largest underwater canyons and closest-to-shore deep ocean environments. Its diverse marine ecosystem also includes rugged rocky shores, wave-swept sandy beaches and tranquil estuaries. These habitats support a variety of marine life, including 36 species of marine mammals, more than 180 species of seabirds and shorebirds, at least 525 species of fishes, and an abundance of invertebrates and algae. Of the 36 species of marine mammals, six are pinnipeds with California sea lions being the most common, and the remainder are 26 species of cetaceans.

Hawaiian Islands Humpback Whale NMS is a single-species managed sanctuary, composed of 1,035 nmi^2 of the waters around Maui, Lānaʻi, and Molokaʻi; and smaller areas off the north shore of Kauaʻi, off Hawaii's west coast, and off the north and southeast coasts of Oʻahu. Hawaiian Islands Humpback Whale NMS is entirely within the HRC of the HCTT Study Area and constitutes one of the world's most important Hawaii humpback whale DPS habitats (81 FR 62259, September 8, 2016), and is a primary region for humpback reproduction in the U.S. (National Marine Sanctuaries Program, 2002). Scientists estimate that more than 50 percent of the entire North Pacific humpback whale population migrates to Hawaiian waters each winter to mate, calve, and nurse their young. The North Pacific humpback whale population has been split into two DPSs. The Hawaii humpback whale DPS migrates to Hawaiian waters each winter and is not listed under the ESA. In addition to protection under the MMPA, the Hawaii humpback whale DPS is protected in sanctuary waters by the Hawaiian Islands Humpback Whale NMS. The sanctuary was created to protect humpback whales and shallow, protected waters important for calving and nursing (Office of National Marine Sanctuaries, 2010).

Papahānaumokuākea NMS, the largest NMS, consists of approximately 439,910 nmi^2 (1,508,849 km^2) of marine habitat. The sanctuary comprises several interconnected ecosystems, such as coral islands surrounded by shallow reefs, low-light mesophotic reefs with extensive algal beds, open ocean waters

connected to the greater North Pacific Ocean, deep-water habitats such as abyssal plains 16,400 ft (4,999 m) below sea level, and deep reef habitat characterized by seamounts, banks, and shoals. Hawaiian monk seals, one of the most endangered marine mammals in the world, live in Papahānaumokuākea NMS.

The Office of National Marine Sanctuaries is in the process of designating the Pacific Remote Islands NMS. The atolls, shoals, banks, reefs, seamounts, and open-ocean waters surrounding the Pacific Remote Islands are home to some of the most diverse tropical marine life on the planet. The region's diverse habitats and pristine reefs provide a haven for marine mammals and numerous threatened, endangered, and depleted species thrive in the area, including spinner dolphins and melon-headed whales. NMFS does not anticipate injury to Sanctuary resources in the proposed Pacific Remote Islands NMS, as the action proponents are not proposing to conduct activities within the vicinity of, or within, the proposed Pacific Islands Heritage NMS.

Unusual Mortality Events

An unusual mortality event (UME) is defined under Section 410(9) of the MMPA as a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response (16 U.S.C. 1421h(9)). From 1991 to the present, there have been 17 formally recognized UMEs affecting marine mammals in California and Hawaii and involving species under NMFS' jurisdiction; however, there are currently none that are active.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995, Wartzok and Ketten, 1999, Au and Hastings, 2008). To reflect this, Southall *et al.* (2007), Southall *et al.* (2019c) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (*e.g.,* behavioral response data, anatomical modeling). NMFS (2024) generalized hearing ranges were chosen based on the approximately 65-dB threshold from the composite audiograms, previous analysis in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019c). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS, 2024) as reflected below in table 16.

TABLE 17—MARINE MAMMAL HEARING GROUPS

[NMFS, 2024]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36** kHz
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* and *L. australis*).	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.
Phocid pinnipeds (PA) (in-air) (true seals)	42 Hz to 52 kHz.
Otariid pinnipeds (OA) (in-air) (sea lions and fur seals)	90 Hz to 40 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on the ~65–dB threshold from composite audiogram, previous analysis in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). Additionally, animals are able to detect very loud sounds above and below that ''generalized'' hearing range.

** The Action Proponents split the LF functional hearing group into LF and VLF based on Houser *et al.,* (2024) while NMFS Updated Technical Guidance (NMFS, 2024) does not include these data. NMFS is aware these data and data collected during a final field season by Houser *et al.* (in prep) have implications for the generalized hearing range for low-frequency cetaceans and their weighting function, however, as described in the 2024 Updated Technical Guidance, it is premature for us to propose any changes to our current Updated Technical Guidance. Mysticete hearing data is identified as a special circumstance that could merit reevaluating the acoustic criteria for low-frequency cetaceans in the 2024 Updated Technical Guidance once the data from the final field season is published. Therefore, we anticipate that once the data are published, it will likely necessitate updating this document (*i.e.,* likely after the data gathered in the summer 2024 field season and associated analysis are published).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024) for a review of available information.

The Navy adjusted these hearing groups using data from recent hearing measurements in minke whales (Houser *et al.,* 2024). These data support separating mysticetes (the LF cetacean marine mammal hearing group in table 17) into two hearing groups, which the Navy designates as ''very low-frequency (VLF) cetaceans'' and ''low-frequency (LF) cetaceans,'' which follows the recommendations of Southall *et al.* (2019c). Within the Navy's adjusted hearing groups, the VLF cetacean group contains the larger mysticetes (*i.e.,* blue, fin, right, and bowhead whales) and the LF cetacean group contains the mysticete species not included in the VLF group (*e.g.,* minke, humpback, gray, pygmy right whales). Although there have been no direct measurements of hearing sensitivity in the larger mysticetes included in Navy's VLF hearing group, an audible frequency range of approximately 10 Hz to 30 kHz has been estimated from measured vocalization frequencies, observed responses to playback of sounds, and anatomical analyses of the auditory system. The upper frequency limit of hearing in Navy's LF hearing group has been estimated in a minke whale from direct measurements of auditory evoked potentials (Houser *et al.,* 2024).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken

by this activity. The Preliminary Analysis and Negligible Impact Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation Measures section to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts on individuals are likely to adversely affect the species or stock through effects on annual rates of recruitment or survival.

The Action Proponents have requested authorization for the take of marine mammals that may occur incidental to training and testing activities in the HCTT Study Area. The Action Proponents analyzed potential impacts to marine mammals from acoustic and explosive sources and from vessel use in the application. NMFS carefully reviewed the information provided by the Action Proponents and concurs with their synthesis of science, along with independently reviewing applicable scientific research and literature and other information to evaluate the potential effects of the Action Proponents' activities on marine mammals, which are presented in this section (see appendix D in the 2024 HCTT Draft EIS/OEIS for additional information).

Other potential impacts to marine mammals from training and testing activities in the HCTT Study Area were analyzed in the 2024 HCTT Draft EIS/OEIS, in consultation with NMFS as a cooperating agency, and determined to be unlikely to result in marine mammal take. Therefore, the Action Proponents have not requested authorization for take of marine mammals incidental to other components of their proposed Specified Activities, and we agree that incidental take is unlikely to occur from those components. In this proposed rule, NMFS analyzes the potential effects on marine mammals from the activity components that may result in take of marine mammals: exposure to acoustic or explosive stressors including non-impulsive (*i.e.,* sonar and other transducers, and vibratory pile driving) and impulsive (*i.e.,* explosives, impact pile driving, launches, and air guns) stressors and vessel movement.

For the purpose of MMPA incidental take authorizations, NMFS' effects assessments serve four primary purposes: (1) to determine whether the specified activities would have a negligible impact on the affected species or stocks of marine mammals (based on whether it is likely that the activities would adversely affect the species or stocks through effects on annual rates of recruitment or survival); (2) to determine whether the specified activities would have an unmitigable adverse impact on the availability of the species or stocks for subsistence uses; (3) to prescribe the permissible methods of taking (*i.e.,* Level B harassment (behavioral harassment and temporary threshold shift (TTS)), Level A harassment (auditory injury (AUD INJ), non-auditory injury), serious injury, or mortality), including identification of the number and types of take that could occur by harassment, serious injury, or mortality, and to prescribe other means of effecting the least practicable adverse impact on the species or stocks and their habitat (*i.e.,* mitigation measures); and (4) to prescribe requirements pertaining to monitoring and reporting.

In this section, NMFS provides a description of the ways marine mammals may be generally affected by these activities in the form of mortality, physical injury, sensory impairment (permanent and temporary threshold shifts and acoustic masking), physiological responses (particular stress responses), behavioral disturbance, or habitat effects. Explosives and vessel strikes, which have the potential to result in incidental take by serious injury and/or mortality, will be discussed in more detail in the Estimated Take of Marine Mammals section. The Estimated Take of Marine Mammals section also discusses how the potential effects on marine mammals from non-impulsive and impulsive sources relate to the MMPA definitions of Level A Harassment and Level B Harassment, and quantifies those effects that do not qualify as a take under the MMPA. The Preliminary Analysis and Negligible Impact Determination section assesses whether the proposed authorized take would have a negligible impact on the affected species and stocks.

Potential Effects of Underwater Sound on Marine Mammals

The marine soundscape is composed of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far (American National Standards Institute, 1995). The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources, which may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activities may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can possibly result in one or more of the following: temporary or permanent hearing impairment, other auditory injury, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2003; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009, Southall *et al.,* 2019a). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high-level sounds can cause auditory injury, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing can occur after exposure to noise and occurs almost exclusively for noise within an animal's hearing range.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the animal, but not strong enough to elicit

any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

We also describe more severe potential effects (*i.e.,* certain non-auditory physical or physiological effects). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or, in the case of explosives, more severe injuries or mortality (Yelverton *et al.,* 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high levels of underwater sound or as a secondary effect of extreme behavioral responses (*e.g.,* change in dive profile as a result of an avoidance response) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Tal *et al.,* 2015).

Hearing

Marine mammals have adapted hearing based on their biology and habitat: amphibious marine mammals (*e.g.,* pinnipeds that spend time on land and underwater) have modified ears that allow them to hear both in-air and in-water, while fully aquatic marine mammals (*e.g.,* cetaceans that are always underwater) have specialized ear adaptations for in-water hearing (Wartzok and Ketten, 1999). These adaptations explain the variation in hearing ability and sensitivity among marine mammals and have led to the characterization of marine mammal functional hearing groups based on those sensitivities: very low-frequency cetaceans (VLF group: blue, fin, right, and bowhead whales), low-frequency cetaceans (LF group: minke, sei, Bryde's, Rice's, humpback, gray, and pygmy right whales), high-frequency (HF) cetaceans (HF group: sperm whales, beaked whales, killer whale, melon-headed whale, false/pygmy killer whale, pilot whales, and some dolphin species), very high-frequency (VHF) cetaceans (VHF group: some dolphin species, porpoises, Amazon River dolphin, *Kogia* species, Baiji, and La Plata dolphin), sirenians (SI) (SI group: manatees, dugongs), otariids (OCW) and other non-phocid marine carnivores (OCA) in water and in air (OCW and OCA groups: sea lion, fur seal, walrus, otter), and phocids in water (PCW) and in air (PCA) (PCW and PCA groups: true seals) (Southall *et al.,* 2019). In Phase III, VLF and LF cetaceans were part of one, combined LF cetacean hearing group. However, as described in the Navy's report ''Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase 4)'' (U.S. Department of the Navy, 2025), hereafter referred to as the Criteria and Thresholds Technical Report, Houser *et al.* (2024) recently reported obtaining hearing measurements for minke whales, the first direct measurements for a baleen whale species, using auditory evoked potential (AEP) methodology. The Action Proponents incorporated these measurements, as well as Southall *et al.* (2019), into their analysis. They determined that the data support dividing mysticetes into two separate hearing groups: VLF and LF cetaceans, and NMFS concurs, (as described further in the Estimated Take of Marine Mammals section), that this approach is appropriate for this action.

The hearing sensitivity of marine mammals is also directional, meaning the angle between an animal's position and the location of a sound source impacts the animal's hearing threshold, thereby impacting an animal's ability to perceive the sound emanating from that source. This directionality is likely useful for determining the general location of a sound, whether for detection of prey, predators, or members of the same species, and can be dependent upon the frequency of the sound (Accomando *et al.,* 2020; Au and Moore, 1984; Byl *et al.,* 2016; Byl *et al.* 2019; Kastelein *et al.,* 2005; Kastelein *et al.,* 2019; Popov and Supin, 2009).

Acoustic Signaling

An acoustic signal refers to the sound waves used to communicate underwater, and marine mammals use a variety of acoustic signals for socially important functions, such as communicating, as well as biologically important functions, such as echolocating (Richardson *et al.,* 1995; Wartzok and Ketten, 1999). Acoustic signals used for communication are lower frequency (*i.e.,* 20 Hz to 30 kHz) than those signals used for echolocation, which are high-frequency (approximately 10–200 kHz peak frequency) signals used by odontocetes to sense their underwater environment. Lower frequency vocalizations used for communication may have a specific, prominent fundamental frequency (Brady *et al.,* 2021) or have a wide frequency range, depending on the functional hearing group and whether the marine mammal is vocalizing in-water or in-air. Acoustic signals used for echolocation are high-frequency, high-energy sounds with patterns and peak frequencies that are often species-specific (Baumann-Pickering *et al.,* 2013).

Marine mammal species typically produce sounds at frequencies within their own hearing range, though auditory and vocal ranges do not perfectly align (*e.g.,* odontocetes may only hear a portion of the frequencies of an echolocation click). Because determining a species vocal range is easier than determining a species' hearing range, vocal ranges are often used to infer a species' hearing range when species-specific hearing data are not available (*e.g.,* large whale species).

Hearing Loss and Auditory Injury

Marine mammals, like all mammals, lose their ability to hear over time due to age-related degeneration of auditory pathways and sensory cells of the inner ear. This natural, age-related hearing loss is distinct from acute noise-induced hearing loss (Møller, 2013). Noise-induced hearing loss can be temporary (*i.e.,* TTS) or permanent (permanent threshold shift (PTS)), and higher-level sound exposures are more likely to cause PTS or other AUD INJ. For marine mammals, AUD INJ is considered to be possible when sound exposures are sufficient to produce 40 dB of TTS measured approximately 4 minutes after exposure (U.S. Department of the Navy, 2025). Numerous studies have directly examined noise-induced hearing loss in marine mammals by measuring an animal's hearing threshold before and after exposure to intense sounds. The difference between the post-exposure and pre-exposure hearing thresholds is then used to determine the amount of TTS (in dB) that was produced as a result of the sound exposure (see appendix D of the 2024 HCTT Draft EIS/OEIS for additional details). The Navy used these studies to generate exposure functions, which are predictions of the onset of TTS or PTS based on sound frequency, level, and type (continuous or impulsive), for each marine mammal functional hearing group (U.S. Department of the Navy, 2025).

TTS can last from minutes or hours to days (*i.e.,* there is recovery back to baseline/pre-exposure hearing threshold), can occur within a specific frequency range (*i.e.,* an animal might only have a temporary loss of hearing sensitivity within a limited frequency band of its auditory range), and can be of varying amounts (*e.g.,* an animal's hearing sensitivity might be reduced by only 6 dB or reduced by 30 dB). While there is no simple functional relationship between TTS and PTS or other AUD INJ (*e.g.,* neural degeneration), as TTS increases, the likelihood that additional exposure to increased SPL or duration will result in PTS or other injury also increases (see appendix D of the 2024 HCTT Draft EIS/OEIS for additional discussion). Exposure thresholds for the occurrence of AUD INJ, which include the potential for PTS, as well as situations when AUD INJ occurs without PTS, can therefore be defined based on a specific amount of TTS; that is, although an exposure has been shown to produce only TTS, we assume that any additional exposure may result in some AUD INJ. The specific upper limit of TTS is based on experimental data showing amounts of TTS that have not resulted in AUD INJ. In other words, we do not need to know the exact functional relationship between TTS and AUD INJ, we only need to know the upper limit for TTS before some AUD INJ is possible. In severe cases of AUD INJ, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

The following physiological mechanisms are thought to play a role in inducing auditory threshold shift: effects to sensory hair cells in the inner ear that reduce their sensitivity; modification of the chemical environment within the sensory cells; residual muscular activity in the middle ear; displacement of certain inner ear membranes; increased blood flow; and post-stimulatory reduction in both efferent and sensory neural output (Southall *et al.,* 2007). The amplitude, duration, frequency, temporal pattern, and energy distribution of sound exposure all can affect the amount of associated threshold shift and the frequency range in which it occurs. Generally, the amount of threshold shift, and the time needed to recover from the effect, increase as amplitude and duration of sound exposure increases. Human non-impulsive noise exposure guidelines are based on the assumption that exposures of equal energy (the same SEL) produce equal amounts of hearing impairment regardless of how the sound energy is distributed in time (NIOSH, 1998). Previous marine mammal TTS studies have also generally supported this equal energy relationship (Southall *et al.,* 2007). SEL is used to predict TTS in marine mammals and is considered a good predictor of TTS for shorter duration exposures than longer duration exposures. The amount of TTS increases with exposure SPL and duration, and is correlated with SEL, but duration of the exposure has a more significant effect on TTS than would be predicted based on SEL alone (*e.g.,* Finneran *et al.,* 2010b; Kastak *et al.,* 2007; Kastak *et al.,* 2005; Kastelein *et al.,* 2014a; Mooney *et al.,* 2009a; Popov *et al.,* 2014; Gransier and Kastelein, 2024). These studies highlight the inherent complexity of predicting TTS onset in marine mammals, as well as the importance of considering exposure duration when assessing potential impacts.

Generally, TTS increases with SEL in a non-linear fashion, where lower SEL exposures will elicit a steady rate of TTS increase while higher SEL exposures will either increase TTS more rapidly or plateau (Finneran, 2015; U.S. Department of the Navy, 2025). Additionally, with sound exposures of equal energy, those that had lower SPL with longer duration were found to induce TTS onset at lower levels than those of higher SPL and shorter duration. Less threshold shift will occur from intermittent sounds than from a continuous exposure with the same energy (some recovery can occur between intermittent exposures) (Kryter *et al.,* 1966; Ward, 1997; Mooney *et al.,* 2009a, 2009b; Finneran *et al.,* 2010; Kastelein *et al.,* 2014; Kastelein *et al.,* 2015). For example, one short, higher SPL sound exposure may induce the same impairment as one longer lower SPL sound, which in turn may cause more impairment than a series of several intermittent softer sounds with the same total energy (Ward, 1997). Additionally, though TTS is temporary, very prolonged or repeated exposure to sound strong enough to elicit TTS, or shorter-term exposure to sound levels well above the TTS threshold, can cause AUD INJ, at least in terrestrial mammals (Kryter, 1985; Lonsbury-Martin *et al.,* 1987).

Although TTS increases non-linearly in marine mammals, recovery from TTS typically occurs in a linear fashion with the logarithm of time (Finneran, 2015; Finneran *et al.,* 2010a; Finneran *et al.,* 2010b; Finneran and Schlundt, 2013; Kastelein *et al.,* 2012a; Kastelein *et al.,* 2012b; Kastelein *et al.,* 2013a; Kastelein *et al.,* 2014a; Kastelein *et al.,* 2014b; Kastelein *et al.,* 2014c; Popov *et al.,* 2014; Popov *et al.,* 2013; Popov *et al.,* 2011; Muslow *et al.,* 2023; Finneran *et al.,* 2023). Considerable variation has been measured in individuals of the same species in both the amount of TTS incurred from similar SELs (Kastelein *et al.,* 2012a; Popov *et al.,* 2013) and the time-to-recovery from TTS (Finneran, 2015; Kastelein *et al.,* 2019e). Many of these studies relied on continuous sound exposures, but intermittent, impulsive sound exposures have also been tested. The sound resulting from an explosive detonation is considered an impulsive sound, but no direct measurements of hearing loss from exposure to explosive sources have been made. Few studies (Finneran *et al.,* 2002; Lucke *et al.,* 2009; Sills *et al.,* 2020; Muslow *et al.,* 2023) using impulsive sounds have produced enough TTS to make predictions about hearing loss due to this source type (see U.S. Department of the Navy, 2025). In general, predictions of TTS based on SEL for this type of sound exposure are likely to overestimate TTS because some recovery from TTS may occur in the quiet periods between impulsive sounds—especially when the duty cycle is low. Peak SPL (unweighted) is also used to predict TTS due to impulsive sounds (Southall *et al.,* 2007; Southall *et al.,* 2019c; U.S. Department of the Navy, 2025).

Specific to land-based missile and target launches (characterized by sudden onset of sound, moderate to high peak sound levels (depending on the type of missile and distance), and short sound duration) although it is possible that some pinnipeds may incur TTS during launches from SNI (TTS is not anticipated during launches from PMRF), hearing impairment has not been measured for pinniped species exposed to launch sounds. Auditory brainstem response (*i.e.,* hearing assessment using measurements of electrical responses of the brain) was used to demonstrate that harbor seals did not exhibit loss in hearing sensitivity following launches of large rockets at Vandenberg Space Force Base (VSFB, formerly Vandenberg Air Force Base) (Thorson *et al.,* 1999; Thorson *et al.,* 1998). However, the hearing tests did not begin until at least 45 minutes after the launch; therefore, harbor seals may have incurred TTS which was undetectable by the time testing began. There was no sign of PTS in any of the harbor seals tested (Thorson *et al.,* 1999; Thorson *et al.,* 1998). Since 2001, no launch events at SNI have exposed pinnipeds to noise levels at or exceeding those where PTS could be incurred. Of note, the range to PTS and

TTS would not reach haulout locations for Hawaiian monk seals on beaches at PMRF (see section 6.3.2 of the application).

Based on measurements of received sound levels during previous launches at SNI (Burke 2017; Holst *et al.,* 2010; Holst *et al.,* 2005a; Holst *et al.,* 2008; Holst *et al.,* 2011; Ugoretz 2016; Ugoretz and Greene Jr. 2012), the Navy expects that there is a very limited potential of TTS for a few of the pinnipeds present, particularly for phocids. Available evidence from launch monitoring at SNI in 2001–2017 suggests that only a limited number of launch events produced sound levels that could elicit TTS for some pinnipeds (Burke 2017; Holst *et al.,* 2008; Holst *et al.,* 2011; Ugoretz 2016; Ugoretz and Greene Jr. 2012). In general, if any TTS were to occur to pinnipeds, it is expected to be mild and reversible. It is possible that some launch sounds as measured close to the launchers may exceed the auditory injury criteria, but it is not expected that any pinnipeds would be close enough to the launchers to be exposed to sounds strong enough to cause auditory injury. Due to the expected sound levels of the activities proposed and the distance of the activity from marine mammal habitat, the effects of sounds from the proposed activities are unlikely to result in auditory injury.

In some cases, intense noise exposures have caused AUD INJ (*e.g.,* loss of cochlear neuron synapses), despite thresholds eventually returning to normal (*i.e.,* it is possible to have AUD INJ without a resulting PTS (*e.g.,* Kujawa and Liberman, 2006, 2009; Fernandez *et al.,* 2015; Ryan *et al.,* 2016; Houser, 2021)). In these situations, however, threshold shifts were 30–50 dB measured 24 hours after the exposure (*i.e.,* there is no evidence that an exposure resulting in less than 40 dB TTS measured a few minutes after exposure can produce AUD INJ). Therefore, an exposure producing 40 dB of TTS, measured a few minutes after exposure, can also be used as an upper limit to prevent AUD INJ (*i.e.,* it is assumed that exposures beyond those capable of causing 40 dB of TTS have the potential to result in INJ (which may or may not result in PTS)).

Irreparable damage to the inner or outer cochlear hair cells may cause PTS; however, other mechanisms are also involved, such as exceeding the elastic limits of certain tissues and membranes in the middle and inner ears and resultant changes in the chemical composition of the inner ear fluids (Southall *et al.,* 2007). When AUD INJ occurs, there is physical damage to the sound receptors in the ear, whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). AUD INJ is permanent (*i.e.,* there is incomplete recovery back to baseline/pre-exposure levels) but also can occur in a specific frequency range and amount as mentioned above for TTS. In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider less than 40 dB of TTS to constitute AUD INJ. The NMFS Acoustic Updated Technical Guidance (NMFS, 2024), which was used in the assessment of effects for this proposed rule, compiled, interpreted, and synthesized the best available scientific information for noise-induced hearing effects for marine mammals to derive updated thresholds for assessing the impacts of noise on marine mammal hearing.

While many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019a) for summaries), published data on the onset of TTS for cetaceans are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise, and for pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals, California sea lions, and bearded seals. These studies examine hearing thresholds measured in marine mammals before and after exposure to intense sounds, which can then be used to determine the amount of threshold shift at various post-exposure times. NMFS has reviewed the available studies, which are summarized below (see also the 2024 HCTT Draft EIS/OEIS which includes additional discussion on TTS studies related to sonar and other transducers).

- The method used to test hearing may affect the resulting amount of measured TTS, with neurophysiological measures producing larger amounts of TTS compared to psychophysical measures (Finneran *et al.,* 2007; Finneran, 2015).
- The amount of TTS varies with the hearing test frequency. As the exposure SPL increases, the frequency at which the maximum TTS occurs also increases (Kastelein *et al.,* 2014b). For high-level exposures, the maximum TTS typically occurs one-half to one octave above the exposure frequency (Finneran *et al.,* 2007; Mooney *et al.,* 2009a; Nachtigall *et al.,* 2004; Popov *et al.,* 2011; Popov *et al.,* 2013; Schlundt *et al.,* 2000). The overall spread of TTS from tonal exposures can therefore extend over a large frequency range (*i.e.,* narrowband exposures can produce broadband (greater than one octave) TTS).
- The amount of TTS increases with exposure SPL and duration and is correlated with SEL, especially if the range of exposure durations is relatively small (Kastak *et al.,* 2007; Kastelein *et al.,* 2014b; Popov *et al.,* 2014). As the exposure duration increases, however, the relationship between TTS and SEL begins to break down. Specifically, duration has a more significant effect on TTS than would be predicted on the basis of SEL alone (Finneran *et al.,* 2010a; Kastak *et al.,* 2005; Mooney *et al.,* 2009a). This means if two exposures have the same SEL but different durations, the exposure with the longer duration (thus lower SPL) will tend to produce more TTS than the exposure with the higher SPL and shorter duration. In most acoustic impact assessments, the scenarios of interest involve shorter duration exposures than the marine mammal experimental data from which impact thresholds are derived; therefore, use of SEL tends to over-estimate the amount of TTS. Despite this, SEL continues to be used in many situations because it is relatively simple, more accurate than SPL alone, and lends itself easily to scenarios involving multiple exposures with different SPL (Finneran, 2015).
- Gradual increases of TTS may not be directly observable with increasing exposure levels, before the onset of PTS (Reichmuth *et al.,* 2019). Similarly, PTS can occur without measurable behavioral modifications (Reichmuth *et al.,* 2019).
- The amount of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). The onset of TTS—defined as the exposure level necessary to produce 6 dB of TTS (*i.e.,* clearly above the typical variation in threshold measurements)—also varies with exposure frequency. At the low frequency end of a species' hearing curve, onset-TTS exposure levels are higher compared to those in the region of best sensitivity.
- TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Finneran *et al.,* 2010a; Kastelein *et al.,* 2014b; Kastelein *et al.,* 2015b; Mooney *et al.,* 2009b). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from

intermittent exposures such as sonars and impulsive sources.

- The amount of observed TTS tends to decrease with increasing time following the exposure; however, the relationship is not monotonic (*i.e.,* increasing exposure does not always increase TTS). The time required for complete recovery of hearing depends on the magnitude of the initial shift; for relatively small shifts recovery may be complete in a few minutes, while large shifts (*e.g.,* approximately 40 dB) may require several days for recovery. Under many circumstances TTS recovers linearly with the logarithm of time (Finneran *et al.,* 2010a, 2010b; Finneran and Schlundt, 2013; Kastelein *et al.,* 2012a; Kastelein *et al.,* 2012b; Kastelein *et al.,* 2013a; Kastelein *et al.,* 2014b; Kastelein *et al.,* 2014c; Popov *et al.,* 2011; Popov *et al.,* 2013; Popov *et al.,* 2014). This means that for each doubling of recovery time, the amount of TTS will decrease by the same amount (*e.g.,* 6 dB recovery per doubling of time).

Nachtigall *et al.* (2018) and Finneran (2018) describe the measurements of hearing sensitivity of multiple odontocete species (*i.e.,* bottlenose dolphin, harbor porpoise, beluga, and false killer whale) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Finneran (2018) recommends further investigation of the mechanisms of hearing sensitivity reduction in order to understand the implications for interpretation of existing TTS data obtained from captive animals, notably for considering TTS due to short duration, unpredictable exposures.

Marine mammal hearing plays a critical role in communication with conspecifics and in interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious similar to those discussed in auditory masking, below. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during a time when communication is critical for successful mother/calf interactions could have more serious impacts if it were in the same frequency band as the necessary vocalizations and of a severity that impeded communication. The fact that animals exposed to high levels of sound that would be expected to result in this physiological response would also be expected to have behavioral responses of a comparatively more severe or sustained nature is potentially more significant than the simple existence of a TTS. However, it is important to note that TTS could occur due to longer exposures to sound at lower levels so that a behavioral response may not be elicited.

Depending on the degree and frequency range, the effects of AUD INJ on an animal could also range in severity, although it is considered generally more serious than TTS because it is a permanent condition (Reichmuth *et al.,* 2019). Of note, reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without some cost to the animal.

As the amount of research on hearing sensitivity has grown, so, too, has the understanding that marine mammals may be able to self-mitigate, or protect, against noise-induced hearing loss. An animal may learn to reduce or suppress their hearing sensitivity when warned of an impending intense sound exposure, or if the duty cycle of the sound source is predictable (Finneran, 2018; Finneran et al., 2024; Nachtigall and Supin, 2013, 2014, 2015; Nachtigall et al., 2016a, 2016b, 2016c, 2018). This has been shown with several species, including the false killer whale (Nachtigall and Supin, 2013), bottlenose dolphin (Finneran, 2018; Nachtigall and Supin, 2014, 2015; Nachtigall *et al.,* 2016c), beluga whale (Nachtigall *et al.,* 2016a), and harbor porpoise (Nachtigall *et al.,* 2016b). Additionally, Finneran *et al.* (2023) and Finneran *et al.* (2024) found that odontocetes that had participated in TTS experiments in the past could have learned from that experience and subsequently protected their hearing during new sound exposure experiments.

Behavioral Responses

Behavioral responses to sound are highly variable and context-specific (Nowacek *et al.,* 2007; Southall *et al.,* 2007; Southall *et al.,* 2019). Many different variables can influence an animal's perception of and response to (nature and magnitude) an acoustic event. An animal's prior experience with a sound or sound source affects whether it is less likely (habituation, self-mitigation) or more likely (sensitization) to respond to certain sounds in the future (animals can also be innately predisposed to respond to certain sounds in certain ways) (Southall *et al.,* 2007; Southall *et al.,* 2016; Finneran, 2018; Finneran *et al.,* 2024; Nachtigall and Supin, 2013, 2014, 2015; Nachtigall *et al.,* 2015; Nachtigall *et al.,* 2016a, 2018; Nachtigall *et al.,* 2016b). Related to the sound itself, the perceived proximity of the sound, bearing of the sound (approaching vs. retreating), the similarity of a sound to biologically relevant sounds in the animal's environment (*i.e.,* calls of predators, prey, or conspecifics), familiarity of the sound, and navigational constraints may affect the way an animal responds to the sound (Ellison *et al.,* 2012; Southall *et al.,* 2007, DeRuiter *et al.,* 2013a, Southall *et al.,* 2021; Wartzok *et al.,* 2003). Individuals (of different age, gender, reproductive status, *etc.*) among most populations will have variable hearing capabilities, and differing behavioral sensitivities to sounds that will be affected by prior conditioning, experience, and current activities of those individuals. Southall *et al.* (2007) and Southall *et al.* (2021) have developed and subsequently refined methods developed to categorize and assess the severity of acute behavioral responses, considering impacts to individuals that may consequently impact populations. Often, specific acoustic features of the sound and contextual variables (*i.e.,* proximity, duration, or recurrence of the sound or the current behavior that the marine mammal is engaged in or its prior experience), as well as entirely separate factors such as the physical presence of a nearby vessel, may be more relevant to the animal's response than the received level alone.

Studies by DeRuiter *et al.* (2013a) indicate that variability of responses to acoustic stimuli depends not only on the species receiving the sound and the sound source, but also on the social, behavioral, or environmental contexts of exposure. Another study by DeRuiter *et al.* (2013b) examined behavioral responses of goose-beaked whales to MF sonar and found that whales responded strongly at low received levels (89–127 dB re 1 µPa) by ceasing normal fluking

and echolocation, swimming rapidly away, and extending both dive duration and subsequent non-foraging intervals when the sound source was 2.1–5.9 mi (3.4–9.5 km) away. Importantly, this study also showed that whales exposed to a similar range of received levels (78–106 dB re: 1 µPa) from distant sonar exercises 73.3 mi (118 km away) did not elicit such responses, suggesting that context may moderate responses.

Ellison *et al.* (2012) outlined an approach to assessing the effects of sound on marine mammals that incorporates contextual-based factors. The authors recommend considering not just the received level of sound, but also the activity the animal is engaged in at the time the sound is received, the nature and novelty of the sound (*i.e.,* whether this a new sound from the animal's perspective), and the distance between the sound source and the animal. They submit that this ''exposure context,'' as described, greatly influences the type of behavioral response exhibited by the animal. Forney *et al.* (2017) also point out that an apparent lack of response (*e.g.,* no displacement or avoidance of a sound source) may not necessarily mean there is no cost to the individual or population, as some resources or habitats may be of such high value that animals may choose to stay, even when experiencing stress or hearing loss. Forney *et al.* (2017) recommend considering both the costs of remaining in an area of noise exposure such as TTS, PTS, or masking, which could lead to an increased risk of predation or other threats or a decreased capability to forage, and the costs of displacement, including potential increased risk of vessel strike, increased risks of predation or competition for resources, or decreased habitat suitable for foraging, resting, or socializing. This sort of contextual information is challenging to predict with accuracy for ongoing activities that occur over large spatial and temporal expanses. However, distance is one contextual factor for which data exist to quantitatively inform a take estimate, and the method for predicting Level B harassment in this proposed rule does consider distance to the source. Other factors are often considered qualitatively in the analysis of the likely consequences of sound exposure, where supporting information is available.

Friedlaender *et al.* (2016) provided the first integration of direct measures of prey distribution and density variables incorporated into across-individual analyses of behavior responses of blue whales to sonar, and demonstrated a five-fold increase in the ability to quantify variability in blue whale diving behavior. These results illustrate that responses evaluated without such measurements for foraging animals may be misleading, which again illustrates the context-dependent nature of the probability of response.

Exposure of marine mammals to sound sources can result in, but is not limited to, no response or any of the following observable responses: increased alertness; orientation or attraction to a sound source; vocal modifications; cessation of feeding; cessation of social interaction; alteration of movement or diving behavior; habitat abandonment (temporary or permanent); and, in severe cases, panic, flight, stampede, or stranding, potentially resulting in death (Southall *et al.,* 2007). A review of marine mammal responses to anthropogenic sound was first conducted by Richardson (1995). More recent reviews (Nowacek *et al.,* 2007; DeRuiter *et al.,* 2013a and 2013b; Ellison *et al.,* 2012; Gomez *et al.,* 2016) address studies conducted since 1995 and focused on observations where the received sound level of the exposed marine mammal(s) was known or could be estimated. Gomez *et al.* (2016) conducted a review of the literature considering the contextual information of exposure in addition to received level and found that higher received levels were not always associated with more severe behavioral responses and vice versa. Southall *et al.* (2016) states that results demonstrate that some individuals of different species display clear yet varied responses, some of which have negative implications, while others appear to tolerate high levels, and that responses may not be fully predictable with simple acoustic exposure metrics (*e.g.,* received sound level). Rather, the authors state that differences among species and individuals along with contextual aspects of exposure (*e.g.,* behavioral state) appear to affect response probability (Southall *et al.,* 2019). The following parts provide examples of behavioral responses to stressors that provide an idea of the variability in responses that would be expected given the differential sensitivities of marine mammal species to sound and the wide range of potential acoustic sources to which a marine mammal may be exposed. Behavioral responses that could occur for a given sound exposure should be determined from the literature that is available for each species (see section D.4.5 (Behavioral Reactions) of the 2024 HCTT Draft EIS/OEIS for a comprehensive list of behavioral studies and species-specific findings) or extrapolated from closely related species when no information exists, along with contextual factors.

Responses Due to Sonar and Other Transducers—

Mysticetes responses to sonar and other duty-cycled tonal sounds are dependent upon the characteristics of the signal, behavioral state of the animal, sensitivity and previous experience of an individual, and other contextual factors including distance of the source, movement of the source, physical presence of vessels, time of year, and geographic location (Goldbogen *et al.,* 2013; Harris *et al.,* 2019a; Harris *et al.,* 2015; Martin *et al.,* 2015; Sivle *et al.,* 2015b). For example, a behavioral response study (BRS) in Southern California demonstrated that individual behavioral state was critically important in determining response of blue whales to Navy sonar. In this BRS, some blue whales engaged in deep (greater than 164 ft (50 m)) feeding behavior had greater dive responses than those in shallow feeding or non-feeding conditions, while some blue whales that were engaged in shallow feeding behavior demonstrated no clear changes in diving or movement even when received levels were high (approximately 160 dB re 1 µPa) from exposures to 3–4 kHz sonar signals, while others showed a clear response at exposures at lower received level of sonar and pseudorandom noise (Goldbogen *et al.,* 2013). Generally, behavioral responses were brief and of low to moderate severity, and the whales returned to baseline behavior shortly after the end of the acoustic exposure (DeRuiter *et al.,* 2017; Goldbogen *et al.,* 2013; Southall *et al.,* 2019c). To better understand the context of these behavioral responses, Friedlaender *et al.* (2016) mapped the prey field of the deep-diving blue whales and found that the response to sound was more apparent for individuals engaged in feeding than those that were not. The probability of a moderate behavioral response increased when the source was closer for these foraging blue whales, although there was a high degree of uncertainty in that relationship (Southall *et al.,* 2019b). In the same BRS, none of the tagged fin whales demonstrated more than a brief or minor response regardless of their behavioral state (Harris *et al.,* 2019a). The fin whales were exposed to both mid-frequency simulated sonar and pseudorandom noise of similar frequency, duration, and source level. They were less sensitive to disturbance than blue whales, with no significant differences

in response between behavioral states or signal types. The authors rated responses as low-to-moderate severity with no negative impact to foraging success (Southall *et al.,* 2023).

Similarly, while the rates of foraging lunges decrease in humpback whales due to sonar exposure, there was variability in the response across individuals, with one animal ceasing to forage completely and another animal starting to forage during the exposure (Sivle *et al.,* 2016). In addition, almost half of the animals that exhibited avoidance behavior were foraging before the exposure, but the others were not; the animals that exhibited avoidance behavior while not feeding responded at a slightly lower received level and greater distance than those that were feeding (Wensveen *et al.,* 2017). These findings indicate that the behavioral state of the animal plays a role in the type and severity of a behavioral response. Henderson *et al.* (2019) examined tagged humpback whale dive and movement behavior, including individuals incidentally exposed to Navy sonar during training activities, at the PMRF off Kauaʻi, Hawaii. Tracking data showed that, regardless of exposure to sonar, individual humpbacks spent limited time, no more than a few days, in the vicinity of Kauaʻi. Potential behavioral responses due to sonar exposure were limited and may have been influenced by breeding and social behaviors. Martin *et al.* (2015) found that the density of calling minke whales was reduced during periods of Navy training involving sonar relative to the periods before training began and increased again in the days following the completion of training activities. The responses of individual whales could not be assessed, so in this case it is unknown whether the decrease in calling animals indicated that the animals left the range or simply ceased calling. Harris *et al.* (2019b) utilized acoustically generated minke whale tracks to statistically demonstrate changes in the spatial distribution of minke whale acoustic presence before, during, and after surface ship MFAS training. The spatial distribution of probability of acoustic presence was different in the ''during'' phase compared to the ''before'' phase, and the probability of presence at the center of ship activity during MFAS training was close to zero for both years. The ''after'' phases for both years retained lower probabilities of presence suggesting the return to baseline conditions may take more than five days. The results show a clear spatial redistribution of calling minke whales during surface ship MFAS training, however a limitation of passive acoustic monitoring is that one cannot conclude if the whales moved away, went silent, or a combination of the two.

Building on this work, Durbach *et al.* (2021) used the same data and determined that individual minke whales tended to be in either a fast or slow movement behavior state while on the missile range, where whales tended to be in the slow state in baseline or before periods but transitioned into the fast state with more directed movement during sonar exposures. They also moved away from the area of sonar activity on the range, either to the north or east depending on where the activity was located; this explains the spatial redistribution found by Harris *et al.* (2019b). Minke whales were also more likely to stop calling when in the fast state, regardless of sonar activity, or when in the slow state during sonar activity (Durbach *et al.,* 2021). Similarly, minke whale detections were reduced or ceased altogether during periods of sonar use off Jacksonville, Florida, (Norris *et al.,* 2012; Simeone *et al.,* 2015; U.S. Department of the Navy, 2013), especially with an increased ping rate (Charif *et al.,* 2015).

Odontocetes have varied, context-dependent behavioral responses to sonar and other transducers. Much of the research on odontocetes has been focused on understanding the impacts of sonar and other transducers on beaked whales because they were hypothesized to be more susceptible to behavioral disturbance after several strandings of beaked whales in which military MFAS was identified as a contributing factor (see *Stranding and Mortality* section). Subsequent BRSs have shown that beaked whales are likely more sensitive to disturbance than most other cetaceans. Many species of odontocetes have been studied during BRSs, including Blainville's beaked whale, goose-beaked whale, Baird's beaked whale, northern bottlenose whale, harbor porpoise, pilot whale, killer whale, sperm whale, false killer whale, melon-headed whale, bottlenose dolphin, rough-toothed dolphin, Risso's dolphin, Pacific white-sided dolphin, and Commerson's dolphin. Observed responses by Blainville's beaked whales, goose-beaked whales, Baird's beaked whales, and northern bottlenose whales (the largest of the beaked whales), to mid-frequency sonar sounds include cessation of clicking, decline in group vocal periods, termination of foraging dives, changes in direction to avoid the sound source, slower ascent rates to the surface, longer deep and shallow dive durations, and other unusual dive behaviors (DeRuiter *et al.,* 2013b; Hewitt *et al.,* 2022; Jacobson *et al.,* 2022; McCarthy *et al.,* 2011; Miller *et al.,* 2015; Moretti *et al.,* 2014; Southall *et al.,* 2011; Stimpert *et al.,* 2014; Tyack *et al.,* 2011).

During a BRS in Southern California, a tagged Baird's beaked whale exposed to simulated MFA sonar within 3 km increased swim speed and modified its dive behavior (Stimpert *et al.,* 2014). One goose-beaked whale was also incidentally exposed to real Navy sonar located over 62.1 mi (100 km) away in addition to the source used in the controlled exposure study, and the authors did not detect similar responses at comparable received levels. Received levels from the MFA sonar signals from the controlled (2.1 to 5.9 mi (3.4 to 9.5 km)) exposures were calculated as 84–144 dB re 1 μPa, and incidental (73.3 mi (118 km)) exposures were calculated as 78–106 dB re 1 μPa, indicating that context of the exposures (*e.g.,* source proximity, controlled source ramp-up) may have been a significant factor in the responses to the simulated sonars (DeRuiter *et al.,* 2013b).

Long-term tagging work during the same BRS demonstrated that the longer duration dives considered a behavioral response by DeRuiter *et al.* (2013b) fell within the normal range of dive durations found for eight tagged goose-beaked whales on the Southern California Offshore Range (Schorr *et al.,* 2014). However, the longer inter-deep dive intervals found by DeRuiter *et al.* (2013b), which were among the longest found by Schorr *et al.* (2014) and Falcone *et al.* (2017), may indicate a response to sonar. Williams *et al.* (2017) note that during normal deep dives or during fast swim speeds, beaked whales and other marine mammals use strategies to reduce their stroke rates (*e.g.,* leaping, wave surfing when swimming, interspersing glides between bouts of stroking when diving). The authors determined that in the post-exposure dives by the tagged goose-beaked whales described in DeRuiter *et al.* (2013b), the whales ceased gliding and swam with almost continuous strokes. This change in swim behavior was calculated to increase metabolic costs by about 30.5 percent and increase the amount of energy expending on fast swim speeds from 27–59 percent of their overall energy budget. This repartitioning of energy was detected in the model up to 1.7 hours after the single sonar exposure. Therefore, while the overall post-exposure dive durations were similar, the metabolic energy calculated by Williams *et al.* (2017) was higher. However, Southall *et al.* (2019a) found that prey availability was higher

in the western area of the Southern California Offshore Range where goose-beaked whales preferentially occurred, while prey resources were lower in the eastern area and moderate in the area just north of the Range. This high prey availability may indicate that goose-beaked whales need fewer foraging dives to meet energy requirements than would be needed in another area with fewer resources.

During a BRS in Norway, northern bottlenose whales avoided a sonar sound source over a wide range of distances (0.5 to 17.4 mi (0.8 to 28 km)) and estimated avoidance thresholds ranging from received SPLs of 117 to 126 dB re 1 µPa. The behavioral response characteristics and avoidance thresholds were comparable to those previously observed in beaked whale studies; however, researchers did not observe an effect of distance on behavioral response and found that onset and intensity of behavioral response were better predicted by received SPL. There was one instance where an individual northern bottlenose whale approached the vessel, circled the sound source (source level was only 122 dB re 1 µPa), and resumed foraging after the exposure. Conversely, one northern bottlenose whale exposed to a sonar source was documented performing the longest and deepest dive on record for the species, and continued swimming away from the source for more than 7 hours (Miller *et al.,* 2015; Siegal *et al.,* 2022; Wensveen *et al.,* 2019).

Research on Blainville's beaked whales at the Atlantic Undersea Test and Evaluation Center (AUTEC) range has shown that individuals move off-range during sonar use, only returning after the cessation of sonar transmission (Boyd *et al.,* 2009; Henderson *et al.,* 2015; Jones-Todd *et al.,* 2021; Manzano-Roth *et al.,* 2022; Manzano-Roth *et al.,* 2016; McCarthy *et al.,* 2011; Tyack *et al.,* 2011). Five Blainville's beaked whales estimated to be within 1.2 to 18 mi (2 to 29 km) of the AUTEC range at the onset of active sonar were displaced a maximum of 17.4 to 42.3 mi (28 to 68 km) after moving away from the range, although one individual did approach the range during active sonar use. Researchers found a decline in deep dives at the onset of the training and an increase in time spent on foraging dives as whales moved away from the range. Predicted received levels at which presumed responses were observed were comparable to those previously observed in beaked whale studies. Acoustic data indicated that vocal periods were detected on the range within 72 hours after training ended (Joyce *et al.,* 2019). However, Blainville's beaked whales have been documented to remain on-range to forage throughout the year (Henderson *et al.,* 2016), indicating the AUTEC range may be a preferred foraging habitat regardless of the effects of active sonar noise, or it could be that there are no long-term consequences of the sonar activity. In the SOCAL Range Complex, researchers conducting photo-identification studies have identified approximately 100 individual goose-beaked whales, with 40 percent having been seen in one or more prior years, with re-sightings up to 7 years apart, indicating a possible on-range resident population (Falcone and Schorr, 2014; Falcone *et al.,* 2009).

The probability of Blainville's beaked whale group vocal periods on the PMRF were modeled during periods of (1) no naval activity, (2) naval activity without hull-mounted MFA sonar, and (3) naval activity with hull-mounted MFA sonar (Jacobson *et al.,* 2022). At a received level of 150 dB re 1 µPa RMS, the probability of detecting a group vocal period during MFA sonar use decreased by 77 percent compared to periods when general training activity was ongoing, and by 87 percent compared to baseline (no naval activity) conditions. Jacobsen et al (2022) found a greater reduction in probability of a group vocal period with MFA sonar than observed in a prior study of the same species at the AUTEC range (Moretti *et al.,* 2014), which may be due to the baseline period in the AUTEC study including naval activity without MFA sonar, potentially lowering the baseline group vocal period activity in that study, or due to differences in the residency of the populations at each range.

Stanistreet *et al.* (2022) used passive acoustic recordings during a multinational navy activity to assess marine mammal acoustic presence and behavioral response to especially long bouts of sonar lasting up to 13 consecutive hours, occurring repeatedly over 8 days (median and maximum SPL = 120 dB and 164 dB). Goose-beaked whales and sperm whales substantially reduced how often they produced clicks during sonar, indicating a decrease or cessation in foraging behavior. Few previous studies have shown sustained changes in foraging or displacement of sperm whales, but there was an absence of sperm whale clicks for 6 consecutive days of sonar activity. Sperm whales returned to baseline levels of clicks within days after the activity, but beaked whale detection rates remained low even 7 days after the exercise. In addition, there were no detections from a Mesoplodon beaked whale species within the area during, and at least 7 days after, the sonar activity. Clicks from northern bottlenose whales and Sowerby's beaked whales were also detected but were not frequent enough at the recording site used to compare clicks between baseline and sonar conditions.

Goose-beaked whale behavioral responses (*i.e.,* deep and shallow dive durations, surface interval durations, inter-deep dive intervals) on the Southern California Anti-Submarine Warfare Range were modeled against predictor values that included helicopter dipping sonar, mid-power MFA sonar and hull-mounted, high-power MFA sonar along with other non-MFA sonar predictors (Falcone *et al.,* 2017). Falcone *et al.* (2017) found both shallow and deep dive durations increased as the proximity to both mid- and high-powered sources decreased and found that surface intervals and inter-deep dive intervals increased in the presence of both types of sonars (helicopter dipping and hull-mounted), although surface intervals shortened during periods without MFA sonar. Proximity of source and receiver were important considerations, as the responses to the mid-power MFA sonar at closer ranges were comparable to the responses to the higher source level vessel sonar, as was the context of the exposure. Helicopter dipping sonars are shorter duration and randomly located, therefore more difficult to predict or track by beaked whales and potentially more likely to elicit a response, especially at closer distances (3.7 to 15.5 mi (6 to 25 km)) (Falcone *et al.,* 2017).

Sea floor depths and quantity of light (*i.e.,* lunar cycle) are also important variables to consider in BRSs, as goose-beaked whale foraging dive depth increased with sea floor depth (maximum 6,561.7 ft (2,000 m)) and the amount of time spent at foraging depths (and likely foraging) was greater at night (likely avoiding predation by staying deeper during periods of bright lunar illumination), although they spent more time near the surface during the night, as well, particularly on dark nights with little moonlight, (Barlow *et al.,* 2020). Sonar occurred during 10 percent of the dives studied and had little effect on the resulting dive metrics. Watwood *et al.* (2017) found that the longer the duration of a sonar event, the greater reduction in detected goose-beaked whale group dives and, as helicopter dipping events occurred more frequently but with shorter durations than periods of hull-mounted sonar, when looking at the number of detected group dives there was a greater reduction during periods of hull-mounted sonar than during helicopter

dipping sonar. DiMarzio *et al.* (2019) also found that group vocal periods (*i.e.,* clusters of foraging pulses), on average, decreased during sonar events on the Southern California Anti-Submarine Warfare Range, though the decline from before the event to during the event was significantly less for helicopter dipping events than hull-mounted events, and there was no difference in the magnitude of the decline between vessel-only events and events with both vessels and helicopters. Manzano-Roth *et al.* (2022) analyzed long-term passive acoustic monitoring data from the PMRF in Kaua'i, Hawaii, and found beaked whales reduced group vocal periods during submarine command course events and remained low for a minimum of 3 days after the MFA sonar activity.

Harbor porpoise behavioral responses have been researched extensively using acoustic deterrent and acoustic harassment devices; however, BRSs using sonar are limited. Kastelein *et al.* (2018b) found harbor porpoises did not respond to low-duty cycle mid-frequency sonar tones (3.5–4.1 kHz at 2.7 percent duty cycle; *e.g.,* one tone per minute) at any received level, but one individual did respond (*i.e.,* increased jumping, increased respiration rates) to high-duty cycle sonar tones (3.5–4.1 kHz at 96 percent duty cycle; *e.g.,* continuous tone for almost a minute).

Behavioral responses by odontocetes (other than beaked whales and harbor porpoises) to sonar and other transducers include horizontal avoidance, reduced breathing rates, changes in behavioral state, changes in dive behavior (Antunes *et al.,* 2014; Isojunno *et al.,* 2018; Isojunno *et al.,* 2017; Isojunno *et al.,* 2020; Miller, 2012; Miller *et al.,* 2011; Miller *et al.,* 2014; Southall *et al.,* 2024), and, in one study, separation of a killer whale calf from its group (Miller *et al.,* 2011). Some species of dolphin (*e.g.,* bottlenose, spotted, spinner, Clymene, Pacific white-sided, rough-toothed) are frequently documented bowriding with vessels and the drive to engage in bowriding, whether for pleasure or energetic savings (Fiori *et al.,* 2024) may supersede the impact of associated sonar noise (Würsig *et al.,* 1998).

In controlled exposure experiments on captive odontocetes, Houser *et al.* (2013a) recorded behavioral responses from bottlenose dolphins with 3 kHz sonar-like tones between 115–185 dB re 1 μPa, and individuals across 10 trials demonstrated a 50 percent probability of response at 172 dB re 1 μPa. Multiple studies have been conducted on bottlenose dolphins and beluga whales to measure TTS (Finneran *et al.,* 2003a; Finneran *et al.,* 2001; Finneran *et al.,* 2005; Finneran and Schlundt, 2004; Schlundt *et al.,* 2000). During these studies, when individuals were presented with 1-second tones up to 203 dB re 1 μPa, responses included changes in respiration rate, fluke slaps, and a refusal to participate or return to the location of the sound stimulus, including what appeared to be deliberate attempts by animals to avoid a sound exposure or to avoid the location of the exposure site during subsequent tests (Finneran *et al.,* 2002; Schlundt *et al.,* 2000). Bottlenose dolphins exposed to more intense 1-second tones exhibited short-term changes in behavior above received levels of 178–193 dB re 1 μPa, and beluga whales did so at received levels of 180–196 dB re 1 μPa and above.

While several opportunistic observations of odontocete (other than beaked whales and harbor porpoises) responses have been recorded during previous Navy activities and BRSs that employed sonar and sonar-like sources, it is difficult to definitively attribute responses of non-focal species to sonar exposure. Responses range from no response to potential highlight-impactful responses, such as the separation of a killer whale calf from its group (Miller *et al.,* 2011). This may be due, in part, to the variety of species and sensitivities of the odontocete taxonomic group, as well as the breadth of study types conducted and field observations, leading to the assessment of both contextually driven and dose-based responses. The available data indicate exposures to sonar in close proximity and with multiple vessels approaching an animal likely lead to higher-level responses by most odontocete species, regardless of received level or behavioral state. However, when sources are further away and moving in variable directions, behavioral responses are likely driven by behavioral state, individual experience, or species-level sensitivities, as well as exposure duration and received level, with the likelihood of response increasing with increased received levels. As such, it is expected odontocete behavioral responses to sonar and other transducers will vary by species, populations, and individuals, and long-term consequences or population-level effects are likely dependent upon the frequency and duration of the exposure and resulting behavioral response.

Pinniped behavioral response to sonar and other transducers is context-dependent (*e.g.,* Hastie *et al.,* 2014; Southall *et al.,* 2019). All studies on pinniped response to sonar thus far have been limited to captive animals, though, based on exposures of wild pinnipeds to vessel noise and impulsive sounds (see Responses Due to Vessel Noise section and Responses Due to Impulsive Noise section below), pinnipeds may only respond strongly to military sonar that is in close proximity or approaching an animal. Kvadsheim *et al.* (2010b) found that captive hooded seals exhibited avoidance response to sonar signals between 1–7 kHz (160 to 170 dB re 1 μPa RMS) by reducing diving activity, rapid surface swimming away from the source, and eventually moving to areas of least SPL. However, the authors noted a rapid adaptation in behavior (passive surface floating) during the second and subsequent exposures, indicating a level of habituation within a short amount of time. Kastelein *et al.* (2015c) exposed captive harbor seals to three different sonar signals at 25 kHz with variable waveform characteristics and duty cycles and found individuals responded to a frequency modulated signal at received levels over 137 dB re 1 μPa by hauling out more, swimming faster, and raising their heads or jumping out of the water. However, seals did not respond to a continuous wave or combination signals at any received level (up to 156 dB re 1 μPa). Houser *et al.* (2013a) conducted a study to determine behavioral responses of captive California sea lions to MFA sonar at various received levels (125 to 185 dB re 1 μPa). They found younger animals (less than 2 years old) were more likely to respond than older animals and responses included increased respiration rate, increased time spent submerged, refusal to participate in a repetitive task, and hauling out. Most responses below 155 dB re 1 μPa were changes in respiration, while more severe responses (*i.e.,* refusing to participate, hauling out) began to occur over 170 dB re 1 μPa, and many of the most severe responses came from the young sea lions.

Responses Due to Impulsive Noise—

Impulsive signals have a rapid rise time and higher instantaneous peak pressure than other signal types, particularly at close range, which means they are more likely to cause startle or avoidance responses. At long distances, however, the rise time increases as the signal duration lengthens (similar to a ''ringing'' sound), making the impulsive signal more similar to a non-impulsive signal (Hastie *et al.,* 2019; Martin *et al.,* 2020). Behavioral responses from explosive sounds are likely to be similar to responses studied for other impulsive noise, such as those produced by air

guns and impact pile driving. Data on behavioral responses to impulsive sound sources are limited across all marine mammal groups, with only a few studies available for mysticetes and odontocetes.

Mysticetes have varied responses to impulsive sound sources, including avoidance, aggressive directed movement towards the source, reduced surface intervals, altered swimming behavior, and changes in vocalization rates (Gordon *et al.,* 2003; McCauley *et al.,* 2000a; Richardson *et al.,* 1985; Southall *et al.,* 2007). Studies have been conducted on many baleen whale species, including gray, humpback, blue, fin, and bowhead whales; it is assumed that these responses are representative of all baleen whale species. The behavioral state of the whale seems to be an integral part of whether the animal responds and how they respond, as does the location and movement of the sound source, more than the received level of the sound.

If an individual is engaged in migratory behavior, it may be more likely to respond to impulsive noise, and some species may be more sensitive than others. Migrating gray whales showed avoidance responses to seismic vessels at received levels between 164 and 190 dB re 1 µPa (Malme *et al.,* 1986, Malme *et al.,* 1988). In one study, McCauley *et al.* (1998) found that migrating humpback whales in Australia showed avoidance behavior at ranges of 3.1–5 mi (5–8 km) from a seismic array during observational studies and controlled exposure experiments, and another study found humpback whales in Australia decreased their dive times and reduced their swimming speeds (Dunlop *et al.,* 2015). However, when comparing received levels and behavioral responses between air gun ramp-up versus constant noise level of air guns, humpback whales did not change their dive behavior but did deviate from their predicted heading and decreased their swim speeds, deviating more during the constant noise source trials but reducing swim speeds more during ramp-up trials (Dunlop *et al.,* 2016). In both cases, there was no dose-response relationship with the received level of the air gun noise, and similar responses were observed in control trials without air guns (vessel movement remained constant across trials), so some responses may have been due to vessel presence and not received level from the air guns. Social interactions between males and mother-calf pairs were reduced in the presence of vessels towing seismic air gun arrays, regardless of whether the air guns were active or not; which indicates that it was likely the presence of vessels (rather than the impulsive noise generated from active air guns) that affected humpback whale behavior (Dunlop *et al.,* 2020).

Proximity of the impulsive source is another important factor to consider when assessing the potential for behavioral responses in marine mammals. Dunlop *et al.* (2017) found that groups of humpback whales were more likely to avoid a smaller air gun array at closer proximity than a larger air gun array, despite the same received level, showing the difference in response between arrays has more to do with the combined effects of received level and source proximity. In this study, responses were varied and generally small, with short-term course deviations of about 1,640 ft (500 m). Studies on bowhead whales have shown they may be more sensitive than other species to impulsive noise, as individuals have shown clear changes in diving and breathing patterns up to 45.4 mi (73 km) from seismic vessels with received levels as low as 125 dB re 1 µPa (Malme *et al.* 1988). Richardson *et al.* (1995b) documented bowhead whales exhibiting avoidance behaviors at a distance of more than 12.4 mi (20 km) from seismic vessels when received levels were as low as 120 dB re 1 µPa, although most did not show active avoidance until 5 mi (8 km) from the source. Although bowhead whales may avoid the area around seismic surveys, from 3.7 to 5 mi (6 to 8 km) (Koski and Johnson 1987, as cited in Gordon *et al.,* 2003) out to 12.4 or 18.6 mi (20 or 30 km) (Richardson *et al.,* 1999), a study by Robertson *et al.* (2013) supports the idea that behavioral responses are contextually dependent, and that during seismic operations, bowhead whales may be less ''available'' for counting due to alterations in dive behavior but that they may not have completely vacated the area.

In contrast, noise from seismic surveys was not found to impact feeding behavior or exhalation rates in western gray whales while resting or diving off the coast of Russia (Gailey *et al.,* 2007; Yazvenko *et al.,* 2007); however, the increase in vessel traffic associated with surveys and the proximity of the vessels to the whales did affect the orientation of the whales relative to the vessels and shortened their dive-surface intervals (Gailey *et al.,* 2016). They also increased their speed and distance from the noise source and have been documented in one case study swimming towards shore to avoid an approaching seismic vessel (Gailey *et al.,* 2022). Todd *et al.* (1996) found no clear short-term behavioral responses by foraging humpbacks to explosions associated with construction operations in Newfoundland but did see a trend of increased rates of net entanglement closer to the noise source, possibly indicating a reduction in net detection associated with the noise through masking or TTS. Distributions of fin and minke whales were modeled with multiple environmental variables and with the occurrence or absence of seismic surveys, and no evidence of a decrease in sighting rates relative to seismic activity was found for either species (Vilela *et al.,* 2016). Their distributions were driven entirely by environmental variables, particularly those linked to prey, including warmer sea surface temperatures, higher chlorophyll-a values, and higher photosynthetically available radiation (a measure of primary productivity). Sighting rates based on over 8,000 hours of baleen and toothed whale survey data were compared on regular vessel surveys versus both active and passive periods of seismic surveys (Kavanagh *et al.,* 2019). Models of sighting numbers were developed, and it was determined that baleen whale sightings were reduced by 88 percent during active and 87 percent during inactive phases of seismic surveys compared to regular surveys. These results seemed to occur regardless of geographic location of the survey; however, when only comparing active versus inactive periods of seismic surveys the geographic location did seem to affect the change in sighting rates.

Mysticetes seem to be the most behaviorally sensitive taxonomic group of marine mammals to impulsive sound sources, with possible avoidance responses occurring out to 18.6 mi (30 km) and vocal changes occurring in response to sounds over 62.1 mi (100 km) away. However, they are also the most studied taxonomic group, yielding a larger sample size and greater chance of finding behavioral responses to impulsive noise. Also, their responses appear to be behavior-dependent, with most avoidance responses occurring during migration behavior and little observed response during feeding behavior. These response patterns are likely to hold true for impulsive sources used by the Action Proponents; however, their impulsive sources would largely be stationary (*e.g.,* explosives fired at a fixed target, small air guns), and short term (hours rather than days or weeks) versus in the aforementioned studies, so responses would likely occur in closer proximity to animals or not at all.

Odontocete responses to impulsive noise are not well studied and the majority of data have come from seismic

(*i.e.,* air gun) surveys, pile driving, and construction activities, while only a few studies have been done to understand how explosive sounds impact odontocetes. What data are available show they may be less sensitive than mysticetes to impulsive sound and that responses occur at closer distances. This may be due to the predominance of low-frequency sound associated with impulsive sources that propagates across long distances and overlaps with the range of best hearing for mysticetes but is below that range for odontocetes. Even harbor porpoises—shown to be highly sensitive to most sound sources, avoiding both stationary (*e.g.,* pile driving) and moving (*e.g.,* seismic survey vessels) impulsive sound sources out to approximately 12.4 mi (20 km) (*e.g.,* Haelters *et al.,* 2014; Pirotta *et al.,* 2014)—have short-term responses, returning to an area within hours upon cessation of the impulsive noise.

Although odontocetes are generally considered less sensitive, impulsive noise does impact toothed whales in a variety of ways. In one study, dolphin detections were compared during 30 second periods before, during, and after underwater detonations near naval mine neutralization exercises in Virginia Capes Operating Area. Lammers *et al.* (2017) found that within 30 seconds after an explosion, the immediate response was an increase in whistles compared to the 30 seconds before an explosion, and that there was a reduction in dolphin acoustic activity during the day of and day after the exercise within 3.7 mi (6 km). This held true only during daytime, as nighttime activity did not appear different than before the exercise, and two days after the explosion there seemed to be an increase in daytime acoustic activity, indicating dolphins may have returned to the area or resumed vocalizations (Lammers *et al.,* 2017). Weaver (2015) documented potential sex-based differences in behavioral responses to impulsive noise during construction (including blasting) of a bridge over a waterway commonly used by bottlenose dolphins, where females decreased area use and males continued using the area, perhaps indicating differential habitat uses.

When exposed to multiple impulses from a seismic air gun, Finneran *et al.* (2015) noted some captive dolphins turned their heads away from the source just before the impulse, indicating they could anticipate the timing of the impulses and may be able to behaviorally mediate the exposure to reduce their received level. Kavanagh *et al.* (2019) found sightings of odontocete whales decreased by 53 percent during active phases of seismic air gun surveys and 29 percent during inactive phases compared to control surveys. Heide-Jorgensen *et al.* (2021) found that narwhals exposed to air gun noise in an Arctic fjord were sensitive to seismic vessels over 6.8 mi (11 km) away, even though the small air gun source reached ambient noise levels around 1.9 mi (3 km) (source level of 231 dB re 1 µPa at 1 m) and large air gun source reached ambient noise levels around 6.2 mi (10 km) (source level 241 dB re 1 µPa at 1 m). Behavioral responses included changes in swimming speed and swimming direction away from the impulsive sound source and towards the shoreline. Changes in narwhal swimming speed was context-dependent and usually increased in the presence of vessels but decreased (a ''freeze'' response) in response to closely approaching air gun pulses (Heide-Jorgensen *et al.,* 2021). A cessation of feeding was also documented, when the impulsive noise was less than 6.2 mi (10 km) away, although received SELs were less than 130 dB re 1 μPa^2s for either air gun at this distance. However, because of this study's research methods and criteria, the long-distance responses of narwhals may be conservatively estimating narwhals' range to behavioral response.

Similarly, harbor porpoises seem to have an avoidance response to seismic surveys by leaving the area and decreasing foraging activity within 3.1–6.2 mi (5–10 km) of the survey, as evidenced by both a decrease in vocalizations near the survey and an increase in vocalizations at a distance (Pirotta *et al.,* 2014; Thompson *et al.,* 2013a). The response was short-term, as the porpoises returned to the area within 1 day upon cessation of the air gun operation. Sarnocińska *et al.* (2020) placed autonomous recording devices near oil and gas platforms and control sites to measure harbor porpoise acoustic activity during seismic air gun surveys. They noted a dose-response effect, with the lowest amount of porpoise activity closest to the seismic vessel ($SEL_{single\ shot}$ = 155 dB re 1 μPa^2s) and increasing porpoise activity out to 5 to 7.5 mi (8 to 12 km), and that distance to the seismic vessel, rather than sound level, was a better model predictor of porpoise activity. Overall porpoise activity in the seismic survey area was similar to the control sites (approximately 9.3 mi (15 km) apart), which may indicate the harbor porpoises were moving around the area to avoid the seismic vessel without leaving the area entirely.

Pile driving, another activity that produces impulsive sound, elicited a similar response in harbor porpoises. Benhemma-Le Gall *et al.,* 2021 examined changes in porpoise presence and foraging at two offshore windfarms between control (102–104 dB) and construction periods (155–161 dB), and found decreased presence (8–17 percent) and decreased foraging activity (41–62 percent) during construction periods. Porpoises were displaced up to 7.5 mi (12 km) away from pile driving and 2.5 mi (4 km) from construction vessels. Multiple studies have documented strong avoidance responses by harbor porpoises out to 12.4 mi (20 km) during pile driving activity, however, animals returned to the area after the activity stopped (Brandt *et al.,* 2011; Dähne *et al.,* 2014; Haelters *et al.,* 2014; Thompson *et al.,* 2010; Tougaard *et al.,* 2005; Tougaard *et al.,* 2009). When bubble curtains were deployed around pile driving, the avoidance distance appeared to be reduced by half to 7.5 mi (12 km), and the animals returned to the area after approximately 5 hours rather than 1 day later (Dähne *et al.,* 2017). Further, Bergström *et al.* (2014) found that although there was a high likelihood of acoustic disturbance during wind farm construction (including pile driving), the impact was short-term, and Graham *et al.* (2019) found that the distance at which behavioral responses of harbor porpoises were likely decreased over the course of a construction project, suggesting habituation to impulsive pile-driving noise. Kastelein *et al.* (2013b) exposed captive harbor porpoises to impact pile driving noise, and found that respiration rates increased above 136 dB re 1 µPa (zero-to-peak), and at higher sound levels individuals jumped more frequently. When a single harbor porpoise was exposed to playbacks of impact pile driving noise with different bandwidths, Kastelein *et al.* (2022) found the animal's behavioral response (*i.e.,* swim speed, respiration rate, jumping) decreased with bandwidth.

Overall, odontocete behavioral responses to impulsive sound sources are likely species- and context-dependent. Responses might be expected close to a noise source, under specific behavioral conditions such as females with offspring, or for sensitive species such as harbor porpoises, while many other species demonstrate little to no behavioral response.

Pinnipeds seem to be the least sensitive marine mammal group to impulsive noise (Richardson *et al.,* 1995b; Southall *et al.,* 2007), and some may even experience hearing effects before exhibiting a behavioral response (Southall *et al.,* 2007). Some species

may be more sensitive and are only likely to respond (*e.g.,* startling, entering the water, ceasing foraging) to loud impulsive noises in close proximity, but only for brief periods of time before returning to their previous behavior. Demarchi *et al.* (2012) exposed Steller sea lions to in-air explosive blasts, which resulted in increased activity levels and often caused re-entry into the water from a hauled out state. These responses were brief (lasting only minutes) and the animals returned to haul outs and there were no documented lasting behavioral impacts in the days following the explosions.

Ringed seals exhibited little or no response to pile driving noise with mean underwater levels of 157 dB re 1 µPa and in-air levels of 112 dB re 20 µPa (Blackwell *et al.,* 2004) while harbor seals vacated the area surrounding an active pile driving site at estimated received levels between 166–178 dB re 1 µPa SPL (peak to peak), returning within 2 hours of the completion of piling activities (Russell *et al.,* 2016). Wild-captured gray seals exposed to a startling treatment (sound with a rapid rise time and a 93 dB sensation level (the level above the animal's hearing threshold at that frequency)) avoided a known food source, whereas animals exposed to a non-startling treatment (sound with a slower rise time but peaking at the same level) did not react or habituated during the exposure period (Götz and Janik, 2011). These results underscore the importance of the characteristics of an acoustic signal in predicting an animal's response of habituation.

Hastie *et al.* (2021) studied how the number and severity of avoidance events may be an outcome of marine mammal cognition and risk assessment using captive grey seals. Five individuals were given the option to forage in a high- or low-density prey patch while continuously exposed to silence or an anthropogenic noise (pile driving or tidal turbine operation) playbacks (148 dB re 1 µPa at 1 m). For each trial, one prey patch was closer to the source, therefore having a higher received level in experimental exposures than the other prey patch. The authors found that foraging success was highest during silent periods and that the seals avoided both anthropogenic noises with higher received levels when the prey density was limited (low-density prey patch). The authors concluded that the seals made foraging decisions within the trials based on both the energetic value of the prey patch (low-density corresponding to low energetic value, high-density corresponding to high energetic value), and the nature and location of the acoustic signal relative to the prey patches of different value.

Pinniped responses to Navy missile launches are limited to observations at SNI on the PMSR, and there are extensive observations from this site over more than two decades (Burke, 2017; Holst *et al.,* 2011; Holst and Greene Jr., 2005; Holst and Greene Jr., 2008; Holst and Greene Jr., 2010; Navy, 2021a, 2021b, 2022; Ugoretz, 2014, 2015, 2016; Ugoretz and Greene Jr., 2012), including observations of northern elephant seals, California sea lions, and harbor seals) to every launch from SNI was required under these authorizations of launch activity. The results from these monitoring efforts (2001–2024) are summarized in this section. Over twenty years of observations of pinniped behavioral responses to land-based rocket and missile launches at VSFB are also available (Force, 2022).The observations at VSFB are consistent with those from SNI, but notable findings from VSFB are detailed below.

Since launches were relatively infrequent, and of such brief duration, it is unlikely that pinnipeds near the SNI launch sites were habituated to launch sounds. The most common type of response to airborne noise from missile and target launches at SNI was a momentary ''alert'' response. When the animals heard or otherwise detected the launch, they were likely to become alert and interrupt prior activities to pay attention to the launch. For both northern elephant seals and California sea lions, the proportion of animals that moved was significantly related to the closest point of approach of the vehicle or the weighted SEL of the event (based on pinniped in-air M-weighting function from Southall *et al.* (2007). These relationships were not evident for harbor seals, despite this species being the most susceptible to disturbance (Holst *et al.,* 2011). In cases where animals were displaced from normal activity, the displacement was typically short in duration (5–15 minutes, although some harbor seals left their haulout site until the following low tide when the haulout site was again accessible).

Observations indicated that elephant seals rarely showed more than a momentary alert, even when exposed to noise levels or types that caused nearby harbor seals and California sea lions to react more. This was also the case for northern fur seals at VSFB. Most elephant seals raised their heads briefly upon hearing the launch sounds and then quickly returned to their previous activity pattern (usually sleeping). During some launches, a small proportion of northern elephant seals moved a short distance on the beach or into the water, away from their resting site, but settled within minutes. Because of this, elephant seals were not specifically targeted for launch monitoring after 2010 (75 FR 71672, November 24, 2010), although in subsequent years they were often in the field of view when monitoring other species.

California sea lions (especially the young animals) exhibited more response than elephant seals, and responses varied by individual and age group. Some exhibited brief startle responses and increased vigilance for a short period after each launch. Others, particularly pups that were playing in groups along the margin of haulouts, appeared to react more vigorously. A greater proportion of hauled-out sea lions typically responded or entered the water when launch sounds were louder.

Harbor seals tended to be the most sensitive of the three target species, and during the majority of launches at SNI, most harbor seals left their haulout sites on rocky ledges to enter the water. In some cases, harbor seals returned to their haulout after a short period of time, while in other cases they did not return during the duration of the video-recording period (which sometimes extended up to several hours after a launch). During the day following a launch, harbor seals usually hauled out again at these sites (Holst and Lawson, 2002). The height of the tide following a launch event may have played a significant role in when harbor seals were able to return to a haulout site.

There were no observations of any sonic booms or stampedes at SNI and, specifically for the monitored launches at SNI from 2001 to 2024, there were no observed launch-related injuries or deaths (National Marine Fisheries Service, 2019b; Naval Air Warfare Center Weapons Division, 2018). On several occasions, harbor seals and California sea lion adults moved over pups (which can also happen without the presence of an anthropogenic noise) as the animals moved in response to the launches, but the pups did not appear to be injured. On one occasion, a stampede of California sea lions was observed in response to a sonic boom at VSFB. This was thought to have resulted from a particularly high amplitude sonic boom and is noted as an isolated incident.

Responses Due to Vessel Noise—

Mysticetes have varied responses to vessel noise and presence, from having no response to approaching vessels to

exhibiting an avoidance response by both horizontal (swimming away) and vertical (increased diving) movement (Baker *et al.,* 1983; Fiori *et al.,* 2019; Gende *et al.,* 2011; Watkins, 1981). Avoidance responses include changing swim patterns, speed, or direction (Jahoda *et al.,* 2003), remaining submerged for longer periods of time (Au and Green, 2000), and performing shallower dives with more frequent surfacing. Behavioral responses to vessels range from smaller-scale changes, such as altered breathing patterns (*e.g.,* Baker *et al.,* 1983; Jahoda *et al.,* 2003), to larger-scale changes such as a decrease in apparent presence (Anderwald *et al.,* 2013). Other common behavioral responses include changes in vocalizations, surface time, feeding and social behaviors (Au and Green, 2000; Dunlop, 2019; Fournet *et al.,* 2018; Machernis *et al.,* 2018; Richter *et al.,* 2003; Williams *et al.,* 2002a). For example, North Atlantic right whales (NARWs) have been reported to increase the amplitude or frequency of their vocalizations or call at a lower rate in the presence of increased vessel noise (Parks *et al.,* 2007; Parks *et al.,* 2011) but generally demonstrate little to no response to vessels or sounds from approaching vessels and often continue to use habitats in high vessel traffic areas (Nowacek *et al.* 2004a). This lack of response may be due to habituation to the presence and associated noise of vessels in NARW habitat or may be due to propagation effects that may attenuate vessel noise near the surface (Nowacek *et al.,* 2004a; Terhune and Verboom, 1999).

Similarly, sei whales have been observed ignoring the presence of vessels entirely and even pass close to vessels (Reeves *et al.,* 1998). Historically, fin whales tend to ignore vessels at a distance (Watkins, 1981) or habituate to vessels over time (Watkins, 1986) but still demonstrate vocal modifications (*e.g.,* decreased frequency parameters of calls) during vessel traffic. Ramesh *et al.* (2021) found that fin whale calls in Ireland were less likely to be detected for every 1 dB re 1 µPa/minute increase in shipping noise levels. In the presence of tour boats in Chile, fin whales were changing their direction of movement more frequently, with less linear movement than occurred before the boats arrived; this behavior may represent evasion or avoidance of the boats (Santos-Carvallo *et al.,* 2021). The increase in travel swim speeds after the vessels departed may be related to the rapid speeds at which the vessels traveled, sometimes in front of fin whales, leading to additional avoidance behavior post-exposure.

Mysticete behavioral responses to vessels may also be affected by vessel behavior (Di Clemente *et al.,* 2018; Fiori *et al.,* 2019). Avoidance responses occurred most often after ''J'' type vessel approaches (*i.e.,* traveling parallel to the whales' direction of travel, then overtaking the whales by turning in front of the group) compared to parallel or direct approaches. Mother humpbacks were particularly sensitive to direct and J type approaches and spent significantly more time diving in response (Fiori *et al.,* 2019). The presence of a passing vessel did not change the behavior of resting humpback whale mother-calf pairs, but fast vessels with louder low-frequency weighted source levels (173 dB re 1 µPa, equating to weighted received levels of 133 dB re 1 µPa) at an average distance of 328 ft (100 m) resulted in a decreased resting behavior and increases in dives, swim speeds, and respiration rates (Sprogis *et al.,* 2020). Humpback whale responses to vessel disturbance were dependent on their behavioral state. Di Clemente *et al.* (2018) found that when vessels passed within 1,640 ft (500 m) of humpback whales, individuals would continue to feed if already engaged in feeding behavior but were more likely to start swimming if they were surface active when approached. In response to an approaching large commercial vessel in an area of high ambient noise levels (125–130 dB re 1 µPa), a tagged female blue whale turned around mid-ascent and descended perpendicular to the vessel's path (Szesciorka *et al.,* 2019). The whale did not respond until the vessel's closest point of approach (328 ft (100 m) distance, 135 dB re 1 µPa RMS), which was 10 dB above the ambient noise levels. After the vessel passed, the whale ascended to the surface again with a three-minute delay.

Overall, mysticete responses to vessel noise and traffic are varied, and habituation or changes to vocalization are predominant long-term responses. When baleen whales do avoid vessels, they seem to do so by altering their swim and dive patterns to move away from the vessel. Although a lack of response in the presence of a vessel may minimize potential disturbance from passing vessels, it does increase the whales' vulnerability to vessel strike, which may be of greater concern for mysticetes than vessel noise.

Odontocete responses due to vessel noise are varied and context-dependent, and it is difficult to separate the impacts of vessel noise from the impacts of vessel presence. Vessel presence has been shown to interrupt feeding behavior in delphinids in some studies (Meissner *et al.,* 2015; Pirotta *et al.,* 2015b) while a recent study by Mills *et al.* (2023) found that, in an important foraging area, bottlenose dolphins may continue to forage and socialize even while constantly exposed to high vessel traffic. Ng and Leung (2003) found that the type of vessel, approach, and speed of approach can all affect the probability of a negative behavioral response and, similarly, Guerra *et al.* (2014) documented varied responses in group structure and vocal behavior.

While most odontocetes have documented neutral responses to vessels, avoidance (Bejder *et al.,* 2006a; Würsig *et al.,* 1998) and attraction (Norris and Prescott, 1961; Ritter, 2002; Shane *et al.,* 1986; Westdal *et al.,* 2023; Würsig *et al.,* 1998) behaviors have also been observed (Hewitt, 1985). Archer *et al.* (2010) compared the responses of dolphin populations far offshore that were often targeted by tuna fisheries to populations closer (less than 100 nmi (185.2 km)) to shore and found the fisheries-associated populations (spotted, spinner, and common dolphins) showed evasive behavior when approached by vessels while those nearshore species not associated with offshore fisheries (coastal spotted and bottlenose dolphins) tended to be attracted to vessels.

Arranz *et al.* (2021) used different engine types to determine whether behavioral responses of short-finned pilot whales were attributable to vessel noise, vessel presence, or both. Mother-calf pairs were approached by the same vessel outfitted with either ''quiet'' electric engines or ''noisy'' traditional combustion engines, controlling for approach speed and distance. Arranz *et al.* (2021) found mother pilot whales rested less and calves nursed less in response to both types of engines compared to control conditions, but only the ''noisy'' engine caused significant impacts (29 percent and 81 percent, respectively).

Smaller vessels tend to generate more noise in higher frequency bands, are more likely to approach odontocetes directly, and spend more time near an animal. Carrera *et al.* (2008) found tour boat activity can cause short-term displacement of dolphins, and Haviland-Howell *et al.* (2007) documented longer term or repetitive displacement of dolphins due to chronic vessel noise. Delphinid behavioral states also change in the presence of small tour vessels that often approach animals: travel and resting increases, foraging and social behavior decreases, and animals move closer together (Cecchetti *et al.,* 2017; Clarkson *et al.,*

2020; Kassamali-Fox *et al.,* 2020; Meissner *et al.,* 2015). Most studies on behavioral responses of bottlenose dolphins to vessel traffic show at least short-term changes in behavior, activities, or vocalization patterns when vessels are nearby (Acevedo, 1991; Arcangeli and Crosti, 2009; Berrow and Holmes, 1999; Fumagalli *et al.,* 2018; Gregory and Rowden, 2001; Janik and Thompson, 1996; Lusseau, 2004; Marega *et al.,* 2018; Mattson *et al.,* 2005; Perez-Ortega *et al.,* 2021; Puszka *et al.,* 2021; Scarpaci *et al.,* 2000).

Information is limited on beaked whale responses to vessel noise, but Würsig *et al.* (1998) noted that most beaked whales seem to exhibit avoidance behaviors when exposed to vessels and beaked whales may respond to all anthropogenic noise (*i.e.,* sonar, vessel) at similar sound levels (Aguilar de Soto *et al.,* 2006; Tyack *et al.,* 2011; Tyack, 2009). The information available includes a disruption of foraging by a vocalizing goose-beaked whale in the presence of a passing vessel (Aguilar de Soto *et al.,* 2006) and restriction of group movement, or possibly reduction in the number of individuals clicking within the group, after exposure to broadband (received level of 135 dB re 1 µPa) vessel noise up to at least 3.2 mi (5.2 km) away from the source, though no change in duration of Blainville's beaked whale foraging dives was observed (Pirotta *et al.,* 2012).

Porpoises and small delphinids are known to be sensitive to vessel noise, as well. Frankish *et al.* (2023) found harbor porpoises more likely to avoid large commercial vessels via horizontal movement during the day and vertical movement at night, which supports previous research that the species routinely avoids large, motorized vessels (Polacheck and Thorpe, 1990). Harbor porpoises have also been documented responding to vessels with increased changes in behavioral state and significantly decreased feeding (Akkaya Bas *et al.,* 2017), fewer clicks (Sairanen, 2014), and fewer prey capture attempts and have disrupted foraging when vessels pass closely and noise levels are higher (Wisniewska *et al.,* 2018). Habituation to vessel noise and presence was observed for a resident population of harbor porpoises that was in regular proximity to vessel traffic (32.8 ft to 0.6 mi (10 m to 1 km) away); the population had no response in 74 percent of interactions and an avoidance response in 26 percent of interactions. It should be noted that fewer responses in populations of odontocetes regularly subjected to high levels of vessel traffic could be a sign of habituation, or it could be that the more sensitive individuals in the population have abandoned that area of higher human activity.

Most avoidance responses were the result of fast-moving or steady plane-hulling motorized vessels and the vessel type and speed were considered to be more relevant than vessel presence, as few responses were observed to non-motorized or stationary vessels (Oakley *et al.,* 2017). Similarly, Akkaya Bas *et al.* (2017) found that when fast moving vessels were within 164 ft (50 m) of harbor porpoises, there was an 80 percent probability of change in swimming direction but only a 40 percent probability of change when vessels were beyond 1,312.3 ft (400 m). Frankish *et al.* (2023) found that harbor porpoises were most likely to avoid vessels less than 984.3 ft (300 m) away but, 5–10 percent of the time, they would also respond to vessels more than 1.2 mi (2 km) away, signifying that they were not just attuning to vessel presence, but to vessel noise as well.

Although most vessel noise is constrained to frequencies below 1 kHz, at close ranges vessel noise can extend into mid- and high frequencies (into the tens of kHz) (Hermannsen *et al.,* 2014; Li *et al.,* 2015) and it is these frequencies that harbor porpoises are likely responding to; the mean M-weighted received SPL threshold for a response at these frequencies is 123 dB re 1 µPa (Dyndo *et al.,* 2015). M-weighting functions are generalized frequency weightings for various groups of marine mammals that were defined by Southall *et al.* (2007) based on known or estimated auditory sensitivity at different frequencies and are used to characterize auditory effects of strong sounds. Hermannsen *et al.* (2019) estimated that noise in the 16 kHz frequency band resulting from small recreational vessels could cause behavioral directions in harbor porpoises and could be elevated up to 124 dB re 1 µPa and raise ambient noise levels by a maximum of 51 dB. The higher noise levels were associated with vessel speed and range, which exceeded the threshold levels found by Dyndo *et al.* (2015) and Wisniewska *et al.* (2018) by 49–85 percent of events with high levels of vessel noise.

Lusseau and Bejder (2007) have reported some long-term consequences of vessel noise on odontocetes but, overall, there is little information on the long-term and cumulative impacts of vessel noise (National Academies of Sciences Engineering and Medicine, 2017; National Marine Fisheries Service, 2007). Many researchers speculate that long-term impacts may occur on odontocete populations that experience repeated interruption of foraging behaviors (Stockin *et al.,* 2008), and Southall *et al.* (2021) indicates that, in many contexts, the localized and coastal home ranges typical of many species make them less resilient to this chronic stressor than mysticetes.

Context and experience likely play a role in pinnipeds response to vessel noise, which vary from negative responses including increased vigilance and alerting to avoidance to reduced time spent doing biologically important activities (*e.g.,* resting, feeding, and nursing) (Martin *et al.,* 2023a; Martin *et al.,* 2022; Mikkelsen *et al.,* 2019; Richardson *et al.,* 1995b) to attraction or lack of observable response (Richardson *et al.,* 1995b). More severe responses, like flushing, could be more detrimental to individuals during biologically important activities and times, such as during pupping season. Blundell and Pendleton (2015) found that vessel presence reduces haul out time of Alaskan harbor seals during pupping season and larger vessels elicit stronger responses. Cates and Acevedo-Gutiérrez (2017) modeled harbor seal responses to passing vessels at haul out sites in less trafficked areas and found the model best predicting flushing behavior included number of boats, type of boats, and distance of seals to boats. The authors noted flushing occurred more in response to non-motorized vessels (*e.g.,* kayaks), likely because they tended to pass closer (82 to 603.7 ft (25 to 184 m)) to haul out sites than motorized vessels (180.4 to 1,939 ft (55 to 591 m)) and tended to occur in groups rather than as a single vessel.

Cape fur seals were also more responsive to vessel noise at sites with a large breeding colony than at sites with lower abundances of conspecifics (Martin *et al.,* 2023a). A field study of harbor and gray seals showed that seal responses to vessels included interruption of resting and foraging during times when vessel noise was increasing or at its peak (Mikkelsen *et al.,* 2019). And, although no behavioral differences were observed in hauled out wild cape fur seals exposed to low (60–64 dB re 20 µPa RMS SPL), medium (64–70 dB) and high-level (70–80 dB) vessel noise playbacks, mother-pup pairs spent less time nursing (15–31 percent) and more time awake (13–26 percent), vigilant (7–31 percent), and mobile (2–4 percent) during vessel noise conditions compared to control conditions (Martin *et al.,* 2022).

Masking

Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, interpret, or

discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, or navigation) (Clark *et al.,* 2009; Richardson *et al.,* 1995; Erbe and Farmer, 2000; Tyack, 2000; Erbe *et al.,* 2016; Branstetter and Sills, 2022). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity and may occur whether the coincident sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin.

As described in detail in appendix D, section D.4.4 (Masking), of the 2024 HCTT Draft EIS/OEIS, the ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age, or TTS hearing loss), and existing ambient noise and propagation conditions. Masking these acoustic signals can disturb the behavior of individual animals, groups of animals, or entire populations. Masking can lead to behavioral changes including vocal changes (*e.g.,* Lombard effect, increasing amplitude, or changing frequency), cessation of foraging, and leaving an area, to both signalers and receivers, in an attempt to compensate for noise levels (Erbe *et al.,* 2016).

Most research on auditory masking is focused on energetic masking, or the ability of the receiver (*i.e.,* listener) to detect a signal in noise. However, from a fitness perspective, both signal detection and signal interpretation are necessary for success. This type of masking is called informational masking and occurs when a signal is detected by an animal but the meaning of that signal has been lost. Few data exist on informational masking in marine mammals but studies have shown that some recognition of predator cues might be missed by species that are preyed upon by killer whales if killer whale vocalizations are masked (Curé *et al.,* 2016; Curé *et al.,* 2015; Deecke *et al.,* 2002; Isojunno *et al.,* 2016; Visser *et al.,* 2016). Von Benda-Beckman *et al.* (2021) modeled the effect of pulsed and continuous active sonars (CAS) on sperm whale echolocation and found that sonar sounds could reduce the ability of sperm whales to find prey under certain conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (*i.e.,* masking) sound is man-made, it may be considered harassment when disrupting natural behavioral patterns to the point where the behavior is abandoned or significantly altered. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which only occurs during the sound exposure. Because masking (without resulting in threshold shift) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

Richardson *et al.* (1995) argued that the maximum radius of influence of anthropogenic noise (including broadband low-frequency sound transmission) on a marine mammal is the distance from the source to the point at which the noise can barely be heard. This range is determined by either the hearing sensitivity (including critical ratios, or the lowest signal-to-noise ratio in which animals can detect a signal) of the animal (Finneran and Branstetter, 2013; Johnson *et al.,* 1989; Southall *et al.,* 2000) or the background noise level present. Masking is most likely to affect some species' ability to detect communication calls and natural sounds (*i.e.,* surf noise, prey noise, *etc.*) (Richardson *et al.,* 1995).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009; Matthews *et al.,* 2016) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species, but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Cholewiak *et al.,* 2018; Branstetter and Sills, 2022; Branstetter *et al.,* 2024).

High-frequency sounds may mask the echolocation calls of toothed whales. Human data indicate low-frequency sound can mask high-frequency sounds (*i.e.,* upward masking). Studies on captive odontocetes by Au *et al.* (1974; 1985; 1993) indicate that some species may use various processes to reduce masking effects (*e.g.,* adjustments in echolocation call intensity or frequency as a function of background noise conditions). Odontocete hearing is highly directional at high frequencies, facilitating echolocation in masked conditions (Au and Moore, 1984). A study by Nachtigall *et al.,* (2018) showed that false killer whales adjust their hearing to compensate for ambient sounds and the intensity of returning echolocation signals.

Impacts on signal detection, measured by masked detection thresholds, are not the only important factors to address when considering the potential effects of masking. As marine mammals use sound to recognize conspecifics, prey, predators, or other biologically significant sources (Branstetter *et al.,* 2016), it is also important to understand the impacts of masked recognition thresholds (*i.e.,* informational masking). Branstetter *et al.* (2016) measured masked recognition thresholds for whistle-like sounds of bottlenose dolphins and observed that they are approximately 4 dB above detection thresholds (energetic masking) for the same signals. Reduced ability to recognize a conspecific call or the acoustic signature of a predator could have severe negative impacts. Branstetter *et al.* (2016) observed that if ''quality communication'' is set at 90 percent recognition the output of communication space models (which are based on 50 percent detection) would likely result in a significant decrease in communication range.

As marine mammals use sound to recognize predators (Allen *et al.,* 2014; Cummings and Thompson, 1971; Cure *et al.,* 2015; Fish and Vania, 1971), the presence of masking noise may also prevent marine mammals from responding to acoustic cues produced by their predators, particularly if it occurs in the same frequency band. For example, harbor seals that reside in the coastal waters of British Columbia are frequently targeted by mammal-eating killer whales. The seals acoustically

discriminate between the calls of mammal-eating and fish-eating killer whales (Deecke *et al.,* 2002), a capability that should increase survivorship while reducing the energy required to identify all killer whale calls. Similarly, sperm whales (Curé *et al.,* 2016; Isojunno *et al.,* 2016), long-finned pilot whales (Visser *et al.,* 2016), and humpback whales (Curé *et al.,* 2015) changed their behavior in response to killer whale vocalization playbacks. The potential effects of masked predator acoustic cues depends on the duration of the masking noise and the likelihood of a marine mammal encountering a predator during the time that detection and recognition of predator cues are impeded.

Redundancy and context can also facilitate detection of weak signals. These phenomena may help marine mammals detect weak sounds in the presence of natural or anthropogenic noise. Most masking studies in marine mammals present the test signal and the masking noise from the same direction. The dominant background noise may be highly directional if it comes from a particular anthropogenic source such as a vessel or industrial site. Directional hearing may significantly reduce the masking effects of these sounds by improving the effective signal-to-noise ratio.

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009; Cholewiak *et al.,* 2018). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from commercial vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking for marine mammals.

Masking Due to Sonar and Other Transducers—

The functional hearing ranges of mysticetes, odontocetes, and pinnipeds underwater overlap the frequencies of the sonar sources used in the Action Proponents' LFAS/MFAS/high-frequency active sonar (HFAS) training and the Navy's testing exercises. Additionally, almost all affected species' vocal repertoires span across the frequencies of these sonar sources used by the Action Proponents. Masking by LFAS or MFAS with relatively low-duty cycles is not anticipated (or would be of very short duration) for most cetaceans as sonar signals occur over a relatively short duration and narrow bandwidth (overlapping with only a small portion of the hearing range). LFAS could overlap in frequency with mysticete vocalizations, however LFAS does not overlap with vocalizations for most marine mammal species. For example, in the presence of LFAS, humpback whales were observed to increase the length of their songs (Fristrup *et al.,* 2003; Miller *et al.,* 2000), potentially due to the overlap in frequencies between the whale song and the LFAS. While dolphin whistles and MFAS are similar in frequency, masking is not anticipated (or would be of very short duration) due to the low-duty cycle and short durations of most sonars.

As described in additional detail in the 2024 HCTT Draft EIS/OEIS, high duty-cycle or CAS have more potential to mask vocalizations. These sonars transmit more frequently (greater than 80 percent duty cycle) than traditional sonars, but typically at lower source levels. HFAS, such as pingers that operate at higher repetition rates, also operate at lower source levels and have faster attenuation rates due to the higher frequencies used. These lower source levels limit the range of impacts, however, compared to traditional sonar systems, individuals close to the source are likely to experience masking at longer time scales. The frequency range at which high-duty cycle systems operate overlaps the vocalization frequency of many odontocetes. Continuous noise at the same frequency of communicative vocalizations may cause disruptions to communication, social interactions, and acoustically mediated cooperative behaviors (Sørensen *et al.,* 2023) such as foraging and mating. Similarly, because the high-duty cycle or CAS includes mid-frequency sources, there is also the potential for the mid-frequency sonar signals to mask important environmental cues (*e.g.,* predator or conspecific acoustic cues), possibly affecting survivorship for targeted animals. Spatial release from masking may occur with higher duty cycle or CAS.

While there are currently few studies of the impacts of high-duty cycle sonars on marine mammals, masking due to these systems is likely analogous to masking produced by other continuous sources (*e.g.,* vessel noise and low-frequency cetaceans), and would likely have similar short-term consequences, though longer in duration due to the duration of the masking noise. These may include changes to vocalization amplitude and frequency (Brumm and Slabbekoorn, 2005; Hotchkin and Parks, 2013) and behavioral impacts such as avoidance of the area and interruptions to foraging or other essential behaviors (Gordon *et al.,* 2003). Long-term consequences could include changes to vocal behavior and vocalization structure (Foote *et al.,* 2004; Parks *et al.,* 2007), abandonment of habitat if masking occurs frequently enough to significantly impair communication (Brumm and Slabbekoorn, 2005), a potential decrease in survivorship if predator vocalizations are masked (Brumm and Slabbekoorn, 2005), and a potential decrease in recruitment if masking interferes with reproductive activities or mother-calf communication (Gordon *et al.,* 2003).

Von Benda-Beckmann *et al.* (2021) modeled the effect of pulsed and continuous 1 to 2 kHz active sonar on sperm whale echolocation clicks and found that the presence of upper harmonics in the sonar signal increased masking of clicks produced in the search phase of foraging compared to buzz clicks produced during prey capture. Different levels of sonar caused intermittent to continuous masking (120 to 160 dB re 1 μPa^2, respectively), but varied based on click level, whale orientation, and prey target strength. CAS resulted in a greater percentage of time that echolocation clicks were masked compared to pulsed active sonar. This means that sonar sounds could reduce the ability of sperm whales to find prey under certain conditions. However, echoes from prey are most likely spatially separated from the sonar source, and so spatial release from masking would be expected.

Masking Due to Impulsive Noise—

Impulsive sound sources, including explosions, are intense and short in duration. Since impulsive noise is intermittent, the length of the gap between sounds (*i.e.,* duty-cycle) and received level are relevant when considering the potential for masking. Impulsive sounds with lower duty cycles or lower received levels are less likely to result in masking than higher duty cycles or received levels. There are no direct observations of masking in marine mammals due to exposure to explosive sources. Potential masking from explosive sounds or weapon noise is likely similar to masking studied for other impulsive sounds, such as air guns.

Masking of mysticete calls could occur due to the overlap between their low-frequency vocalizations and the dominant frequencies of impulsive sources (Castellote *et al.,* 2012; Nieukirk

et al., 2012). For example, blue whale feeding/social calls increased when seismic exploration was underway (Di Lorio and Clark, 2010), indicative of a possible compensatory response to masking effects of the increased noise level. However, mysticetes that call at higher rates are less likely to be masked by impulsive noise with lower duty cycles (Clark *et al.,* 2009) because of the decreased likelihood that the noise would overlap with the calls, and because of dip listening. Field observations of masking effects such as vocal modifications are difficult to interpret because when recordings indicate that call rates decline, this could be caused by (1) animals calling less frequently (*i.e.,* actual noise-induced vocal modifications), (2) the calls being masked from the recording hydrophone due to the noise (*e.g.,* animals are not calling less frequently but are being detected less frequently), or (3) the animals moving away from the noise, or any combination of these causes (Blackwell *et al.,* 2013; Cerchio *et al.,* 2014).

Masking of pinniped communication sounds at 100 Hz center frequency is possible when vocalizations occur at the same time as an air gun pulse (Sills *et al.,* 2017). This might result in some percentage of vocalizations being masked if an activity such as a seismic survey is being conducted in the vicinity, even when the sender and receiver are near one another. Release from masking due to ''dip listening'' is likely in this scenario.

While a masking effect of impulsive noise can depend on the received level (Blackwell *et al.,* 2015) and other characteristics of the noise, the vocal response of the affected animal to masking noise is an equally important consideration for inferring overall impacts to an animal. It is possible that the receiver would increase the rate and/or level of calls to compensate for masking; or, conversely, cease calling.

In general, impulsive noise has the potential to mask sounds that are biologically important for marine mammals, reducing communication space or resulting in noise-induced vocal modifications that might impact marine mammals. Masking by close-range impulsive sound sources is most likely to impact marine mammal communication.

Masking Due to Vessel Noise—

Masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as vessels. Several studies have shown decreases in marine mammal communication space and changes in behavior as a result of the presence of vessel noise. For example, North Atlantic right whales were observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007) as well as increasing the amplitude (intensity) of their calls (Parks, 2009; Parks *et al.,* 2011). Fournet *et al.* (2018) observed that humpback whales in Alaska responded to increasing ambient sound levels (natural and anthropogenic) by increasing the source levels of their calls (non-song vocalizations). Clark *et al.* (2009) also observed that right whales communication space decreased by up to 84 percent in the presence of vessels (Clark *et al.,* 2009). Cholewiak *et al.* (2018) also observed loss in communication space in Stellwagen National Marine Sanctuary for North Atlantic right whales, fin whales, and humpback whales with increased ambient noise and shipping noise. Gabriele *et al.* (2018) modeled the effects of vessel traffic sound on communication space in Glacier Bay National Park in Alaska and found that typical summer vessel traffic in Glacier Bay National Park causes losses of communication space to singing whales (reduced by 13–28 percent), calling whales (18–51 percent), and roaring seals (32–61 percent), particularly during daylight hours and even in the absence of cruise ships. Dunlop (2019) observed that an increase in vessel noise reduced modeled communication space and resulted in significant reduction in group social interactions in Australian humpback whales. However, communication signal masking did not fully explain this change in social behavior in the model, indicating there may also be an additional effect of the physical presence of the vessel on social behavior (Dunlop, 2019). Although humpback whales off Australia did not change the frequency or duration of their vocalizations in the presence of ship noise, their source levels were lower than expected based on source level changes to wind noise, potentially indicating some signal masking (Dunlop, 2016). Multiple delphinid species have also been shown to increase the minimum or maximum frequencies of their whistles in the presence of anthropogenic noise and reduced communication space (*e.g.,* Holt *et al.,* 2009; Holt *et al.,* 2011; Gervaise *et al.,* 2012; Williams *et al.,* 2014; Hermannsen *et al.,* 2014; Papale *et al.,* 2015; Liu *et al.,* 2017).

Other Physiological Response

Physiological stress is a natural and adaptive process that helps an animal survive changing conditions. When an animal perceives a potential threat, whether or not the stimulus actually poses a threat, a stress response is triggered (Selye, 1950; Moberg, 2000; Sapolsky, 2005). Once an animal's central nervous system perceives a threat, it mounts a biological response or defense that consists of a combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses.

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and distress is the biotic cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other biotic functions. For example, when a stress response diverts energy away from growth in young animals, those animals may experience stunted growth. When a stress response diverts energy from a fetus, an animal's reproductive success and its fitness will suffer. In these cases, the animals will have entered a pre-pathological or pathological state which is called ''distress'' (Selye, 1950) or ''allostatic loading'' (McEwen and Wingfield, 2003). This pathological state of distress will last until the animal replenishes its energetic reserves sufficiently to restore normal function.

According to Moberg (2000), in the case of many stressors, an animal's first and sometimes most economical (in terms of biotic costs) response is behavioral avoidance of the potential stressor or avoidance of continued exposure to a stressor. An animal's second line of defense to stressors involves the sympathetic part of the autonomic nervous system and the classical ''fight or flight'' response, which includes the cardiovascular system, the gastrointestinal system, the exocrine glands, and the adrenal medulla to produce changes in heart rate, blood pressure, and gastrointestinal activity that humans commonly associate with ''stress.'' These responses have a relatively short duration and may or may not have significant long-term effect on an animal's welfare.

An animal's third line of defense to stressors involves its neuroendocrine systems or sympathetic nervous systems; the system that has received the most study has been the hypothalamus-pituitary-adrenal (HPA) system (also known as the HPA axis in mammals or the hypothalamus-pituitary-interrenal axis in fish and some reptiles). Unlike stress responses associated with the autonomic nervous system, virtually all neuro-endocrine functions that are affected by stress, including immune competence, reproduction, metabolism, and behavior, are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction (Moberg, 1987; Rivier and Rivest, 1991), altered metabolism (Elasser *et al.,* 2000), reduced immune competence (Blecha, 2000), and behavioral disturbance (Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticosteroids (cortisol, corticosterone, and aldosterone in marine mammals; see Romano *et al.,* 2004) have been equated with stress for many years.

Marine mammals naturally experience stressors within their environment and as part of their life histories. Changing weather and ocean conditions, exposure to disease and naturally occurring toxins, lack of prey availability, and interactions with predators all contribute to the stress a marine mammal experiences (Atkinson *et al.,* 2015). Breeding cycles, periods of fasting, social interactions with members of the same species, and molting (for pinnipeds) are also stressors, although they are natural components of an animal's life history. Anthropogenic activities have the potential to provide additional stressors beyond those that occur naturally (*e.g.,* fishery interactions, pollution, tourism, ocean noise) (Fair *et al.,* 2014; Meissner *et al.,* 2015; Rolland *et al.,* 2012).

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005; Reneerkens *et al.,* 2002; Thompson and Hamer, 2000). However, it should be noted (and as is described in additional detail in the 2024 HCTT Draft EIS/OEIS) that our understanding of the functions of various stress hormones (*e.g.,* cortisol), is based largely upon observations of the stress response in terrestrial mammals. Atkinson *et al.,* (2015) note that the endocrine response of marine mammals to stress may not be the same as that of terrestrial mammals because of the selective pressures marine mammals faced during their evolution in an ocean environment. For example, due to the necessity of breath-holding while diving and foraging at depth, the physiological role of epinephrine and norepinephrine (the catecholamines) in marine mammals might be different than in other mammals. Relatively little information exists on the linkage between anthropogenic sound exposure and stress in marine mammals, and even less information exists on the ultimate consequences of sound-induced stress responses (either acute or chronic). Most studies to date have focused on acute responses to sound either by measuring catecholamines, a neurohormone, or heart rate as a proxy for an acute stress response.

The ability to make predictions from stress hormones about impacts on individuals and populations exposed to various forms of natural and anthropogenic stressors relies on understanding the linkages between changes in stress hormones and resulting physiological impacts. Currently, the sound characteristics that correlate with specific stress responses in marine mammals are poorly understood, as are the ultimate consequences of these changes. Several research efforts have improved the understanding of, and the ability to predict, how stressors ultimately affect marine mammal populations (*e.g.,* King *et al.,* 2015; New *et al.,* 2013a; Pirotta *et al.,* 2015a; Pirotta *et al.,* 2022b). This includes determining how and to what degree various types of anthropogenic sound cause stress in marine mammals and understanding what factors may mitigate those physiological stress responses. Factors potentially affecting an animal's response to a stressor include life history, sex, age, reproductive status, overall physiological and behavioral adaptability, and whether they are naïve or experienced with the sound (*e.g.,* prior experience with a stressor may result in a reduced response due to habituation) (Finneran and Branstetter, 2013; St. Aubin and Dierauf, 2001). Because there are many unknowns regarding the occurrence of acoustically induced stress responses in marine mammals, any physiological response (*e.g.,* hearing loss or injury) or significant behavioral response is assumed to be associated with a stress response.

Non-impulsive sources of sound can cause direct physiological effects including noise-induced loss of hearing sensitivity (or ''threshold shift'') or other auditory injury, nitrogen decompression, acoustically-induced bubble growth, and injury due to sound-induced acoustic resonance. Separately, an animal's behavioral response to an acoustic exposure might lead to physiological effects that might ultimately lead to injury or death, which is discussed later in the *Stranding and Mortality* section.

Heart Rate Response—

Several experimental studies have measured the heart rate response of a variety of marine mammals. For example, Miksis *et al.* (2001) observed increases in heart rates of captive bottlenose dolphins to which known calls of other dolphins were played, although no increase in heart rate was observed when background tank noise was played back. However, it cannot be determined whether the increase in heart rate was due to stress or social factors, such as expectation of an encounter with a known conspecific. Similarly, a young captive beluga's heart rate increased during exposure to noise, with increases dependent upon the frequency band of noise and duration of exposure, and with a sharp decrease to normal or below normal levels upon cessation of the exposure (Lyamin *et al.,* 2011). Spectral analysis of heart rate variability corroborated direct measures of heart rate (Bakhchina *et al.,* 2017). This response might have been in part due to the conditions during testing, the young age of the animal, and the novelty of the exposure; a year later the exposure was repeated at a slightly higher received level and there was no heart rate response, indicating the beluga whale had potentially habituated to the noise exposure.

Kvadsheim *et al.* (2010a) measured the heart rate of captive hooded seals during exposure to sonar signals and found an increase in the heart rate of the seals during exposure periods versus control periods when the animals were at the surface. When the animals dove, the normal dive-related heart rate decrease was not impacted by the sonar exposure. Similarly, Thompson *et al.* (1998) observed a rapid, short-lived decrease in heart rates in wild harbor and grey seals exposed to seismic air guns (cited in Gordon *et al.,* 2003).

Two captive harbor porpoises showed significant bradycardia (reduced heart rate), below that which occurs with diving, when they were exposed to pinger-like sounds with frequencies between 100–140 kHz (Teilmann *et al.,* 2006). The bradycardia was found only in the early noise exposures and the porpoises acclimated quickly across

successive noise exposures. Elmegaard *et al.* (2021) also found that initial exposures to sonar sweeps produced bradycardia but did not elicit a startle response in captive harbor porpoises. As with Teilmann *et al.* (2006), the cardiac response disappeared over several repeat exposures suggesting rapid acclimation to the noise. In the same animals, 40-kHz noise pulses induced startle responses but without a change in heart rate. Bakkeren *et al.* (2023) found no change in the heart rate of a harbor porpoise during exposure to masking noise (⅓ octave band noise, centered frequency of 125 kHz, maximum received level of 125 dB re 1 µPa) during an echolocation task but showed significant bradycardia while blindfolded for the same task. The authors attributed the change in heart rate to sensory deprivation, although no strong conclusions about acoustic masking could be made since the animal was still able to perform the echolocation task in the presence of the masking noise. Williams *et al.* (2022) observed periods of increased heart rate variability in narwhals during seismic air gun impulse exposure, but profound bradycardia was not noted. Conversely, Williams *et al.* (2017) found that a profound bradycardia persisted in narwhals, even though exercise effort increased dramatically as part of their escape response following release from capture and handling.

Limited evidence across several different species suggests that increased heart rate might occur as part of the acute stress response of marine mammals that are at the surface. However, the decreased heart rate typical of diving marine mammals can be enhanced in response to an acute stressor, suggesting that the context of the exposure is critical to understanding the cardiac response. Furthermore, in instances where a cardiac response was noted, there appears to be rapid habituation when repeat exposures occur. Additional research is required to understand the interaction of dive bradycardia, noise-induced cardiac responses, and the role of habituation in marine mammals.

Stress Hormone and Immune Response—

What is known about the function of the various stress hormones is based largely upon observations of the stress response in terrestrial mammals. The endocrine response of marine mammals to stress may not be the same as that of terrestrial mammals because of the selective pressures marine mammals faced during their evolution in an ocean environment (Atkinson *et al.,* 2015). For example, due to the necessity of breath-holding while diving and foraging at depth, the physiological role of epinephrine and norepinephrine (the catecholamines) might be different in marine versus other mammals.

Catecholamines increase during breath-hold diving in seals, co-occurring with a reduction in heart rate, peripheral vasoconstriction (*i.e.,* constriction of blood vessels), and an increased reliance on anaerobic metabolism during extended dives (Hance *et al.,* 1982; Hochachka *et al.,* 1995; Hurford *et al.,* 1996); the catecholamine increase is not associated with increased heart rate, glycemic release, and increased oxygen consumption typical of terrestrial mammals. Captive belugas demonstrated no catecholamine response to the playback of oil drilling sounds (Thomas *et al.,* 1990b) but showed a small but statistically significant increase in catecholamines following exposure to impulsive sounds produced from a seismic water gun (Romano *et al.,* 2004). A captive bottlenose dolphin exposed to the same sounds did not demonstrate a catecholamine response but did demonstrate a statistically significant elevation in aldosterone (Romano *et al.,* 2004); however, the increase was within the normal daily variation observed in this species (St. Aubin *et al.,* 1996) and was likely of little biological significance. Aldosterone has been speculated to not only contribute to electrolyte balance, but possibly also the maintenance of blood pressure during periods of vasoconstriction (Houser *et al.,* 2011). In marine mammals, aldosterone is thought to play a role in mediating stress (St. Aubin and Dierauf, 2001; St. Aubin and Geraci, 1989).

Yang *et al.* (2021) measured cortisol concentrations in two captive bottlenose dolphins and found significantly higher concentrations after exposure to 140 dB re 1 µPa impulsive noise playbacks. Two out of six tested indicators of immune system function underwent acoustic dose-dependent changes, suggesting that repeated exposures or sustained stress response to impulsive sounds may increase an affected individual's susceptibility to pathogens. Unfortunately, absolute values of cortisol were not provided, and it is not possible from the study to tell if cortisol rose to problematic levels (*e.g.,* see normal variation and changes due to handling in Houser *et al.* (2021) and Champagne *et al.* (2018)). Exposing dolphins to a different acoustic stressor yielded contrasting results. Houser *et al.* (2020) measured cortisol and epinephrine obtained from 30 captive bottlenose dolphins exposed to simulated Navy MFAS and found no correlation between SPL and stress hormone levels, even though sound exposures were as high as 185 dB re 1 µPa. In the same experiment (Houser *et al.,* 2013b), behavioral responses were shown to increase in severity with increasing received SPLs. These results suggest that behavioral responses to sonar signals are not necessarily indicative of a hormonal stress response.

Whereas a limited amount of work has addressed the potential for acute sound exposures to produce a stress response, almost nothing is known about how chronic exposure to acoustic stressors affects stress hormones in marine mammals, particularly as it relates to survival or reproduction. In what is probably the only study of chronic noise exposure in marine mammals associating changes in a stress hormone with changes in anthropogenic noise, Rolland *et al.* (2012) compared the levels of cortisol metabolites in NARW feces collected before and after September 11, 2001. Following the events of September 11, 2001, shipping was significantly reduced in the region where fecal collections were made, and regional ocean background noise declined. Fecal cortisol metabolites significantly decreased during the period of reduced ship traffic and ocean noise (Rolland *et al.,* 2012). Rolland *et al.* (2017) also compared acute (death by vessel strike) to chronic (entanglement or live stranding) stressors in NARW and found that whales subject to chronic stressors had higher levels of glucocorticoid stress hormones (cortisol and corticosterone) than either healthy whales or those killed by ships. It was presumed that whales subjected to acute stress may have died too quickly for increases in fecal glucocorticoids to be detected.

Considerably more work has been conducted in an attempt to determine the potential effect of vessel disturbance on smaller cetaceans, particularly killer whales (Bain, 2002; Erbe, 2002; Lusseau, 2006; Noren *et al.,* 2009; Pirotta *et al.,* 2015b; Read *et al.,* 2014; Rolland *et al.,* 2012; Williams *et al.,* 2009; Williams *et al.,* 2014a; Williams *et al.,* 2014b; Williams *et al.,* 2006b). Most of these efforts focused primarily on estimates of metabolic costs associated with altered behavior or inferred consequences of boat presence and noise but did not directly measure stress hormones. However, Ayres *et al.* (2012) investigated Southern Resident killer whale fecal thyroid hormone and cortisol metabolites to assess two potential threats to the species'

recovery: lack of prey (salmon) and impacts from exposure to the physical presence of vessel traffic (but without measuring vessel traffic noise). Ayres *et al.* (2012) concluded from these stress hormone measures that the lack of prey overshadowed any population-level physiological impacts on Southern Resident killer whales due to vessel traffic. Lemos *et al.* (2022) investigated the potential for vessel traffic to affect gray whales. By assessing gray whale fecal cortisol metabolites across years in which vessel traffic was variable, Lemos *et al.* (2022) found a direct relationship between the presence/density of vessel traffic and fecal cortisol metabolite levels. Unfortunately, no direct noise exposure measurements were made on any individual making it impossible to tell if other natural and anthropogenic factors could also be related to the results. Collectively, these studies indicate the difficulty in determining which factors are primarily influence the secretion of stress hormones, including the separate and additive effects of vessel presence and vessel noise. While vessel presence could contribute to the variation in fecal cortisol metabolites in North Atlantic right whales and gray whales, there are other potential influences on fecal hormone metabolites, so it is difficult to establish a direct link between ocean noise and fecal hormone metabolites.

Non-Auditory Injury

Non-auditory injury, or direct injury, is considered less likely to occur in the context of the Action Proponents' activities than auditory injury and the primary anticipated source of non-auditory injury for these activities is exposure to the pressure generated by explosive detonations, which is discussed in the *Potential Effects of Explosive Sources on Marine Mammals* section below. Here, we discuss less direct non-auditory injury impacts, including acoustically induced bubble formation, injury from sonar-induced acoustic resonance, and behaviorally mediated injury.

One theoretical cause of injury to marine mammals is rectified diffusion (Crum and Mao, 1996), the process of increasing the size of a bubble by exposing it to a sound field. This process could be facilitated if the environment in which the ensonified bubbles exist is supersaturated with gas. Repetitive diving by marine mammals can cause the blood and some tissues to accumulate gas to a greater degree than is supported by the surrounding environmental pressure (Ridgway and Howard, 1979). The deeper and longer dives of some marine mammals (for example, beaked whales) are theoretically predicted to induce greater supersaturation (Houser *et al.,* 2001b). If rectified diffusion were possible in marine mammals exposed to high-level sound, conditions of tissue supersaturation could theoretically speed the rate and increase the size of bubble growth. Subsequent effects due to tissue trauma and emboli would presumably mirror those observed in humans suffering from decompression sickness. Acoustically-induced (or mediated) bubble growth and other pressure-related physiological impacts are addressed below but are not expected to result from the Action Proponents' proposed activities.

It is unlikely that the short duration (in combination with the source levels) of sonar pings would be long enough to drive bubble growth to any substantial size, if such a phenomenon occurs. However, an alternative but related hypothesis has also been suggested: stable bubbles could be destabilized by high-level sound exposures such that bubble growth then occurs through static diffusion of gas out of the tissues. In such a scenario the marine mammal would need to be in a gas-supersaturated state for a long enough period of time for bubbles to become of a problematic size. Recent research with ex vivo supersaturated bovine tissues suggested that, for a 37 kHz signal, a sound exposure of approximately 215 dB re 1 µPa would be required before microbubbles became destabilized and grew (Crum *et al.,* 2005). Assuming spherical spreading loss and a nominal sonar source level of 235 dB re 1 µPa at 1 m, a whale would need to be within 33 ft (10 m) of the sonar dome to be exposed to such sound levels. Furthermore, tissues in the study were supersaturated by exposing them to pressures of 400–700 kilopascals for periods of hours and then releasing them to ambient pressures. Assuming the equilibration of gases with the tissues occurred when the tissues were exposed to the high pressures, levels of supersaturation in the tissues could have been as high as 400–700 percent. These levels of tissue supersaturation are substantially higher than model predictions for marine mammals (Fahlman *et al.,* 2009; Fahlman *et al.,* 2014; Houser *et al.,* 2001; Saunders *et al.,* 2008). It is improbable that this mechanism is responsible for stranding events or traumas associated with beaked whale strandings because both the degree of supersaturation and exposure levels observed to cause microbubble destabilization are unlikely to occur, either alone or in concert.

Yet another hypothesis has speculated that rapid ascent to the surface following exposure to a startling sound might produce tissue gas saturation sufficient for the evolution of nitrogen bubbles (*i.e.,* decompression sickness) (Jepson *et al.,* 2003; Fernandez *et al.,* 2005). In this scenario, the rate of ascent would need to be sufficiently rapid to compromise behavioral or physiological protections against nitrogen bubble formation. Alternatively, Tyack *et al.* (2006) studied the deep diving behavior of beaked whales and concluded that: ''Using current models of breath-hold diving, we infer that their natural diving behavior is inconsistent with known problems of acute nitrogen supersaturation and embolism.'' Collectively, these hypotheses can be referred to as ''hypotheses of acoustically mediated bubble growth.''

Although theoretical predictions suggest the possibility for acoustically mediated bubble growth, there is considerable disagreement among scientists as to its likelihood (Piantadosi and Thalmann, 2004; Evans and Miller, 2003; Cox *et al.,* 2006; Rommel *et al.,* 2006). Crum and Mao (1996) hypothesized that received levels would have to exceed 190 dB in order for there to be the possibility of significant bubble growth due to supersaturation of gases in the blood (*i.e.,* rectified diffusion). Work conducted by Crum *et al.* (2005) demonstrated the possibility of rectified diffusion for short duration signals, but at SELs and tissue saturation levels that are highly improbable to occur in diving marine mammals. To date, energy levels predicted to cause in vivo bubble formation within diving cetaceans have not been evaluated (NOAA, 2002b). Jepson *et al.* (2003, 2005) and Fernandez *et al.* (2004, 2005) concluded that in vivo bubble formation, which may be exacerbated by deep, long-duration, repetitive dives may explain why beaked whales appear to be relatively vulnerable to MFAS/HFAS exposures. It has also been argued that traumas from some beaked whale strandings are consistent with gas emboli and bubble-induced tissue separations (Jepson *et al.,* 2003); however, there is no conclusive evidence of this (Rommel *et al.,* 2006). Based on examination of sonar-associated strandings, Bernaldo de Quiros *et al.* (2019) list diagnostic features, the presence of all of which suggest gas and fat embolic syndrome for beaked whales stranded in association with sonar exposure.

As described in additional detail in the Behaviorally Mediated Injury section of appendix D the 2024 HCTT Draft EIS/OEIS, marine mammals

generally are thought to deal with nitrogen loads in their blood and other tissues, caused by gas exchange from the lungs under conditions of high ambient pressure during diving, through anatomical, behavioral, and physiological adaptations (Hooker *et al.,* 2012). Although not a direct injury, variations in marine mammal diving behavior or avoidance responses have been hypothesized to result in nitrogen off-gassing in super-saturated tissues, possibly to the point of deleterious vascular and tissue bubble formation (Hooker *et al.,* 2012; Jepson *et al.,* 2003; Saunders *et al.,* 2008) with resulting symptoms similar to decompression sickness, however the process is still not well understood.

In 2009, Hooker *et al.* tested two mathematical models to predict blood and tissue tension N2 (P_{N2}) using field data from three beaked whale species: northern bottlenose whales, goose-beaked whales, and Blainville's beaked whales. The researchers aimed to determine if physiology (body mass, diving lung volume, and dive response) or dive behavior (dive depth and duration, changes in ascent rate, and diel behavior) would lead to differences in P_{N2} levels and thereby decompression sickness risk between species. In their study, they compared results for previously published time depth recorder data (Hooker and Baird, 1999; Baird *et al.,* 2006, 2008) from goose-beaked whale, Blainville's beaked whale, and northern bottlenose whale. They reported that diving lung volume and extent of the dive response had a large effect on end-dive P_{N2}. Also, results showed that dive profiles had a larger influence on end-dive P_{N2} than body mass differences between species. Despite diel changes (*i.e.,* variation that occurs regularly every day or most days) in dive behavior, P_{N2} levels showed no consistent trend. Model output suggested that all three species live with tissue P_{N2} levels that would cause a significant proportion of decompression sickness cases in terrestrial mammals. The authors concluded that the dive behavior of goose-beaked whale was different from both Blainville's beaked whale and northern bottlenose whale and resulted in higher predicted tissue and blood N2 levels (Hooker *et al.,* 2009). They also suggested that the prevalence of goose-beaked whales stranding after naval sonar exercises could be explained by either a higher abundance of this species in the affected areas or by possible species differences in behavior and/or physiology related to MF active sonar (Hooker *et al.,* 2009).

Bernaldo de Quiros *et al.* (2012) showed that, among stranded whales, deep diving species of whales had higher abundances of gas bubbles compared to shallow diving species. Kvadsheim *et al.* (2012) estimated blood and tissue P_{N2} levels in species representing shallow, intermediate, and deep diving cetaceans following behavioral responses to sonar and their comparisons found that deep diving species had higher end-dive blood and tissue N2 levels, indicating a higher risk of developing gas bubble emboli compared with shallow diving species. Fahlmann *et al.* (2014) evaluated dive data recorded from sperm, killer, long-finned pilot, Blainville's, and goose-beaked whales before and during exposure to low-frequency (1–2 kHz), as defined by the authors, and mid-frequency (2–7 kHz) active sonar in an attempt to determine if either differences in dive behavior or physiological responses to sonar are plausible risk factors for bubble formation. The authors suggested that CO_2 may initiate bubble formation and growth, while elevated levels of N2 may be important for continued bubble growth. The authors also suggest that if CO_2 plays an important role in bubble formation, a cetacean escaping a sound source may experience increased metabolic rate, CO_2 production, and alteration in cardiac output, which could increase risk of gas bubble emboli. However, as discussed in Kvadsheim *et al.* (2012), the actual observed behavioral responses to sonar from the species in their study (sperm, killer, long-finned pilot, Blainville's beaked, and goose-beaked whales) did not imply any significantly increased risk of decompression sickness due to high levels of N2. Therefore, further information is needed to understand the relationship between exposure to stimuli, behavioral response (discussed in more detail below), elevated N2 levels, and gas bubble emboli in marine mammals. The hypotheses for gas bubble formation related to beaked whale strandings is that beaked whales potentially have strong avoidance responses to MFAS because they sound similar to their main predator, the killer whale (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Baird *et al.,* 2008; Hooker *et al.,* 2009). Further investigation is needed to assess the potential validity of these hypotheses.

To summarize, while there are several hypotheses, there is little data directly connecting intense, anthropogenic underwater sounds with non-auditory physical effects in marine mammals. The available data do not support identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.,* 2007) or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in these ways. In addition, such effects, if they occur at all, would be expected to be limited to situations where marine mammals were exposed to high powered sounds at very close range over a prolonged period of time, which is not expected to occur based on the speed of the vessels operating sonar in combination with the speed and behavior of marine mammals in the vicinity of sonar.

An object exposed to its resonant frequency will tend to amplify its vibration at that frequency, a phenomenon called acoustic resonance. Acoustic resonance has been proposed as a potential mechanism by which a sonar or sources with similar operating characteristics could damage tissues of marine mammals. In 2002, NMFS convened a panel of government and private scientists to investigate the potential for acoustic resonance to occur in marine mammals (NOAA, 2002). They modeled and evaluated the likelihood that Navy MFAS (2–10 kHz) caused resonance effects in beaked whales that eventually led to their stranding. The workshop participants concluded that resonance in air-filled structures was not likely to have played a primary role in the Bahamas stranding in 2000. They listed several reasons supporting this finding including (among others): tissue displacements at resonance are estimated to be too small to cause tissue damage; tissue-lined air spaces most susceptible to resonance are too large in marine mammals to have resonant frequencies in the ranges used by MFAS or LFAS; lung resonant frequencies increase with depth, and tissue displacements decrease with depth so if resonance is more likely to be caused at depth it is also less likely to have an affect there; and lung tissue damage has not been observed in any mass, multi-species stranding of beaked whales. The frequency at which resonance was predicted to occur in the animals' lungs was 50 Hz, well below the frequencies used by the MFAS systems associated with the Bahamas event. The workshop participants focused on the March 2000 stranding of beaked whales in the Bahamas as high-quality data were available, but the workshop report notes that the results apply to other sonar-related stranding events. For the reasons given by the 2002 workshop participants, we do not anticipate injury due to sonar-induced acoustic resonance from the Action Proponents' proposed activity.

Potential Effects of Explosive Sources on Marine Mammals

Explosive detonations that occur in water send a shock wave and sound energy through the water and can release gaseous by-products, create an oscillating bubble, or cause a plume of water to shoot up from the water surface. The shock wave and accompanying noise are of most concern to marine animals and the potential effects of an explosive injury to marine mammals would consist of primary blast injury, which refers to injuries resulting from the compression of a body exposed to a blast wave. Blast effects are greatest at the gas-liquid interface (Landsberg, 2000) and are usually observed as barotrauma of gas-containing structures (*e.g.,* lung, gastrointestinal tract) and structural damage to the auditory system (Goertner, 1982; Greaves *et al.,* 1943; Hill, 1978; Office of the Surgeon General, 1991; Richmond *et al.,* 1973; Yelverton *et al.,* 1973). Depending on the intensity of the shock wave and size, location, and depth of the animal, an animal can be injured, killed, suffer non-lethal physical effects, experience hearing related effects with or without behavioral responses, or exhibit temporary behavioral responses or tolerance from hearing the blast sound. Generally, exposures to higher levels of impulse and pressure levels would result in greater impacts to an individual animal.

The near instantaneous high magnitude pressure change near an explosion can injure an animal where tissue material properties significantly differ from the surrounding environment, such as around air-filled cavities in the lungs or gastrointestinal tract. Large pressure changes at tissue-air interfaces in the lungs and gastrointestinal tract may cause tissue rupture, resulting in a range of injuries depending on degree of exposure. The lungs are typically the first site to show any damage, while the solid organs (*e.g.,* liver, spleen, and kidney) are more resistant to blast injury (Clark and Ward, 1943). Odontocetes can also incur hemorrhaging in the acoustic fats in the melon and jaw (Siebert *et al.,* 2022). Recoverable injuries would include slight lung injury, such as capillary interstitial bleeding, and contusions to the gastrointestinal tract. More severe injuries, such as tissue lacerations, major hemorrhage, organ rupture, or air in the chest cavity (pneumothorax), would significantly reduce fitness and likely cause death in the wild. Rupture of the lung may also introduce air into the vascular system, producing air emboli that can cause a stroke or heart attack by restricting oxygen delivery to critical organs.

Injuries resulting from a shock wave take place at boundaries between tissues of different densities. Different velocities are imparted to tissues of different densities, and this can lead to their physical disruption. Intestinal walls can bruise or rupture, with subsequent hemorrhage and escape of gut contents into the body cavity. Less severe gastrointestinal tract injuries include contusions, petechiae (*i.e.,* small red or purple spots caused by bleeding in the skin), and slight hemorrhaging (Yelverton *et al.,* 1973).

Relatively little is known about auditory system trauma in marine mammals resulting from explosive exposure, although it is assumed that auditory structures would be vulnerable to blast injuries because the ears are the most sensitive to pressure and, therefore, they are the organs most sensitive to injury (Ketten, 2000). Sound-related damage associated with sound energy from detonations can be theoretically distinct from injury from the shock wave, particularly farther from the explosion. If a noise is audible to an animal, it has the potential to damage the animal's hearing by causing decreased sensitivity (Ketten, 1995). Lethal impacts are those that result in immediate death or serious debilitation in or near an intense source and are not, technically, pure acoustic trauma (Ketten, 1995). Sublethal impacts include hearing loss, which is caused by exposures to perceptible sounds. Severe damage (from the shock wave) to the ears includes tympanic membrane rupture, fracture of the ossicles, damage to the cochlea, hemorrhage, and cerebrospinal fluid leakage into the middle ear. Moderate injury implies partial hearing loss due to tympanic membrane rupture and blood in the middle ear. Permanent hearing loss also can occur when the hair cells are damaged by one very loud event, as well as by prolonged exposure to a loud noise or chronic exposure to noise. The level of impact from blasts depends on both an animal's location and, at outer zones, on its sensitivity to the residual noise (Ketten, 1995). Auditory trauma was found in 2 humpback whales that died after the detonation of an 11,023 lb (5,000 kg) explosive used off Newfoundland during demolition of an offshore oil rig platform (Ketten *et al.,* 1993), but the proximity of the whales to the detonation was unknown. Eardrum rupture was examined in submerged terrestrial mammals exposed to underwater explosions (Richmond *et al.,* 1973; Yelverton *et al.,* 1973); however, results may not be applicable to the anatomical adaptations for underwater hearing in marine mammals given differences in impedance (Wartzok and Ketten 1999).

In general, models predict that an animal would be less susceptible to injury near the water surface because the pressure wave reflected from the water surface would interfere with the direct path pressure wave, reducing positive pressure exposure (Goertner, 1982; Yelverton and Richmond, 1981). This is shown in the records of humans exposed to blast while in the water, which show that the gastrointestinal tract was more likely to be injured than the lungs, likely due to the shallower exposure geometry of the lungs (*i.e.,* closer to the water surface) (Lance *et al.,* 2015). Susceptibility would increase with depth, until normal lung collapse (due to increasing hydrostatic pressure) and increasing ambient pressures again reduce susceptibility (Goertner, 1982). The only known occurrence of mortality or injury to a marine mammal due to a Navy training event involving explosives occurred in March 2011 in nearshore waters off San Diego, California, at the Silver Strand Training Complex (see Strandings Associated with Explosive Use section below).

Controlled tests with a variety of lab animals (*i.e.,* mice, rats, dogs, pigs, sheep, and other species) are the best data sources on actual injury to mammals due to underwater exposure to explosions. In the early 1970s, the Lovelace Foundation for Medical Education and Research conducted a series of tests in an artificial pond at Kirtland Air Force Base, New Mexico, to determine the effects of underwater explosions on mammals, with the goal of determining safe ranges for human divers. The resulting data were summarized in two reports (Richmond *et al.,* 1973; Yelverton *et al.,* 1973). Specific physiological observations for each test animal are documented in Richmond *et al.* (1973). Gas-containing internal organs, such as lungs and intestines, were the principle damage sites in submerged terrestrial mammals; this is consistent with earlier studies of mammal exposures to underwater explosions in which lungs were consistently the first areas to show damage, with less consistent damage observed in the gastrointestinal tract (Clark and Ward, 1943; Greaves *et al.,* 1943).

In the Lovelace studies, the first positive acoustic impulse was found to be the metric most related to degree of injury, and size of an animal's gas-containing cavities was thought to play a role in blast injury susceptibility. For

these shallow exposures of small terrestrial mammals (masses ranging from 3.4 to 50 kg) to underwater detonations, Richmond *et al.* (1973) reported that no blast injuries were observed when exposures were less than 6 pounds per square inch per millisecond (psi-ms) (40 pascal seconds (Pa-s)), no instances of slight lung hemorrhage occurred below 20 psi-ms (140 Pa-s), and instances of no lung damage were observed in some exposures at higher levels up to 40 psi-ms (280 Pa-s). An impulse of 34 psi-ms (230 Pa-s) resulted in about 50 percent incidence of slight lung hemorrhage. About half of the animals had gastrointestinal tract contusions (with slight ulceration, *i.e.,* some perforation of the mucosal layer) at exposures of 25–27 psi-ms (170–190 Pa-s). Lung injuries were found to be slightly more prevalent than gastrointestinal tract injuries for the same exposure. The anatomical differences between the terrestrial animals used in the Lovelace tests and marine mammals are summarized in Fetherston *et al.* (2019). Goertner (1982) examined how lung cavity size would affect susceptibility to blast injury by considering both marine mammal size and depth in a bubble oscillation model of the lung; however, the Goertner (1982) model did not consider how tissues surrounding the respiratory air spaces would reflect shock wave energy or constrain oscillation (Fetherston *et al.,* 2019).

Goertner (1982) suggested a peak overpressure gastrointestinal tract injury criterion because the size of gas bubbles in the gastrointestinal tract are variable, and their oscillation period could be short relative to primary blast wave exposure duration. The potential for gastrointestinal tract injury, therefore, may not be adequately modeled by the single oscillation bubble methodology used to estimate lung injury due to impulse. Like impulse, however, high instantaneous pressures may damage many parts of the body, but damage to the gastrointestinal tract is used as an indicator of any peak pressure-induced injury due to its vulnerability.

Because gas-containing organs are more vulnerable to primary blast injury, adaptations for diving that allow for collapse of lung tissues with depth may make animals less vulnerable to lung injury with depth. Adaptations for diving include a flexible thoracic cavity, distensible veins that can fill space as air compresses, elastic lung tissue, and resilient tracheas with interlocking cartilaginous rings that provide strength and flexibility (Ridgway, 1972). Denk *et al.* (2020) found intra-species differences in the compliance of tracheobronchial structures of post-mortem cetaceans and pinnipeds under diving hydrostatic pressures, which would affect depth of alveolar collapse. Older literature suggested complete lung collapse depths at approximately 229.7 ft (70 m) for dolphins (Ridgway and Howard, 1979) and 65.6 to 164 ft (20 to 50 m) for phocid seals (Falke *et al.,* 1985; Kooyman *et al.,* 1972). Follow-on work by Kooyman and Sinnett (1982), in which pulmonary shunting was studied in harbor seals and sea lions, suggested that complete lung collapse for these species would be about 557.7 ft (170 m) and about 590.6 (180 m), respectively. Evidence in sea lions suggests that complete collapse might not occur until depths as great as 738.2 ft (225 m); although the depth of collapse and depth of the dive are related, sea lions can affect the depth of lung collapse by varying the amount of air inhaled on a dive (McDonald and Ponganis, 2012). This is an important consideration for all divers who can modulate lung volume and gas exchange prior to diving via the degree of inhalation and during diving via exhalation (Fahlman *et al.,* 2009); indeed, there are noted differences in pre-dive respiratory behavior, with some marine mammals exhibiting pre-dive exhalation to reduce the lung volume (*e.g.,* phocid seals) (Kooyman *et al.,* 1973).

Further Potential Effects of Behavioral Disturbance on Marine Mammal Fitness

The different ways in which marine mammals respond to sound are sometimes indicators of the ultimate effect that exposure to a given stimulus will have on the well-being (survival, reproduction, *etc.*) of an animal. The long-term consequences of disturbance, hearing loss, chronic masking, and acute or chronic physiological stress are difficult to predict because of the different factors experienced by individual animals, such as context of stressor exposure, underlying health conditions, and other environmental or anthropogenic stressors. Linking these non-lethal effects on individuals to changes in population growth rates requires long-term data, which is lacking for many populations. We summarize several studies below, but there are few quantitative marine mammal data relating the exposure of marine mammals to sound to effects on reproduction or survival, though data exists for terrestrial species to which we can draw comparisons for marine mammals. Several authors have reported that disturbance stimuli may cause animals to abandon nesting and foraging sites (Sutherland and Crockford, 1993); may cause animals to increase their activity levels and suffer premature deaths or reduced reproductive success when their energy expenditures exceed their energy budgets (Daan *et al.,* 1996; Feare, 1976; Mullner *et al.,* 2004); or may cause animals to experience higher predation rates when they adopt risk-prone foraging or migratory strategies (Frid and Dill, 2002). Each of these studies addressed the consequences of animals shifting from one behavioral state (*e.g.,* resting or foraging) to another behavioral state (*e.g.,* avoidance or escape behavior) because of human disturbance or disturbance stimuli.

Lusseau and Bejder (2007) present data from three long-term studies illustrating the connections between disturbance from whale-watching boats and population-level effects in cetaceans. In Shark Bay Australia, the abundance of bottlenose dolphins was compared within adjacent control and tourism sites over three consecutive 4.5-year periods of increasing tourism levels. Between the second and third time periods, in which tourism doubled, dolphin abundance decreased by 15 percent in the tourism area and did not change significantly in the control area. In Fiordland, New Zealand, two populations (Milford and Doubtful Sounds) of bottlenose dolphins with tourism levels that differed by a factor of seven were observed and significant increases in travelling time and decreases in resting time were documented for both. Consistent short-term avoidance strategies were observed in response to tour boats until a threshold of disturbance was reached (average 68 minutes between interactions), after which the response switched to a longer-term habitat displacement strategy. For one population, tourism only occurred in a part of the home range. However, tourism occurred throughout the home range of the Doubtful Sound population and once boat traffic increased beyond the 68-minute threshold (resulting in abandonment of their home range/preferred habitat), reproductive success drastically decreased (*i.e.,* increased stillbirths) and abundance decreased significantly (from 67 to 56 individuals in a short period). Last, in a study of Northern Resident killer whales off Vancouver Island, exposure to boat traffic was shown to reduce foraging opportunities and increase traveling time. A simple bioenergetics model was applied to show that the reduced foraging opportunities equated to a decreased energy intake of 18 percent, while the increased traveling incurred

an increased energy output of 3–4 percent, which suggests that a management action based on avoiding interference with foraging might be particularly effective.

An important variable to consider is duration of disturbance. Severity scales used to assess behavioral responses of marine mammals to acute sound exposures are not appropriate to apply to sustained or chronic exposures, which requires considering the health of a population over time rather than a focus on immediate impacts to individuals (Southall *et al.,* 2021). For example, short-term costs experienced over the course of a week by an otherwise healthy individual may be recouped over time after exposure to the stressor ends. These short-term costs would be unlikely to result in long-term consequences to that individual or to that individual's population. Comparatively, long-term costs accumulated by otherwise healthy individuals over an entire season, year, or throughout a life stage (*e.g.,* pup, juvenile, adult) would be less easily recouped and more likely to result in long-term consequences to that individual or population.

Marine mammals exposed to frequent or intense anthropogenic activities may leave the area, habituate to the activity, or tolerate the disturbance and remain in the area (Wartzok *et al.,* 2003). Highly resident or localized populations may also stay in an area of disturbance because the cost of displacement is higher than the cost of remaining in the area (Forney *et al.,* 2017). As such, an apparent lack of response (*e.g.,* no displacement or avoidance of a sound source) does not necessarily indicate there is no cost to the individual or population, as some resources or habitats may be of such high value that animals may choose to stay, even when experiencing the consequences of stress, masking, or hearing loss (Forney *et al.,* 2017).

Longer term displacement can lead to changes in abundance or distribution patterns of the species in the affected region (Bejder *et al.,* 2006b; Blackwell *et al.,* 2004; Teilmann *et al.,* 2006). For example, gray whales in Baja California, Mexico, abandoned a historical breeding lagoon in the mid-1960s due to an increase in dredging and commercial shipping operations, and only repopulated the lagoon after shipping activities had ceased for several years (Bryant *et al.,* 1984). Mysticetes in the northeast tended to adjust to vessel traffic over several years, trending towards more neutral behavioral responses to passing vessels (Watkins, 1986), indicating that some animals may habituate to high levels of human activity. A study on bottlenose dolphin responses to vessel approaches found that lesser responses in populations of dolphins regularly subjected to high levels of vessel traffic could be a sign of habituation, or it could be that the more sensitive animals in this population previously abandoned the area of higher human activity (Bejder *et al.,* 2006a).

Population characteristics (*e.g.,* whether a population is open or closed to immigration and emigration) can influence sensitivity to disturbance as well; closed populations could not withstand a higher probability of disturbance compared to open populations with no limitation on food (New *et al.,* 2020). Predicting population trends or long-term displacement patterns due to anthropogenic disturbance is challenging due to limited information and survey data for many species over sufficient spatiotemporal scales, as well as a full understanding of how other factors, such as oceanographic oscillations, affect marine mammal presence (Moore and Barlow, 2013; Barlow, 2016; Moore and Barlow, 2017).

Population models are necessary to understand and link short-term effects to individuals from disturbance (anthropogenic impacts or environmental change) to long-term population consequences. Population models require inputs for the population size and changes in vital rates of the population (*e.g.,* the mean values for survival age, lifetime reproductive success, recruitment of new individuals into the population), to predict changes in population dynamics (*e.g.,* population growth rate). These efforts often rely on bioenergetic models, or energy budget models, which analyze energy intake from food and energy costs for life functions, such as maintenance, growth, and reproduction, either at the individual or population level (Pirotta, 2022), and model sensitivity analyses have identified the most consequential parameters, including prey characteristics, feeding processes, energy expenditure, body size, energy storage, and lactation capability (Pirotta, 2022). However, there is a high level of uncertainty around many parameters in these models (Hütt *et al.,* 2023).

The U.S. National Research Council (NRC) committee on Characterizing Biologically Significant Marine Mammal Behavior developed an initial conceptual model to link acoustic disturbance to population effects and inform data and research needs (NRC, 2005). This Population Consequences of Acoustic Disturbance, or PCAD, conceptual model linked the parameters of sound exposure, behavior change, life function immediately affected, vital rates, and population effects. In its report, the committee found that the relationships between vital rates and population effects were relatively well understood, but that the relationships between the other components of the model were not well-known or easily observed.

Following the PCAD framework (NRC, 2005), an ONR working group developed the Potential Consequences of Disturbance (PCoD), outlining an updated conceptual model of the relationships linking disturbance to changes in behavior and physiology, health, vital rates, and population dynamics. The PCoD model considers all types of disturbance, not solely anthropogenic or acoustic, and incorporates physiological changes, such as stress or injury, along with behavioral changes as a direct result of disturbance (National Academies of Sciences Engineering and Medicine, 2017). In this framework, behavioral and physiological changes can have direct (acute) effects on vital rates, such as when changes in habitat use or increased stress levels raise the probability of mother-calf separation or predation; they can have indirect and long-term (chronic) effects on vital rates, such as when changes in time/energy budgets or increased disease susceptibility affect health, which then affects vital rates; or they can have no effect to vital rates (New *et al.,* 2014; Pirotta *et al.,* 2018a). In addition to outlining this general framework and compiling the relevant literature that supports it, the authors chose four example species for which extensive long-term monitoring data exist (southern elephant seals, North Atlantic right whale, *Ziphiidae* beaked whales, and bottlenose dolphins) and developed state-space energetic models that can be used to forecast longer-term, population-level impacts from behavioral changes. While these models cannot yet be applied broadly to project-specific risk assessments for the majority of species, as well as requiring significant resources and time to conduct (more than is typically available to support regulatory compliance for one project), they are a critical first step towards being able to quantify the likelihood of a population level effect. Since New *et al.* (2014), several publications have described models developed to examine the long-term effects of environmental or anthropogenic disturbance of foraging on various life stages of selected species

(sperm whale, Farmer *et al.* (2018); California sea lion, McHuron *et al.* (2018); and blue whale, Pirotta, *et al.* (2018a)).

The PCoD model identifies the types of data that would be needed to assess population-level impacts. These data are lacking for many marine mammal species (Booth *et al.,* 2020). Southall *et al.* (2021) states that future modeling and population simulation studies can help determine population-wide long-term consequences and impact analysis. However, the method to do so is still developing, as there are gaps in the literature, possible sampling biases, and results are rarely ground-truthed, with a few exceptions (Booth *et al.,* 2022; Schwarz *et al.,* 2022). Nowacek *et al.* (2016) reviewed technologies such as passive acoustic monitoring, tagging, and the use of unmanned aerial vehicles which can improve scientists' abilities to study these model inputs and link behavioral changes to individual life functions and ultimately population-level effects. Relevant data needed for improving analyses of population-level consequences resulting from disturbances will continue to be collected during the 7-year period of the LOAs through projects funded by the Navy's Marine Species Monitoring Program. Multiple case studies across marine mammal taxonomic groups have been conducted following the PCoD framework. From these studies, Keen *et al.* (2021) identified themes and contextual factors relevant to assessing impacts to populations due to disturbance, which have been considered in the context of the impacts of the Action Proponents' activities.

A population's movement ecology determines the potential for spatiotemporal overlap with a disturbance. Resident populations or populations that rely on spatially limited habitats for critical life functions (*i.e.,* foraging, breeding) would be at greater risk of repeated or chronic exposure to disturbances than populations that are wide-ranging relative to the footprint of a disturbance (Keen *et al.,* 2021). Even for the same species, differences in habitat use between populations can result in different potential for repeated exposure to individuals for a similar stressor (Costa *et al.,* 2016a). The location and radius of disturbance can impact how many animals are exposed and for how long (Costa *et al.,* 2016b). While some models have shown the advantages of populations with larger ranges, namely the decreased chance of being exposed (Costa *et al.,* 2016b), it's important to consider that for some species, the energetic cost of a longer migration could make a population more sensitive to energy lost through disturbance (Villegas-Amtmann *et al.,* 2017). In addition to ranging patterns, a species' activity budgets and lunging rates can cause variability in their predicted cost of disturbance as well (Pirotta *et al.,* 2021).

Bioenergetics frameworks that examine the impact of foraging disruption on body reserves of individual whales found that rates of daily foraging disruption can predict the number of days to terminal starvation for various life stages (Farmer *et al.,* 2018b). Similarly, when a population is displaced by a stressor, and only has access to areas of poor habitat quality (*i.e.,* low prey abundance) for relocation, bioenergetic models may be more likely to predict starvation, longer recovery times, or extinction (Hin *et al.,* 2023). There is some debate over the use of blubber thickness as a metric of cetacean energy stores and health, as marine mammals may not use their fat stores in a similar manner to terrestrial mammals (Derous *et al.,* 2020).

Resource limitation can impact marine mammal population growth rate regardless of additional anthropogenic disturbance. Stochastic Dynamic Programming models have been used to explore the impact declining prey species has on focal marine mammal predators (McHuron *et al.,* 2023a; McHuron *et al.,* 2023b). A Stochastic Dynamic Programming model determined that a decrease in walleye pollock (*Gadus chalcogrammus*) availability increased the time and distance northern fur seal mothers had to travel offshore, which negatively impacted pup growth rate and wean mass, despite attempts to compensate with longer recovery time on land (McHuron *et al.,* 2023b). Prey is an important factor in long-term consequence models for many species of marine mammals. In disturbance models that predict habitat displacement or otherwise reduced foraging opportunities, populations are being deprived of energy dense prey or ''high quality'' areas which can lead to long-term impacts on fecundity and survival (Czapanskiy *et al.,* 2021; Hin *et al.,* 2019; McHuron *et al.,* 2023a; New *et al.,* 2013b). Prey density limits the energy available for growth, reproduction, and survival. Some disturbance models indicate that the immediate decrease in a portion of the population (*e.g.,* young lactating mothers) is not necessarily detrimental to a population, since as a result, prey availability increases and the population's overall improved body condition reduces the age at first calf (Hin *et al.,* 2021). The timing of a disturbance with seasonally available resources is also important; if a disturbance occurs during periods of low resource availability, the population-level consequences are greater and occur faster than if the disturbance occurs during periods when resource levels are high (Hin *et al.,* 2019). Further, when resources are not evenly distributed, populations with cautious strategies and knowledge of resource variation have an advantage (Pirotta *et al.,* 2020).

Even when modeled alongside several anthropogenic sources of disturbance (*e.g.,* vessel strike, vessel noise, chemical contaminants, sonar), several species of marine mammals are most influenced by lack of prey (Czapanskiy *et al.,* 2021; Murray *et al.,* 2021). Some species like killer whales are especially sensitive to prey abundance due to their limited diet (Murray *et al.,* 2021). The short-term energetic cost of eleven species of cetaceans and mysticetes exposed to mid-frequency active sonar was influenced more by lost foraging opportunities than increased locomotor effort during avoidance (Czapanskiy *et al.,* 2021). Additionally, the model found that mysticetes incurred more energetic cost than odontocetes, even during mild behavioral responses to sonar. These results may be useful in the development of future Population Consequences of Multiple Stressors and PCoD models since they should seek to qualify cetacean health in a more ecologically relevant manner.

PCoD models have been used to assess the impacts of multiple and recurring stressors. A marine mammal population that is already subject to chronic stressors will likely be more vulnerable to acute disturbances. Models that have looked at populations of cetaceans who are exposed to multiple stressors over several years have found that even one major chronic stressor (*e.g.,* epizootic disease, oil spill) has severe impacts on population size. A layer of one or more stressor (*e.g.,* seismic surveys) in addition to a chronic stressor (*e.g.,* an oil spill) can yield devastating impacts on a population. These results may vary based on species and location, as one population may be more impacted by chronic shipping noise, while another population may not. However, just because a population doesn't appear to be impacted by one chronic stressor (*e.g.,* shipping noise), does not mean they aren't affected by others (*e.g.,* disease) (Reed *et al.,* 2020). Recurring or chronic stressors can impact population abundance even when instances of disturbance are short and have minimal behavioral impact on

an individual (Farmer *et al.,* 2018a; McHuron *et al.,* 2018b; Pirotta *et al.,* 2019). Some changes to response variables like pup recruitment (survival to age one) are not noticeable for several years, as the impacts on pup survival does not affect the population until those pups are mature but impacts to young animals will ultimately lead to population-wide declines. The severity of the repeated disturbance can also impact a population's long-term reproductive success. Scenarios with severe repeated disturbance (*e.g.,* 95 percent probability of exposure, with 95 percent reduction in feeding efficiency) can severely reduce fecundity and calf survival, while a weaker disturbance (25 percent probability of exposure, with 25 percent reduction in feeding efficiency) had no population-wide effect on vital rates (Pirotta *et al.,* 2019).

Farmer *et al.* (2018a) modeled how an oil spill led to chronic declines in a sperm whale population over 10 years, and if models included even one more stressor (*i.e.,* behavioral responses to air guns), the population declined even further. However, the amount of additional population decline due to acoustic disturbance depended on the way the dose-response of the noise levels were modeled. A single step-function led to higher impacts than a function with multiple steps and frequency weighting. In addition, the amount of impact from both disturbances was mediated when the metric in the model that described animal resilience was changed to increase resilience to disturbance (*e.g.,* able to make up reserves through increased foraging).

Not all stressors have the same impact for all species and all locations. Another model analyzed the effect of a number of chronic disturbances on two bottlenose dolphin populations in Australia over 5 years (Reed *et al.,* 2020). Results indicated that disturbance from fisheries interactions and shipping noise had little overall impact on population abundances in either location, even in the most extreme impact scenarios modeled. At least in this area, other factors (*e.g.,* epizootic scenarios) had the largest impact on population size and fecundity.

Recurring stressors can impact population abundance even when individual instances of disturbance are short and have minimal behavioral impact on an individual. A model on California sea lions introduced a generalized disturbance at different times throughout the breeding cycle, with their behavior response being an increase in the duration of a foraging trip by the female (McHuron *et al.,* 2018b). Very short duration disturbances or responses led to little change, particularly if the disturbance was a single event, and changes in the timing of the event in the year had little effect. However, with even relatively short disturbances or mild responses, when a disturbance was modeled as recurring there were resulting reductions in population size and pup recruitment (survival to age one). Often, the effects weren't noticeable for several years, as the impacts on pup survival did not affect the population until those pups were mature.

Stranding and Mortality

The definition for a stranding under title IV of the MMPA is an event in the wild in which (A) a marine mammal is dead and is (i) on a beach or shore of the United States; or (ii) in waters under the jurisdiction of the United States (including any navigable waters); or (B) a marine mammal is alive and is (i) on a beach or shore of the United States and is unable to return to the water; (ii) on a beach or shore of the United States and, although able to return to the water, is in need of apparent medical attention; or (iii) in the waters under the jurisdiction of the United States (including any navigable waters), but is unable to return to its natural habitat under its own power or without assistance (see 16 U.S.C. 1421h(6)). This definition is useful for considering stranding events even when they occur beyond lands and waters under the jurisdiction of the United States.

Marine mammal strandings have been linked to a variety of causes, such as illness from exposure to infectious agents, biotoxins, or parasites; starvation; unusual oceanographic or weather events; or anthropogenic causes including fishery interaction, vessel strike, entrainment, entrapment, sound exposure, or combinations of these stressors sustained concurrently or in series. Historically, the cause or causes of most strandings have remained unknown (*e.g.,* Odell *et al.,* 1980), but the development of trained, professional stranding response networks and improved analyses have led to a greater understanding of marine mammal stranding causes (Simeone and Moore 2018).

Numerous studies suggest that the physiology, behavior, habitat, social relationships, age, or condition of cetaceans may cause them to strand or might predispose them to strand when exposed to another phenomenon. These suggestions are consistent with the conclusions of numerous other studies that have demonstrated that combinations of dissimilar stressors commonly combine to kill an animal or dramatically reduce its fitness, even though one exposure without the other does not produce the same result (Bernaldo de Quiros *et al.,* 2019; Chroussos, 2000; Creel, 2005 Fair and Becker, 2000; Foley *et al.,* 2001; Moberg, 2000; Relyea, 2005a; 2005b, Romero, 2004; Sih *et al.,* 2004).

Historically, stranding reporting and response efforts have been inconsistent, although significant improvements have occurred over the last 25 years. Reporting forms for basic (''Level A'') information, rehabilitation disposition, and human interaction have been standardized nationally are available at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/level-data-collection-marine-mammal-stranding-events.* However, data collected beyond basic information varies by region (and may vary from case to case) and are not standardized across the United States. Logistical conditions such as weather, time, location, and decomposition state may also affect the ability of the stranding network to thoroughly examine a specimen (Carretta *et al.,* 2023; Moore *et al.,* 2013). While the investigation of stranded animals provides insight into the types of threats marine mammal populations face, full investigations are only possible and conducted on a small fraction of the total number of strandings that occur, limiting our understanding of the causes of strandings (Carretta *et al.,* 2016a). Additionally, and due to the variability in effort and data collected, the ability to interpret long-term trends in stranded marine mammals is complicated.

In the United States from 2006–2022, there were 27,781 cetacean strandings and 79,572 pinniped strandings (107,353 total) (P. Onens, NMFS, *pers comm.,* 2024). Several mass strandings (strandings that involve two or more individuals of the same species, excluding a single mother-calf pair) that have occurred over the past two decades have been associated with anthropogenic activities that introduced sound into the marine environment such as naval operations and seismic surveys. An in-depth discussion of strandings can be found in appendix D of the 2024 HCTT Draft EIS/OEIS and in the Navy's Technical Report on Marine Mammal Strandings Associated with U.S. Navy Sonar Activities (U.S. Navy Marine Mammal Program and Space and Naval Warfare Systems Command Center Pacific, 2017b).

Worldwide, there have been several efforts to identify relationships between cetacean mass stranding events and

military active sonar (Cox *et al.,* 2006, Hildebrand, 2004; Taylor *et al.,* 2004). D'Amico *et al.* (2009) reviewed beaked whale stranding data compiled primarily from the published literature, which provides an incomplete record of stranding events, as many are not written up for publication, along with unpublished information from some regions of the world.

Most of the stranding events reviewed by the IWC involved beaked whales. A mass stranding of goose-beaked whales in the eastern Mediterranean Sea occurred in 1996 (Frantzis, 1998), and mass stranding events involving Gervais' beaked whales, Blainville's beaked whales, and goose-beaked whales occurred off the coast of the Canary Islands in the late 1980s (Simmonds and Lopez-Jurado, 1991). The stranding events that occurred in the Canary Islands and Kyparissiakos Gulf in the late 1990s and the Bahamas in 2000 have been the most intensively-studied mass stranding events and have been associated with naval maneuvers involving the use of tactical sonar. Other cetacean species with naval sonar implicated in stranding events include harbor porpoise (Norman *et al.,* 2004, Wright *et al.,* 2013) and common dolphin (Jepson *et al.,* 2013).

Strandings Associated With Active Sonar

Over the past 21 years, there have been 5 stranding events coincident with naval MFAS use in which exposure to sonar is believed to have been a contributing factor: Greece (1996); the Bahamas (2000); Madeira (2000); Canary Islands (2002); and Spain (2006) (Cox *et al.,* 2006; Fernandez, 2006; U.S. Navy Marine Mammal Program and Space and Naval Warfare Systems Command Center Pacific, 2017). These five mass strandings have resulted in about 40 known cetacean deaths consisting mostly of beaked whales and with close linkages to MFAS activity. In these circumstances, exposure to non-impulsive acoustic energy was considered a potential indirect cause of death of the marine mammals (Cox *et al.,* 2006). Only one of these stranding events, the Bahamas (2000), was associated with exercises conducted by the U.S. Navy. Additionally, in 2004, during the RIMPAC exercises, between 150 and 200 usually pelagic melon-headed whales occupied the shallow waters of Hanalei Bay, Kaua'i, Hawaii for over 28 hours. NMFS determined that MFAS was a plausible, if not likely, contributing factor in what may have been a confluence of events that led to the Hanalei Bay stranding. A number of other stranding events coincident with the operation of MFAS, including the death of beaked whales or other species (*i.e.,* minke whales, dwarf sperm whales, pilot whales), have been reported; however, the majority have not been investigated to the degree necessary to determine the cause of the stranding. Most recently, the Independent Scientific Review Panel investigating potential contributing factors to a 2008 mass stranding of melon-headed whales in Antsohihy, Madagascar released its final report suggesting that the stranding was likely initially triggered by an industry seismic survey (Southall *et al.,* 2013). This report suggests that the operation of a commercial high-powered 12 kHz multibeam echosounder during an industry seismic survey was a plausible and likely initial trigger that caused a large group of melon-headed whales to leave their typical habitat and then ultimately strand as a result of secondary factors such as malnourishment and dehydration. The report indicates that the risk of this particular convergence of factors and ultimate outcome is likely very low but recommends that the potential be considered in environmental planning. Because of the association between tactical MFAS use and a limited number of marine mammal strandings, the Navy and NMFS have been considering and addressing the potential for strandings in association with Navy activities for years. In addition to the proposed mitigation measures intended to more broadly minimize impacts to marine mammals, the Navy will abide by the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or stranded marine mammals are detected in certain circumstances.

Greece (1996)—

Twelve goose-beaked whales stranded atypically (in both time and space) along a 23.7 mi (38.2 km) strand of the Kyparissiakos Gulf coast on May 12 and 13, 1996 (Frantzis, 1998). From May 11 through May 15, the North Atlantic Treaty Organization (NATO) research vessel Alliance was conducting sonar tests with signals of 600 Hz and 3 kHz and source levels of 228 and 226 dB re 1 µPa, respectively (D'Amico and Verboom, 1998; D'Spain *et al.,* 2006). The timing and location of the testing encompassed the time and location of the strandings (Frantzis, 1998).

Necropsies of eight of the animals were performed but were limited to basic external examination and sampling of stomach contents, blood, and skin. No ears or organs were collected, and no histological samples were preserved. No significant apparent abnormalities or wounds were found, however examination of photos of the animals, taken soon after their death, revealed that the eyes of at least four of the individuals were bleeding (Frantzis, 2004). Stomach contents contained the flesh of cephalopods, indicating that feeding had recently taken place (Frantzis, 1998).

All available information regarding the conditions associated with this stranding event was compiled, and many potential causes were examined including major pollution events, prominent tectonic activity, unusual physical or meteorological events, magnetic anomalies, epizootics, and conventional military activities (International Council for the Exploration of the Sea, 2005). However, none of these potential causes coincided in time or space with the mass stranding or could explain its characteristics (International Council for the Exploration of the Sea, 2005). The robust condition of the animals, plus the recent stomach contents, is inconsistent with pathogenic causes. In addition, environmental causes can be ruled out as there were no unusual environmental circumstances or events before or during this time period and within the general proximity (Frantzis, 2004).

Because of the rarity of this mass stranding of goose-beaked whales in the Kyparissiakos Gulf (first one in historical records), the probability for the two events (the military exercises and the strandings) to coincide in time and location, while being independent of each other, was thought to be extremely low (Frantzis, 1998). However, because full necropsies had not been conducted, and no abnormalities were noted, the cause of the strandings could not be precisely determined (Cox *et al.,* 2006). A Bioacoustics Panel convened by NATO concluded that the evidence available did not allow them to accept or reject sonar exposures as a causal agent in these stranding events. The analysis of this stranding event provided support for, but no clear evidence for, the cause-and-effect relationship of tactical sonar training activities and beaked whale strandings (Cox *et al.,* 2006).

Bahamas (2000)—

NMFS and the Navy prepared a joint report addressing the multi-species stranding in the Bahamas in 2000, which took place within 24 hours of U.S. Navy ships using MFAS as they passed through the Northeast and Northwest Providence Channels on March 15–16, 2000. The ships, which operated both AN/SQS–53C and AN/

SQS–56 sonar, moved through the channel while emitting pings approximately every 24 seconds. Of the 17 cetaceans that stranded over a 36-hour period (goose-beaked whales, Blainville's beaked whales, minke whales, and a spotted dolphin), 7 animals died on the beach (5 goose-beaked whales, 1 Blainville's beaked whale, and 1 spotted dolphin), while the other 10 were returned to the water alive (though their ultimate fate is unknown). As discussed in the Bahamas report (DOC/DON, 2001), there is no likely association between the minke whale and spotted dolphin strandings and the operation of MFAS.

Necropsies were performed on five of the stranded beaked whales. All five necropsied beaked whales were in good body condition, showing no signs of infection, disease, vessel strike, blunt trauma, or fishery related injuries, and three still had food remains in their stomachs. Auditory structural damage was discovered in four of the whales, specifically bloody effusions or hemorrhaging around the ears. Bilateral intracochlear and unilateral temporal region subarachnoid hemorrhage, with blood clots in the lateral ventricles, were found in two of the whales. Three of the whales had small hemorrhages in their acoustic fats (located along the jaw and in the melon).

A comprehensive investigation was conducted and all possible causes of the stranding event were considered, whether they seemed likely at the outset or not. Based on the way in which the strandings coincided with ongoing naval activity involving tactical MFAS use, in terms of both time and geography, the nature of the physiological effects experienced by the dead animals, and the absence of any other acoustic sources, the investigation team concluded that MFAS aboard U.S. Navy ships that were in use during the active sonar exercise in question were the most plausible source of this acoustic or impulse trauma to beaked whales. This sound source was active in a complex environment that included the presence of a surface duct, unusual and steep bathymetry, a constricted channel with limited egress, intensive use of multiple, active sonar units over an extended period of time, and the presence of beaked whales that appear to be sensitive to the frequencies produced by these active sonars. The investigation team concluded that the cause of this stranding event was the confluence of the Navy MFAS and these contributory factors working together and further recommended that the Navy avoid operating MFAS in situations where these five factors would be likely to occur. This report does not conclude that all five of these factors must be present for a stranding to occur, nor that beaked whales are the only species that could potentially be affected by the confluence of the other factors. Based on this, NMFS believes that the operation of MFAS in situations where surface ducts exist, or in marine environments defined by steep bathymetry and/or constricted channels may increase the likelihood of producing a sound field with the potential to cause cetaceans (especially beaked whales) to strand, and therefore, suggests the need for increased vigilance while operating MFAS in these areas, especially when beaked whales (or potentially other deep divers) are likely present.

Madeira, Portugal (2000)—

From May 10–14, 2000, three goose-beaked whales were found stranded on two islands in the Madeira Archipelago, Portugal (Cox *et al.,* 2006). A fourth animal was reported floating in the Madeiran waters by fisherman but did not come ashore (Ketten, 2005). Joint NATO amphibious training peacekeeping exercises involving participants from 17 countries and 80 warships, took place in Portugal during May 2–15, 2000.

The bodies of the three stranded whales were examined postmortem (Ketten, 2005), though only one of the stranded whales was fresh enough (24 hours after stranding) to be necropsied (Cox *et al.,* 2006). Results from the necropsy revealed evidence of hemorrhage and congestion in the right lung and both kidneys (Cox *et al.,* 2006). There was also evidence of intracochlear and intracranial hemorrhage similar to that which was observed in the whales that stranded in the Bahamas event (Cox *et al.,* 2006). There were no signs of blunt trauma, and no major fractures, and the cranial sinuses and airways were found to be clear with little or no fluid deposition, which may indicate good preservation of tissues (Woods Hole Oceanographic Institution, 2005).

Several observations on the Madeira stranded beaked whales, such as the pattern of injury to the auditory system, are the same as those observed in the Bahamas strandings. Blood in and around the eyes, kidney lesions, pleural hemorrhages, and congestion in the lungs are particularly consistent with the pathologies from the whales stranded in the Bahamas and are consistent with stress and pressure related trauma. The similarities in pathology and stranding patterns between these two events suggest that a similar pressure event may have precipitated or contributed to the strandings at both sites (Woods Hole Oceanographic Institution, 2005).

Even though no definitive causal link can be made between the stranding event and naval exercises, certain conditions may have existed in the exercise area that, in their aggregate, may have contributed to the marine mammal strandings (Freitas, 2004): Exercises were conducted in areas of at least 547 fathoms (1,000 m) depth near a shoreline where there is a rapid change in bathymetry on the order of 547 to 3,281 fathoms (1,000 to 6,000 m) occurring across a relatively short horizontal distance (Freitas, 2004); multiple ships were operating around Madeira, though it is not known if MFAS was used, and the specifics of the sound sources used are unknown (Cox *et al.,* 2006; Freitas, 2004); and exercises took place in an area surrounded by landmasses separated by less than 35 nmi (65 km) and at least 10 nmi (19 km) in length, or in an embayment. Exercises involving multiple ships employing MFAS near land may produce sound directed towards a channel or embayment that may cut off the lines of egress for marine mammals (Freitas, 2004).

Canary Islands, Spain (2002)—

The southeastern area within the Canary Islands is well known for aggregations of beaked whales due to its ocean depths of greater than 547 fathoms (1,000 m) within a few hundred meters of the coastline (Fernandez *et al.,* 2005). On September 24, 2002, 14 beaked whales were found stranded on Fuerteventura and Lanzarote Islands in the Canary Islands (International Council for Exploration of the Sea, 2005a). Seven whales died, while the remaining seven live whales were returned to deeper waters (Fernandez *et al.,* 2005). Four beaked whales were found stranded dead over the next three days either on the coast or floating offshore. These strandings occurred within close proximity of an international naval exercise that utilized MFAS and involved numerous surface warships and several submarines. Strandings began about four hours after the onset of MFAS activity (International Council for Exploration of the Sea, 2005a; Fernandez *et al.,* 2005).

Eight goose-beaked whales, one Blainville's beaked whale, and one Gervais' beaked whale were necropsied, six of them within 12 hours of stranding (Fernandez *et al.,* 2005). No pathogenic bacteria were isolated from the carcasses (Jepson *et al.,* 2003). The animals displayed severe vascular congestion and hemorrhage especially around the

tissues in the jaw, ears, brain, and kidneys, displaying marked disseminated microvascular hemorrhages associated with widespread fat emboli (Jepson *et al.,* 2003; International Council for Exploration of the Sea, 2005a). Several organs contained intravascular bubbles, although definitive evidence of gas embolism in vivo is difficult to determine after death (Jepson *et al.,* 2003). The livers of the necropsied animals were the most consistently affected organ, which contained macroscopic gas-filled cavities and had variable degrees of fibrotic encapsulation. In some animals, cavitary lesions had extensively replaced the normal tissue (Jepson *et al.,* 2003). Stomachs contained a large amount of fresh and undigested contents, suggesting a rapid onset of disease and death (Fernandez *et al.,* 2005). Head and neck lymph nodes were enlarged and congested, and parasites were found in the kidneys of all animals (Fernandez *et al.,* 2005).

The association of NATO MFAS use close in space and time to the beaked whale strandings, and the similarity between this stranding event and previous beaked whale mass strandings coincident with sonar use, suggests that a similar scenario and causative mechanism of stranding may be shared between the events. Beaked whales stranded in this event demonstrated brain and auditory system injuries, hemorrhages, and congestion in multiple organs, similar to the pathological findings of the Bahamas and Madeira stranding events. In addition, the necropsy results of the Canary Islands stranding event lead to the hypothesis that the presence of disseminated and widespread gas bubbles and fat emboli were indicative of nitrogen bubble formation, similar to what might be expected in decompression sickness (Jepson *et al.,* 2003; Fernández *et al.,* 2005).

Hanalei Bay (2004)—

On July 3 and 4, 2004, approximately 150 to 200 melon-headed whales occupied the shallow waters of Hanalei Bay, Kauaʻi, Hawaii for over 28 hours. Attendees of a canoe blessing observed the animals entering Hanalei Bay in a single wave formation at 7 a.m. on July 3, 2004. The animals were observed moving back into the shore from the mouth of the Bay at 9 a.m. The usually pelagic animals milled in the shallow bay and were returned to deeper water with human assistance beginning at 9:30 a.m. on July 4, 2004, and were out of sight by 10:30 a.m.

Only one animal, a calf, was known to have died following this event. The animal was noted alive and alone in Hanalei Bay on the afternoon of July 4, 2004, and was found dead in Hanalei Bay the morning of July 5, 2004. A full necropsy, magnetic resonance imaging, and computerized tomography examination were performed on the calf to determine the manner and cause of death. The combination of imaging, necropsy and histological analyses found no evidence of infectious, internal traumatic, congenital, or toxic factors. Cause of death could not be definitively determined, but it is likely that maternal separation, poor nutritional condition, and dehydration contributed to the final demise of the animal. Although it is not known when the calf was separated from its mother, the animals' movement into Hanalei Bay and subsequent milling and re-grouping may have contributed to the separation or lack of nursing, especially if the maternal bond was weak or this was an inexperienced mother with her first calf.

Environmental factors, abiotic and biotic, were analyzed for any anomalous occurrences that would have contributed to the animals entering and remaining in Hanalei Bay. The Bay's bathymetry is similar to many other sites within the Hawaiian Island chain and dissimilar to sites that have been associated with mass strandings in other parts of the United States. The weather conditions appeared to be normal for that time of year with no fronts or other significant features noted. There was no evidence of unusual distribution, occurrence of predator or prey species, or unusual harmful algal blooms, although Mobley (2007) suggested that the full moon cycle that occurred at that time may have influenced a run of squid into the Bay. Weather patterns and bathymetry that have been associated with mass strandings elsewhere were not found to occur in this instance.

The Hanalei Bay event was spatially and temporally correlated with RIMPAC. Official sonar training and tracking exercises in the PMRF warning area did not commence until approximately 8 a.m. on July 3 and were thus ruled out as a possible trigger for the initial movement into the bay. However, six naval surface vessels transiting to the operational area on July 2 intermittently transmitted active sonar (for approximately 9 hours total from 1:15 p.m. to 12:30 a.m.) as they approached from the south. The potential for these transmissions to have triggered the whales' movement into Hanalei Bay was investigated. Analyses with the information available indicated that animals to the south and east of Kauaʻi could have detected active sonar transmissions on July 2 and reached Hanalei Bay on or before 7 a.m. on July 3. However, data limitations regarding the position of the whales prior to their arrival in Hanalei Bay, the magnitude of sonar exposure, behavioral responses of melon-headed whales to acoustic stimuli, and other possible relevant factors preclude a conclusive finding regarding the role of sonar in triggering this event. Propagation modeling suggests that transmissions from sonar use during the July 3 exercise in the PMRF warning area may have been detectable at the mouth of the Hanalei Bay. If the animals responded negatively to these signals, it may have contributed to their continued presence in Hanalei Bay. The U.S. Navy ceased all active sonar transmissions during exercises in this range on the afternoon of July 3. Subsequent to the cessation of sonar use, the animals were herded out of Hanalei Bay.

While causation of this stranding event may never be unequivocally determined, NMFS considers the active sonar transmissions of July 2–3, 2004 a plausible, if not likely, contributing factor in what may have been a confluence of events. This conclusion is based on the following: (1) the evidently anomalous nature of the stranding; (2) its close spatiotemporal correlation with wide-scale, sustained use of sonar systems previously associated with stranding of deep-diving marine mammals; (3) the directed movement of two groups of transmitting vessels toward the southeast and southwest coast of Kauaʻi; (4) the results of acoustic propagation modeling and an analysis of possible animal transit times to the bay; and (5) the absence of any other compelling causative explanation. The initiation and persistence of this event may have resulted from an interaction of biological and physical factors. The biological factors may have included the presence of an apparently uncommon, deep-diving cetacean species (and possibly an offshore, non-resident group), social interactions among the animals before or after they entered the Bay, and/or unknown predator or prey conditions. The physical factors may have included the presence of nearby deep water, multiple vessels transiting in a directed manner while transmitting active sonar over a sustained period, the presence of surface sound ducting conditions, and/or intermittent and random human interactions while the animals were in Hanalei Bay.

A separate event involving melon-headed whales and rough-toothed dolphins took place over the same period of time in the Northern Mariana

Islands (Jefferson *et al.,* 2006), which is several thousand miles from Hawaii. Some 500 to 700 melon-headed whales came into Sasanhaya Bay on July 4, 2004, near the island of Rota and then left of their own accord after 5.5 hours; no known active sonar transmissions occurred in the vicinity of that event. The Rota incident led to scientific debate regarding what, if any, relationship the event had to the simultaneous events in Hawaii and whether they might be related by some common factor (*e.g.,* there was a full moon on July 2, 2004, as well as during other melon-headed whale strandings and nearshore aggregations (Brownell *et al.,* 2009; Lignon *et al.,* 2007; Mobley, 2007). Brownell *et al.* (2009) compared the two incidents, along with one other stranding incident at Nuka Hiva in French Polynesia and normal resting behaviors observed at Palmyra Island, in regard to physical features in the areas, melon-headed whale behavior, and lunar cycles. Brownell *et al.,* (2009) concluded that the rapid entry of the whales into Hanalei Bay, their movement into very shallow water far from the 328-ft (100-m) contour, their milling behavior (typical pre-stranding behavior), and their reluctance to leave the bay constituted an unusual event that was not similar to the events that occurred at Rota, which appear to be similar to observations of melon-headed whales resting normally at Palmyra Island. Additionally, there was no correlation between lunar cycle and the types of behaviors observed in the Brownell *et al.* (2009) examples.

Spain (2006)—

The Spanish Cetacean Society reported an atypical mass stranding of four beaked whales that occurred January 26, 2006, on the southeast coast of Spain, near Mojácar (Gulf of Vera) in the Western Mediterranean Sea. According to the report, two of the whales were discovered the evening of January 26 and were found to be still alive. Two other whales were discovered during the day on January 27 but had already died. The first three animals were located near the town of Mojácar and the fourth animal was found dead, a few kilometers north of the first three animals. From January 25–26, 2006, Standing NATO Response Force Maritime Group Two (five of seven ships including one U.S. ship under NATO Operational Control) had conducted active sonar training against a Spanish submarine within 50 nmi (93 km) of the stranding site.

Veterinary pathologists necropsied the two male and two female goose-beaked whales. According to the pathologists, the most likely primary cause of this type of beaked whale mass stranding event was anthropogenic acoustic activities, most probably anti-submarine MFAS used during the military naval exercises. However, no positive acoustic link was established as a direct cause of the stranding. Even though no causal link can be made between the stranding event and naval exercises, certain conditions may have existed in the exercise area that, in their aggregate, may have contributed to the marine mammal strandings (Freitas, 2004). Exercises were conducted in areas of at least 547 fathoms (1,000 m) depth near a shoreline where there is a rapid change in bathymetry on the order of 547 to 3,281 fathoms (1,000 to 6,000 m) occurring across a relatively short horizontal distance (Freitas, 2004). Multiple ships (in this instance, five) were operating MFAS in the same area over extended periods of time (in this case, 20 hours) in close proximity; and exercises took place in an area surrounded by landmasses, or in an embayment. Exercises involving multiple ships employing MFAS near land may have produced sound directed towards a channel or embayment that may have cut off the lines of egress for the affected marine mammals (Freitas, 2004).

Honaunau Bay (2022)—

On March 25, 2022, a beaked whale (species unknown) stranded in Honaunau Bay, Hawaii. The animal was observed swimming into shore and over rocks. Bystanders intervened to turn the animal off of the rocks, and it swam back out of Honaunau Bay on its own. Locals reported hearing a siren or alarm type of sound underwater on the same day, and a Navy vessel was observed from shore on the following day. The Navy confirmed it used CAS within 27 nmi (50 km) and 48 hours of the time of stranding, though the stranding has not been definitively linked to the Navy's CAS use, and there is no evidence to determine whether the animal had any further short- or long-term effects.

Behaviorally Mediated Responses to MFAS That May Lead to Stranding

Although the confluence of Navy MFAS with the other contributory factors noted in the 2001 NMFS/Navy joint report was identified as the cause of the 2000 Bahamas stranding event, the specific mechanisms that led to that stranding (or the others) are not well understood, and there is uncertainty regarding the ordering of effects that led to the stranding. It is unclear whether beaked whales were directly injured by sound (*e.g.,* acoustically mediated bubble growth, as addressed above) prior to stranding or whether a behavioral response to sound occurred that ultimately caused the beaked whales to be injured and strand.

Although causal relationships between beaked whale stranding events and active sonar remain unknown, several authors have hypothesized that stranding events involving these species in the Bahamas and Canary Islands may have been triggered when the whales changed their dive behavior in a startled response to exposure to active sonar or to further avoid exposure (Cox *et al.,* 2006; Rommel *et al.,* 2006). These authors proposed three mechanisms by which the behavioral responses of beaked whales upon being exposed to active sonar might result in a stranding event. These include the following: gas bubble formation caused by excessively fast surfacing; remaining at the surface too long when tissues are supersaturated with nitrogen; or diving prematurely when extended time at the surface is necessary to eliminate excess nitrogen. More specifically, beaked whales that occur in deep waters that are in close proximity to shallow waters (for example, the ''canyon areas'' that are cited in the Bahamas stranding event; see D'Spain and D'Amico, 2006), may respond to active sonar by swimming into shallow waters to avoid further exposures and strand if they were not able to swim back to deeper waters. Second, beaked whales exposed to active sonar might alter their dive behavior. Changes in their dive behavior might cause them to remain at the surface or at depth for extended periods of time which could lead to hypoxia directly by increasing their oxygen demands or indirectly by increasing their energy expenditures (to remain at depth) and increase their oxygen demands as a result. If beaked whales are at depth when they detect a ping from an active sonar transmission and change their dive profile, this could lead to the formation of significant gas bubbles, which could damage multiple organs or interfere with normal physiological function (Cox *et al.,* 2006; Rommel *et al.,* 2006; Zimmer and Tyack, 2007). Baird *et al.* (2006) found that slow ascent rates from deep dives and long periods of time spent within 164 ft (50 m) of the surface were typical for both goose-beaked and Blainville's beaked whales, the two species involved in mass strandings related to naval sonar. These two behavioral mechanisms may be necessary to purge excessive dissolved nitrogen concentrated in their tissues during

their frequent long dives (Baird *et al.,* 2005). Baird *et al.* (2005) further suggests that abnormally rapid ascents or premature dives in response to high-intensity sonar could indirectly result in physical harm to the beaked whales, through the mechanisms described above (gas bubble formation or non-elimination of excess nitrogen). In a review of the previously published data on the potential impacts of sonar on beaked whales, Bernaldo de Quirós *et al.* (2019) suggested that the effect of MFAS on beaked whales varies among individuals or populations, and that predisposing conditions such as previous exposure to sonar and individual health risk factors may contribute to individual outcomes (*e.g.,* decompression sickness).

Because many species of marine mammals make repetitive and prolonged dives to great depths, it has long been assumed that marine mammals have evolved physiological mechanisms to protect against the effects of rapid and repeated decompressions. Although several investigators have identified physiological adaptations that may protect marine mammals against nitrogen gas supersaturation (*i.e.,* alveolar collapse and elective circulation; Kooyman *et al.,* 1972; Ridgway and Howard, 1979), Ridgway and Howard (1979) reported that bottlenose dolphins that were trained to dive repeatedly had muscle tissues that were substantially supersaturated with nitrogen gas. Houser *et al.* (2001b) used these data to model the accumulation of nitrogen gas within the muscle tissue of other marine mammal species and concluded that cetaceans that dive deep and have slow ascent or descent speeds would have tissues that are more supersaturated with nitrogen gas than other marine mammals. Based on these data, Cox *et al.* (2006) hypothesized that a critical dive sequence might make beaked whales more prone to stranding in response to acoustic exposures. The sequence began with (1) very deep (to depths as deep as 1.2 mi (2 km)) and long (as long as 90 minutes) foraging dives; (2) relatively slow, controlled ascents; and (3) a series of ''bounce'' dives between 328 and 1,312 ft (100 and 400 m) in depth (see Zimmer and Tyack, 2007). They concluded that acoustic exposures that disrupted any part of this dive sequence (for example, causing beaked whales to spend more time at surface without the bounce dives that are necessary to recover from the deep dive) could produce excessive levels of nitrogen supersaturation in their tissues, leading to gas bubble and emboli formation that produces pathologies similar to decompression sickness.

Zimmer and Tyack (2007) modeled nitrogen tension and bubble growth in several tissue compartments for several hypothetical dive profiles and concluded that repetitive shallow dives (defined as a dive where depth does not exceed the depth of alveolar collapse, approximately 236 ft (72 m) for goose-beaked whale), perhaps as a consequence of an extended avoidance response to sonar sound, could pose a risk for decompression sickness and that this risk should increase with the duration of the response. Their models also suggested that unrealistically rapid rates of ascent from normal dive behaviors are unlikely to result in supersaturation to the extent that bubble formation would be expected. Tyack *et al.* (2006) suggested that emboli observed in animals exposed to mid-frequency range sonar (Jepson *et al.,* 2003; Fernandez *et al.,* 2005) could stem from a behavioral response that involves repeated dives shallower than the depth of lung collapse. Given that nitrogen gas accumulation is a passive process (*i.e.,* nitrogen is metabolically inert), a bottlenose dolphin was trained to repetitively dive a profile predicted to elevate nitrogen saturation to the point that nitrogen bubble formation was predicted to occur. However, inspection of the vascular system of the dolphin via ultrasound did not demonstrate the formation of asymptomatic nitrogen gas bubbles (Houser *et al.,* 2010). Baird *et al.* (2008), in a beaked whale tagging study off Hawaii, showed that deep dives are equally common during day or night, but ''bounce dives'' are typically a daytime behavior, possibly associated with visual predator avoidance. This may indicate that ''bounce dives'' are associated with something other than behavioral regulation of dissolved nitrogen levels, which would be necessary day and night.

Additional predictive modeling conducted to date has been performed with many unknowns about the respiratory physiology of deep-diving breath-hold animals. For example, Denk *et al.* (2020) found intra-species differences in the compliance of tracheobronchial structures of post-mortem cetaceans and pinnipeds under diving hydrostatic pressures, which would affect depth of alveolar collapse. Although, as hypothesized by Garcia Parraga *et al.* (2018) and reviewed in Fahlman *et al.,* (2021), mechanisms may exist that allow marine mammals to create a pulmonary shunt without the need for hydrostatic pressure-induced lung collapse (*i.e.,* by varying perfusion to the lung independent of lung collapse and degree of ventilation). If such a mechanism exists, then assumptions in prior gas models require reconsideration, the degree of nitrogen gas accumulation associated with dive profiles needs to be re-evaluated, and behavioral responses potentially leading to a destabilization of the relationship between pulmonary ventilation and perfusion should be considered. Costidis and Rommel (2016) suggested that gas exchange may continue to occur across the tissues of air-filled sinuses in deep diving odontocetes below the depth of lung collapse if hydrostatic pressures are high enough to drive gas exchange across into non-capillary veins.

If marine mammals respond to an Action Proponent vessel that is transmitting active sonar in the same way that they might respond to a predator, their probability of flight responses could increase when they perceive that Action Proponent vessels are approaching them directly, because a direct approach may convey detection and intent to capture (Burger and Gochfeld, 1981, 1990; Cooper, 1997; Cooper, 1998). The probability of flight responses could also increase as received levels of active sonar increase (and the ship is, therefore, closer) and as ship speeds increase (that is, as approach speeds increase). For example, the probability of flight responses in ringed seals (Born *et al.,* 1999), Pacific brant (*Branta bernicla nigricans*) and Canada geese (*B. canadensis*) increased as a helicopter or fixed-wing aircraft approached groups of these animals more directly (Ward *et al.,* 1999). Bald eagles (*Haliaeetus leucocephalus*) perched on trees alongside a river were also more likely to flee from a paddle raft when their perches were closer to the river or were closer to the ground (Steidl and Anthony, 1996).

Despite the many theories involving bubble formation (both as a direct cause of injury (see Non-Auditory Injury section) and an indirect cause of stranding), Southall *et al.* (2007) summarizes that there is either scientific disagreement or a lack of information regarding each of the following important points: (1) received acoustical exposure conditions for animals involved in stranding events; (2) pathological interpretation of observed lesions in stranded marine mammals; (3) acoustic exposure conditions required to induce such physical trauma directly; (4) whether noise exposure may cause behavioral responses (*e.g.,* atypical diving behavior) that secondarily cause bubble formation and tissue damage; and (5) the extent the post mortem artifacts introduced by

decomposition before sampling, handling, freezing, or necropsy procedures affect interpretation of observed lesions.

Strandings Associated With Explosive Use

Silver Strand (2011)—

During a Navy training event on March 4, 2011, at the Silver Strand Training Complex in San Diego, California, three or possibly four dolphins were killed in an explosion. During an underwater detonation training event, a pod of 100 to 150 long-beaked common dolphins were observed moving towards the 700-yard (yd) (640.1-m) exclusion zone around the explosive charge, monitored by personnel in a safety boat and participants in a dive boat. Approximately 5 minutes remained on a time-delay fuse connected to a single 8.76 lb (3.97 kg) explosive charge (C–4 and detonation cord). Although the dive boat was placed between the pod and the explosive in an effort to guide the dolphins away from the area, that effort was unsuccessful and three long-beaked common dolphins near the explosion died. The Navy recovered those animals and transferred them to the local stranding network for necropsy. In addition to the three dolphins found dead on March 4, the remains of a fourth dolphin were discovered on March 7, 2011, near Oceanside, California (3 days later and approximately 42 mi (68 km) north of the detonation), which might also have been related to this event. Upon necropsy, all four animals were found to have sustained typical mammalian primary blast injuries (Danil and St. Leger, 2011). Association of the fourth stranding with the training event is uncertain because dolphins strand on a regular basis in the San Diego area. Details such as the dolphins' depth and distance from the explosive at the time of the detonation could not be estimated from the 250 yd (228.6 m) standoff point of the observers in the dive boat or the safety boat.

These dolphin mortalities are the only known occurrence of a Navy training or testing event involving impulsive energy (underwater detonation) that caused mortality or injury to a marine mammal. Despite this being a rare occurrence, the Navy reviewed training requirements, safety procedures, and possible mitigation measures and implemented changes to reduce the potential for this to occur in the future. Discussions of procedures associated with underwater explosives training and other training events are presented in the Proposed Mitigation Measures section.

Kyle of Durness, Scotland (2011)—

On July 22, 2011, a mass stranding event involving long-finned pilot whales occurred at Kyle of Durness, Scotland. An investigation by Brownlow *et al.* (2015) considered unexploded ordnance detonation activities at a Ministry of Defense bombing range, conducted by the Royal Navy prior to and during the strandings, as a plausible contributing factor in the mass stranding event. While Brownlow *et al.* (2015) concluded that the serial detonations of underwater ordnance were an influential factor in the mass stranding event (along with the presence of a potentially compromised animal and navigational error in a topographically complex region), they also suggest that mitigation measures—which included observations from a zodiac only and by personnel not experienced in marine mammal observation, among other deficiencies—were likely insufficient to assess if cetaceans were in the vicinity of the detonations. The authors also cite information from the Ministry of Defense indicating ''an extraordinarily high level of activity'' (*i.e.,* frequency and intensity of underwater explosions) on the range in the days leading up to the stranding.

Strandings on the Hawaii and California Coasts

Stranded marine mammals are reported along the Hawaii and California coasts each year. Marine mammals strand due to natural or anthropogenic causes, and the majority of reported type of occurrences in marine mammal strandings in this region include fishery interactions, illness, predation, and vessel strikes (Carretta *et al.,* 2024).

Potential Effects of Vessel Strike

Vessel strikes of marine mammals can result in death or serious injury of the animal. Wounds resulting from vessel strike may include massive trauma, hemorrhaging, broken bones, or propeller lacerations (Knowlton and Kraus, 2001). An animal at the surface could be struck directly by a vessel, a surfacing animal could hit the bottom of a vessel, or an animal just below the surface could be cut by a vessel's propeller. Superficial strikes may not kill or result in the death of the animal. Lethal interactions are typically associated with large whales, which are occasionally found draped across the bulbous bow of large commercial ships upon arrival in port. Although smaller cetaceans are more maneuverable in relation to large vessels than are large whales, they may also be susceptible to strike. The severity of injuries typically depends on the size and speed of the vessel (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Vanderlaan and Taggart, 2007; Conn and Silber, 2013). Impact forces increase with speed, as does the probability of a strike at a given distance (Silber *et al.,* 2010; Gende *et al.,* 2011).

The most vulnerable marine mammals are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* the sperm whale; Jaquet and Whitehead, 1996; Watkins *et al.,* 1999). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel strikes (Nowacek *et al.,* 2004). These species are primarily large, slow moving whales. Marine mammal responses to vessels may include avoidance and changes in dive pattern (NRC, 2003).

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Jensen and Silber (2003) detailed 292 records of known or probable vessel strikes of all large whale species from 1975 to 2002. Of these, vessel speed at the time of collision was reported for 58 cases. Of these 58 cases, 39 (or 67 percent) resulted in serious injury or death (19 of those resulted in serious injury as determined by blood in the water, propeller gashes, or severed tailstock, and fractured skull, jaw, vertebrae, hemorrhaging, massive bruising or other injuries noted during necropsy, and 20 resulted in death).

Operating speeds of vessels that struck various species of large whales ranged from 2 to 51 kn (3.7 to 94.5 km/hr). The majority (79 percent) of these strikes occurred at speeds of 13 kn (24 km/hr) or greater. The average speed that resulted in serious injury or death was 18.6 kn (34.4 km/hr). Pace and Silber (2005) found that the probability of death or serious injury increased rapidly with increasing vessel speed. Specifically, the predicted probability of serious injury or death increased from 45 to 75 percent as vessel speed increased from 10 to 14 kn (18.5 to 25.9 km/hr) and exceeded 90 percent at 17 kn (31.5 km/hr). Higher speeds during strikes result in greater force of impact and also appear to increase the chance of severe injuries or death. While modeling studies have suggested that hydrodynamic forces pulling whales toward the vessel hull increase with increasing speed (Clyne, 1999; Knowlton *et al.,* 1995), this is inconsistent with Silber *et al.* (2010), which demonstrated that there is no such relationship (*i.e.,* hydrodynamic forces are independent of speed).

In a separate study, Vanderlaan and Taggart (2007) analyzed the probability of lethal mortality of large whales at a given speed, showing that the greatest rate of change in the probability of a lethal injury to a large whale as a function of vessel speed occurs between 8.6 and 15 kn (15.9 and 27.8 km/hr). The chances of a lethal injury decline from approximately 80 percent at 15 kn to approximately 20 percent at 8.6 kn (15.9 km/hr). At speeds below 11.8 kn (21.9 km/hr), the chances of lethal injury drop below 50 percent, while the probability asymptotically increases toward 100 percent above 15 kn (27.8 km/hr). Garrison *et al.* (2025) reviewed and updated available data on whale-vessel interactions in U.S. waters to determine the effects of vessel speed and size on lethality of strikes of large whales and found vessel size class had a significant effect on the probability of lethality. Decreasing vessel speeds reduced the likelihood of a lethal outcome for all vessel size classes modeled, with the strongest effect for vessels less than 354 ft (108 m) long. Notably, the probability that a strike by a very large (*i.e.,* in length) vessel will be lethal exceeded 0.80 at all speeds greater than 5 kn (9.26 km/hr) (Garrison *et al.,* 2025).

The Jensen and Silber (2003) report notes that the database represents a minimum number of strikes, because the vast majority probably goes undetected or unreported. In contrast, Action Proponent vessels are likely to detect any strike that does occur because of the required personnel training and Lookouts (as described in the Proposed Mitigation Measures section), and they are required to report all vessel strikes involving marine mammals.

In the HCTT Study Area, commercial traffic is heaviest in the nearshore waters, near major ports and in the shipping lanes along the California coast and in Hawaii (specifically Honolulu), including a lane of high intensity farther off the California coast running northwest–southeast, which is a great circle route between the Panama Canal and Asia. Military vessel traffic is primarily concentrated in the waters off San Diego, CA, and the coasts of the Hawaiian islands, particularly south of O'ahu and east of Hawaii Island (Navy 2025, unpublished data).

In the SOCAL portion of the Study Area, the U.S. Navy has struck a total of 19 marine mammals in the 32-year period from 1993 through 2025, an average of just under one per year. The species struck include gray whale, humpback whale, blue whale, and either fin or sei whale, though for some strikes, the species could not be determined.

In the HRC portion of the Study Area, the Navy struck a total of five marine mammals in the 22-year period from 1993 through 2025, an average of zero to one strikes per year. The Coast Guard has had one known marine mammal strike in Hawaii, a humpback whale in 2020. Of the five Navy vessel strikes over the 22-year period in the HRC, all were reported as injuries. The vessel struck species include: one humpback whale in 1998, one unknown species and one humpback whale in 2003, one sperm whale in 2007, and an unknown species in 2008. No more than two whales were struck by Navy vessels in any given year in the HRC portion of the HSTT within the last 32 years.

Between 2007 and 2009, the Navy developed and distributed additional training, mitigation, and reporting tools to Navy operators to improve marine mammal protection and to ensure compliance with permit requirements. In 2009, the Navy implemented Marine Species Awareness Training designed to improve effectiveness of visual observation for marine mammals and other marine resources. In subsequent years, the Navy issued refined policy guidance on vessel strikes in order to collect the most accurate and detailed data possible in response to a possible incident (also see the Notification and Reporting Plan for this proposed rule). For over a decade, the Navy has implemented the Protective Measures Assessment Protocol software tool, which provides operators with notification of the required mitigation and a visual display of the planned training or testing activity location overlaid with relevant environmental data.

Marine Mammal Habitat

The proposed training and testing activities could potentially affect marine mammal habitat through the introduction of impacts to the prey species of marine mammals, acoustic habitat (sound in the water column), water quality, and biologically important habitat for marine mammals. Each of these potential effects was considered in the 2024 HCTT Draft EIS/OEIS and was determined not to have adverse effects on marine mammal habitat. Based on the information below and the supporting information included in the 2024 HCTT Draft EIS/OEIS, NMFS has determined that the proposed training and testing activities would not have adverse or long-term impacts on marine mammal habitat.

Effects to Prey

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some species, is not well-documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). The most likely effects on fishes exposed to loud, intermittent, low-frequency sounds are behavioral responses (*i.e.,* flight or avoidance). Short duration, sharp sounds (such as pile driving or air guns) can cause overt or subtle changes in fish behavior and local distribution. The response of fish to acoustic sources depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (*i.e.,* pressure-related injuries), and mortality. While it is clear that the behavioral responses of individual prey, such as displacement or other changes in distribution, can have direct impacts on the foraging success of marine mammals, the effects on marine mammals of individual prey that experience hearing damage, barotrauma, or mortality is less clear,

though obviously population scale impacts that meaningfully reduce the amount of prey available could have more serious impacts.

Fishes, like other vertebrates, have a variety of different sensory systems to glean information from ocean around them (Astrup and Mohl, 1993; Astrup, 1999; Braun and Grande, 2008; Carroll *et al.,* 2017; Hawkins and Johnstone, 1978; Ladich and Popper, 2004; Ladich and Schulz-Mirbach, 2016; Mann, 2016; Nedwell *et al.,* 2004; Popper *et al.,* 2003; Popper *et al.,* 2005). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008), while terrestrial vertebrates generally only detect pressure. Most marine fishes primarily detect particle motion using the inner ear and lateral line system, while some fishes possess additional morphological adaptations or specializations that can enhance their sensitivity to sound pressure, such as a gas-filled swim bladder (Braun and Grande, 2008; Popper and Fay, 2011).

Hearing capabilities vary considerably between different fish species with data only available for just over 100 species out of the 34,000 marine and freshwater fish species (Eschmeyer and Fong, 2016). In order to better understand acoustic impacts on fishes, fish hearing groups are defined by species that possess a similar continuum of anatomical features which result in varying degrees of hearing sensitivity (Popper and Hastings, 2009a). There are four hearing groups defined for all fish species (modified from Popper *et al.,* 2014) within this analysis and they include: fishes without a swim bladder (*e.g.,* flatfish, sharks, rays, *etc.*); fishes with a swim bladder not involved in hearing (*e.g.,* salmon, cod, pollock, *etc.*); fishes with a swim bladder involved in hearing (*e.g.,* sardines, anchovy, herring, *etc.*); and fishes with a swim bladder involved in hearing and high-frequency hearing (*e.g.,* shad and menhaden). Most marine mammal fish prey species would not be likely to perceive or hear mid- or high-frequency sonars. While hearing studies have not been done on sardines and northern anchovies, it would not be unexpected for them to possess hearing similarities to Pacific herring (up to 2–5 kHz) (Mann *et al.,* 2005). Currently, less data are available to estimate the range of best sensitivity for fishes without a swim bladder.

In terms of physiology, multiple scientific studies have documented a lack of mortality or physiological effects to fish from exposure to low- and mid-frequency sonar and other sounds (Cox *et al.,* 2018; Halvorsen *et al.,* 2012; Jørgensen *et al.,* 2005; Kane *et al.,* 2010; Kvadsheim and Sevaldsen, 2005; Popper *et al.,* 2007; Popper *et al.,* 2016; Watwood *et al.,* 2016). Techer *et al.* (2017) exposed carp in floating cages for up to 30 days to low-power 23 and 46 kHz sources without any significant physiological response. Other studies have documented either a lack of TTS in species whose hearing range cannot perceive military sonar, or for those species that could perceive sonar-like signals, any TTS experienced would be recoverable (Halvorsen *et al.,* 2012; Ladich and Fay, 2013; Popper and Hastings, 2009a, 2009b; Popper *et al.,* 2014; Smith, 2016). Only fishes that have specializations that enable them to hear sounds above about 2,500 Hz (2.5 kHz) such as herring (Halvorsen *et al.,* 2012; Mann *et al.,* 2005; Mann, 2016; Popper *et al.,* 2014) would have the potential to receive TTS or exhibit behavioral responses from exposure to mid-frequency sonar. In addition, any sonar induced TTS to fish whose hearing range could perceive sonar would only occur in the narrow spectrum of the source (*e.g.,* 3.5 kHz) compared to the fish's total hearing range (*e.g.,* 0.01 kHz to 5 kHz). Overall, military sonar sources are much narrower in terms of source frequency compared to a given fish species full hearing range (Halvorsen *et al.,* 2012; Jørgensen *et al.,* 2005; Juanes *et al.,* 2017; Kane *et al.,* 2010; Kvadsheim and Sevaldsen, 2005; Popper *et al.,* 2007; Popper and Hawkins, 2016; Watwood *et al.,* 2016).

In terms of behavioral responses, Juanes *et al.* (2017) discuss the potential for negative impacts from anthropogenic soundscapes on fish, but the author's focus was on broader based sounds such as ship and boat noise sources. Watwood *et al.* (2016) also documented no behavioral responses by reef fish after exposure to MFAS. Doksaeter *et al.* (2009; 2012) reported no behavioral responses to mid-frequency naval sonar by Atlantic herring; specifically, no escape responses (vertically or horizontally) were observed in free swimming herring exposed to mid-frequency sonar transmissions. Based on these results (Doksaeter *et al.,* 2009; Doksaeter *et al.,* 2012; Sivle *et al.,* 2012), Sivle *et al.* (2015) created a model in order to report on the possible population-level effects on Atlantic herring from active naval sonar. The authors concluded that the use of naval sonar poses little risk to populations of herring regardless of season, even when the herring populations are aggregated and directly exposed to sonar. Finally, Bruintjes *et al.* (2016) commented that fish exposed to any short-term noise within their hearing range might initially startle, but would quickly return to normal behavior.

Occasional behavioral responses to intermittent explosions and impulsive sound sources are unlikely to cause long-term consequences for individual fish or populations. Fish that experience hearing loss as a result of exposure to explosions and impulsive sound sources may have a reduced ability to detect relevant sounds such as predators, prey, or social vocalizations. However, PTS has not been known to occur in fishes and any hearing loss in fish may be as temporary as the timeframe required to repair or replace the sensory cells that were damaged or destroyed (Popper *et al.,* 2005; Popper *et al.,* 2014; Smith *et al.,* 2006). It is not known if damage to auditory nerve fibers could occur, and if so, whether fibers would recover during this process.

It is also possible for fish to be injured or killed by an explosion in the immediate vicinity of the surface from dropped or fired ordnance, or near the bottom from shallow water bottom-placed underwater mine warfare detonations. Physical effects from pressure waves generated by underwater sounds (*e.g.,* underwater explosions) could potentially affect fish within proximity of training or testing activities. SPLs of sufficient strength have been known to cause injury to fish and fish mortality (summarized in Popper *et al.,* 2014). The shock wave from an underwater explosion is lethal to fish at close range, causing massive organ and tissue damage and internal bleeding (Keevin and Hempen, 1997). At greater distance from the detonation point, the extent of mortality or injury depends on a number of factors including fish size, body shape, orientation, and species (Keevin and Hempen, 1997; Wright, 1982). At the same distance from the source, larger fish are generally less susceptible to death or injury, elongated forms that are round in cross-section are less at risk than deep-bodied forms, and fish oriented sideways to the blast suffer the greatest impact (Edds-Walton and Finneran, 2006; O'Keeffe, 1984; O'Keeffe and Young, 1984; Wiley *et al.,* 1981; Yelverton *et al.,* 1975). Species with gas-filled organs are more susceptible to injury and mortality than those without them (Gaspin, 1975; Gaspin *et al.,* 1976; Goertner *et al.,* 1994). Barotrauma injuries have been documented during controlled exposure to impact pile driving (an impulsive noise source, as are explosives and air

guns) (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013).

Fish not killed or driven from a location by an explosion might change their behavior, feeding pattern, or distribution. Changes in behavior of fish have been observed as a result of sound produced by explosives, with effect intensified in areas of hard substrate (Wright, 1982). However, Navy explosive use avoids hard substrate to the best extent practical during underwater detonations, or deep-water surface detonations. Stunning from pressure waves could also temporarily immobilize fish, making them more susceptible to predation. The abundances of various fish (and invertebrates) near the detonation point for explosives could be altered for a few hours before animals from surrounding areas repopulate the area. However, these populations would likely be replenished as waters near the detonation point are mixed with adjacent waters. Repeated exposure of individual fish to sounds from underwater explosions is not likely and exposures are expected to be short-term and localized. Long-term consequences for fish populations would not be expected. Several studies have demonstrated that air gun sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017).

For fishes exposed to military sonar, there would be limited sonar use spread out in time and space across large offshore areas such that only small areas are actually ensonified (tens of miles) compared to the total life history distribution of fish prey species. There would be no probability for mortality or physical injury from sonar, and for most species, no or little potential for hearing or behavioral effects, except to a few select fishes with hearing specializations (*e.g.,* herring) that could perceive mid-frequency sonar. Training and testing exercises involving explosions are dispersed in space and time; therefore, repeated exposure of individual fishes is unlikely. Mortality and injury effects to fishes from explosives would be localized around the area of a given in-water explosion, but only if individual fish and the explosive (and immediate pressure field) were co-located at the same time. Fishes deeper in the water column or on the bottom would not be affected by water surface explosions. Repeated exposure of individual fish to sound and energy from underwater explosions is not likely given fish movement patterns, especially schooling prey species. Most acoustic effects, if any, are expected to be short-term and localized. Long-term consequences for fish populations, including key prey species within the HCTT Study Area, would not be expected.

Vessels and in-water devices do not normally collide with adult fish, particularly those that are common marine mammal prey, most of which can detect and avoid them. Exposure of fishes to vessel strike stressors is limited to those fish groups that are large, slow-moving, and may occur near the surface, such as ocean sunfish, whale sharks, basking sharks, and manta rays. These species are distributed widely in offshore portions of the HCTT Study Area. Any isolated cases of a military vessel striking an individual could injure that individual, impacting the fitness of an individual fish. Vessel strikes would not pose a risk to most of the other marine fish groups, because many fish can detect and avoid vessel movements, making strikes rare and allowing the fish to return to their normal behavior after the ship or device passes. As a vessel approaches a fish, they could have a detectable behavioral or physiological response (*e.g.,* swimming away and increased heart rate) as the passing vessel displaces them. However, such responses are not expected to have lasting effects on the survival, growth, recruitment, or reproduction of these marine fish groups at the population level and therefore would not have an impact on marine mammal species as prey items.

In addition to fish, prey sources such as marine invertebrates could potentially be impacted by sound stressors as a result of the proposed activities. However, most marine invertebrates' ability to sense sounds is very limited. In most cases, marine invertebrates would not respond to impulsive and non-impulsive sounds, although they may detect and briefly respond to nearby low-frequency sounds. These short-term responses would likely be inconsequential to invertebrate populations.

Invertebrates appear to be able to detect sounds (Pumphrey, 1950; Frings and Frings, 1967) and are most sensitive to low-frequency sounds (Packard *et al.,* 1990; Budelmann and Williamson, 1994; Lovell *et al.,* 2005; Mooney *et al.,* 2010). Data on response of invertebrates such as squid, another marine mammal prey species, to anthropogenic sound is more limited (de Soto, 2016; Sole *et al.,* 2017). Data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect air gun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Sole *et al.* (2017) reported physiological injuries to cuttlefish in cages placed at-sea when exposed during a controlled exposure experiment to low-frequency sources (315 Hz, 139 to 142 dB re: 1 μPa^2 and 400 Hz, 139 to 141 dB re: 1 μPa^2). Fewtrell and McCauley (2012) reported squids maintained in cages displayed startle responses and behavioral changes when exposed to seismic air gun sonar (136–162 re: 1 $\mu Pa^2 \cdot s$). However, the sources Sole *et al.* (2017) and Fewtrell and McCauley (2012) used are not similar and were much lower than typical Navy sources within the HCTT Study Area. Nor do the studies address the issue of individual displacement outside of a zone of impact when exposed to sound. Jones *et al.* (2020) found that when squid (*Doryteuthis (Amerigo) pealeii*) were exposed to impulse pile driving noise, body pattern changes, inking, jetting, and startle responses were observed and nearly all squid exhibited at least one response. However, these responses occurred primarily during the first eight impulses and diminished quickly, indicating potential rapid, short-term habituation.

Cephalopods have a specialized sensory organ inside the head called a statocyst that may help an animal determine its position in space (orientation) and maintain balance (Budelmann, 1992). Packard *et al.* (1990) showed that cephalopods were sensitive to particle motion, not sound pressure, and Mooney *et al.* (2010) demonstrated that squid statocysts act as an accelerometer through which particle motion of the sound field can be detected. Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Squids, like most fish species, are likely more sensitive to low frequency sounds, and may not perceive mid- and high-frequency sonars such as Navy sonars. Cumulatively for squid as a prey species, individual and population impacts from exposure to Navy sonar and explosives, like fish, are not likely to be significant, and explosive impacts would be short-term and localized.

Explosions and pile driving would likely kill or injure nearby marine invertebrates. Vessels also have the potential to impact marine invertebrates by disturbing the water column or sediments, or directly striking organisms (Bishop, 2008). The propeller wash (water displaced by propellers used for propulsion) from vessel movement and water displaced from vessel hulls can potentially disturb marine invertebrates in the water column and is a likely cause of zooplankton mortality (Bickel *et al.,* 2011). The localized and short-term exposure to explosions or vessels could displace, injure, or kill zooplankton, invertebrate eggs or larvae, and macro-invertebrates. However, mortality or long-term consequences for a few animals is unlikely to have measurable effects on overall populations. Long-term consequences to marine invertebrate populations would not be expected as a result of exposure to sounds of vessels in the HCTT Study Area.

Impacts to benthic communities from impulsive sound generated by active acoustic sound sources are not well documented. (*e.g.,* Andriguetto-Filho *et al.,* 2005; Payne *et al.,* 2007; 2008; Boudreau *et al.,* 2009). There are no published data that indicate whether temporary or permanent threshold shifts, auditory masking, or behavioral effects occur in benthic invertebrates (Hawkins *et al.,* 2014) and some studies showed no short-term or long-term effects of air gun exposure (*e.g.,* Andriguetto-Filho *et al.,* 2005; Payne *et al.,* 2007; 2008; Boudreau *et al.,* 2009). Exposure to air gun signals was found to significantly increase mortality in scallops, in addition to causing significant changes in behavioral patterns during exposure (Day *et al.,* 2017). However, the authors state that the observed levels of mortality were not beyond naturally occurring rates. Explosions and pile driving could potentially kill or injure nearby marine invertebrates; however, mortality or long-term consequences for a few animals is unlikely to have measurable effects on overall populations.

There is little information concerning potential impacts of noise on zooplankton populations. However, one study (McCauley *et al.,* 2017) investigated zooplankton abundance, diversity, and mortality before and after exposure to air gun noise, finding that the mortality rate for zooplankton after air gun exposure was two to three times more compared with controls for all taxa. The majority of taxa present were copepods and cladocerans; for these taxa, the range within which effects on abundance were detected was up to approximately 0.75 mi (1.2 km). In order to have significant impacts on *r*-selected species (*i.e.,* species that produce a large number of offspring and contribute few resources to each individual offspring) such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned (McCauley *et al.,* 2017).

Notably, a recently described study produced results inconsistent with those of McCauley *et al.* (2017). Researchers conducted a field and laboratory study to assess if exposure to air gun noise affects mortality, predator escape response, or gene expression of the copepod *Calanus finmarchicus* (Fields *et al.,* 2019). Immediate mortality of copepods was significantly higher, relative to controls, at distances of 16.4 ft (5 m) or less from the air guns. Mortality one week after the air gun blast was significantly higher in the copepods placed 32.8 ft (10 m) from the air gun but was not significantly different from the controls at a distance of 65.6 ft (20 m) from the air gun. The increase in mortality, relative to controls, did not exceed 30 percent at any distance from the air gun. Moreover, the authors caution that even this higher mortality in the immediate vicinity of the air guns may be more pronounced than what would be observed in free-swimming animals due to increased flow speed of fluid inside bags containing the experimental animals. There were no sublethal effects on the escape performance or the sensory threshold needed to initiate an escape response at any of the distances from the air gun that were tested. Whereas McCauley *et al.* (2017) reported an SEL of 156 dB at a range of 1,670–2,158.8 ft (509–658 m), with zooplankton mortality observed at that range, Fields *et al.* (2019) reported an SEL of 186 dB at a range of 82 ft (25 m), with no reported mortality at that distance. The large scale of effect observed here is of concern—particularly where repeated noise exposure is expected—and further study is warranted.

Military expended materials resulting from training and testing activities could potentially result in minor long-term changes to benthic habitat; however, the impacts of small amount of expended materials are unlikely to have measurable effects on overall populations. Military expended materials may be colonized over time by benthic organisms that prefer hard substrate and would provide structure that could attract some species of fish or invertebrates.

Overall, the combined impacts of sound exposure, explosions, vessel strikes, and military expended materials resulting from the proposed activities would not be expected to have measurable effects on populations of marine mammal prey species. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to air gun noise exposure are available (Fields *et al.,* 2019, Hawkins *et al.,* 2014, McCauley *et al.,* 2017). The most likely impacts for most prey species in a given area would be temporary avoidance of the area. Surveys using towed air gun arrays move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once a survey ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of most surveys and the likelihood of temporary avoidance behavior suggest that impacts would be minor. Long-term consequences to marine invertebrate populations would not be expected as a result of exposure to sounds or vessels in the HCTT Study Area.

Acoustic Habitat

Acoustic habitat is the soundscape which encompasses all of the sound present in a particular location and time, as a whole when considered from the perspective of the animals experiencing it. Animals produce sound for, or listen for sounds produced by, conspecifics (*e.g.,* communication during feeding, mating, and other social activities), other animals (*e.g.,* finding prey or avoiding predators), and the physical environment (*e.g.,* finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain, waves) make up the natural contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

Soundscapes are also defined by, and acoustic habitat influenced by, the total

contribution of anthropogenic sound. This may include incidental emissions from sources such as vessel traffic or may be intentionally introduced to the marine environment for data acquisition purposes (*e.g.,* the use of air gun arrays) or for military training and testing purposes (*e.g.,* the use of sonar and explosives and other acoustic sources). Anthropogenic noise varies widely in its frequency, content, duration, and SPL, and these characteristics greatly influence the potential habitat-mediated effects to marine mammals (please also see the previous discussion in the Masking section), which may range from local effects for brief periods of time to chronic effects over large areas and for long durations. Depending on the extent of effects to habitat, animals may alter their communications signals (thereby potentially expending additional energy) or miss acoustic cues (either conspecific or adventitious). Problems arising from a failure to detect cues are more likely to occur when noise stimuli are chronic and overlap with biologically relevant cues used for communication, orientation, and predator/prey detection (Francis and Barber, 2013). For more detail on these concepts see, *e.g.,* Barber *et al.,* 2009; Pijanowski *et al.,* 2011; Lillis *et al.,* 2014.

The term ''listening area'' refers to the region of ocean over which sources of sound can be detected by an animal at the center of the space. Loss of communication space concerns the area over which a specific animal signal (used to communicate with conspecifics in biologically important contexts such as foraging or mating) can be heard, in noisier relative to quieter conditions (Clark *et al.,* 2009). Lost listening area concerns the more generalized contraction of the range over which animals would be able to detect a variety of signals of biological importance, including eavesdropping on predators and prey (Barber *et al.,* 2009). Such metrics do not, in and of themselves, document fitness consequences for the marine animals that live in chronically noisy environments. Long-term population-level consequences mediated through changes in the ultimate survival and reproductive success of individuals are difficult to study, and particularly so underwater. However, it is increasingly well documented that aquatic species rely on qualities of natural acoustic habitats, with researchers quantifying reduced detection of important ecological cues (*e.g.,* Francis and Barber, 2013; Slabbekoorn *et al.,* 2010) as well as survivorship consequences in several species (*e.g.,* Simpson *et al.,* 2015; Nedelec *et al.,* 2015).

The sounds produced during training and testing activities can be widely dispersed or concentrated in small areas for varying periods. Sound produced from training and testing activities in the HCTT Study Area is temporary and transitory. Any anthropogenic noise attributed to training and testing activities in the HCTT Study Area would be temporary and the affected area would be expected to immediately return to the original state when these activities cease.

Water Quality

Training and testing activities may introduce constituents into the water column. Based on the analysis of the 2024 HCTT Draft EIS/OEIS, military expended materials (*e.g.,* undetonated explosive materials) would be released in quantities and at rates that would not result in a violation of any water quality standard or criteria. NMFS has reviewed this analysis and concurs that it reflects the best available science. High-order explosions consume most of the explosive material, creating typical combustion products. For example, in the case of Royal Demolition Explosive, 98 percent of the products are common seawater constituents and the remainder is rapidly diluted below threshold effect level. Explosion by-products associated with high order detonations present no secondary stressors to marine mammals through sediment or water. However, low order detonations and unexploded ordnance present elevated likelihood of impacts on marine mammals.

Indirect effects of explosives and unexploded ordnance to marine mammals via sediment is possible in the immediate vicinity of the ordnance. Degradation products of Royal Demolition Explosive are not toxic to marine organisms at realistic exposure levels (Rosen and Lotufo, 2010). Relatively low solubility of most explosives and their degradation products means that concentrations of these contaminants in the marine environment are relatively low and readily diluted. Furthermore, while explosives and their degradation products were detectable in marine sediment approximately 6–12 inches (0.15–0.3 m) away from degrading ordnance, the concentrations of these compounds were not statistically distinguishable from background beyond 3–6 ft (1–2 m) from the degrading ordnance. Taken together, it is possible that marine mammals could be exposed to degrading explosives, but it would be within a very small radius of the explosive (1–6 ft (0.3–2 m)).

Equipment used by the Action Proponents within the HCTT Study Area, including ships and other marine vessels, aircraft, and other equipment, are also potential sources of by-products. All equipment is properly maintained in accordance with applicable Navy, Coast Guard, Army, and legal requirements. All such operating equipment meets Federal water quality standards, where applicable.

Estimated Take of Marine Mammals

This section indicates the number of takes that NMFS is proposing to authorize, which is based on the amount of take that NMFS anticipates is reasonably likely to occur. NMFS coordinated closely with the Action Proponents in the development of their incidental take application, and preliminarily agrees that the methods the Action Proponents have put forth described herein to estimate take (including the model, thresholds, and density estimates), and the resulting numbers are based on the best available science and appropriate for authorization.

Takes would be predominantly in the form of harassment, but a limited number of mortalities are also possible. For this military readiness activity, the MMPA defines ''harassment'' as (1) any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (2) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where the behavioral patterns are abandoned or significantly altered (Level B harassment) (16 U.S.C. 1362(18)(B)).

Proposed authorized takes would primarily be in the form of Level B harassment, as use of the acoustic (*e.g.,* active sonar, pile driving, and seismic air guns) and explosive sources and missile launches is most likely to result in disruption of natural behavioral patterns to a point where they are abandoned or significantly altered (as defined specifically at the beginning of this section, but referred to generally as behavioral disturbance) for marine mammals, either via direct behavioral disturbance or TTS. There is also the potential for Level A harassment, in the form of auditory injury to result from exposure to the sound sources utilized in military readiness activities. Lastly, no more than 7 serious injuries or mortalities total (over the 7-year period)

of large whales could potentially occur through vessel strikes, and 40 serious injuries or mortalities (over the 7-year period) from explosive use. Although we analyze the impacts of these potential serious injuries or mortalities that are proposed for authorization, the proposed mitigation and monitoring measures are expected to minimize the likelihood (*i.e.,* further lower the already low probability) that vessel strike (and the associated serious injury or mortality) would occur, as well as the severity of other takes.

Generally speaking, for acoustic impacts NMFS estimates the amount and type of harassment by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals would experience behavioral disturbance or incur some degree of temporary or permanent hearing impairment; (2) the area or volume of water that would be ensonified above these levels in a day or event; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) the number of days of activities or events.

Acoustic Thresholds

Using the best available science, NMFS, in coordination with the Navy, has established acoustic thresholds that identify the most appropriate received level of underwater sound above which marine mammals exposed to these sound sources could be reasonably expected to directly incur a disruption in behavior patterns to a point where they are abandoned or significantly altered (equated to onset of Level B harassment), or to incur TTS onset (equated to Level B harassment via the indirect disruptions of behavioral patterns) or AUD INJ onset (equated to Level A harassment). Thresholds have also been developed to identify the pressure and impulse levels above which animals may incur non-auditory injury or mortality from exposure to explosive detonation.

Hearing Impairment (TTS/AUD INJ), Non-Auditory Injury, and Mortality

NMFS' 2024 Technical Guidance (NMFS, 2024) identifies dual criteria to assess AUD INJ (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The Updated Technical Guidance also identifies criteria to predict TTS, which is not considered injury and falls into the Level B harassment category. The Action Proponents' specified activities include the use of non-impulsive (*i.e.,* sonar, vibratory pile driving) and impulsive (*i.e.,* explosives, air guns, impact pile driving) sources.

For the consideration of impacts on hearing in Phase IV, marine mammals were divided into nine groups for analysis: VLF, LF, HF, VHF, SI, PCW and PCA, and OCW and OCA. For each group, a frequency-dependent weighting function and numeric thresholds for the onset of TTS and the onset of AUD INJ were estimated. The onset of TTS is defined as a TTS of 6 dB measured approximately 2–5 minutes after exposure. A TTS of 40 dB is used as a proxy for the onset of AUD INJ (*i.e.,* it is assumed that exposures beyond those capable of causing 40 dB of TTS have the potential to result in PTS or other auditory injury (*e.g.,* loss of cochlear neuron synapses)). Exposures just sufficient to cause TTS or AUD INJ are denoted as ''TTS onset'' or ''AUD INJ onset'' exposures. Onset levels are treated as step functions or ''all-or-nothing'' thresholds: exposures above the TTS or AUD INJ onset level are assumed to always result in TTS or AUD INJ, while exposures below the TTS or AUD INJ onset level are assumed to not cause TTS or AUD INJ. For non-impulsive exposures, onset levels are specified in frequency-weighted sound exposure level (SEL); for impulsive exposures, dual metrics of weighted SEL and unweighted peak sound pressure level (SPL) are used.

To compare Phase IV weighting functions and TTS/AUD INJ SEL thresholds to those used in Phase III, both the weighting function shape and the weighted threshold values were considered; the weighted thresholds by themselves only indicate the TTS/AUD INJ threshold at the most susceptible frequency (based on the relevant weighting function). In contrast, the TTS/AUD INJ exposure functions incorporate both the shape of the weighting function and the weighted threshold value and provide the best means of comparing the frequency-dependent TTS/AUD INJ thresholds for Phase III and Phase IV.

The most significant differences between the Phase III and Phase IV functions and thresholds include the following:

- Mysticetes were divided into two groups (VLF and LF), with the upper hearing limit for the LF group increased from Phase III to match recent hearing measurements in minke whales (Houser *et al.,* 2024);
- Group names were changed from Phase III to be consistent with Southall *et al.* (2019). Specifically, the Phase III mid-frequency (MF) cetacean group is now designated as the high-frequency (HF) cetacean group, and the group previously designated as high-frequency (HF) cetaceans is now the very-high frequency (VHF) cetacean group;
- For the HF group, Phase IV onset TTS/AUD INJ thresholds are lower compared to Phase III at frequencies below approximately 10 kHz. This is a result of new TTS onset data for dolphins at low frequencies (Finneran *et al.,* 2023);
- For the PCW group, new TTS data for harbor seals (Kastelein *et al.,* 2020a; Kastelein *et al.,* 2020b) resulted in slightly lower TTS/AUD INJ thresholds at high frequencies compared to Phase III; and
- For group OCW, new TTS data for California sea lions (Kastelein *et al.,* 2021b; Kastelein *et al.,* 2022a, 2022b) resulted in significantly lower TTS/AUD INJ thresholds compared to Phase III.

Of note, the thresholds and weighting function for the LF cetacean hearing group in NMFS' 2024 Technical Guidance (NMFS, 2024) match the Navy's VLF cetacean hearing group. However, the weighting function for those hearing groups differs between the two documents (*i.e.,* the Navy's LF cetacean group has a different weighting function from NMFS) due to the Houser *et al.* (2024) minke whale data incorporated into Navy 2024, but not NMFS (2024). While NMFS' 2024 Technical Guidance differs from the criteria that the Action Proponents used to assess AUD INJ and TTS for low-frequency cetaceans, NMFS concurs that the criteria the Action Proponents applied are appropriate for assessing the impacts of their proposed action. The criteria used by the Action Proponents are conservative in that those criteria show greater sensitivity at higher frequencies (*i.e.,* application of those criteria result in a higher amount of estimated take by higher frequency sonars than would result from application of NMFS' 2024 Technical Guidance) which is where more of the take is expected.

These thresholds (table 18 and table 19) were developed by compiling and synthesizing the best available science and soliciting input multiple times from both public and peer reviewers. The references, analysis, and methodology used in the development of the thresholds are described in Updated Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 18—ACOUSTIC THRESHOLDS IDENTIFYING THE ONSET OF TTS

Group	TTS threshold SEL (weighted)	AUD INJ threshold SEL (weighted)
Very low-frequency (VLF)	177	197
Low-frequency (LF)	177	197
High-frequency (HF)	181	201
Very high-frequency (VHF)	161	181
Phocid carnivores in water (PW)	175	195
Otariid carnivores in water (OW)	179	199
Phocid carnivores in air (PA)	134	154
Otariid carnivores in air (OA)	157	177

Note: SEL thresholds in dB re 1 μPa^2 s underwater and dB re 20 μPa^2 s in air.

Based on the best available science, the Action Proponents (in coordination with NMFS) used the acoustic and pressure thresholds indicated in table 18 to predict the onset of behavioral harassment, AUD INJ, TTS, tissue damage, and mortality due to explosive sources.

For explosive activities using single detonations (*i.e.,* no more than one detonation within a day), such as those described in the proposed activity, NMFS uses TTS onset thresholds to assess the likelihood of behavioral harassment, rather than the Level B harassment threshold for multiple detonations indicated in table 19. While marine mammals may also respond to single explosive detonations, these responses are expected to more typically be in the form of startle response, rather than a more meaningful disruption of a behavioral pattern. On the rare occasion that a single detonation might result in a behavioral response that qualifies as Level B harassment, it would be expected to be in response to a comparatively higher received level. Accordingly, NMFS considers the potential for these responses to be quantitatively accounted for through the application of the TTS criteria, which, as noted above, is 5 dB higher than the behavioral harassment threshold for multiple explosives.

TABLE 19—EXPLOSIVE THRESHOLDS FOR MARINE MAMMALS FOR AUD INJ, TTS, AND BEHAVIOR

[Multiple detonations]

Hearing group	AUD INJ impulsive threshold *	TTS impulsive threshold *	Behavioral threshold (multiple detonations)
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-}pk,flat}$*:* 222 dB; $L_{E,p,LF,24h}$*:* 183 dB.	*Cell 2:* $L_{p,0\text{-}pk,flat}$*:* 216 dB; $L_{E,LF,24h}$*:* 168 dB.	*Cell 3:* $L_{E,LF,24h}$*:* 163 dB.
High-Frequency (HF) Cetaceans	*Cell 4:* $L_{p,0\text{-}pk,flat}$*:* 230 dB; $L_{E,p,HF,24h}$*:* 193 dB.	*Cell 5:* $L_{p,0\text{-}pk,flat}$*:* 224 dB; $L_{E,HF,24h}$*:* 178 dB.	*Cell 6:* $L_{E,HF,24h}$*:* 173 dB.
Very High-Frequency (VHF) Cetaceans.	*Cell 7:* $L_{p,0\text{-}pk,flat}$*:* 202 dB; $L_{E,p,VHF,24h}$*:* 159 dB.	*Cell 8:* $L_{p,0\text{-}pk,flat}$*:* 196 dB; $L_{E,VHF,24h}$*:* 144 dB.	*Cell 9:* $L_{E,VHF,24h}$*:* 139 dB.
Phocid Pinnipeds (PW) (Underwater).	*Cell 10:* $L_{p,0\text{-}pk,flat}$*:* 223 dB; $L_{E,p,PW,24h}$*:* 183 dB.	*Cell 11:* $L_{p,0\text{-}pk,flat}$*:* 217 dB; $L_{E,PW,24h}$*:* 168 dB.	*Cell 12:* $L_{E,PW,24h}$*:* 163 dB.
Otariid Pinnipeds (OW) (Underwater).	*Cell 13:* $L_{p,0\text{-}pk,flat}$*:* 230 dB; $L_{E,p,OW,24h}$*:* 185 dB.	*Cell 14:* $L_{p,0\text{-}pk,flat}$*:* 224 dB; $L_{E,OW,24h}$*:* 170 dB.	*Cell 15:* $L_{E,OW,24h}$*:* 165 dB.
Phocid Pinnipeds (PA) (In-Air)	*Cell 16:* $L_{p,0\text{-}pk,flat}$*:* 162 dB; $L_{E,p,PA,24h}$*:* 140 dB.	*Cell 17:* $L_{p,0\text{-}pk,flat}$*:* 156 dB; $L_{E,PA,24h}$*:* 125 dB.	*Cell 18:* N/A.
Otariid Pinnipeds (OA) (In-Air)	*Cell 19:* $L_{p,0\text{-}pk,flat}$: 177 dB; $L_{E,p,OA,24h}$*:* 163 dB.	*Cell 20:* $L_{p,0\text{-}pk,flat}$: 171 dB; $L_{E,OA,24h}$*:* 148 dB.	*Cell 21:* N/A.

Note: N/A = Not Applicable. Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 µPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μPa^2s. In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017; ISO, 2020). The subscript ''flat'' is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.,* 7 Hz to 165 kHz) or in air (*i.e.,* 42 Hz to 52 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

* Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

The criterion for mortality is based on severe lung injury observed in terrestrial mammals exposed to underwater explosions as recorded in Goertner (1982). The criteria for non-auditory injury are based on slight lung injury or gastrointestinal (commonly referred to as G.I.) tract injury observed in the same data set. Mortality and slight lung injury impacts to marine mammals are estimated using impulse thresholds based on both calf/pup/juvenile and adult masses (see the Criteria and Thresholds Technical Report). The peak pressure threshold applies to all species and age classes. Unlike the prior analysis (Phase III), this analysis relies on the onset rather than the mean estimated threshold for these effects. This revision results in a small increase in the predicted non-auditory injuries and mortalities for the same event versus prior analyses. Thresholds are provided in table 20 for use in non-auditory injury assessment for marine mammals exposed to underwater explosives. Of note, non-auditory injury and mortality from land-based missile and target launches are so unlikely as to

be discountable under normal conditions.

TABLE 20—NON-AUDITORY INJURY THRESHOLDS FOR UNDERWATER EXPLOSIVES

Hearing group	Mortality—impulse *	Injury—impulse *	Injury—peak pressure
All Marine Mammals	*Cell 1:* Modified Goertner model; Equation 1.	*Cell 2:* Modified Goertner model; Equation 2.	*Cell 3:* $L_{p0\text{-}pk,flat}$*:* 237 dB.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa. In this table, thresholds are abbreviated to reflect ANSI (2013). However, ANSI defines peak sound pressure as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the overall marine mammal generalized hearing range.

* Lung injury (severe and slight) thresholds are dependent on animal mass (Recommendation: table C.9 from U.S. Department of the Navy (2017a) based on adult and/or calf/pup mass by species).

Modified Goertner Equations for severe and slight lung injury (pascal-second)

Equation 1: $103M^{1/3}(1 + D/10.1)^{1/6}$ Pa-s

Equation 2: $47.5M^{1/3}(1 + D/10.1)^{1/6}$ Pa-s

M animal (adult and/or calf/pup) mass (kg) (table C.9 in DoN 2017)

D animal depth (meters).

Level B Harassment by Behavioral Disturbance

Though significantly driven by received level and distance, the onset of Level B harassment by behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors and can be difficult to predict (Southall *et al.,* 2007; Ellison *et al.,* 2012). As discussed in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section, marine mammal responses to sound (some of which are considered disturbances that qualify as take under the MMPA) are highly variable and context specific (*i.e.,* they are affected by differences in acoustic conditions; differences between species and populations; differences in gender, age, reproductive status, or social behavior; and other prior experience of the individuals). This means there is support for considering alternative approaches for estimating Level B behavioral harassment.

Despite the rapidly evolving science, there are still challenges in quantifying expected behavioral responses that qualify as take by Level B harassment, especially where the goal is to use one or two predictable indicators (*e.g.,* received level and distance) to predict responses that are also driven by additional factors that cannot be easily incorporated into the thresholds (*e.g.,* context). So, while the criteria that identify Level B harassment by behavioral disturbance (referred to *as* ''behavioral harassment thresholds'') have been refined to better consider the best available science (*e.g.,* incorporating both received level and distance), they also still have some built-in factors to address the challenge noted. For example, while duration of observed responses in the data are now considered in the thresholds, some of the responses that are informing take thresholds are of a very short duration, such that it is possible some of these responses might not always rise to the level of disrupting behavior patterns to a point where they are abandoned or significantly altered. We describe the application of this behavioral harassment threshold as identifying the maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered. In summary, we believe these behavioral harassment criteria are the most appropriate method for predicting Level B harassment by behavioral disturbance given the best available science and the associated uncertainty.

Sonar—

In its analysis of impacts associated with sonar acoustic sources (which was coordinated with NMFS), the Action Proponents used an updated approach, as described below. Many of the behavioral responses identified using the Action Proponents' quantitative analysis are most likely to be of moderate severity as described in the Southall *et al.* (2021) behavioral response severity scale. These ''moderate'' severity responses were considered significant if they were sustained for the duration of the exposure or longer. Within the Action Proponents' quantitative analysis, many responses are predicted from exposure to sound that may exceed an animal's Level B behavioral harassment threshold for only a single exposure (lasting a few seconds) to several minutes, and it is likely that some of the resulting estimated behavioral responses that are counted as Level B harassment would not constitute ''significantly altering or abandoning natural behavioral patterns'' (*i.e.,* the estimated number of takes by Level B harassment due to behavioral disturbance and response is likely somewhat of an overestimate).

As noted above, the Action Proponents coordinated with NMFS to develop behavioral harassment thresholds specific to their military readiness activities utilizing active sonar that identify at what received level and distance Level B harassment by behavioral disturbance would be expected to result. These behavioral harassment thresholds consist of behavioral response functions (BRFs) and associated distance cut-off conditions, and are also referred to, together, as ''the criteria.'' These criteria are used to estimate the number of animals that may exhibit a behavioral response that qualifies as take under the MMPA when exposed to sonar and other transducers. The way the criteria were derived is discussed in detail in the Criteria and Thresholds Technical Report. Developing these behavioral harassment criteria involved multiple steps. All peer-reviewed published behavioral response studies conducted both in the field and on captive animals were examined in order to understand the breadth of behavioral responses of marine mammals to sonar and other transducers. Marine mammals were divided into four groups for analysis: mysticetes (all baleen whales); odontocetes (most toothed whales, dolphins, and porpoises); sensitive species (beaked whales and harbor porpoise); and pinnipeds and other marine carnivores (true seals, sea lions, walruses, sea otters, polar bears). These groups are like the groups used in the behavioral response analysis (Phase III), with the exception of combining beaked whales and harbor porpoise into a single curve. For each group, a biphasic BRF was developed using the best available data and Bayesian dose response models

developed at the University of St. Andrews. The BRF base probability of response on the highest SPL (RMS) received level.

The analysis of BRFs differs from the previous phase (Phase III) due to the addition of new data and the separation of some species groups. Figure 10 in the Criteria and Thresholds Technical Report indicates the changes in BRFs from Phase III to Phase IV. The sensitive species BRF is more sensitive at lower received levels but less sensitive at higher received levels than the prior beaked whale and harbor porpoise functions. The odontocete BRF is less sensitive overall due to additional behavioral response research, which will result in a lower number of behavioral responses than in the prior analysis for the same event, but also reduces the avoidance of auditory effects. The pinnipeds (in-water) BRF is more sensitive due to the inclusion of additional captive pinniped data (only three behavioral studies using captive pinnipeds were available for the derivation of the BRF). Behavioral studies of captive animals can be difficult to extrapolate to wild animals due to several factors (*e.g.,* use of trained subjects). This means the pinniped BRF likely overestimates effects compared to observed responses of wild pinnipeds to sound and anthropogenic activity. The mysticete BRF is less sensitive across most received levels due to including additional behavioral response research. This will result in a lower number of behavioral responses than in the prior analysis for the same event, but also reduces the avoidance of auditory effects.

The BRFs only relate the highest received level of sound to the probability that an animal will have a behavioral response. The BRFs do not account for the duration or pattern of use of any individual sound source or of the activity as a whole, the number of sound sources that may be operating simultaneously, or how loud the animal may perceive the sonar signal to be based on the frequency of the sonar versus the animal's hearing range.

Criteria for assessing marine mammal behavioral responses to sonars use the metric of highest received sound level (RMS) to evaluate the risk of immediate responses by exposed animals. Currently, there are limited data to develop criteria that include the context of an exposure, characteristics of individual animals, behavioral state, duration of an exposure, sound source duty cycle, and the number of individual sources in an activity (although these factors certainly influence the severity of a behavioral response) and, further, even where certain contextual factors may be predictive where known, it is difficult to reliably predict when such factors will be present.

The BRFs also do not account for distance. At moderate to low received levels the correlation between probability of response and received level is very poor and it appears that other variables mediate behavioral responses (*e.g.,* Ellison *et al.,* 2012) such as the distance between the animal and the sound source. For this analysis, distance between the animal and the sound source (*i.e.,* range) was initially included, however, range was too confounded with received level and therefore did not provide additional information about the possibility of response.

Data suggest that beyond a certain distance, significant behavioral responses are unlikely. At shorter ranges (less than 10 km) some behavioral responses have been observed at received levels below 140 dB re 1 µPa. Thus, proximity may mediate behavioral responses at lower received levels. Since most data used to derive the BRFs are within 10 km of the source, probability of response at farther ranges is not well-represented. Therefore, the source-receiver range must be considered separately to estimate likely significant behavioral responses.

This analysis applies behavioral cut-off conditions to responses predicted using the BRFs. Animals within a specified distance and above a minimum probability of response are assumed to have a significant behavioral response. The cut-off distance is based on the farthest source-animal distance across all known studies where animals exhibited a significant behavioral response. Animals beyond the cut-off distance but with received levels above the sound pressure level associated with a probability of response of 0.50 on the BRF are also assumed to have a significant behavioral response. The actual likelihood of significant behavioral responses occurring beyond the distance cut-off is unknown. Significant behavioral responses beyond 100 km are unlikely based on source-animal distance and attenuated received levels. The behavioral cut-off conditions and additional information on the derivation of the cut-off conditions can be found in table 2.2–3 of the Criteria and Thresholds Technical Report.

The Action Proponents used cutoff distances beyond which the potential of significant behavioral responses (and therefore Level B harassment) is considered to be unlikely (see table 21). These distances were determined by examining all available published field observations of behavioral responses to sonar or sonar-like signals that included the distance between the sound source and the marine mammal. Behavioral effects calculations are based on the maximum SPL to which a modeled marine mammal is exposed. There is empirical evidence to suggest that animals are more likely to exhibit significant behavioral responses to moderate levels sounds that are closer and less likely to exhibit behavioral responses when exposed to moderate levels of sound from a source that is far away. To account for this, the Action Proponents have implemented behavioral cutoffs that consider both received sound level and distance from the source. These updated cutoffs conditions are unique to each behavioral hearing group and are outlined in table 21.

TABLE 21—BEHAVIORAL CUT-OFF CONDITIONS FOR EACH BEHAVIORAL HEARING GROUP

Behavioral group	Received level associated with p(0.50) on the behavioral response function (dB RMS)	Cut-off range (km)
Sensitive Species	133	40
Odontocetes	168	15
Mysticetes	185	10
Pinnipeds	156	5

Note: Sensitive Species includes beaked whales and harbor porpoises.

The Action Proponents and NMFS have used the best available science to address the challenging differentiation between significant and non-significant behavioral responses (*i.e.,* whether the behavior has been abandoned or significantly altered such that it qualifies as harassment), but have erred on the cautious side where uncertainty exists (*e.g.,* counting these lower duration responses as take), which likely results in some degree of overestimation of Level B harassment by behavioral disturbance. We consider application of these behavioral harassment thresholds, therefore, as identifying the maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered (*i.e.,* Level B harassment). NMFS has carefully reviewed the criteria (*i.e.,* BRFs and cutoff distances for the species), and agrees that it is the best available science and is the appropriate method to use at this time for determining impacts to marine mammals from military sonar and other transducers and for calculating take and to support the determinations made in this proposed rule. Because this is the most appropriate method for estimating Level B harassment given the best available science and uncertainty on the topic, it is these numbers of Level B harassment by behavioral disturbance that are analyzed in the Preliminary Analysis and Negligible Impact Determination section and would be authorized.

Air Guns, Pile Driving, and Explosives—

Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses generalized acoustic thresholds based on received level to estimate the onset of behavioral harassment for sources other than active sonar. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 µPa (RMS) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 µPa (RMS) for non-explosive impulsive (*e.g.,* seismic air guns) or intermittent (*e.g.,* scientific sonar) sources. For the Action Proponents' activities, to estimate behavioral effects from air guns, the threshold of 160 dB re 1 µPa (RMS) is used and the root mean square calculation for air guns is based on the duration defined by 90 percent of the cumulative energy in the impulse. The indicated thresholds were also applied to estimate behavioral effects from impact and vibratory pile driving (see table 22). These thresholds are the same as those applied in the prior analysis (Phase III) of these stressors in the Study Area, although the explosive behavioral threshold has shifted, corresponding to changes in the TTS thresholds.

TABLE 22—BEHAVIORAL RESPONSE THRESHOLDS FOR AIR GUNS, PILE DRIVING, AND EXPLOSIVES

Sound source	Behavioral threshold
Air gun	160 dB RMS re 1 µPa SPL.
Impact pile driving	160 dB RMS re 1 µPa SPL.
Vibratory pile driving	120 dB RMS re 1 µPa SPL.
Single explosion (underwater)	TTS onset threshold (weighted SEL).
Multiple explosions (underwater)	5 dB less than the TTS onset threshold (weighted SEL).
Explosion in Air*	100 dB 20 µPa (otariid and phocid).

*Estimated takes from land-based missile and rocket launches are based on pinniped observations during prior activities rather than in-air thresholds.

While the best available science for assessing behavioral responses of marine mammals to impulsive sounds relies on data from seismic and pile driving sources, it is likely that these predicted responses using a threshold based on seismic and pile driving represent a worst-case scenario compared to behavioral responses to explosives used in military readiness activities, which would typically consist of single impulses or a cluster of impulses rather than long-duration, repeated impulses (*e.g.,* large-scale air gun arrays).

For single explosions at received sound levels below hearing loss thresholds, the most likely behavioral response is a brief alerting or orienting response. Since no further sounds follow the initial brief impulses, significant behavioral responses would not be expected to occur. If a significant response were to occur, the Action Proponents' analysis assumes it would be as a result of an exposure at levels within the range of auditory impacts (TTS and AUD INJ). Because of this approach, the number of auditory impacts is higher than the number of behavioral impacts in the quantified results for some stocks.

If more than one explosive event occurs within any given 24-hour period during a military readiness activity, behavioral disturbance is considered more likely to occur and specific criteria are applied to predict the number of animals that may have a behavioral response. For events with multiple explosions, the behavioral threshold used in this analysis is 5 dB less than the TTS onset threshold. This value is derived from observed onsets of behavioral response by test subjects (bottlenose dolphins) during non-impulse TTS testing (Schlundt *et al.,* 2000).

Navy Acoustic Effects Model

The Navy Acoustic Effects Model (NAEMO) is their standard model for assessing acoustic effects on marine mammals. NAEMO calculates sound energy propagation from sonar and other transducers, air guns, and explosives during military readiness activities and the sound received by animat dosimeters. Animat dosimeters are virtual representations of marine mammals distributed in the area around the modeled activity and each dosimeter records its individual sound ''dose.'' The model bases the distribution of animats over the HCTT Study Area on the density values in the Navy Marine Species Density Database (NMSDD) and distributes animats in the water column proportional to the known time that species spend at varying depths.

The model accounts for environmental variability of sound propagation in both distance and depth when computing the sound level received by the animats. The model conducts a statistical analysis based on multiple model runs to compute the estimated effects on animals. The number of animats that exceed the thresholds for effects is tallied to provide an estimate of the number of marine mammals that could be affected.

Assumptions in NAEMO intentionally err on the side of overestimation when there are unknowns. The specified activities are modeled as though they would occur regardless of proximity to marine mammals, meaning that the implementation of power downs or shutdowns are not modeled or, thereby, considered in the take estimates. For more information on this process, see the discussion in the *Estimated Take from Acoustic Stressors* section below. Many explosions from ordnance such as bombs and missiles actually occur upon impact with above-water targets. However, for this analysis, sources such as these were modeled as exploding underwater. This overestimates the amount of explosive and acoustic energy entering the water.

The model estimates the acoustic impacts caused by sonars and other transducers, explosives, and air guns during individual military readiness activities. During any individual modeled event, impacts to individual animats are considered over 24-hour periods. The animats do not represent actual animals, but rather they represent a distribution of animals based on density and abundance data, which allows for a statistical analysis of the number of instances that marine mammals may be exposed to sound levels resulting in an effect. Therefore, the model estimates the number of instances in which an effect threshold was exceeded over the course of a year, but does not estimate the number of individual marine mammals that may be impacted over a year (*i.e.,* some marine mammals could be impacted several times, while others would not experience any impact). A detailed explanation of NAEMO is provided in the Acoustic Impacts Technical Report.

As NAEMO interrogates the simulation data in the Animat Processor, exposures that are both outside the distance cutoff and below the received level cutoff are omitted when determining the maximum SPL for each animat. This differs from Phase III, in which only distance cutoffs were applied, meaning that all exposures outside the distance cutoffs were omitted, with no consideration of received level.

The presence of the two cutoff criteria in Phase IV provides a more accurate and conservative estimation of behavioral effects because louder exposures that would have been omitted previously, when only a distance cutoff was applied, are considered in Phase IV, while the estimation of behavioral effects still omits exposures at distances and received levels that would be unlikely to produce a significant behavioral response. NAEMO retains the capability of calculating behavioral effects without the cutoffs applied, depending on user preference.

The impulsive behavioral criteria are not based on the probability of a behavioral response but rather on a single SPL metric. For consideration of impulsive behavioral effects, the cutoff conditions in table 21 are not applied.

Pile Driving

The Action Proponents performed a quantitative analysis without NAEMO to estimate the number of times marine mammals could be affected by pile driving and extraction used during port damage repair activities at Port Hueneme. The analysis considered details of the activity, sound exposure criteria, and the number and distribution of marine mammals. This information was then used in an ''area*density'' model in which the areas within each footprint (*i.e.,* harassment zone) that encompassed a potential effect were calculated for a given day's activities. The effects analyzed included behavioral response, TTS, and AUD INJ for marine mammals.

Then, these areas were multiplied by the density of each marine species within the Port Hueneme area (California sea lion and harbor seal) to estimate the number of effects. Uniform density values for species expected to be present in the nearshore areas where pile driving could occur were estimated using the NMSDD or available survey data specific to the activity location. More detail is provided in the 2024 HCTT Draft EIS/OEIS. Since the same animal can be ''taken'' every day (*i.e.,* 24-hour reset time), the number of predicted effects from a given day were multiplied by the number of days for that activity. This generated a total estimated number of effects over the entire activity, which was then multiplied by the maximum number of times per year this activity could happen. The result was the estimated effects per species and stock in a year.

Range to Effects

This section provides range (distance) to effects for sonar and other active acoustic sources as well as explosives to specific acoustic thresholds determined using NAEMO. Ranges are determined by modeling the distance that noise from a source will need to propagate to reach exposure level thresholds specific to a hearing group that will cause behavioral response, TTS, AUD INJ, non-auditory injury, and mortality. Ranges to effects (table 23 through table 36) are utilized to help predict impacts from acoustic and explosive sources and assess the benefit of mitigation zones. Marine mammals exposed within these ranges for the shown duration are predicted to experience the associated effect. Range to effects is important information in not only predicting acoustic impacts, but also in verifying the accuracy of model results against real-world situations and determining adequate mitigation ranges to avoid higher level effects, especially physiological effects to marine mammals.

Sonar

Ranges to effects for sonar were determined by modeling the distance that sound would need to propagate to reach exposure level thresholds specific to a hearing group that would cause behavioral response, TTS, and AUD INJ, as described in the Criteria and Thresholds Technical Report. The ranges do not account for an animal avoiding a source nor for the movement of the platform, both of which would influence the actual range to onset of auditory effects during an actual exposure.

Table 23 through table 28 below provide the ranges to TTS and AUD INJ for marine mammals from exposure durations of 1, 30, 60, and 120 seconds (s) for six sonar systems proposed for use (see also appendix A of the application). Due to the lower acoustic thresholds for TTS versus AUD INJ, ranges to TTS are larger. Successive pings can be expected to add together, further increasing the range to the onset of TTS and AUD INJ.

TABLE 23—VERY LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	1	160 m (30 m)	12 m (4 m).
Dipping sonar	≤200	30	312 m (75 m)	21 m (6 m).
Dipping sonar	≤200	60	423 m (97 m)	25 m (5 m).

TABLE 23—VERY LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR—Continued

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	120	628 m (135 m)	35 m (6 m).
Dipping sonar	>200	1	140 m (20 m)	0 m (1 m).
Dipping sonar	>200	30	260 m (49 m)	0 m (8 m).
Dipping sonar	>200	60	340 m (70 m)	23 m (10 m).
Dipping sonar	>200	120	500 m (112 m)	35 m (15 m).
MF1 ship sonar	≤200	1	1,069 m (252 m)	90 m (17 m).
MF1 ship sonar	≤200	30	1,069 m (252 m)	90 m (17 m).
MF1 ship sonar	≤200	60	1,528 m (465 m)	140 m (24 m).
MF1 ship sonar	≤200	120	1,792 m (636 m)	180 m (32 m).
MF1 ship sonar	>200	1	1,000 m (85 m)	85 m (3 m).
MF1 ship sonar	>200	30	1,000 m (85 m)	85 m (3 m).
MF1 ship sonar	>200	60	1,500 m (252 m)	130 m (7 m).
MF1 ship sonar	>200	120	1,944 m (484 m)	170 m (9 m).
MF1C ship sonar	≤200	1	1,069 m (252 m)	90 m (17 m).
MF1C ship sonar	≤200	30	1,792 m (636 m)	180 m (32 m).
MF1C ship sonar	≤200	60	2,319 m (1,021 m)	260 m (56 m).
MF1C ship sonar	≤200	120	2,845 m (1,479 m)	390 m (72 m).
MF1C ship sonar	>200	1	1,000 m (85 m)	85 m (3 m).
MF1C ship sonar	>200	30	1,944 m (484 m)	170 m (9 m).
MF1C ship sonar	>200	60	2,792 m (1,103 m)	250 m (21 m).
MF1C ship sonar	>200	120	4,000 m (1,599 m)	370 m (31 m).
MF1K ship sonar	≤200	1	193 m (37 m)	12 m (4 m).
MF1K ship sonar	≤200	30	355 m (73 m)	24 m (2 m).
MF1K ship sonar	≤200	60	470 m (83 m)	30 m (3 m).
MF1K ship sonar	≤200	120	668 m (126 m)	45 m (13 m).
MF1K ship sonar	>200	1	190 m (15 m)	5 m (5 m).
MF1K ship sonar	>200	30	340 m (34 m)	21 m (11 m).
MF1K ship sonar	>200	60	440 m (52 m)	25 m (3 m).
MF1K ship sonar	>200	120	625 m (66 m)	40 m (2 m).
Mine-hunting sonar	≤200	1	3 m (1 m)	0 m (0 m).
Mine-hunting sonar	≤200	30	6 m (1 m)	0 m (0 m).
Mine-hunting sonar	≤200	60	9 m (1 m)	0 m (0 m).
Mine-hunting sonar	≤200	120	13 m (2 m)	1 m (0 m).
Mine-hunting sonar	>200	1	0 m (0 m)	0 m (0 m).
Mine-hunting sonar	>200	30	5 m (2 m)	0 m (0 m).
Mine-hunting sonar	>200	60	8 m (3 m)	0 m (0 m).
Mine-hunting sonar	>200	120	12 m (0 m)	0 m (0 m).
Sonobuoy sonar	≤200	1	13 m (6 m)	0 m (0 m).
Sonobuoy sonar	≤200	30	25 m (6 m)	0 m (0 m).
Sonobuoy sonar	≤200	60	35 m (7 m)	0 m (1 m).
Sonobuoy sonar	≤200	120	50 m (4 m)	0 m (1 m).
Sonobuoy sonar	>200	1	0 m (6 m)	0 m (0 m).
Sonobuoy sonar	>200	30	23 m (10 m)	0 m (0 m).
Sonobuoy sonar	>200	60	35 m (11 m)	0 m (0 m).
Sonobuoy sonar	>200	120	50 m (3 m)	0 m (0 m).

Note: Median ranges are shown with standard deviation (SD) in parentheses. The Action Proponents split the LF functional hearing group into LF and VLF based on Houser *et al.,* (2024). NMFS updated acoustic technical guidance (NMFS, 2024) does not include these data but we have included the VLF group here for reference.

TABLE 24—LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	1	160 m (56 m)	12 m (4 m).
Dipping sonar	≤200	30	311 m (100 m)	21 m (6 m).
Dipping sonar	≤200	60	411 m (119 m)	25 m (7 m).
Dipping sonar	≤200	120	581 m (137 m)	35 m (11 m).
Dipping sonar	>200	1	150 m (82 m)	0 m (6 m).
Dipping sonar	>200	30	240 m (123 m)	17 m (10 m).
Dipping sonar	>200	60	287 m (160 m)	25 m (13 m).
Dipping sonar	>200	120	409 m (133 m)	35 m (18 m).
MF1 ship sonar	≤200	1	1,069 m (280 m)	95 m (19 m).
MF1 ship sonar	≤200	30	1,069 m (280 m)	95 m (19 m).
MF1 ship sonar	≤200	60	1,500 m (500 m)	140 m (24 m).
MF1 ship sonar	≤200	120	1,736 m (668 m)	180 m (30 m).
MF1 ship sonar	>200	1	1,000 m (185 m)	90 m (5 m).
MF1 ship sonar	>200	30	1,000 m (185 m)	90 m (5 m).
MF1 ship sonar	>200	60	1,569 m (415 m)	140 m (12 m).
MF1 ship sonar	>200	120	2,153 m (734 m)	180 m (14 m).

TABLE 24—LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR—Continued

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
MF1C ship sonar	≤200	1	1,069 m (280 m)	95 m (19 m).
MF1C ship sonar	≤200	30	1,736 m (668 m)	180 m (30 m).
MF1C ship sonar	≤200	60	2,194 m (1,062 m)	270 m (49 m).
MF1C ship sonar	≤200	120	2,667 m (1,519 m)	399 m (68 m).
MF1C ship sonar	>200	1	1,000 m (185 m)	90 m (5 m).
MF1C ship sonar	>200	30	2,153 m (734 m)	180 m (14 m).
MF1C ship sonar	>200	60	3,111 m (1,305 m)	260 m (21 m).
MF1C ship sonar	>200	120	4,333 m (1,845 m)	380 m (29 m).
MF1K ship sonar	≤200	1	200 m (34 m)	14 m (1 m).
MF1K ship sonar	≤200	30	360 m (67 m)	25 m (1 m).
MF1K ship sonar	≤200	60	480 m (84 m)	30 m (4 m).
MF1K ship sonar	≤200	120	661 m (135 m)	45 m (14 m).
MF1K ship sonar	>200	1	200 m (21 m)	12 m (1 m).
MF1K ship sonar	>200	30	350 m (32 m)	24 m (0 m).
MF1K ship sonar	>200	60	450 m (44 m)	30 m (0 m).
MF1K ship sonar	>200	120	650 m (88 m)	45 m (0 m).
Mine-hunting sonar	≤200	1	8 m (5 m)	0 m (0 m).
Mine-hunting sonar	≤200	30	15 m (8 m)	1 m (0 m).
Mine-hunting sonar	≤200	60	21 m (12 m)	2 m (1 m).
Mine-hunting sonar	≤200	120	30 m (12 m)	3 m (2 m).
Mine-hunting sonar	>200	1	8 m (5 m)	0 m (0 m).
Mine-hunting sonar	>200	30	15 m (8 m)	0 m (0 m).
Mine-hunting sonar	>200	60	21 m (12 m)	0 m (1 m).
Mine-hunting sonar	>200	120	30 m (12 m)	0 m (1 m).
Sonobuoy sonar	≤200	1	0 m (8 m)	0 m (0 m).
Sonobuoy sonar	≤200	30	25 m (12 m)	0 m (0 m).
Sonobuoy sonar	≤200	60	35 m (18 m)	0 m (0 m).
Sonobuoy sonar	≤200	120	55 m (25 m)	0 m (1 m).
Sonobuoy sonar	>200	1	0 m (7 m)	0 m (0 m).
Sonobuoy sonar	>200	30	19 m (12 m)	0 m (0 m).
Sonobuoy sonar	>200	60	35 m (19 m)	0 m (0 m).
Sonobuoy sonar	>200	120	55 m (28 m)	0 m (1 m).

Note: Median ranges are shown with standard deviation (SD) in parentheses. The Action Proponents split the LF functional hearing group into LF and VLF based on Houser *et al.,* (2024). NMFS updated acoustic technical guidance (NMFS, 2024) does not include these data but we have included the VLF group here for reference.

TABLE 25—HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	1	55 m (15 m)	5 m (2 m).
Dipping sonar	≤200	30	120 m (34 m)	9 m (4 m).
Dipping sonar	≤200	60	170 m (50 m)	12 m (5 m).
Dipping sonar	≤200	120	250 m (85 m)	18 m (6 m).
Dipping sonar	>200	1	50 m (28 m)	0 m (2 m).
Dipping sonar	>200	30	100 m (54 m)	0 m (4 m).
Dipping sonar	>200	60	130 m (74 m)	0 m (5 m).
Dipping sonar	>200	120	200 m (105 m)	0 m (8 m).
MF1 ship sonar	≤200	1	644 m (113 m)	45 m (7 m).
MF1 ship sonar	≤200	30	644 m (113 m)	45 m (7 m).
MF1 ship sonar	≤200	60	910 m (177 m)	65 m (12 m).
MF1 ship sonar	≤200	120	1,011 m (243 m)	85 m (14 m).
MF1 ship sonar	>200	1	600 m (52 m)	40 m (11 m).
MF1 ship sonar	>200	30	600 m (52 m)	40 m (11 m).
MF1 ship sonar	>200	60	875 m (93 m)	65 m (14 m).
MF1 ship sonar	>200	120	1,000 m (126 m)	85 m (7 m).
MF1C ship sonar	≤200	1	644 m (113 m)	45 m (7 m).
MF1C ship sonar	≤200	30	1,011 m (243 m)	85 m (14 m).
MF1C ship sonar	≤200	60	1,458 m (437 m)	130 m (23 m).
MF1C ship sonar	≤200	120	1,903 m (730 m)	200 m (36 m).
MF1C ship sonar	>200	1	600 m (52 m)	40 m (11 m).
MF1C ship sonar	>200	30	1,000 m (126 m)	85 m (7 m).
MF1C ship sonar	>200	60	1,500 m (309 m)	130 m (12 m).
MF1C ship sonar	>200	120	2,142 m (786 m)	200 m (17 m).
MF1K ship sonar	≤200	1	100 m (21 m)	7 m (3 m).
MF1K ship sonar	≤200	30	190 m (34 m)	13 m (4 m).
MF1K ship sonar	≤200	60	250 m (51 m)	17 m (5 m).
MF1K ship sonar	≤200	120	363 m (72 m)	25 m (2 m).
MF1K ship sonar	>200	1	100 m (19 m)	0 m (3 m).

TABLE 25—HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR—Continued

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
MF1K ship sonar	>200	30	180 m (20 m)	11 m (6 m).
MF1K ship sonar	>200	60	240 m (27 m)	16 m (8 m).
MF1K ship sonar	>200	120	350 m (39 m)	24 m (11 m).
Mine-hunting sonar	≤200	1	8 m (3 m)	0 m (0 m).
Mine-hunting sonar	≤200	30	15 m (5 m)	1 m (0 m).
Mine-hunting sonar	≤200	60	21 m (6 m)	1 m (1 m).
Mine-hunting sonar	≤200	120	30 m (6 m)	2 m (1 m).
Mine-hunting sonar	>200	1	7 m (3 m)	0 m (0 m).
Mine-hunting sonar	>200	30	15 m (6 m)	0 m (0 m).
Mine-hunting sonar	>200	60	21 m (7 m)	0 m (1 m).
Mine-hunting sonar	>200	120	30 m (5 m)	0 m (1 m).
Sonobuoy sonar	≤200	1	8 m (4 m)	0 m (0 m).
Sonobuoy sonar	≤200	30	18 m (8 m)	0 m (0 m).
Sonobuoy sonar	≤200	60	25 m (12 m)	0 m (0 m).
Sonobuoy sonar	≤200	120	35 m (14 m)	0 m (1 m).
Sonobuoy sonar	>200	1	0 m (4 m)	0 m (0 m).
Sonobuoy sonar	>200	30	0 m (9 m)	0 m (0 m).
Sonobuoy sonar	>200	60	0 m (12 m)	0 m (0 m).
Sonobuoy sonar	>200	120	30 m (16 m)	0 m (1 m).

Note: Median ranges are shown with standard deviation (SD) in parentheses.

TABLE 26—VERY HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	1	100 m (30 m)	8 m (2 m).
Dipping sonar	≤200	30	202 m (77 m)	14 m (4 m).
Dipping sonar	≤200	60	278 m (93 m)	19 m (5 m).
Dipping sonar	≤200	120	420 m (100 m)	25 m (7 m).
Dipping sonar	>200	1	95 m (50 m)	0 m (3 m).
Dipping sonar	>200	30	180 m (101 m)	0 m (6 m).
Dipping sonar	>200	60	240 m (123 m)	14 m (8 m).
Dipping sonar	>200	120	330 m (85 m)	24 m (12 m).
MF1 ship sonar	≤200	1	1,528 m (471 m)	150 m (25 m).
MF1 ship sonar	≤200	30	1,528 m (471 m)	150 m (25 m).
MF1 ship sonar	≤200	60	2,000 m (756 m)	220 m (39 m).
MF1 ship sonar	≤200	120	2,250 m (974 m)	280 m (57 m).
MF1 ship sonar	>200	1	1,569 m (357 m)	150 m (12 m).
MF1 ship sonar	>200	30	1,569 m (357 m)	150 m (12 m).
MF1 ship sonar	>200	60	2,403 m (885 m)	220 m (20 m).
MF1 ship sonar	>200	120	2,944 m (1,143 m)	270 m (27 m).
MF1C ship sonar	≤200	1	1,528 m (471 m)	150 m (25 m).
MF1C ship sonar	≤200	30	2,250 m (974 m)	280 m (57 m).
MF1C ship sonar	≤200	60	2,722 m (1,373 m)	417 m (68 m).
MF1C ship sonar	≤200	120	3,330 m (1,819 m)	588 m (99 m).
MF1C ship sonar	>200	1	1,569 m (357 m)	150 m (12 m).
MF1C ship sonar	>200	30	2,944 m (1,143 m)	270 m (27 m).
MF1C ship sonar	>200	60	4,097 m (1,620 m)	390 m (29 m).
MF1C ship sonar	>200	120	5,972 m (2,314 m)	550 m (38 m).
MF1K ship sonar	≤200	1	315 m (60 m)	20 m (2 m).
MF1K ship sonar	≤200	30	550 m (103 m)	35 m (5 m).
MF1K ship sonar	≤200	60	712 m (139 m)	50 m (12 m).
MF1K ship sonar	≤200	120	958 m (214 m)	85 m (12 m).
MF1K ship sonar	>200	1	300 m (37 m)	16 m (2 m).
MF1K ship sonar	>200	30	525 m (43 m)	35 m (1 m).
MF1K ship sonar	>200	60	675 m (66 m)	50 m (2 m).
MF1K ship sonar	>200	120	975 m (116 m)	85 m (4 m).
Mine-hunting sonar	≤200	1	90 m (26 m)	9 m (1 m).
Mine-hunting sonar	≤200	30	190 m (85 m)	16 m (2 m).
Mine-hunting sonar	≤200	60	329 m (128 m)	22 m (2 m).
Mine-hunting sonar	≤200	120	521 m (166 m)	30 m (3 m).
Mine-hunting sonar	>200	1	90 m (6 m)	7 m (1 m).
Mine-hunting sonar	>200	30	150 m (30 m)	15 m (0 m).
Mine-hunting sonar	>200	60	210 m (57 m)	22 m (0 m).
Mine-hunting sonar	>200	120	300 m (79 m)	30 m (0 m).
Sonobuoy sonar	≤200	1	65 m (20 m)	0 m (2 m).
Sonobuoy sonar	≤200	30	126 m (39 m)	9 m (5 m).
Sonobuoy sonar	≤200	60	191 m (79 m)	15 m (5 m).
Sonobuoy sonar	≤200	120	314 m (120 m)	22 m (7 m).

TABLE 26—VERY HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR SONAR—Continued

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Sonobuoy sonar	>200	1	65 m (31 m)	0 m (1 m).
Sonobuoy sonar	>200	30	110 m (59 m)	0 m (4 m).
Sonobuoy sonar	>200	60	180 m (75 m)	10 m (7 m).
Sonobuoy sonar	>200	120	276 m (72 m)	21 m (10 m).

Note: Median ranges are shown with standard deviation (SD) in parentheses.

TABLE 27—PHOCID CARNIVORE IN WATER RANGES TO EFFECTS FOR SONAR

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	1	200 m (52 m)	0 m (7 m).
Dipping sonar	≤200	30	370 m (101 m)	21 m (12 m).
Dipping sonar	≤200	60	496 m (134 m)	30 m (15 m).
Dipping sonar	≤200	120	707 m (144 m)	45 m (12 m).
Dipping sonar	>200	1	160 m (71 m)	0 m (4 m).
Dipping sonar	>200	30	298 m (129 m)	0 m (8 m).
Dipping sonar	>200	60	370 m (170 m)	0 m (10 m).
Dipping sonar	>200	120	550 m (80 m)	0 m (19 m).
MF1 ship sonar	≤200	1	1,250 m (384 m)	120 m (20 m).
MF1 ship sonar	≤200	30	1,250 m (384 m)	120 m (20 m).
MF1 ship sonar	≤200	60	1,625 m (632 m)	180 m (33 m).
MF1 ship sonar	≤200	120	1,875 m (833 m)	230 m (45 m).
MF1 ship sonar	>200	1	1,250 m (282 m)	120 m (53 m).
MF1 ship sonar	>200	30	1,250 m (282 m)	120 m (53 m).
MF1 ship sonar	>200	60	1,792 m (696 m)	180 m (21 m).
MF1 ship sonar	>200	120	2,264 m (982 m)	230 m (23 m).
MF1C ship sonar	≤200	1	1,250 m (384 m)	120 m (20 m).
MF1C ship sonar	≤200	30	1,875 m (833 m)	230 m (45 m).
MF1C ship sonar	≤200	60	2,333 m (1,223 m)	330 m (73 m).
MF1C ship sonar	≤200	120	2,833 m (1,633 m)	481 m (97 m).
MF1C ship sonar	>200	1	1,250 m (282 m)	120 m (53 m).
MF1C ship sonar	>200	30	2,264 m (982 m)	230 m (23 m).
MF1C ship sonar	>200	60	3,368 m (1,399 m)	330 m (31 m).
MF1C ship sonar	>200	120	4,500 m (1,973 m)	462 m (46 m).
MF1K ship sonar	≤200	1	248 m (58 m)	0 m (9 m).
MF1K ship sonar	≤200	30	435 m (97 m)	25 m (8 m).
MF1K ship sonar	≤200	60	550 m (133 m)	35 m (10 m).
MF1K ship sonar	≤200	120	771 m (190 m)	65 m (14 m).
MF1K ship sonar	>200	1	240 m (26 m)	0 m (8 m).
MF1K ship sonar	>200	30	430 m (48 m)	24 m (13 m).
MF1K ship sonar	>200	60	550 m (61 m)	35 m (16 m).
MF1K ship sonar	>200	120	775 m (105 m)	65 m (28 m).
Mine-hunting sonar	≤200	1	12 m (7 m)	0 m (0 m).
Mine-hunting sonar	≤200	30	24 m (11 m)	0 m (1 m).
Mine-hunting sonar	≤200	60	35 m (11 m)	0 m (1 m).
Mine-hunting sonar	≤200	120	50 m (15 m)	0 m (2 m).
Mine-hunting sonar	>200	1	0 m (5 m)	0 m (0 m).
Mine-hunting sonar	>200	30	22 m (9 m)	0 m (0 m).
Mine-hunting sonar	>200	60	30 m (4 m)	0 m (1 m).
Mine-hunting sonar	>200	120	45 m (5 m)	0 m (1 m).
Sonobuoy sonar	≤200	1	0 m (11 m)	0 m (0 m).
Sonobuoy sonar	≤200	30	35 m (16 m)	0 m (1 m).
Sonobuoy sonar	≤200	60	50 m (19 m)	0 m (1 m).
Sonobuoy sonar	≤200	120	75 m (20 m)	0 m (3 m).
Sonobuoy sonar	>200	1	0 m (7 m)	0 m (0 m).
Sonobuoy sonar	>200	30	0 m (16 m)	0 m (0 m).
Sonobuoy sonar	>200	60	45 m (23 m)	0 m (0 m).
Sonobuoy sonar	>200	120	70 m (32 m)	0 m (1 m).

Note: Median ranges are shown with standard deviation (SD) in parentheses.

TABLE 28—OTARIID CARNIVORE IN WATER RANGES TO EFFECTS FOR SONAR

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	1	60 m (16 m)	0 m (3 m).
Dipping sonar	≤200	30	130 m (40 m)	0 m (5 m).
Dipping sonar	≤200	60	180 m (58 m)	0 m (6 m).

TABLE 28—OTARIID CARNIVORE IN WATER RANGES TO EFFECTS FOR SONAR—Continued

Sonar type	Depth (m)	Duration (s)	Range to TTS (SD)	Range to AUD INJ (SD)
Dipping sonar	≤200	120	274 m (88 m)	11 m (9 m).
Dipping sonar	>200	1	55 m (30 m)	0 m (2 m).
Dipping sonar	>200	30	120 m (66 m)	0 m (4 m).
Dipping sonar	>200	60	160 m (90 m)	0 m (5 m).
Dipping sonar	>200	120	210 m (116 m)	0 m (8 m).
MF1 ship sonar	≤200	1	726 m (148 m)	50 m (10 m).
MF1 ship sonar	≤200	30	726 m (148 m)	50 m (10 m).
MF1 ship sonar	≤200	60	981 m (220 m)	80 m (12 m).
MF1 ship sonar	≤200	120	1,139 m (296 m)	109 m (18 m).
MF1 ship sonar	>200	1	725 m (93 m)	50 m (1 m).
MF1 ship sonar	>200	30	725 m (93 m)	50 m (1 m).
MF1 ship sonar	>200	60	1,000 m (157 m)	80 m (5 m).
MF1 ship sonar	>200	120	1,250 m (251 m)	100 m (8 m).
MF1C ship sonar	≤200	1	726 m (148 m)	50 m (10 m).
MF1C ship sonar	≤200	30	1,139 m (296 m)	109 m (18 m).
MF1C ship sonar	≤200	60	1,500 m (462 m)	160 m (23 m).
MF1C ship sonar	≤200	120	1,861 m (690 m)	240 m (40 m).
MF1C ship sonar	>200	1	725 m (93 m)	50 m (1 m).
MF1C ship sonar	>200	30	1,250 m (251 m)	100 m (8 m).
MF1C ship sonar	>200	60	1,750 m (549 m)	160 m (12 m).
MF1C ship sonar	>200	120	2,250 m (1,071 m)	240 m (22 m).
MF1K ship sonar	≤200	1	120 m (22 m)	8 m (4 m).
MF1K ship sonar	≤200	30	230 m (40 m)	16 m (4 m).
MF1K ship sonar	≤200	60	300 m (56 m)	20 m (3 m).
MF1K ship sonar	≤200	120	426 m (77 m)	25 m (4 m).
MF1K ship sonar	>200	1	120 m (12 m)	0 m (4 m).
MF1K ship sonar	>200	30	220 m (30 m)	14 m (6 m).
MF1K ship sonar	>200	60	290 m (38 m)	20 m (5 m).
MF1K ship sonar	>200	120	420 m (58 m)	25 m (1 m).
Mine-hunting sonar	≤200	1	6 m (3 m)	0 m (0 m).
Mine-hunting sonar	≤200	30	11 m (6 m)	0 m (0 m).
Mine-hunting sonar	≤200	60	18 m (8 m)	0 m (0 m).
Mine-hunting sonar	≤200	120	25 m (10 m)	0 m (1 m).
Mine-hunting sonar	>200	1	6 m (3 m)	0 m (0 m).
Mine-hunting sonar	>200	30	11 m (5 m)	0 m (0 m).
Mine-hunting sonar	>200	60	18 m (7 m)	0 m (0 m).
Mine-hunting sonar	>200	120	25 m (10 m)	0 m (1 m).
Sonobuoy sonar	≤200	1	0 m (6 m)	0 m (0 m).
Sonobuoy sonar	≤200	30	18 m (11 m)	0 m (0 m).
Sonobuoy sonar	≤200	60	30 m (13 m)	0 m (1 m).
Sonobuoy sonar	≤200	120	45 m (20 m)	0 m (1 m).
Sonobuoy sonar	>200	1	0 m (5 m)	0 m (0 m).
Sonobuoy sonar	>200	30	0 m (11 m)	0 m (0 m).
Sonobuoy sonar	>200	60	25 m (14 m)	0 m (0 m).
Sonobuoy sonar	>200	120	40 m (22 m)	0 m (1 m).

Note: Median ranges are shown with standard deviation (SD) in parentheses.

Air Guns

Ranges to effects for air guns were determined by modeling the distance that sound would need to propagate to reach exposure level thresholds specific to a hearing group that would cause behavioral response, TTS, and AUD INJ, as described in the Criteria and Thresholds Technical Report. The air gun ranges to effects for TTS and AUD INJ in table 29 are based on the metric (*i.e.,* SEL or SPL) that produced larger ranges.

TABLE 29—RANGE TO EFFECTS FOR AIR GUNS

Functional hearing group	Depth (m)	Cluster size	Behavioral disturbance	Range to TTS (SD)	Range to AUD INJ (SD)
VLF	≤200	1	N/A	5 m (0 m)	1 m (1 m).
VLF	≤200	10	114 m (6 m)	81 m (1 m)	14 m (0 m).
VLF	>200	1	N/A	5 m (0 m)	1 m (1 m).
VLF	>200	10	115 m (7 m)	81 m (1 m)	14 m (0 m).
LF	≤200	1	N/A	5 m (0 m)	2 m (0 m).
LF	≤200	10	104 m (10 m)	36 m (1 m)	6 m (0 m).
LF	>200	1	N/A	5 m (0 m)	2 m (0 m).
LF	>200	10	107 m (11 m)	35 m (1 m)	6 m (0 m).
HF	≤200	1	N/A	2 m (1 m)	0 m (0 m).
HF	≤200	10	111 m (10 m)	2 m (1 m)	0 m (0 m).

TABLE 29—RANGE TO EFFECTS FOR AIR GUNS—Continued

Functional hearing group	Depth (m)	Cluster size	Behavioral disturbance	Range to TTS (SD)	Range to AUD INJ (SD)
HF	>200	1	N/A	2 m (1 m)	0 m (0 m).
HF	>200	10	112 m (13 m)	2 m (1 m)	0 m (0 m).
VHF	≤200	1	N/A	51 m (2 m)	25 m (0 m).
VHF	≤200	10	111 m (13 m)	51 m (2 m)	25 m (0 m).
VHF	>200	1	N/A	50 m (1 m)	25 m (0 m).
VHF	>200	10	119 m (14 m)	50 m (1 m)	25 m (0 m).
PCW	≤200	1	N/A	5 m (2 m)	2 m (1 m).
PCW	≤200	10	110 m (11 m)	7 m (3 m)	2 m (1 m).
PCW	>200	1	N/A	5 m (2 m)	2 m (1 m).
PCW	>200	10	113 m (23 m)	7 m (3 m)	2 m (1 m).
OCW	≤200	1	N/A	2 m (0 m)	1 m (0 m).
OCW	≤200	10	112 m (18 m)	2 m (0 m)	1 m (0 m).
OCW	>200	1	N/A	2 m (0 m)	1 m (0 m).
OCW	>200	10	118 m (19 m)	2 m (0 m)	1 m (0 m).

Note: N/A = Not Applicable. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. The Action Proponents split the LF functional hearing group into LF and VLF based on Houser *et al.,* (2024). NMFS updated acoustic technical guidance (NMFS, 2024) does not include these data but we have included the VLF group here for reference.

Pile Driving

Only California sea lions (U.S. stock) and harbor seals (California stock) are expected to be present in the waters of Port Hueneme, where impact and vibratory pile driving and extraction is proposed to occur up to 12 times per year. Table 30 shows the predicted ranges to AUD INJ, TTS, and behavioral response for the otariid carnivore in water and phocid carnivore in water hearing groups (the only functional hearing groups expected in the vicinity of pile driving and extraction activities) that were analyzed for their exposure to impact and vibratory pile driving. These ranges were estimated based on activity parameters described in the Acoustic Stressors section of the Explosive and Acoustic Analysis Report (see appendix A of the application) and using the calculations described in the Acoustic Impacts Technical Report.

TABLE 30—RANGE TO EFFECTS FOR PINNIPEDS FROM PILE DRIVING

Pile type	Method	Functional hearing group	Behavioral response (m)	Range to TTS (m)	Range to AUD INJ (m)
20-inch (51 cm) round timber/plastic	Impact	OCW	46	43	4
20-inch (51 cm) H steel	Impact	OCW	215	201	20
20-inch (51 cm) round or H steel/timber/plastic	Impact	OCW	858	685	69
27.5-inch (70 cm) sheet or Z steel	Vibratory	OCW	3,981	12	1
20-inch (51 cm) round steel/timber/plastic	Vibratory	OCW	3,981	36	2
20-inch (51 cm) round timber/plastic	Impact	PCW	46	116	12
20-inch (51 cm) H steel	Impact	PCW	215	538	54
20-inch (51 cm) round or H steel/timber/plastic	Impact	PCW	858	1,839	184
27.5-inch (70 cm) sheet or Z steel	Vibratory	PCW	11,659	35	2
20-inch (51 cm) round steel/timber/plastic	Vibratory	PCW	11,659	105	5

Note: cm = centimeter.

Explosives

This section provides the range (*i.e.,* distance) over which specific physiological or behavioral effects are expected to occur based on the explosive criteria (see section 6.2.1 (Impacts from Explosives) of the application and the Criteria and Thresholds Technical Report and the explosive propagation calculations from NAEMO. The range to effects are shown for a range of explosive bins, from E1 (0.1–0.25 lb (0.045–0.113 kg) NEW) to E16 (greater than 7,250–14,500 lb (3,288–6,577 kg) NEW (ship shock trial only)) (table 31 through table 36). Ranges are determined by modeling the distance that noise from an explosion would need to propagate to reach exposure level thresholds specific to a hearing group that would cause behavioral response (to the degree of Level B behavioral harassment), TTS, and AUD INJ. NMFS has reviewed the range distance to effect data provided by the Action Proponents and concurs with the analysis. Range to effects is important information in not only predicting impacts from explosives, but also in verifying the accuracy of model results against real-world situations and determining appropriate mitigation ranges to avoid higher level effects, especially injury to marine mammals. For additional information on how ranges to impacts from explosions were estimated, see the Acoustic Impacts Technical Report.

Table 31 through table 36 show the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that qualify as Level B harassment for all functional hearing groups based on the developed thresholds. Ranges are provided for a representative source depth and cluster size (*i.e.,* the number of rounds fired, or buoys dropped, within a very short duration) for each bin. Ranges for behavioral response are only provided if more than one explosive cluster occurs. As noted previously, single explosions at received sound levels below TTS and AUD INJ thresholds are most likely to result in a brief alerting or orienting

response. For events with multiple explosions, sound from successive explosions can be expected to accumulate and increase the range to the onset of an impact based on SEL thresholds. Modeled ranges to TTS and AUD INJ based on peak pressure for a single explosion generally exceed the modeled ranges based on SEL even when accumulated for multiple explosions. Peak pressure-based ranges are estimated using the best available science; however, data on peak pressure at far distances from explosions are very limited. The explosive ranges to effects for TTS and AUD INJ that are in the tables are based on the metric (*i.e.,* SEL or SPL) that produced larger ranges.

Table 37 shows ranges to non-auditory injury and mortality as a function of animal mass and explosive bin. For non-auditory injury, the larger of the ranges to slight lung injury or gastrointestinal tract injury was used as a conservative estimate, and the boxplots in appendix A to the application present ranges for both metrics for comparison. For the non-auditory metric, ranges are only available for a cluster size of one. Animals within water volumes encompassing the estimated range to non-auditory injury would be expected to receive minor injuries at the outer ranges, increasing to more substantial injuries, and finally mortality as an animal approaches the detonation point.

TABLE 31—VERY LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	1	N/A	206 m (73 m)	95 m (2 m).
E1	≤200	5	618 m (230 m)	390 m (161 m)	95 m (19 m).
E1	≤200	25	1,246 m (444 m)	785 m (267 m)	182 m (61 m).
E1	≤200	50	1,419 m (471 m)	800 m (178 m)	250 m (34 m).
E1	>200	1	N/A	220 m (55 m)	95 m (3 m).
E1	>200	5	600 m (61 m)	430 m (18 m)	95 m (2 m).
E1	>200	25	950 m (155 m)	700 m (84 m)	190 m (5 m).
E1	>200	50	1,000 m (290 m)	850 m (98 m)	270 m (5 m).
E2	≤200	1	N/A	362 m (42 m)	130 m (12 m).
E2	>200	1	N/A	370 m (46 m)	130 m (13 m).
E3	≤200	1	N/A	489 m (387 m)	213 m (6 m).
E3	≤200	5	1,531 m (615 m)	909 m (370 m)	213 m (6 m).
E3	≤200	25	2,764 m (1,211 m)	1,722 m (685 m)	414 m (178 m).
E3	>200	1	N/A	825 m (304 m)	214 m (7 m).
E3	>200	5	1,000 m (346 m)	751 m (154 m)	220 m (5 m).
E3	>200	25	1,750 m (971 m)	1,000 m (369 m)	420 m (26 m).
E4	≤200	1	N/A	1,875 m (768 m)	382 m (26 m).
E4	>200	1	N/A	1,250 m (277 m)	377 m (28 m).
E5	≤200	1	N/A	815 m (851 m)	358 m (27 m).
E5	≤200	5	2,986 m (1,306 m)	1,586 m (714 m)	358 m (27 m).
E5	>200	1	N/A	650 m (152 m)	343 m (25 m).
E5	>200	5	2,146 m (956 m)	1,056 m (452 m)	350 m (54 m).
E5	>200	20	3,889 m (975 m)	2,625 m (600 m)	575 m (178 m).
E6	≤200	1	N/A	1,836 m (1,341 m)	534 m (382 m).
E6	≤200	15	7,258 m (1,106 m)	5,397 m (814 m)	2,029 m (104 m).
E6	>200	1	N/A	1,347 m (762 m)	516 m (48 m).
E7	≤200	1	N/A	1,651 m (729 m)	535 m (25 m).
E7	>200	1	N/A	1,556 m (1,347 m)	537 m (24 m).
E8	≤200	1	N/A	2,549 m (485 m)	769 m (55 m).
E8	>200	1	N/A	2,519 m (477 m)	754 m (54 m).
E9	≤200	1	N/A	3,417 m (1,563 m)	755 m (49 m).
E9	>200	1	N/A	2,667 m (1,186 m)	754 m (49 m).
E10	≤200	1	N/A	4,272 m (840 m)	891 m (88 m).
E10	>200	1	N/A	4,264 m (820 m)	889 m (100 m).
E11	≤200	1	N/A	14,182 m (3,939 m)	1,778 m (60 m).
E11	>200	1	N/A	14,814 m (4,258 m)	1,833 m (116 m).
E12	≤200	1	N/A	4,523 m (910 m)	992 m (78 m).
E12	>200	1	N/A	4,349 m (813 m)	981 m (165 m).
E13	≤200	1	N/A	7,208 m (5,750 m)	3,361 m (1,875 m).
E16	>200	1	N/A	10,778 m (8,250 m)	2,438 m (65 m).

Note: N/A = Not Applicable. Behavioral response criteria are applied to explosive clusters >1. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. The Action Proponents split the LF functional hearing group into LF and VLF based on Houser *et al.* (2024). NMFS updated acoustic technical guidance (NMFS, 2024) does not include these data but we have included the VLF group here for reference. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

TABLE 32—LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	1	N/A	214 m (76 m)	92 m (7 m).

TABLE 32—LOW-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES—Continued

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	5	726 m (232 m)	428 m (164 m)	100 m (22 m).
E1	≤200	25	1,342 m (462 m)	884 m (266 m)	194 m (63 m).
E1	≤200	50	1,457 m (602 m)	846 m (296 m)	240 m (47 m).
E1	>200	1	N/A	250 m (60 m)	93 m (7 m).
E1	>200	5	725 m (140 m)	480 m (87 m)	110 m (8 m).
E1	>200	25	1,000 m (243 m)	800 m (162 m)	220 m (24 m).
E1	>200	50	1,153 m (318 m)	950 m (179 m)	310 m (39 m).
E2	≤200	1	N/A	375 m (57 m)	128 m (16 m).
E2	>200	1	N/A	381 m (59 m)	129 m (17 m).
E3	≤200	1	N/A	542 m (257 m)	198 m (13 m).
E3	≤200	5	1,482 m (563 m)	946 m (328 m)	205 m (86 m).
E3	≤200	25	2,346 m (1,019 m)	1,664 m (605 m)	435 m (159 m).
E3	>200	1	N/A	775 m (206 m)	199 m (14 m).
E3	>200	5	1,000 m (364 m)	861 m (191 m)	240 m (33 m).
E3	>200	25	1,500 m (916 m)	1,000 m (405 m)	361 m (110 m).
E4	≤200	1	N/A	1,586 m (653 m)	372 m (42 m).
E4	>200	1	N/A	1,000 m (257 m)	365 m (44 m).
E5	≤200	1	N/A	854 m (753 m)	305 m (39 m).
E5	≤200	5	2,306 m (1,138 m)	1,433 m (604 m)	319 m (83 m).
E5	>200	1	N/A	725 m (184 m)	297 m (38 m).
E5	>200	5	1,861 m (965 m)	1,000 m (415 m)	380 m (70 m).
E5	>200	20	3,944 m (1,014 m)	2,618 m (614 m)	747 m (112 m).
E6	≤200	1	N/A	1,597 m (1,167 m)	485 m (63 m).
E6	≤200	15	4,916 m (981 m)	3,605 m (763 m)	1,433 m (181 m).
E6	>200	1	N/A	1,250 m (836 m)	488 m (61 m).
E7	≤200	1	N/A	1,372 m (576 m)	427 m (80 m).
E7	>200	1	N/A	1,458 m (1,037 m)	429 m (82 m).
E8	≤200	1	N/A	2,013 m (388 m)	652 m (83 m).
E8	>200	1	N/A	1,985 m (376 m)	643 m (82 m).
E9	≤200	1	N/A	2,528 m (1,170 m)	689 m (85 m).
E9	>200	1	N/A	2,183 m (938 m)	692 m (84 m).
E10	≤200	1	N/A	3,220 m (660 m)	841 m (112 m).
E10	>200	1	N/A	3,203 m (664 m)	836 m (122 m).
E11	≤200	1	N/A	7,977 m (2,054 m)	1,468 m (173 m).
E11	>200	1	N/A	7,750 m (3,163 m)	1,570 m (266 m).
E12	≤200	1	N/A	3,844 m (1,097 m)	903 m (163 m).
E12	>200	1	N/A	3,453 m (1,050 m)	979 m (170 m).
E13	≤200	1	N/A	4,542 m (1,609 m)	2,757 m (1,128 m).
E16	>200	1	N/A	5,194 m (1,347 m)	2,667 m (513 m).

Note: N/A = Not Applicable. Behavioral response criteria are applied to explosive clusters >1. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. The Action Proponents split the LF functional hearing group into LF and VLF based on Houser *et al.* (2024). NMFS updated acoustic technical guidance (NMFS, 2024) does not include these data but we have included the VLF group here for reference. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

TABLE 33—HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	1	N/A	91 m (18 m)	42 m (2 m).
E1	≤200	5	260 m (90 m)	180 m (49 m)	42 m (2 m).
E1	≤200	25	479 m (201 m)	316 m (122 m)	85 m (17 m).
E1	≤200	50	497 m (182 m)	367 m (101 m)	110 m (8 m).
E1	>200	1	N/A	90 m (3 m)	42 m (2 m).
E1	>200	5	280 m (29 m)	180 m (9 m)	42 m (2 m).
E1	>200	25	490 m (109 m)	310 m (46 m)	85 m (3 m).
E1	>200	50	800 m (176 m)	500 m (80 m)	110 m (4 m).
E2	≤200	1	N/A	122 m (12 m)	57 m (6 m).
E2	>200	1	N/A	122 m (12 m)	57 m (7 m).
E3	≤200	1	N/A	181 m (48 m)	93 m (4 m).
E3	≤200	5	491 m (183 m)	321 m (110 m)	93 m (4 m).
E3	≤200	25	847 m (281 m)	582 m (182 m)	154 m (43 m).
E3	>200	1	N/A	180 m (15 m)	93 m (5 m).
E3	>200	5	538 m (106 m)	330 m (46 m)	93 m (5 m).
E3	>200	25	986 m (258 m)	725 m (173 m)	160 m (6 m).
E4	≤200	1	N/A	356 m (106 m)	135 m (34 m).

TABLE 33—HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES—Continued

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E4	>200	1	N/A	282 m (35 m)	132 m (19 m).
E5	≤200	1	N/A	294 m (137 m)	151 m (17 m).
E5	≤200	5	812 m (233 m)	513 m (166 m)	151 m (17 m).
E5	>200	1	N/A	260 m (25 m)	149 m (14 m).
E5	>200	5	794 m (213 m)	500 m (98 m)	149 m (14 m).
E5	>200	20	1,250 m (299 m)	875 m (178 m)	220 m (17 m).
E6	≤200	1	N/A	455 m (218 m)	213 m (28 m).
E6	≤200	15	1,624 m (167 m)	1,223 m (117 m)	427 m (47 m).
E6	>200	1	N/A	403 m (50 m)	216 m (26 m).
E7	≤200	1	N/A	422 m (93 m)	237 m (42 m).
E7	>200	1	N/A	450 m (154 m)	236 m (44 m).
E8	≤200	1	N/A	621 m (71 m)	334 m (32 m).
E8	>200	1	N/A	610 m (70 m)	332 m (32 m).
E9	≤200	1	N/A	646 m (99 m)	378 m (48 m).
E9	>200	1	N/A	701 m (160 m)	381 m (46 m).
E10	≤200	1	N/A	830 m (142 m)	482 m (76 m).
E10	>200	1	N/A	820 m (164 m)	481 m (73 m).
E11	≤200	1	N/A	1,271 m (157 m)	699 m (70 m).
E11	>200	1	N/A	1,325 m (194 m)	738 m (88 m).
E12	≤200	1	N/A	1,005 m (226 m)	650 m (114 m).
E12	>200	1	N/A	1,008 m (219 m)	632 m (109 m).
E13	≤200	1	N/A	5,569 m (4,190 m)	2,701 m (4,433 m).
E16	>200	1	N/A	3,778 m (8,655 m)	1,882 m (7,911 m)

Note: N/A = Not Applicable. Behavioral response criteria are applied to explosive clusters >1. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

TABLE 34—VERY HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	1	N/A	1,034 m8 (156 m)	662 m (87 m).
E1	≤200	5	1,778 m (1,398 m)	1,250 m (1,056 m)	662 m (87 m).
E1	≤200	25	2,667 m (1,883 m)	1,965 m (1,556 m)	835 m (577 m).
E1	≤200	50	4,056 m (2,398 m)	2,917 m (2,027 m)	924 m (695 m).
E1	>200	1	N/A	1,500 m (413 m)	646 m (85 m).
E1	>200	5	2,500 m (1,219 m)	2,000 m (708 m)	729 m (105 m).
E1	>200	25	3,972 m (2,279 m)	2,861 m (1,520 m)	1,250 m (251 m).
E1	>200	50	3,806 m (2,522 m)	3,035 m (1,737 m)	1,000 m (428 m).
E2	≤200	1	N/A	1,397 m (241 m)	798 m (107 m).
E2	>200	1	N/A	1,431 m (235 m)	799 m (104 m).
E3	≤200	1	N/A	2,100 m (410 m)	1,350 m (173 m).
E3	≤200	5	2,708 m (1,843 m)	2,100 m (410 m)	1,350 m (173 m).
E3	≤200	25	3,171 m (2,026 m)	2,500 m (1,738 m)	1,350 m (173 m).
E3	>200	1	N/A	2,250 m (913 m)	1,352 m (167 m).
E3	>200	5	3,708 m (2,026 m)	2,750 m (1,330 m)	1,352 m (167 m).
E3	>200	25	3,000 m (2,086 m)	2,500 m (1,596 m)	1,471 m (526 m).
E4	≤200	1	N/A	3,216 m (516 m)	2,189 m (251 m).
E4	>200	1	N/A	3,321 m (522 m)	2,250 m (256 m).
E5	≤200	1	N/A	2,229 m (447 m)	1,472 m (260 m).
E5	≤200	5	3,931 m (2,098 m)	3,322 m (1,800 m)	1,642 m (786 m).
E5	>200	1	N/A	2,264 m (1,091 m)	1,415 m (254 m).
E5	>200	5	4,924 m (3,027 m)	3,681 m (2,102 m)	1,750 m (457 m).
E5	>200	20	11,958 m (2,934 m)	8,125 m (2,005 m)	2,250 m (555 m).
E6	≤200	1	N/A	3,622 m (828 m)	2,385 m (514 m).
E6	≤200	15	4,411 m (761 m)	3,945 m (631 m)	2,633 m (362 m).
E6	>200	1	N/A	3,667 m (779 m)	2,423 m (488 m).
E7	≤200	1	N/A	4,083 m (767 m)	2,750 m (478 m).
E7	>200	1	N/A	4,458 m (1,831 m)	2,838 m (465 m).
E8	≤200	1	N/A	7,163 m (3,017 m)	3,215 m (825 m).
E8	>200	1	N/A	6,023 m (2,763 m)	3,069 m (731 m).
E9	≤200	1	N/A	5,469 m (992 m)	3,194 m (633 m).
E9	>200	1	N/A	5,319 m (1,041 m)	3,092 m (601 m).
E10	≤200	1	N/A	7,028 m (1,433 m)	4,067 m (867 m).
E10	>200	1	N/A	6,974 m (1,482 m)	4,000 m (825 m).

TABLE 34—VERY HIGH-FREQUENCY CETACEAN RANGES TO EFFECTS FOR EXPLOSIVES—Continued

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E11	≤200	1	N/A	27,993 m (6,335 m)	16,304 m (5,256 m).
E11	>200	1	N/A	26,087 m (6,856 m)	15,150 m (6,163 m).
E12	≤200	1	N/A	8,639 m (1,966 m)	4,514 m (1,389 m).
E12	>200	1	N/A	8,882 m (2,905 m)	4,812 m (1,608 m).
E13	≤200	1	N/A	11,222 m (3,196 m)	4,931 m (1,169 m).
E16	>200	1	N/A	6,639 m (6,673 m)	2,257 m (1,560 m).

Note: N/A = Not Applicable. Behavioral response criteria are applied to explosive clusters >1. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

TABLE 35—PHOCID CARNIVORE IN WATER RANGES TO EFFECTS FOR EXPLOSIVES

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	1	N/A	227 m (67 m)	83 m (6 m).
E1	≤200	5	673 m (210 m)	421 m (145 m)	110 m (27 m).
E1	≤200	25	1,138 m (420 m)	822 m (242 m)	199 m (61 m).
E1	≤200	50	1,264 m (577 m)	785 m (286 m)	259 m (51 m).
E1	>200	1	N/A	260 m (41 m)	84 m (6 m).
E1	>200	5	675 m (179 m)	480 m (85 m)	110 m (4 m).
E1	>200	25	975 m (360 m)	725 m (209 m)	230 m (20 m).
E1	>200	50	1,500 m (563 m)	1,000 m (295 m)	305 m (35 m).
E2	≤200	1	N/A	347 m (52 m)	110 m (15 m).
E2	>200	1	N/A	355 m (55 m)	112 m (16 m).
E3	≤200	1	N/A	490 m (227 m)	188 m (13 m).
E3	≤200	5	1,221 m (433 m)	837 m (245 m)	209 m (59 m).
E3	≤200	25	1,969 m (787 m)	1,428 m (468 m)	397 m (113 m).
E3	>200	1	N/A	675 m (141 m)	188 m (13 m).
E3	>200	5	1,250 m (396 m)	917 m (205 m)	240 m (20 m).
E3	>200	25	2,250 m (868 m)	1,499 m (559 m)	490 m (103 m).
E4	≤200	1	N/A	1,124 m (441 m)	295 m (114 m).
E4	>200	1	N/A	900 m (114 m)	283 m (59 m).
E5	≤200	1	N/A	748 m (445 m)	301 m (45 m).
E5	≤200	5	1,917 m (829 m)	1,258 m (431 m)	311 m (85 m).
E5	>200	1	N/A	768 m (184 m)	294 m (42 m).
E5	>200	5	1,611 m (814 m)	1,000 m (379 m)	370 m (60 m).
E5	>200	20	3,674 m (1,149 m)	1,750 m (581 m)	664 m (82 m).
E6	≤200	1	N/A	1,108 m (704 m)	431 m (79 m).
E6	≤200	15	3,584 m (735 m)	2,786 m (457 m)	1,048 m (152 m).
E6	>200	1	N/A	1,000 m (546 m)	429 m (69 m).
E7	≤200	1	N/A	1,080 m (368 m)	472 m (95 m).
E7	>200	1	N/A	1,250 m (545 m)	471 m (96 m).
E8	≤200	1	N/A	1,780 m (552 m)	646 m (90 m).
E8	>200	1	N/A	1,750 m (531 m)	642 m (91 m).
E9	≤200	1	N/A	1,708 m (690 m)	721 m (138 m).
E9	>200	1	N/A	1,604 m (628 m)	711 m (128 m).
E10	≤200	1	N/A	2,078 m (579 m)	839 m (162 m).
E10	>200	1	N/A	2,114 m (550 m)	836 m (167 m).
E11	≤200	1	N/A	4,881 m (1,625 m)	1,433 m (588 m).
E11	>200	1	N/A	5,028 m (1,523 m)	1,556 m (568 m).
E12	≤200	1	N/A	2,489 m (848 m)	1,020 m (322 m).
E12	>200	1	N/A	2,480 m (822 m)	1,058 m (310 m).
E13	≤200	1	N/A	4,139 m (776 m)	2,146 m (522 m).
E16	>200	1	N/A	2,389 m (840 m)	1,361 m (528 m).

Note: N/A = Not Applicable. Behavioral response criteria are applied to explosive clusters >1. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

TABLE 36—OTARIID CARNIVORE IN WATER RANGES TO EFFECTS FOR EXPLOSIVES

Bin	Depth (m)	Cluster size	Range to behavioral disturbance (SD)	Range to TTS (SD)	Range to AUD INJ (SD)
E1	≤200	1	N/A	156 m (48 m)	41 m (2 m).
E1	≤200	5	424 m (170 m)	288 m (102 m)	85 m (17 m).
E1	≤200	25	779 m (306 m)	543 m (198 m)	140 m (45 m).
E1	≤200	50	835 m (454 m)	550 m (229 m)	210 m (37 m).
E1	>200	1	N/A	190 m (25 m)	41 m (2 m).
E1	>200	5	450 m (78 m)	322 m (52 m)	85 m (4 m).
E1	>200	25	600 m (135 m)	480 m (93 m)	170 m (19 m).
E1	>200	50	769 m (133 m)	597 m (96 m)	230 m (30 m).
E2	≤200	1	N/A	258 m (39 m)	60 m (8 m).
E2	>200	1	N/A	261 m (41 m)	62 m (9 m).
E3	≤200	1	N/A	321 m (126 m)	90 m (8 m).
E3	≤200	5	757 m (286 m)	532 m (185 m)	140 m (42 m).
E3	≤200	25	1,306 m (572 m)	903 m (358 m)	260 m (91 m).
E3	>200	1	N/A	400 m (111 m)	90 m (9 m).
E3	>200	5	675 m (135 m)	525 m (89 m)	170 m (19 m).
E3	>200	25	876 m (285 m)	674 m (158 m)	300 m (52 m).
E4	≤200	1	N/A	764 m (196 m)	122 m (36 m).
E4	>200	1	N/A	525 m (118 m)	117 m (18 m).
E5	≤200	1	N/A	525 m (253 m)	147 m (22 m).
E5	≤200	5	1,264 m (472 m)	873 m (285 m)	225 m (60 m).
E5	>200	1	N/A	440 m (77 m)	141 m (19 m).
E5	>200	5	758 m (197 m)	575 m (129 m)	250 m (38 m).
E6	≤200	1	N/A	808 m (379 m)	208 m (34 m).
E6	≤200	15	2,221 m (258 m)	1,767 m (186 m)	791 m (65 m).
E6	>200	1	N/A	565 m (265 m)	215 m (31 m).
E7	≤200	1	N/A	694 m (244 m)	200 m (46 m).
E7	>200	1	N/A	650 m (210 m)	180 m (100 m).
E8	≤200	1	N/A	877 m (114 m)	320 m (46 m).
E8	>200	1	N/A	846 m (118 m)	314 m (46 m).
E9	≤200	1	N/A	929 m (361 m)	317 m (40 m).
E9	>200	1	N/A	729 m (158 m)	331 m (44 m).
E10	≤200	1	N/A	1,055 m (174 m)	406 m (73 m).
E10	>200	1	N/A	1,014 m (222 m)	413 m (71 m).
E11	≤200	1	N/A	1,764 m (212 m)	717 m (86 m).
E11	>200	1	N/A	1,694 m (280 m)	750 m (108 m).
E12	≤200	1	N/A	880 m (132 m)	406 m (67 m).
E12	>200	1	N/A	854 m (152 m)	418 m (71 m).
E13	≤200	1	N/A	4,514 m (1,620 m)	2,701 m (1,249 m).
E16	>200	1	N/A	3,708 m (7,259 m)	2,181 m (822 m).

Note: N/A = Not Applicable. Behavioral response criteria are applied to explosive clusters >1. The values listed for TTS and AUD INJ are the greater of the respective SPL and SEL ranges. Median ranges are shown with standard deviation (SD) in parentheses. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

TABLE 37—EXPLOSIVE RANGES TO NON-AUDITORY INJURY AND MORTALITY FOR ALL MARINE MAMMAL HEARING GROUPS AS A FUNCTION OF ANIMAL MASS

Bin	Effect	10 kg (SD)	250 kg (SD)	1,000 kg (SD)	5,000 kg (SD)	25,000 kg (SD)	72,000 kg (SD)
E1	Non-auditory injury	22 m (2 m)	21 m (2 m)	19 m (3 m)	21 m (2 m)	22 m (1 m)	21 m (1 m).
E1	Mortality	3 m (1 m)	1 m (1 m)	0 m (0 m)	0 m (0 m)	0 m (0 m)	0 m (0 m).
E2	Non-auditory injury	27 m (3 m)	26 m (3 m)	26 m (2 m)	25 m (2 m)	26 m (2 m)	26 m (1 m).
E2	Mortality	6 m (2 m)	2 m (2 m)	1 m (1 m)	0 m (0 m)	0 m (0 m)	0 m (0 m).
E3	Non-auditory injury	37 m (8 m)	38 m (8 m)	41 m (6 m)	43 m (3 m)	38 m (6 m)	45 m (1 m).
E3	Mortality	6 m (3 m)	3 m (2 m)	0 m (1 m)	0 m (0 m)	0 m (0 m)	0 m (0 m).
E4	Non-auditory injury	55 m (9 m)	57 m (9 m)	60 m (7 m)	61 m (7 m)	60 m (8 m)	60 m (6 m).
E4	Mortality	19 m (6 m)	9 m (5 m)	4 m (1 m)	1 m (1 m)	1 m (0 m)	0 m (0 m).
E5	Non-auditory injury	76 m (4 m)	76 m (4 m)	76 m (4 m)	75 m (3 m)	75 m (4 m)	76 m (3 m).

TABLE 37—EXPLOSIVE RANGES TO NON-AUDITORY INJURY AND MORTALITY FOR ALL MARINE MAMMAL HEARING GROUPS AS A FUNCTION OF ANIMAL MASS—Continued

Bin	Effect	10 kg (SD)	250 kg (SD)	1,000 kg (SD)	5,000 kg (SD)	25,000 kg (SD)	72,000 kg (SD)
E5	Mortality	16 m (4 m)	8 m (3 m)	3 m (1 m)	2 m (1 m)	0 m (0 m)	0 m (0 m).
E6	Non-auditory injury	102 m (11 m)	101 m (11 m)	102 m (11 m)	103 m (10 m)	102 m (11 m)	102 m (9 m).
E6	Mortality	41 m (14 m)	19 m (8 m)	9 m (2 m)	6 m (1 m)	3 m (1 m)	2 m (0 m).
E7	Non-auditory injury	101 m (17 m)	109 m (21 m)	127 m (21 m)	116 m (16 m)	98 m (22 m)	109 m (13 m).
E7	Mortality	20 m (7 m)	10 m (4 m)	5 m (1 m)	3 m (1 m)	2 m (1 m)	1 m (0 m).
E8	Non-auditory injury	215 m (41 m)	160 m (10 m)	160 m (11 m)	164 m (5 m)	149 m (12 m)	165 m (4 m).
E8	Mortality	64 m (27 m)	30 m (13 m)	14 m (3 m)	9 m (2 m)	4 m (1 m)	2 m (1 m).
E9	Non-auditory injury	345 m (75 m)	192 m (19 m)	194 m (21 m)	204 m (13 m)	180 m (18 m)	211 m (10 m).
E9	Mortality	156 m (47 m)	22 m (30 m)	11 m (2 m)	8 m (2 m)	4 m (1 m)	3 m (1 m).
E10	Non-auditory injury	501 m (131 m)	243 m (127 m)	247 m (34 m)	256 m (28 m)	236 m (31 m)	267 m (23 m).
E10	Mortality	258 m (69 m)	67 m (64 m)	15 m (5 m)	10 m (2 m)	5 m (1 m)	4 m (0 m).
E11	Non-auditory injury	652 m (125 m)	367 m (50 m)	374 m (48 m)	361 m (26 m)	363 m (27 m)	371 m (26 m).
E11	Mortality	346 m (71 m)	176 m (55 m)	90 m (8 m)	55 m (7 m)	25 m (3 m)	22 m (3 m).
E12	Non-auditory injury	522 m (181 m)	317 m (41 m)	334 m (36 m)	345 m (32 m)	326 m (50 m)	353 m (2 m).
E12	Mortality	309 m (85 m)	136 m (92 m)	19 m (1 m)	12 m (3 m)	7 m (1 m)	5 m (0 m).
E13	Non-auditory injury	4,167 m (1,504 m)	2,135 m (1,522 m)	1,906 m (1,156 m)	2,073 m (1,404 m)	1,199 m (1,046 m)	953 m (182 m).
E13	Mortality	1,831 m (783 m)	717 m (759 m)	573 m (572 m)	677 m (658 m)	335 m (410 m)	260 m (202 m).
E16	Non-auditory injury	1,597 m (484 m)	1,000 m (628 m)	1,053 m (205 m)	1,069 m (341 m)	1,081 m (257 m)	975 m (4 m).
E16	Mortality	1,024 m (225 m)	678 m (284 m)	665 m (214 m)	753 m (263 m)	529 m (277 m)	415 m (233 m).

Note: Median ranges with standard deviation (SD) in parentheses. For non-auditory injury ranges, the greater of the respective ranges for 1 percent chance of gastro-intestinal tract injury and 1 percent chance of injury. E1 (0.1–0.25 lbs (0.045–0.113 kg)), E2 (>0.25–0.5 lbs (0.113–0.23 kg)), E3 (>0.5–2.5 lbs (0.23–1.13 kg)), E4 (>2.5–5 lbs (1.13–2.27 kg)), E5 (>5–10 lbs (2.27–4.54 kg)), E6 (>10–20 lbs (4.54–9.07 kg)), E7 (>20–60 lbs (9.07–27.2 kg)), E8 (>60–100 lbs (27.2–45.4 kg)), E9 (>100–250 lbs (45.4–113 kg)), E10 (>250–500 lbs (113–227 kg)), E11 (>500–675 lbs (227–306 kg)), E12 (>675–1,000 lbs (306–454 kg)), E13 (>1,000–1,740 lbs (454–789 kg)), E16 (10,000 lbs (4,536 kg)).

Marine Mammal Density

A quantitative analysis of impacts on a species or stock requires data on their abundance and distribution that may be affected by anthropogenic activities in the potentially impacted area. The most appropriate metric for this type of analysis is density, which is the number of animals present per unit area. Marine species density estimation requires a significant amount of effort to both collect and analyze data to produce a reasonable estimate. Unlike surveys for terrestrial wildlife, many marine species spend much of their time submerged and are not easily observed. In order to collect enough sighting data to make reasonable density estimates, multiple observations are required, often in areas that are not easily accessible (*e.g.,* far offshore). Ideally, marine mammal species sighting data would be collected for the specific area and time period (*e.g.,* season) of interest and density estimates derived accordingly. However, in many places, poor weather conditions and high sea states prohibit the completion of comprehensive visual surveys.

For most cetacean species, abundance is estimated using line-transect surveys or mark-recapture studies (*e.g.,* Barlow, 2010; Barlow and Forney, 2007; Calambokidis *et al.,* 2008). This is the general approach applied in estimating cetacean abundance in NMFS SARs. Although the single value provides a good average estimate of abundance (*i.e.,* total number of individuals) for a specified area, it does not provide information on the species distribution or concentrations within that area, and it does not estimate density for other timeframes or seasons that were not surveyed. More recently, spatial habitat modeling has been used to estimate cetacean densities (*e.g.,* Becker *et al.,* 2022a, Becker *et al.,* 2022b, Becker *et al.,* 2021, Becker *et al.,* 2020a; Becker *et al.,* 2020b). These models estimate cetacean density as a continuous function of habitat variables (*e.g.,* sea surface temperature, seafloor depth, *etc.*) and thus allow predictions of cetacean densities on finer spatial scales than traditional line-transect or mark recapture analyses, and for areas that have not been surveyed. Within the geographic area that was modeled, densities can be predicted wherever these habitat variables can be measured or estimated.

Ideally, density data would be available for all species throughout the Study Area year-round, in order to best

estimate the impacts of specified activities on marine species. However, in many places, vessel availability, lack of funding, inclement weather conditions, and high sea states prevent the completion of comprehensive year-round surveys. Even with surveys that are completed, poor conditions may result in lower sighting rates for species that would typically be sighted with greater frequency under favorable conditions. Lower sighting rates preclude having an acceptably low uncertainty in the density estimates. A high level of uncertainty, indicating a low level of confidence in the density estimate, is typical for species that are rare or difficult to sight. In areas where survey data are limited or non-existent, known or inferred associations between marine habitat features and the likely presence of specific species are sometimes used to predict densities in the absence of actual animal sightings. Consequently, there is no single source of density data for every area, species, and season because of the fiscal costs, resources, and effort involved in providing enough survey coverage to sufficiently estimate density.

To characterize the marine species density for large oceanic regions, the Action Proponents review, critically assess, and prioritize existing density estimates from multiple sources, requiring the development of a systematic method for selecting the most appropriate density estimate for each combination of species/stock, area, and season. The selection and compilation of the best available marine species density data resulted in the NMSDD, which includes seasonal density values for every marine mammal species and stock present within the HCTT Study Area. This database is described in the ''U.S. Navy Marine Species Density Database Phase IV for the Hawaii-California Training and Testing Study Area'' technical report (U.S. Department of the Navy, 2024), hereafter referred to as the Density Technical Report. NMFS reviewed all marine mammal densities provided by the Action Proponents prior to use in their acoustic analysis for the current rulemaking process.

A variety of density data and density models are needed to develop a density database that encompasses the entirety of the HCTT Study Area. Because these data are collected using different methods with varying amounts of accuracy and uncertainty, the Action Proponents have developed a hierarchy to ensure the most accurate data are used when available. The Density Technical Report describes these models in detail and provides detailed explanations of the best available density estimate for each species. The list below describes possible sources of density data in order of preference:

1. Density spatial models are preferred and used when available because they provide spatially-explicit density estimates (typically at 10 km by 10 km (5.4 nmi by 5.4 nmi) spatial resolution) throughout the study area with the least amount of uncertainty). These models (see Becker *et al.,* 2022a, Becker *et al.,* 2022b, Becker *et al.,* 2021, Becker *et al.,* 2020a; Becker *et al.,* 2020b, Becker *et al.,* 2018, Forney *et al.,* 2015) predict spatial variability of animal density based on habitat variables (*e.g.,* sea surface temperature, seafloor depth, *etc.*). Density spatial models are developed for areas, species, and, when available, specific timeframes (*e.g.,* months or seasons) with sufficient survey data; therefore, these models cannot be used for species with low numbers of sightings.

2. Stratified design-based density estimates use line-transect survey data with the sampling area divided (*i.e.,* stratified) into sub-regions, and a density is derived for each sub-region (see Barlow, 2016; Barlow and Forney, 2007; Bradford *et al.,* 2021). While geographically stratified density estimates provide a better indication of a species' distribution within the study area, the uncertainty is typically high because each sub-region estimate is based on a smaller stratified segment of the overall survey effort.

3. Design-based density estimations use line-transect survey data collected from ship or aerial surveys designed to cover a specific geographic area (see Carretta *et al.,* 2024). These estimates use the same survey data as stratified design-based estimates, but are not segmented into sub-regions and instead provide one estimate for a large, surveyed area.

When interpreting the results of the quantitative analysis, as described in the Density Technical Report for the Phase III Atlantic Fleet Training and Testing Study Area (U.S. Department of the Navy, 2017a), ''it is important to consider that even the best estimate of marine species density is really a model representation of the values of concentration where these animals might occur. Each model is limited to the variables and assumptions considered by the original data source provider. No mathematical model representation of any biological population is perfect and with regards to marine species biodiversity, any single model method will not completely explain the actual distribution and abundance of marine mammal species. It is expected that there would be anomalies in the results that need to be evaluated, with independent information for each case, to support if we might accept or reject a model or portions of the model.''

The Action Proponents' estimates of abundance (based on density estimates used in the HCTT Study Area) utilize NMFS' SARs. For some species, the stock assessment for a given species may exceed the Navy's density prediction because those species' home range extends beyond the study area boundaries. For other species, the stock assessment abundance may be much less than the number of animals in the Navy's modeling given that the HCTT Study Area extends beyond the U.S. waters covered by the SAR abundance estimate. The primary source of density estimates are geographically specific survey data and either peer-reviewed line-transect estimates or habitat-based density models that have been extensively validated to provide the most accurate estimates possible.

NMFS coordinated with the Navy in the development of its take estimates and concurs that the Navy's approach for density appropriately utilizes the best available science. Later, in the Preliminary Analysis and Negligible Impact Determination section, we assess how the estimated take numbers compare to stock abundance in order to better understand the potential number of individuals impacted, and the rationale for which abundance estimate is used is included there.

Estimated Take From Acoustic Stressors

The 2024 HCTT Draft EIS/OEIS considered all military readiness activities proposed to occur in the HCTT Study Area that have the potential to result in the MMPA defined take of marine mammals. The Action Proponents determined that the four stressors below could result in the incidental taking of marine mammals. NMFS has reviewed the Action Proponents' data and analysis and determined that it is complete and accurate and agrees that the following stressors have the potential to result in takes by harassment of marine mammals from the specified activities:

- Acoustics (*i.e.,* sonars and other transducers, air guns, pile driving/extraction);
- Explosives (*i.e.,* explosive shock wave and sound, assumed to encompass the risk due to fragmentation);
- Land-based launch noise from missile and target launches at SNI and weapons firing and launch noise at PMRF; and
- Vessel strike.

Acoustic and explosive sources and land-based launch noise are likely to result in incidental takes of marine mammals by harassment. Vessel strikes have the potential to result in incidental take from injury, serious injury, and/or mortality.

The quantitative analysis process used for the 2024 HCTT Draft EIS/OEIS and the application to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors is detailed in the Acoustic Impacts Technical Report.

Regarding how avoidance of loud sources is considered in the take estimation, NAEMO does not simulate horizontal animat (*i.e.,* a virtual animal) movement during an event. However, NAEMO approximates marine mammal avoidance of high sound levels due to exposure to sonars in a one-dimensional calculation that scales how far an animat would be from a sound source based on sensitivity to disturbance, swim speed, and avoidance duration. This process reduces the SEL, defined as the accumulation for a given animat, by reducing the received SPL of individual exposures based on a spherical spreading calculation from sources on each unique platform in an event. The onset of avoidance was based on the behavioral response functions. Avoidance speeds and durations were informed by a review of available exposure and baseline data. This method captures a more accurate representation of avoidance by using the received sound levels, distance to platform, and species-specific criteria to calculate potential avoidance for each animat than the approach used in Phase III. However, this avoidance method may underestimate avoidance of long-duration sources with lower sound levels because it triggers avoidance calculations based on the highest modeled SPL received level exceeding p(0.5) on the BRF, rather than on cumulative exposure. This is because initiation of the avoidance calculation is based on the highest modeled SPL received level over p(0.5) on the BRF. Please see section 4.4.2.2 of the Acoustic Impacts Technical Report.

Regarding the consideration of mitigation effectiveness in the take estimation, during military readiness activities, there is typically at least one, if not numerous, support personnel involved in the activity (*e.g.,* range support personnel aboard a torpedo retrieval boat or support aircraft). In addition to the Lookout posted for the purpose of mitigation, these additional personnel observe and disseminate marine species sighting information amongst the units participating in the activity whenever possible as they conduct their primary mission responsibilities. However, unlike in previous phases of HCTT, this quantitative analysis does not reduce model-estimated impacts to account for activity-based mitigation. While the activity-based mitigation is not quantitatively included in the take estimates (which, of note, would result in a reduction in the number of takes), table A–6 of appendix A of the application indicates the percentage of the instances of take where an animal's closest point of approach was within a mitigation zone and, therefore, AUD INJ could potentially be mitigated. Note that these percentages do not account for other factors, such as the sightability of a given species or viewing conditions.

Unlike activity-based mitigation, in some cases, implementation of the proposed geographic mitigation areas are incorporated into the quantitative analysis. The extent to which the mitigation areas reduce impacts on the affected species is addressed in the Preliminary Analysis and Negligible Impact Determination section.

For additional information on the quantitative analysis process, refer to the Acoustic Impacts Technical Report and sections 6 and 11 of the application.

As a general matter, NMFS does not prescribe the methods for estimating take for any applicant, but we review and ensure that applicants use the best available science, and methodologies that are logical and technically sound. Applicants may use different methods of calculating take (especially when using models) and still get to a result that is representative of the best available science and that allows for a rigorous and accurate evaluation of the effects on the affected populations. There are multiple pieces of the Navy's take estimation methods—propagation models, animat movement models, and behavioral thresholds, for example. NMFS evaluates the acceptability of these pieces as they evolve and are used in different rules and impact analyses. Some of the pieces of the Action Proponents' take estimation process have been used in Navy incidental take rules since 2009 and undergone multiple public comment processes; all of them have undergone extensive internal Navy review, and all of them have undergone comprehensive review by NMFS, which has sometimes resulted in modifications to methods or models.

The Navy uses rigorous review processes (verification, validation, and accreditation processes; peer and public review) to ensure the data and methodology it uses represent the best available science. For instance, NAEMO is the result of a NMFS-led Center for Independent Experts review of the components used in earlier models. The acoustic propagation component of NAEMO (titled CASS/GRAB) is accredited by the Oceanographic and Atmospheric Master Library (OAML), and many of the environmental variables used in NAEMO come from approved OAML databases and are based on in-situ data collection. The animal density components of NAEMO are base products of the NMSDD, which includes animal density components that have been validated and reviewed by a variety of scientists from NMFS Science Centers and academic institutions. Several components of the model, for example, habitat-based density model results for species off Hawaii and California have been published in several peer-reviewed journals (Becker *et al.,* 2020; Becker *et al.,* 2021; Becker *et al.,* 2022a; Becker *et al.,* 2022b). Additionally, NAEMO simulation components underwent quality assurance and quality control (commonly referred to as QA/QC) review and validation for model parts such as the scenario builder, acoustic builder, scenario simulator, *etc.,* conducted by qualified statisticians and modelers to ensure accuracy. Other models and methodologies have gone through similar review processes.

In summary, we believe the Action Proponents' methods, including the method for incorporating avoidance, are the most appropriate methods for predicting AUD INJ, non-auditory injury, TTS, and behavioral disturbance. But even with the consideration of avoidance, given some of the more conservative components of the methodology (*e.g.,* the thresholds do not consider ear recovery between pulses), we would describe the application of these methods as identifying the maximum number of instances in which marine mammals would be reasonably expected to be taken through AUD INJ, non-auditory injury, TTS, or behavioral disturbance.

Based on the methods discussed in the previous sections and NAEMO, the Action Proponents provided their take estimate and request for authorization of takes incidental to the use of acoustic and explosive sources for military readiness activities annually (based on the maximum number of activities that could occur per 12-month period) and over the 7-year period, as well as the Navy's take request for ship shock trials, covered by the application. The following species/stocks present in the HCTT Study Area were modeled by the Navy and estimated to have 0 takes of

any type from any activity source: killer whale (Eastern North Pacific Southern Resident stock) and spinner dolphin (Midway Atoll/Kure stock and Pearl and Hermes stock). NMFS has reviewed the Action Proponents' data, methodology, and analysis and determined that it is complete and accurate. NMFS agrees that the estimates for incidental takes by harassment from all sources requested for authorization are the maximum number of instances in which marine mammals are reasonably expected to be taken and that the takes by mortality requested for authorization are for the maximum number of instances mortality or serious injury could occur, as in the case of ship shock trials and vessel strikes.

Table 38, table 39, table 40, and table 41 summarize the maximum annual and 7-year total amount and type of Level A harassment and Level B harassment that NMFS concurs is reasonably expected to occur by species and stock for Navy training activities, Navy testing activities, Coast Guard training activities, and Army training activities, respectively.

TABLE 38—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING NAVY TRAINING ACTIVITIES

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Gray Whale	Eastern North Pacific.	4,918	98	0	32,444	645	0
Gray Whale	Western North Pacific.	48	1	0	305	2	0
Blue Whale	Central North Pacific.	67	0	0	389	0	0
Blue Whale	Eastern North Pacific.	2,716	17	0	14,681	84	0
Bryde's Whale	Eastern Tropical Pacific.	179	2	0	1,041	5	0
Bryde's Whale	Hawaii	306	2	0	1,809	10	0
Fin Whale	Hawaii	59	0	0	334	0	0
Fin Whale	California/Oregon/Washington.	7,409	28	0	37,629	144	0
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	1,042	14	0	5,361	68	0
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	2,401	34	0	12,414	171	0
Humpback Whale	Hawaii	2,244	18	0	14,250	113	0
Minke Whale	Hawaii	229	2	0	1,330	12	0
Minke Whale	California/Oregon/Washington.	1,686	24	0	8,980	144	0
Sei Whale	Hawaii	200	1	0	1,146	2	0
Sei Whale	Eastern North Pacific.	195	1	0	1,028	7	0
Sperm Whale	Hawaii	1,296	1	0	7,829	1	0
Sperm Whale	California/Oregon/Washington.	2,897	2	0	15,447	4	0
Dwarf Sperm Whale.	Hawaii	36,298	501	0	215,688	3,065	0
Dwarf Sperm Whale.	California/Oregon/Washington.	4,329	50	0	22,647	271	0
Pygmy Sperm Whale.	Hawaii	36,722	518	0	217,948	3,153	0
Pygmy Sperm Whale.	California/Oregon/Washington.	4,240	66	0	22,246	371	0
Baird's Beaked Whale.	California/Oregon/Washington.	7,290	0	0	39,692	0	0
Blainville's Beaked Whale.	Hawaii	5,812	0	0	36,916	0	0
Goose-Beaked Whale.	Hawaii	23,258	0	0	147,787	0	0
Goose-Beaked Whale.	California/Oregon/Washington.	110,853	1	0	638,374	2	0
Longman's Beaked Whale.	Hawaii	14,051	1	0	89,592	4	0
Mesoplodont Beaked Whale.	California/Oregon/Washington.	64,655	1	0	371,374	2	0
False Killer Whale	Main Hawaiian Islands Insular.	122	0	0	752	0	0
False Killer Whale	Northwest Hawaiian Islands.	151	0	0	959	0	0

TABLE 38—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING NAVY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
False Killer Whale	Hawaii Pelagic	1,371	0	0	8,293	0	0
False Killer Whale	Baja California Peninsula Mexico.	2,127	1	0	11,552	1	0
Killer Whale	Hawaii	103	0	0	610	0	0
Killer Whale	Eastern North Pacific Offshore.	545	3	0	3,310	21	0
Killer Whale	West Coast Transient.	46	0	0	204	0	0
Melon-Headed Whale.	Hawaiian Islands ..	26,120	9	0	155,607	53	0
Melon-Headed Whale.	Kohala Resident (Hawaii).	23	0	0	130	0	0
Pygmy Killer Whale	Hawaii	7,428	2	0	44,514	7	0
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	477	0	0	2,705	0	0
Short-Finned Pilot Whale.	Hawaii	13,851	3	0	85,991	18	0
Short-Finned Pilot Whale.	California/Oregon/Washington.	1,995	9	1	11,567	54	4
Bottlenose Dolphin	Maui Nui	189	0	0	1,301	0	0
Bottlenose Dolphin	Hawaii Island	6	0	0	25	0	0
Bottlenose Dolphin	Hawaii Pelagic	37,546	18	1	252,429	123	2
Bottlenose Dolphin	Kauaʻi/Niʻihau	1,179	0	0	7,728	0	0
Bottlenose Dolphin	Oʻahu	6,789	5	1	47,410	29	1
Bottlenose Dolphin	California Coastal	516	7	0	3,521	42	0
Bottlenose Dolphin	California/Oregon/Washington Offshore.	16,938	13	0	94,638	74	0
Fraser's Dolphin	Hawaii	30,371	5	0	184,274	26	0
Long-Beaked Common Dolphin.	California	102,352	113	3	583,062	722	15
Northern Right Whale Dolphin.	California/Oregon/Washington.	35,313	15	0	170,387	64	0
Pacific White-Sided Dolphin.	California/Oregon/Washington.	41,928	33	1	209,903	188	1
Pantropical Spotted Dolphin.	Maui Nui	830	2	0	5,549	10	0
Pantropical Spotted Dolphin.	Hawaii Island	4,974	5	0	29,501	23	0
Pantropical Spotted Dolphin.	Hawaii Pelagic	36,298	13	0	219,400	67	0
Pantropical Spotted Dolphin.	Oʻahu	5,618	5	0	39,051	21	0
Pantropical Spotted Dolphin.	Baja California Peninsula Mexico.	82,440	43	1	448,311	224	1
Risso's Dolphin	Hawaii	5,380	1	0	32,054	1	0
Risso's Dolphin	California/Oregon/Washington.	25,085	15	0	140,377	98	0
Rough-Toothed Dolphin.	Hawaii	80,173	27	1	497,078	157	1
Short-Beaked Common Dolphin.	California/Oregon/Washington.	1,428,183	694	13	7,867,127	4,036	91
Spinner Dolphin	Hawaii Pelagic	3,781	1	0	22,583	3	0
Spinner Dolphin	Hawaii Island	97	1	0	562	1	0
Spinner Dolphin	Kauaʻi/Niʻihau	3,528	1	0	23,147	5	0
Spinner Dolphin	Oʻahu/4 Islands Region.	991	1	0	6,922	2	0
Striped Dolphin	Hawaii Pelagic	31,260	8	0	186,357	43	0
Striped Dolphin	California/Oregon/Washington.	110,641	37	1	600,412	193	1
Dall's Porpoise	California/Oregon/Washington.	43,844	708	0	218,178	3,727	0
Harbor Porpoise	Monterey Bay	1,314	0	0	5,627	0	0
Harbor Porpoise	Morro Bay	3,883	11	0	23,051	71	0
Harbor Porpoise	Northern California/Southern Oregon.	357	0	0	1,576	0	0

TABLE 38—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING NAVY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Harbor Porpoise	San Francisco/ Russian River.	6,920	24	0	30,248	164	0
California Sea Lion	U.S.	876,054	532	4	4,997,524	3,406	22
Guadalupe Fur Seal.	Mexico	295,304	37	1	1,598,780	194	1
Northern Fur Seal	Eastern Pacific	29,250	3	0	134,187	10	0
Northern Fur Seal	California	19,649	3	0	90,918	9	0
Steller Sea Lion	Eastern	524	3	0	2,470	13	0
Harbor Seal	California	16,662	243	1	98,994	1,536	7
Hawaiian Monk Seal.	Hawaii	748	4	0	5,065	18	0
Northern Elephant Seal.	California Breeding	68,627	49	0	351,382	284	0

Note: The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 39—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCE DURING NAVY TESTING

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Gray Whale	Eastern North Pacific.	11,777	69	0	54,745	365	0
Gray Whale	Western North Pacific.	120	1	0	545	3	0
Blue Whale	Central North Pacific.	24	1	0	134	2	0
Blue Whale	Eastern North Pacific.	1,836	10	0	10,002	66	0
Bryde's Whale	Eastern Tropical Pacific.	142	3	0	828	9	0
Bryde's Whale	Hawaii	99	1	0	531	1	0
Fin Whale	Hawaii	25	1	0	145	1	0
Fin Whale	California/Oregon/ Washington.	6,030	27	0	30,497	156	0
Humpback Whale ..	Central America/ Southern Mexico—California/ Oregon/Washington.	839	5	0	4,492	28	0
Humpback Whale ..	Mainland Mexico—California/Oregon/Washington.	2,033	10	0	10,859	49	0
Humpback Whale ..	Hawaii	779	6	0	4,627	38	0
Minke Whale	Hawaii	64	1	0	351	1	0
Minke Whale	California/Oregon/ Washington.	1,300	8	0	7,088	49	0
Sei Whale	Hawaii	52	1	0	287	3	0
Sei Whale	Eastern North Pacific.	106	2	0	579	2	0
Sperm Whale	Hawaii	346	0	0	1,745	0	0
Sperm Whale	California/Oregon/ Washington.	966	1	0	4,963	1	0
Dwarf Sperm Whale.	Hawaii	8,443	399	0	43,341	1,941	0
Dwarf Sperm Whale.	California/Oregon/ Washington.	1,283	43	0	7,101	245	0
Pygmy Sperm Whale.	Hawaii	8,603	402	0	44,150	1,966	0
Pygmy Sperm Whale.	California/Oregon/ Washington.	1,325	41	0	7,289	238	0
Baird's Beaked Whale.	California/Oregon/ Washington.	2,830	0	0	16,079	0	0
Blainville's Beaked Whale.	Hawaii	1,704	0	0	8,917	0	0

TABLE 39—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCE DURING NAVY TESTING—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Goose-Beaked Whale.	Hawaii	6,956	0	0	36,245	0	0
Goose-Beaked Whale.	California/Oregon/ Washington.	55,310	1	0	296,069	2	0
Longman's Beaked Whale.	Hawaii	4,118	0	0	21,544	0	0
Mesoplodont Beaked Whale.	California/Oregon/ Washington.	27,768	1	0	146,662	4	0
False Killer Whale	Main Hawaiian Islands Insular.	43	0	0	230	0	0
False Killer Whale	Northwest Hawaiian Islands.	38	0	0	197	0	0
False Killer Whale	Hawaii Pelagic	287	1	0	1,489	1	0
False Killer Whale	Baja California Peninsula Mexico.	393	0	0	2,226	0	0
Killer Whale	Hawaii	22	0	0	113	0	0
Killer Whale	Eastern North Pacific Offshore.	477	1	0	2,772	2	0
Killer Whale	West Coast Transient.	8	0	0	52	0	0
Melon-Headed Whale.	Hawaiian Islands	5,110	3	0	26,599	14	0
Melon-Headed Whale.	Kohala Resident (Hawaii).	31	0	0	195	0	0
Pygmy Killer Whale	Hawaii	1,410	1	0	7,152	1	0
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	315	0	0	1,635	0	0
Short-Finned Pilot Whale.	Hawaii	3,367	2	0	18,188	5	0
Short-Finned Pilot Whale.	California/Oregon/ Washington.	2,274	2	0	12,896	2	0
Bottlenose Dolphin	Maui Nui	137	0	0	850	0	0
Bottlenose Dolphin	Hawaii Island	3	0	0	19	0	0
Bottlenose Dolphin	Hawaii Pelagic	5,731	6	0	34,450	39	0
Bottlenose Dolphin	Kaua'i/Ni'ihau	281	0	0	1,586	0	0
Bottlenose Dolphin	O'ahu	443	1	0	2,965	1	0
Bottlenose Dolphin	California Coastal	832	0	0	5,228	0	0
Bottlenose Dolphin	California/Oregon/ Washington Offshore.	10,999	2	0	62,160	9	0
Fraser's Dolphin	Hawaii	5,086	1	0	26,111	2	0
Long-Beaked Common Dolphin.	California	193,599	39	1	1,215,256	230	2
Northern Right Whale Dolphin.	California/Oregon/ Washington.	9,950	6	1	51,898	32	1
Pacific White-Sided Dolphin.	California/Oregon/ Washington.	27,035	9	1	149,417	54	1
Pantropical Spotted Dolphin.	Maui Nui	1,542	2	0	9,642	8	0
Pantropical Spotted Dolphin.	Hawaii Island	1,026	2	0	5,919	2	0
Pantropical Spotted Dolphin.	Hawaii Pelagic	7,862	4	0	41,161	12	0
Pantropical Spotted Dolphin.	O'ahu	807	1	0	5,142	2	0
Pantropical Spotted Dolphin.	Baja California Peninsula Mexico.	14,695	4	1	83,941	15	1
Risso's Dolphin	Hawaii	1,143	2	0	5,746	3	0
Risso's Dolphin	California/Oregon/ Washington.	18,560	6	0	99,161	27	0
Rough-Toothed Dolphin.	Hawaii	16,289	7	1	87,872	37	1
Short-Beaked Common Dolphin.	California/Oregon/ Washington.	731,713	182	5	3,869,698	1,037	16
Spinner Dolphin	Hawaii Pelagic	739	1	0	3,791	1	0
Spinner Dolphin	Hawaii Island	13	0	0	82	0	0
Spinner Dolphin	Kaua'i/Ni'ihau	918	1	0	5,187	1	0

TABLE 39—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCE DURING NAVY TESTING—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Spinner Dolphin	O'ahu/4 Islands Region.	210	0	0	1,283	0	0
Striped Dolphin	Hawaii Pelagic	6,270	2	0	31,482	7	0
Striped Dolphin	California/Oregon/Washington.	21,982	7	0	118,342	38	0
Dall's Porpoise	California/Oregon/Washington.	15,363	528	0	84,387	3,056	0
Harbor Porpoise	Monterey Bay	865	0	0	5,307	0	0
Harbor Porpoise	Morro Bay	490	77	0	3,265	519	0
Harbor Porpoise	Northern California/Southern Oregon.	124	0	0	763	0	0
Harbor Porpoise	San Francisco/Russian River.	3,038	2	0	18,641	5	0
California Sea Lion	U.S.	997,758	191	1	5,449,070	1,166	5
Guadalupe Fur Seal.	Mexico	48,392	17	0	275,065	106	0
Northern Fur Seal	Eastern Pacific	3,311	9	0	20,183	45	0
Northern Fur Seal	California	1,894	7	0	11,495	38	0
Steller Sea Lion	Eastern	471	0	0	2,854	0	0
Harbor Seal	California	54,180	18	0	287,858	106	0
Hawaiian Monk Seal.	Hawaii	139	2	0	802	7	0
Northern Elephant Seal.	California Breeding	48,052	61	0	262,329	360	0

Note: The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 40—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING COAST GUARD TRAINING ACTIVITIES

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Gray Whale	Eastern North Pacific	16	0	0	103	0	0
Gray Whale	Western North Pacific	1	0	0	2	0	0
Blue Whale	Central North Pacific	1	0	0	1	0	0
Blue Whale	Eastern North Pacific	19	0	0	125	0	0
Bryde's Whale	Eastern Tropical Pacific	1	0	0	5	0	0
Bryde's Whale	Hawaii	2	0	0	13	0	0
Fin Whale	Hawaii	2	0	0	8	0	0
Fin Whale	California/Oregon/Washington.	62	0	0	432	0	0
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	7	0	0	45	0	0
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	15	0	0	97	0	0
Humpback Whale	Hawaii	7	0	0	46	0	0
Minke Whale	Hawaii	2	0	0	14	0	0
Minke Whale	California/Oregon/Washington.	7	0	0	48	0	0
Sei Whale	Hawaii	1	0	0	4	0	0
Sei Whale	Eastern North Pacific	1	0	0	4	0	0
Sperm Whale	Hawaii	7	0	0	45	0	0
Sperm Whale	California/Oregon/Washington.	28	0	0	196	0	0
Dwarf Sperm Whale	Hawaii	386	3	0	2,695	13	0
Dwarf Sperm Whale	California/Oregon/Washington.	52	1	0	345	1	0
Pygmy Sperm Whale	Hawaii	354	1	0	2,469	1	0
Pygmy Sperm Whale	California/Oregon/Washington.	50	0	0	333	0	0
Baird's Beaked Whale	California/Oregon/Washington.	54	0	0	378	0	0
Blainville's Beaked Whale	Hawaii	25	0	0	170	0	0
Goose-Beaked Whale	Hawaii	143	0	0	1,001	0	0
Goose-Beaked Whale	California/Oregon/Washington.	653	0	0	4,569	0	0
Longman's Beaked Whale	Hawaii	145	0	0	1,013	0	0

TABLE 40—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING COAST GUARD TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Mesoplodont Beaked Whale	California/Oregon/Washington.	416	0	0	2,902	0	0
False Killer Whale	Main Hawaiian Islands Insular.	4	0	0	27	0	0
False Killer Whale	Northwest Hawaiian Islands	2	0	0	9	0	0
False Killer Whale	Hawaii Pelagic	12	0	0	83	0	0
False Killer Whale	Baja California Peninsula Mexico.	17	1	0	110	1	0
Killer Whale	Hawaii	2	0	0	10	0	0
Killer Whale	Eastern North Pacific Offshore.	1	0	0	7	0	0
Killer Whale	West Coast Transient	1	0	0	5	0	0
Melon-Headed Whale	Hawaiian Islands	224	0	0	1,559	0	0
Pygmy Killer Whale	Hawaii	56	0	0	390	0	0
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	3	0	0	18	0	0
Short-Finned Pilot Whale	Hawaii	83	0	0	578	0	0
Short-Finned Pilot Whale	California/Oregon/Washington.	10	0	0	69	0	0
Bottlenose Dolphin	Hawaii Pelagic	33	0	0	226	0	0
Bottlenose Dolphin	California Coastal	2	0	0	12	0	0
Bottlenose Dolphin	California/Oregon/Washington Offshore.	121	0	0	830	0	0
Fraser's Dolphin	Hawaii	18	0	0	114	0	0
Long-Beaked Common Dolphin.	California	927	0	0	6,475	0	0
Northern Right Whale Dolphin.	California/Oregon/Washington.	251	0	0	1,754	0	0
Pacific White-Sided Dolphin	California/Oregon/Washington.	247	0	0	1,729	0	0
Pantropical Spotted Dolphin	Hawaii Island	24	0	0	164	0	0
Pantropical Spotted Dolphin	Hawaii Pelagic	227	0	0	1,580	0	0
Pantropical Spotted Dolphin	O'ahu	1	0	0	7	0	0
Pantropical Spotted Dolphin	Baja California Peninsula Mexico.	491	0	0	3,429	0	0
Risso's Dolphin	Hawaii	35	0	0	240	0	0
Risso's Dolphin	California/Oregon/Washington.	188	0	0	1,309	0	0
Rough-Toothed Dolphin	Hawaii	406	0	0	2,838	0	0
Short-Beaked Common Dolphin.	California/Oregon/Washington.	9,658	1	0	67,598	2	0
Spinner Dolphin	Hawaii Pelagic	24	0	0	165	0	0
Striped Dolphin	Hawaii Pelagic	249	0	0	1,738	0	0
Striped Dolphin	California/Oregon/Washington.	776	0	0	5,420	0	0
Dall's Porpoise	California/Oregon/Washington.	412	1	0	2,867	3	0
Harbor Porpoise	San Francisco/Russian River	2	0	0	11	0	0
California Sea Lion	U.S.	14,937	0	0	104,545	0	0
Guadalupe Fur Seal	Mexico	3,857	0	0	26,989	0	0
Northern Fur Seal	Eastern Pacific	634	0	0	4,426	0	0
Northern Fur Seal	California	555	0	0	3,885	0	0
Steller Sea Lion	Eastern	4	0	0	22	0	0
Harbor Seal	California	141	0	0	977	0	0
Hawaiian Monk Seal	Hawaii	1	0	0	5	0	0
Northern Elephant Seal	California Breeding	1,795	1	0	12,549	1	0

Note: The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 41—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING NAVY TRAINING ACTIVITIES

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Bryde's Whale	Hawaii	2	0	0	3	0	0
Humpback Whale	Hawaii	4	0	0	22	0	0
Minke Whale	Hawaii	1	0	0	3	0	0
Dwarf Sperm Whale	Hawaii	97	12	0	677	84	0
Pygmy Sperm Whale	Hawaii	108	15	0	755	101	0
Blainville's Beaked Whale	Hawaii	1	0	0	1	0	0
Goose-Beaked Whale	Hawaii	2	0	0	6	0	0
Longman's Beaked Whale	Hawaii	2	0	0	3	0	0
Melon-Headed Whale	Hawaiian Islands	2	1	0	8	1	0
Melon-Headed Whale	Kohala Resident (Hawaii)	2	0	0	7	0	0

TABLE 41—INCIDENTAL TAKE ESTIMATE BY STOCK DUE TO ACOUSTIC AND EXPLOSIVE SOURCES DURING NAVY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-year total Level B harassment	7-year total Level A harassment	7-year total mortality
Pygmy Killer Whale	Hawaii	1	0	0	3	0	0
Short-Finned Pilot Whale	Hawaii	3	2	0	15	3	0
Bottlenose Dolphin	Hawaii Pelagic	3	1	0	14	1	0
Fraser's Dolphin	Hawaii	5	2	0	27	6	0
Pantropical Spotted Dolphin	Maui Nui	1	0	0	1	0	0
Pantropical Spotted Dolphin	Hawaii Pelagic	3	2	0	14	2	0
Risso's Dolphin	Hawaii	0	1	0	0	1	0
Rough-Toothed Dolphin	Hawaii	5	2	0	31	2	0
Striped Dolphin	Hawaii Pelagic	3	2	0	17	2	0
Hawaiian Monk Seal	Hawaii	1	0	0	3	0	0

Note: The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

Estimated Take From Sonar and Other Transducers

Table 42, table 43, and table 44 provide estimated effects from sonar and other transducers, including the comparative amounts of TTS and behavioral disturbance for each species and stock annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disturbance in the model, it was recorded as a TTS. Of note, a higher proportion of the takes by Level B harassment of mysticetes include the potential for TTS (as compared to other taxa and prior rules) due to a combination of the fact that mysticetes are relatively less sensitive to behavioral disturbance and the number of auditory impacts from sonar (both TTS and AUD INJ) have increased for some species since the Phase III analysis (84 FR 70712, December 23, 2019) largely due to changes in how avoidance was modeled; for some stocks, changes in densities in areas that overlap activities have also contributed to increased or decreased impacts compared to those modeled in Phase III.

Compared to the prior analysis, the Action Proponents propose to use more hours of hull-mounted surface ship sonar, and these activities are newly analyzed in the NOCAL range complex and in PMSR. Compared to the prior analysis, this analysis considers increased use of MF1 (regular duty cycle) and MF1C (continuous duty cycle) associated with Navy training activities and decreased use of MF1 and MF1C associated with Navy testing activities. This analysis also considers the training and testing usage of these sonars across an expanded study area. For the maximum analyzed year of training and testing activities under this proposed action, MF1 has increased 20 percent and MF1C has increased 50 percent in the expanded California Study Area (which now includes PMSR and NOCAL). In the Hawaii Study Area MF1 and MF1C is proposed to increase greater than 10 percent and 60 percent respectively when compared to the prior HSTT analysis.

Additionally, the updated HF cetacean criteria reflect greater susceptibility to auditory effects at low and mid-frequencies than previously analyzed. Consequently, the predicted auditory effects due to sources under 10 kHz, including but not limited to MF1 hull-mounted sonar and other anti-submarine warfare sonars, are substantially higher for this auditory group than in prior analyses of the same activities. Thus, for activities with sonars, some modeled exposures that would previously have been categorized as significant behavioral responses may now instead be counted as auditory effects (TTS and AUD INJ). Similarly, the updated HF cetacean criteria reflect greater susceptibility to auditory effects at low and mid-frequencies in impulsive sounds. For VHF cetaceans, susceptibility to auditory effects has not changed substantially since the prior analysis.

TABLE 42—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING NAVY TRAINING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Gray Whale	Eastern North Pacific	1,903	2,390	65	12,356	16,019	428
Gray Whale	Western North Pacific	18	28	1	119	182	2
Blue Whale	Central North Pacific	10	56	0	63	325	0
Blue Whale	Eastern North Pacific	646	1,924	16	3,810	9,921	80
Bryde's Whale	Eastern Tropical Pacific	48	80	1	295	414	1
Bryde's Whale	Hawaii	41	263	2	259	1,543	10
Fin Whale	Hawaii	12	46	0	73	260	0
Fin Whale	California/Oregon/Washington.	1,727	5,470	22	9,743	26,506	108
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	166	831	13	989	4,076	65
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	375	1,906	31	2,245	9,370	153
Humpback Whale	Hawaii	780	1,358	11	5,134	8,414	70
Minke Whale	Hawaii	27	200	2	171	1,154	12
Minke Whale	California/Oregon/Washington.	334	1,242	15	2,035	6,234	81
Sei Whale	Hawaii	25	173	1	162	978	2
Sei Whale	Eastern North Pacific	38	151	1	223	765	7

TABLE 42—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING NAVY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Sperm Whale	Hawaii	939	354	0	5,806	2,008	0
Sperm Whale	California/Oregon/Washington.	2,133	758	1	11,738	3,677	1
Dwarf Sperm Whale	Hawaii	8,114	27,505	329	53,404	157,962	1,955
Dwarf Sperm Whale	California/Oregon/Washington.	936	3,346	37	5,472	16,881	188
Pygmy Sperm Whale	Hawaii	8,131	27,918	350	53,462	160,158	2,068
Pygmy Sperm Whale	California/Oregon/Washington.	964	3,216	43	5,629	16,228	218
Baird's Beaked Whale	California/Oregon/Washington.	7,234	55	-	39,426	262	-
Blainville's Beaked Whale	Hawaii	5,780	31	-	36,734	180	-
Goose-Beaked Whale	Hawaii	23,137	118	-	147,104	668	-
Goose-Beaked Whale	California/Oregon/Washington.	110,330	504	-	635,735	2,514	-
Longman's Beaked Whale	Hawaii	13,966	83	-	89,112	475	-
Mesoplodont Beaked Whale	California/Oregon/Washington.	64,298	350	0	369,597	1,732	0
False Killer Whale	Main Hawaiian Islands Insular.	68	54	-	436	316	-
False Killer Whale	Northwest Hawaiian Islands	96	55	-	616	343	-
False Killer Whale	Hawaii Pelagic	731	638	0	4,647	3,641	0
False Killer Whale	Baja California Peninsula Mexico*.	1,361	765	1	7,599	3,949	1
Killer Whale	Hawaii	41	62	-	256	354	-
Killer Whale	Eastern North Pacific Offshore.	422	110	0	2,682	543	0
Killer Whale	West Coast Transient	19	27	-	87	117	-
Melon-Headed Whale	Hawaiian Islands	12,560	13,553	8	79,341	76,222	48
Melon-Headed Whale	Kohala Resident (Hawaii)	15	8	-	85	45	-
Pygmy Killer Whale	Hawaii	3,666	3,758	1	23,256	21,234	4
Pygmy Killer Whale	California—Baja California Peninsula Mexico*.	357	118	-	2,103	600	-
Short-Finned Pilot Whale	Hawaii	8,905	4,931	2	57,475	28,419	11
Short-Finned Pilot Whale	California/Oregon/Washington.	1,436	547	1	8,777	2,716	1
Bottlenose Dolphin	Maui Nui	186	2	-	1,285	12	-
Bottlenose Dolphin	Hawaii Island	2	3	-	8	16	-
Bottlenose Dolphin	Hawaii Pelagic	32,258	5,040	3	220,679	30,047	20
Bottlenose Dolphin	Kaua'i/Ni'ihau	945	233	-	6,098	1,629	-
Bottlenose Dolphin	O'ahu	6,672	67	0	46,638	430	0
Bottlenose Dolphin	California Coastal	484	8	-	3,308	51	-
Bottlenose Dolphin	California/Oregon/Washington Offshore.	11,368	5,492	3	65,775	28,363	14
Fraser's Dolphin	Hawaii	16,259	14,089	1	103,900	80,236	7
Long-Beaked Common Dolphin.	California	70,884	30,889	20	423,266	156,179	107
Northern Right Whale Dolphin.	California/Oregon/Washington.	15,672	19,635	13	81,148	89,202	60
Pacific White-Sided Dolphin	California/Oregon/Washington.	22,095	19,683	14	119,888	89,082	68
Pantropical Spotted Dolphin	Maui Nui	811	14	-	5,444	75	-
Pantropical Spotted Dolphin	Hawaii Island	2,086	2,879	2	13,121	16,318	8
Pantropical Spotted Dolphin	Hawaii Pelagic	18,458	17,816	9	118,066	101,178	50
Pantropical Spotted Dolphin	O'ahu	5,489	97	1	38,207	626	2
Pantropical Spotted Dolphin	Baja California Peninsula Mexico*.	48,096	34,318	37	270,474	177,669	189
Risso's Dolphin	Hawaii	2,781	2,595	1	17,461	14,575	1
Risso's Dolphin	California/Oregon/Washington.	17,117	7,907	3	99,536	40,443	19
Rough-Toothed Dolphin	Hawaii	45,968	34,070	18	301,367	194,804	102
Short-Beaked Common Dolphin.	California/Oregon/Washington.	876,990	548,702	389	5,081,159	2,770,024	2,023
Spinner Dolphin	Hawaii Pelagic	1,679	2,100	1	10,633	11,946	3
Spinner Dolphin	Hawaii Island	46	49	-	273	280	-
Spinner Dolphin	Kaua'i/Ni'ihau	2,660	866	1	17,090	6,046	5
Spinner Dolphin	O'ahu/4 Islands Region	971	13	-	6,790	86	-
Striped Dolphin	Hawaii Pelagic	14,566	16,678	6	92,249	94,018	36
Striped Dolphin	California/Oregon/Washington.	63,661	46,945	32	359,520	240,671	160
Dall's Porpoise	California/Oregon/Washington.	6,430	36,826	522	37,679	176,737	2,512
Harbor Porpoise	Monterey Bay	1,314	0	-	5,627	0	-
Harbor Porpoise	Morro Bay	3,824	46	0	22,754	221	0
Harbor Porpoise	Northern California/Southern Oregon.	357	0	-	1,576	0	-
Harbor Porpoise	San Francisco/Russian River	6,869	29	0	29,968	127	0
California Sea Lion	U.S.	662,716	186,625	115	3,903,717	911,677	653

TABLE 42—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING NAVY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Guadalupe Fur Seal	Mexico	217,808	77,386	32	1,213,525	384,582	162
Northern Fur Seal	Eastern Pacific	19,371	9,876	2	90,896	43,276	9
Northern Fur Seal	California	13,512	6,134	2	63,833	27,073	8
Steller Sea Lion	Eastern	389	122	1	1,870	519	1
Harbor Seal	California	10,510	1,457	3	61,064	8,093	13
Hawaiian Monk Seal	Hawaii	590	123	0	4,076	764	0
Northern Elephant Seal	California Breeding	28,461	39,790	17	160,245	188,696	82

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 43—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING NAVY TESTING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Gray Whale	Eastern North Pacific.	4,876	6,722	64	28,937	24,742	335
Gray Whale	Western North Pacific.	50	67	1	302	233	3
Blue Whale	Central North Pacific.	5	19	1	27	107	2
Blue Whale	Eastern North Pacific.	696	1,094	8	4,028	5,743	52
Bryde's Whale	Eastern Tropical Pacific.	47	89	2	275	517	8
Bryde's Whale	Hawaii	22	75	1	112	412	1
Fin Whale	Hawaii	5	19	1	29	114	1
Fin Whale	California/Oregon/Washington.	1,741	4,144	21	10,107	19,655	117
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	343	472	4	2,076	2,269	23
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	818	1,155	8	4,947	5,553	43
Humpback Whale	Hawaii	348	358	4	2,045	2,082	27
Minke Whale	Hawaii	12	50	1	64	283	1
Minke Whale	California/Oregon/Washington.	563	718	7	3,412	3,555	43
Sei Whale	Hawaii	11	41	1	57	230	3
Sei Whale	Eastern North Pacific.	37	65	1	215	345	1
Sperm Whale	Hawaii	288	56	0	1,452	291	0
Sperm Whale	California/Oregon/Washington.	834	129	-	4,350	594	-
Dwarf Sperm Whale.	Hawaii	2,189	6,048	371	10,769	31,271	1,805
Dwarf Sperm Whale.	California/Oregon/Washington.	519	709	26	2,796	3,966	149
Pygmy Sperm Whale.	Hawaii	2,243	6,137	373	10,987	31,760	1,821
Pygmy Sperm Whale.	California/Oregon/Washington.	525	743	23	2,819	4,116	129
Baird's Beaked Whale.	California/Oregon/Washington.	2,823	5	-	16,049	23	-
Blainville's Beaked Whale.	Hawaii	1,702	2	-	8,904	13	-
Goose-Beaked Whale.	Hawaii	6,945	8	-	36,195	44	-
Goose-Beaked Whale.	California/Oregon/Washington.	55,207	92	-	295,610	393	-

TABLE 43—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING NAVY TESTING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Longman's Beaked Whale.	Hawaii	4,106	12	-	21,483	61	-
Mesoplodont Beaked Whale.	California/Oregon/ Washington.	27,697	62	-	146,347	259	-
False Killer Whale	Main Hawaiian Islands Insular.	32	9	-	171	53	-
False Killer Whale	Northwest Hawaiian Islands.	30	8	-	150	47	-
False Killer Whale	Hawaii Pelagic	192	95	1	987	502	1
False Killer Whale	Baja California Peninsula Mexico*.	332	60	0	1,831	392	0
Killer Whale	Hawaii	14	8	-	71	42	-
Killer Whale	Eastern North Pacific Offshore.	399	75	0	2,318	440	0
Killer Whale	West Coast Transient.	7	1	-	45	7	-
Melon-Headed Whale.	Hawaiian Islands	3,396	1,711	2	17,285	9,306	13
Melon-Headed Whale.	Kohala Resident (Hawaii).	25	6	-	161	34	-
Pygmy Killer Whale	Hawaii	928	481	1	4,641	2,510	1
Pygmy Killer Whale	California—Baja California Peninsula Mexico*.	260	53	-	1,376	257	-
Short-Finned Pilot Whale.	Hawaii	2,625	734	1	14,186	3,955	2
Short-Finned Pilot Whale.	California/Oregon/ Washington.	1,899	371	1	10,796	2,075	1
Bottlenose Dolphin	Maui Nui	121	12	0	751	72	0
Bottlenose Dolphin	Hawaii Island	3	-	-	19	-	-
Bottlenose Dolphin	Hawaii Pelagic	4,805	842	1	28,873	4,998	7
Bottlenose Dolphin	Kaua'i/Ni'ihau	276	5	-	1,559	27	-
Bottlenose Dolphin	O'ahu	407	35	1	2,727	237	1
Bottlenose Dolphin	California Coastal	811	20	-	5,123	103	-
Bottlenose Dolphin	California/Oregon/ Washington Offshore.	9,699	1,286	1	55,144	6,926	3
Fraser's Dolphin	Hawaii	3,562	1,524	1	18,148	7,963	2
Long-Beaked Common Dolphin.	California	181,795	11,646	6	1,156,935	57,311	31
Northern Right Whale Dolphin.	California/Oregon/ Washington.	7,934	1,997	2	43,020	8,762	9
Pacific White-Sided Dolphin.	California/Oregon/ Washington.	23,127	3,851	2	132,034	17,006	13
Pantropical Spotted Dolphin.	Maui Nui	1,358	157	1	8,514	943	1
Pantropical Spotted Dolphin.	Hawaii Island	789	234	1	4,524	1,389	1
Pantropical Spotted Dolphin.	Hawaii Pelagic	5,521	2,324	2	28,528	12,527	9
Pantropical Spotted Dolphin.	O'ahu	748	58	1	4,749	392	2
Pantropical Spotted Dolphin.	Baja California Peninsula Mexico*.	12,181	2,468	2	67,222	16,411	10
Risso's Dolphin	Hawaii	745	396	1	3,652	2,091	2
Risso's Dolphin	California/Oregon/ Washington.	15,852	2,686	1	86,994	12,028	5
Rough-Toothed Dolphin.	Hawaii	11,455	4,768	3	62,028	25,394	15
Short-Beaked Common Dolphin.	California/Oregon/ Washington.	611,376	119,400	58	3,312,917	550,748	324
Spinner Dolphin	Hawaii Pelagic	473	265	1	2,345	1,445	1
Spinner Dolphin	Hawaii Island	13	0	-	82	0	-
Spinner Dolphin	Kaua'i/Ni'ihau	901	16	-	5,096	90	-
Spinner Dolphin	O'ahu/4 Islands Region.	180	28	0	1,120	155	0
Striped Dolphin	Hawaii Pelagic	3,793	2,473	1	18,660	12,807	6
Striped Dolphin	California/Oregon/ Washington.	16,581	5,362	2	88,084	29,998	12

TABLE 43—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING NAVY TESTING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Dall's Porpoise	California/Oregon/Washington.	6,191	8,086	222	34,212	43,404	1,300
Harbor Porpoise	Monterey Bay	865	-	-	5,307	-	-
Harbor Porpoise	Morro Bay	254	3	1	1,660	19	1
Harbor Porpoise	Northern California/Southern Oregon.	124	-	-	763	-	-
Harbor Porpoise	San Francisco/Russian River.	3,023	6	0	18,554	36	0
California Sea Lion	U.S.	928,540	67,321	16	5,191,344	245,578	71
Guadalupe Fur Seal.	Mexico	44,414	3,814	3	249,924	24,054	21
Northern Fur Seal	Eastern Pacific	3,080	183	1	18,776	1,111	1
Northern Fur Seal	California	1,769	87	0	10,740	521	0
Steller Sea Lion	Eastern	439	31	-	2,678	174	-
Harbor Seal	California	38,391	15,461	3	204,018	81,833	14
Hawaiian Monk Seal.	Hawaii	75	43	1	406	257	1
Northern Elephant Seal.	California Breeding	34,434	13,065	5	203,952	54,851	27

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 44—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING COAST GUARD TRAINING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Gray Whale	Eastern North Pacific	15	-	-	102	-	-
Gray Whale	Western North Pacific	1	-	-	2	-	-
Blue Whale	Central North Pacific	1	-	-	1	-	-
Blue Whale	Eastern North Pacific	18	-	-	124	-	-
Bryde's Whale	Eastern Tropical Pacific	1	-	-	5	-	-
Bryde's Whale	Hawaii	2	-	-	13	-	-
Fin Whale	Hawaii	2	-	-	8	-	-
Fin Whale	California/Oregon/Washington.	62	-	-	432	-	-
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	7	-	-	45	-	-
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	14	-	-	96	-	-
Humpback Whale	Hawaii	7	-	-	46	-	-
Minke Whale	Hawaii	2	-	-	14	-	-
Minke Whale	California/Oregon/Washington.	7	-	-	48	-	-
Sei Whale	Hawaii	1	-	-	4	-	-
Sei Whale	Eastern North Pacific	1	-	-	4	-	-
Sperm Whale	Hawaii	7	-	-	45	-	-
Sperm Whale	California/Oregon/Washington.	28	-	-	196	-	-
Dwarf Sperm Whale	Hawaii	159	225	2	1,109	1,575	12
Dwarf Sperm Whale	California/Oregon/Washington.	16	34	-	108	235	-
Pygmy Sperm Whale	Hawaii	160	192	-	1,117	1,342	-
Pygmy Sperm Whale	California/Oregon/Washington.	17	31	-	116	215	-
Baird's Beaked Whale	California/Oregon/Washington.	54	-	-	378	-	-
Blainville's Beaked Whale	Hawaii	25	-	-	170	-	-
Goose-Beaked Whale	Hawaii	143	-	-	1,001	-	-
Goose-Beaked Whale	California/Oregon/Washington.	653	-	-	4,569	-	-
Longman's Beaked Whale	Hawaii	145	-	-	1,013	-	-
Mesoplodont Beaked Whale	California/Oregon/Washington.	415	-	-	2,901	-	-
False Killer Whale	Main Hawaiian Islands Insular.	4	-	-	27	-	-

TABLE 44—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SONAR AND OTHER ACTIVE TRANSDUCERS DURING COAST GUARD TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
False Killer Whale	Northwest Hawaiian Islands	2	-	-	9	-	-
False Killer Whale	Hawaii Pelagic	12	-	-	83	-	-
False Killer Whale	Baja California Peninsula Mexico*.	16	-	-	109	-	-
Killer Whale	Hawaii	2	-	-	10	-	-
Killer Whale	Eastern North Pacific Offshore.	1	-	-	7	-	-
Killer Whale	West Coast Transient	1	-	-	5	-	-
Melon-Headed Whale	Hawaiian Islands	223	-	-	1,558	-	-
Pygmy Killer Whale	Hawaii	56	-	-	390	-	-
Pygmy Killer Whale	California—Baja California Peninsula Mexico*.	3	-	-	18	-	-
Short-Finned Pilot Whale	Hawaii	83	-	-	578	-	-
Short-Finned Pilot Whale	California/Oregon/Washington.	10	-	-	69	-	-
Bottlenose Dolphin	Hawaii Pelagic	33	-	-	226	-	-
Bottlenose Dolphin	California Coastal	2	-	-	12	-	-
Bottlenose Dolphin	California/Oregon/Washington Offshore.	119	-	-	828	-	-
Fraser's Dolphin	Hawaii	17	-	-	113	-	-
Long-Beaked Common Dolphin.	California	924	1	-	6,467	6	-
Northern Right Whale Dolphin.	California/Oregon/Washington.	249	2	-	1,742	12	-
Pacific White-Sided Dolphin	California/Oregon/Washington.	246	1	-	1,722	7	-
Pantropical Spotted Dolphin	Hawaii Island	24	-	-	164	-	-
Pantropical Spotted Dolphin	Hawaii Pelagic	226	-	-	1,579	-	-
Pantropical Spotted Dolphin	O'ahu	1	-	-	7	-	-
Pantropical Spotted Dolphin	Baja California Peninsula Mexico*.	490	-	-	3,428	-	-
Risso's Dolphin	Hawaii	35	-	-	240	-	-
Risso's Dolphin	California/Oregon/Washington.	187	-	-	1,308	-	-
Rough-Toothed Dolphin	Hawaii	406	-	-	2,838	-	-
Short-Beaked Common Dolphin.	California/Oregon/Washington.	9,634	19	-	67,436	131	-
Spinner Dolphin	Hawaii Pelagic	24	-	-	165	-	-
Striped Dolphin	Hawaii Pelagic	247	2	-	1,726	12	-
Striped Dolphin	California/Oregon/Washington.	775	-	-	5,419	-	-
Dall's Porpoise	California/Oregon/Washington.	169	239	-	1,178	1,669	-
Harbor Porpoise	San Francisco/Russian River	2	-	-	11	-	-
California Sea Lion	U.S.	14,931	2	-	104,514	13	-
Guadalupe Fur Seal	Mexico	3,852	4	-	26,963	24	-
Northern Fur Seal	Eastern Pacific	633	-	-	4,425	-	-
Northern Fur Seal	California	555	-	-	3,885	-	-
Steller Sea Lion	Eastern	4	-	-	22	-	-
Harbor Seal	California	140	-	-	976	-	-
Hawaiian Monk Seal	Hawaii	1	-	-	5	-	-
Northern Elephant Seal	California Breeding	1,790	1	-	12,529	1	-

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

Estimated Take From Air Guns and Pile Driving

Table 45 provides estimated effects from air guns, including the comparative amounts of TTS and behavioral disturbance for each species and stock annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disturbance in the model, it was recorded as a TTS.

TABLE 45—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM AIR GUNS DURING NAVY TRAINING AND TESTING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Gray Whale	Eastern North Pacific	0	-	-	0	-	-
Blue Whale	Eastern North Pacific	0	-	-	0	-	-

TABLE 45—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM AIR GUNS DURING NAVY TRAINING AND TESTING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
Fin Whale	California/Oregon/Washington.	0	0	-	0	0	-
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	0	-	-	0	-	-
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	0	0	-	0	0	-
Humpback Whale	Hawaii	1	-	-	1	-	-
Minke Whale	California/Oregon/Washington.	0	-	-	0	-	-
Sperm Whale	Hawaii	1	-	-	1	-	-
Dwarf Sperm Whale	Hawaii	8	5	1	50	34	1
Dwarf Sperm Whale	California/Oregon/Washington.	1	1	-	4	3	-
Pygmy Sperm Whale	Hawaii	6	6	1	34	37	3
Pygmy Sperm Whale	California/Oregon/Washington.	1	1	-	3	6	-
Goose-Beaked Whale	Hawaii	1	-	-	1	-	-
Mesoplodont Beaked Whale	California/Oregon/Washington.	0	-	-	0	-	-
Melon-Headed Whale	Hawaiian Islands	1	-	-	2	-	-
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	1	-	-	1	-	-
Short-Finned Pilot Whale	Hawaii	1	-	-	1	-	-
Bottlenose Dolphin	Hawaii Pelagic	1	-	-	3	-	-
Bottlenose Dolphin	California/Oregon/Washington Offshore.	1	-	-	2	-	-
Long-Beaked Common Dolphin.	California	3	-	-	13	-	-
Northern Right Whale Dolphin.	California/Oregon/Washington.	1	-	-	2	-	-
Pacific White-Sided Dolphin	California/Oregon/Washington.	1	-	-	5	-	-
Pantropical Spotted Dolphin	Hawaii Island	1	-	-	1	-	-
Pantropical Spotted Dolphin	Hawaii Pelagic	1	-	-	1	-	-
Pantropical Spotted Dolphin	Baja California Peninsula Mexico.	2	-	-	9	-	-
Risso's Dolphin	California/Oregon/Washington.	1	-	-	6	-	-
Rough-Toothed Dolphin	Hawaii	1	-	-	1	-	-
Short-Beaked Common Dolphin.	California/Oregon/Washington.	17	-	-	85	-	-
Striped Dolphin	Hawaii Pelagic	-	1	-	-	1	-
Striped Dolphin	California/Oregon/Washington.	1	-	-	5	-	-
Dall's Porpoise	California/Oregon/Washington.	9	8	1	58	48	4
Harbor Porpoise	San Francisco/Russian River	1	2	1	6	12	1
California Sea Lion	U.S.	8	1	-	33	1	-
Guadalupe Fur Seal	Mexico	1	-	-	5	-	-
Northern Fur Seal	Eastern Pacific	1	-	-	2	-	-
Northern Fur Seal	California	1	-	-	1	-	-
Northern Elephant Seal	California Breeding	1	-	-	3	-	-

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

Table 46 provides the estimated effects from pile driving and extraction, including the comparative amounts of TTS and behavioral disturbance for each species and stock annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disturbance in the model, it was recorded as a TTS.

TABLE 46—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM PILE DRIVING DURING NAVY TRAINING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ
California Sea Lion	U.S	16,992	1,891	61	118,938	13,237	423
Harbor Seal	California	952	183	20	6,664	1,281	138

Estimated Take From Target and Missile Launch Activities

Table 47 provides the estimated effects from target and missile launch activities at SNI and PMRF, including the amounts of behavioral disturbance for each species and stock annually. Pinnipeds hauled out on the shoreline of SNI have been observed to behaviorally react to the sound of launches of targets and missiles from launch pads on the island (Naval Air Warfare Center Weapons Division, 2018; U.S. Department of the Navy, 2020b, 2022b, 2023). The estimate of the number of behavioral effects that would be expected due to in-air noise from launches was based on observations of pinnipeds over three monitoring seasons (2015–2017) divided by the number of launch events over that same time period. The Navy determined that the numbers presented in table 46 (see table 5–6 of the application) represent the number of pinnipeds expected to be hauled out at SNI based on surveys over the five-year period from 2014 to 2019 (U.S. Department of the Navy, 2020a) and the average number of effects observed per launch event (U.S. Department of the Navy, 2020b, 2022b, 2023). Of note, the estimated behavioral effects presented in table 47 are the same as those authorized in the July 2022 PMSR LOA (87 FR 40888, July 8, 2022).

For California sea lions, take estimates at SNI were derived from three monitoring seasons (2015 to 2017) where an average of 274.44 instances of take of sea lions by Level B harassment occurred per launch event. Therefore, 275 sea lions was multiplied by 40 launch events, for a take estimate of 11,000 instances of take by Level B harassment of California sea lions annually (table 47). Of note, the Navy has not conducted more than 25 launch events in a given year since 2001. For harbor seals, a total of 12 takes were derived from the 2016 and 2017 monitoring seasons and multiplied by 40 launch events for a total of 480 instances of take by Level B harassment annually (table 47). For northern elephant seals, take estimates were derived from three monitoring seasons (2015 to 2017) where an average of 0.61 instances of take of northern elephant seals by Level B harassment occurred per launch event. Therefore, one northern elephant seal was multiplied by 40 launch events for a take estimate of 40 instances of take by Level B harassment of northern elephant seals annually (table 47). Generally, northern elephant seals do not react to launch events other than simple alerting responses such as raising their heads or temporarily going from sleeping to being awake; however, to account for the rare instances where they have reacted, the Navy considered that some northern elephant seals could be taken during launch events.

At PMRF from 2020 to 2023, an annual average of 215 monk seals have been counted hauled out on the beach (unpublished Navy data). The maximum number of seals observed during a single observation was five and the minimum was zero; on most observations no hauled out seals were observed. Based on the annual average number of animals documented at the site, the Action Proponents estimate that weapons firing noise at PMRF would result in 215 behavioral effects annually on hauled out monk seals (table 47; see table 5–7 of the application). The analysis conservatively assumes that: (1) at least one monk seal is hauled out when a launch or firing event would occur, an assumption contradicted by the observational data, which indicates that most frequently no monk seals are hauled out on the beach; and (2) that a monk seal would be disturbed and behaviorally respond during each event. This estimate is well beyond the anticipated take due to the 35 missile, rocket, drone launches and 3 artillery events (38 total) events on average per year. Monk seal in-air hearing is less sensitive than hearing in other phocid seals (Ruscher *et al.,* 2021; Ruscher *et al.,* 2025), suggesting that monk seals may be less likely to respond to in-air noise.

Neither TTS nor auditory injury is anticipated from missile and launch activities, as marine mammals are not anticipated to be exposed to noise from these activities that exceed the TTS or auditory injury thresholds (see the 2024 HCTT Draft EIS/OEIS appendix E.1, In-Air Acoustic Effects on Pinnipeds from Weapons Firing Noise).

TABLE 47—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM IN-AIR ACOUSTIC STRESSORS FROM MISSILE, AERIAL TARGET, AND AIR VEHICLE LAUNCHES AND ARTILLERY FIRING

Species	Stock	Maximum annual behavioral	Maximum 7-year behavioral
California sea lion	U.S	11,000	77,000
Harbor seal	California	480	3,360
Hawaiian monk seal	Hawai'i	215	1,505
Northern elephant seal	California	40	280

Note: California sea lion, harbor seal, and northern elephant seal are expected at San Nicolas Island only. Hawaiian monk seal is expected at the Pacific Missile Range Facility only.

Estimated Take From Explosives

Table 48 provides estimated effects from explosives during Navy training activities and table 49 provides estimated effects from explosives including small ship shock trials from Navy testing activities. Table 50 provides estimated effects from small ship shock trials over a maximum year (*i.e.,* one event) of Navy testing activities, which is a subset of the information included in table 49. Table 51 provides estimated effects from explosives during Coast Guard training activities, and table 52 provides estimated effects from explosives during Army training activities.

TABLE 48—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM EXPLOSIVES DURING NAVY TRAINING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Gray Whale	Eastern North Pacific	234	391	33	0	.....	1,491	2,578	217	0	.....
Gray Whale	Western North Pacific	1	1	0	.....	.....	2	2	0	.....	.....
Blue Whale	Central North Pacific	1	.....	.....	.....	.....	1	.....	.....	.....	.....
Blue Whale	Eastern North Pacific	65	81	1	.....	.....	415	535	4	.....	.....
Bryde's Whale	Eastern Tropical Pacific	12	39	1	.....	.....	73	259	4	.....	.....
Bryde's Whale	Hawaii	1	1	0	.....	.....	5	2	0	.....	.....
Fin Whale	Hawaii	1	0	0	.....	.....	1	0	0	.....	.....
Fin Whale	California/Oregon/Washington	98	114	5	1	.....	633	747	35	1	.....
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	18	27	1	.....	.....	115	181	3	.....	.....
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	35	85	3	.....	.....	225	574	18	.....	.....
Humpback Whale	Hawaii	48	58	7	.....	.....	312	390	43	.....	.....
Minke Whale	Hawaii	1	1	.....	.....	.....	4	1	.....	.....	.....
Minke Whale	California/Oregon/Washington	29	81	9	.....	.....	182	529	63	.....	.....
Sei Whale	Hawaii	1	1	0	.....	.....	4	2	0	.....	.....
Sei Whale	Eastern North Pacific	5	1	0	.....	.....	34	6	0	.....	.....
Sperm Whale	Hawaii	2	1	1	.....	.....	9	6	1	.....	.....
Sperm Whale	California/Oregon/Washington	2	4	1	.....	.....	8	24	3	.....	.....
Dwarf Sperm Whale	Hawaii	272	407	171	1	0	1,692	2,630	1,109	1	0
Dwarf Sperm Whale	California/Oregon/Washington	12	35	13	.....	.....	75	219	83	.....	.....
Pygmy Sperm Whale	Hawaii	259	414	167	1	0	1,617	2,711	1,084	1	0
Pygmy Sperm Whale	California/Oregon/Washington	19	41	23	0	.....	117	272	153	0	.....
Baird's Beaked Whale	California/Oregon/Washington	.....	1	.....	.....	.....	.....	4	.....	.....	.....
Blainville's Beaked Whale	Hawaii	1	.....	.....	.....	.....	2	.....	.....	.....	.....
Goose-Beaked Whale	Hawaii	2	1	0	.....	.....	11	4	0	.....	.....
Goose-Beaked Whale	California/Oregon/Washington	6	13	1	.....	.....	36	89	2	.....	.....
Longman's Beaked Whale	Hawaii	1	1	1	.....	.....	2	3	4	.....	.....
Mesoplodont Beaked Whale	California/Oregon/Washington	2	5	1	.....	.....	11	34	2	.....	.....
False Killer Whale	Main Hawaiian Islands Insular	.....	0	.....	.....	.....	.....	0	.....	.....	.....
False Killer Whale	Hawaii Pelagic	1	1	.....	.....	.....	2	3	.....	.....	.....
False Killer Whale	Baja California Peninsula Mexico	0	1	.....	.....	.....	0	4	.....	.....	.....
Killer Whale	Hawaii	.....	0	0	.....	.....	.....	0	0	.....	.....
Killer Whale	Eastern North Pacific Offshore	6	7	3	.....	.....	38	47	21	.....	.....
Melon-Headed Whale	Hawaiian Islands	4	3	1	0	0	24	20	5	0	0
Pygmy Killer Whale	Hawaii	2	2	1	0	.....	11	13	3	0	.....
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	1	1	.....	.....	.....	1	1	.....	.....	.....
Short-Finned Pilot Whale	Hawaii	6	9	1	0	0	40	57	7	0	0
Short-Finned Pilot Whale	California/Oregon/Washington	6	6	6	2	1	35	39	41	12	4
Bottlenose Dolphin	Maui Nui	0	1	.....	.....	.....	0	4	.....	.....	.....
Bottlenose Dolphin	Hawaii Island	0	1	.....	.....	.....	0	1	.....	.....	.....
Bottlenose Dolphin	Hawaii Pelagic	134	114	14	1	1	920	783	96	7	2
Bottlenose Dolphin	Kaua'i/Ni'ihau	.....	1	0	0	.....	.....	1	0	0	.....
Bottlenose Dolphin	O'ahu	29	21	4	1	1	200	142	26	3	1
Bottlenose Dolphin	California Coastal	9	15	6	1	.....	59	103	41	1	.....
Bottlenose Dolphin	California/Oregon/Washington Offshore.	38	40	9	1	0	240	260	57	3	0
Fraser's Dolphin	Hawaii	13	10	3	1	.....	74	64	18	1	.....
Long-Beaked Common Dolphin	California	273	306	75	18	3	1,641	1,976	498	117	15
Northern Right Whale Dolphin	California/Oregon/Washington	2	4	1	1	0	13	24	1	3	0
Pacific White-Sided Dolphin	California/Oregon/Washington	77	73	16	3	1	463	470	101	19	1
Pantropical Spotted Dolphin	Maui Nui	3	2	2	0	.....	18	12	10	0	.....
Pantropical Spotted Dolphin	Hawaii Island	1	8	2	1	.....	7	55	13	2	.....
Pantropical Spotted Dolphin	Hawaii Pelagic	11	13	3	1	0	69	87	15	2	0
Pantropical Spotted Dolphin	O'ahu	17	15	3	1	.....	118	100	18	1	.....
Pantropical Spotted Dolphin	Baja California Peninsula Mexico	15	11	5	1	1	93	75	29	6	1
Risso's Dolphin	Hawaii	2	2	0	0	.....	9	9	0	0	.....

TABLE 48—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM EXPLOSIVES DURING NAVY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Risso's Dolphin	California/Oregon/Washington	23	38	9	3	.....	146	252	62	17	.....
Rough-Toothed Dolphin	Hawaii	72	63	6	3	1	481	426	38	17	1
Short-Beaked Common Dolphin	California/Oregon/Washington	1,413	1,078	255	50	13	8,979	6,965	1,684	329	91
Spinner Dolphin	Hawaii Pelagic	1	1	0	0	.....	2	2	0	0	.....
Spinner Dolphin	Hawaii Island	1	1	1	0	.....	7	2	1	0	.....
Spinner Dolphin	Kaua'i/Ni'ihau	0	2	0	0	0	0	11	0	0	0
Spinner Dolphin	O'ahu/4 Islands Region	4	3	1	0	0	27	19	2	0	0
Striped Dolphin	Hawaii Pelagic	11	5	1	1	.....	59	31	4	3	.....
Striped Dolphin	California/Oregon/Washington	12	23	4	1	1	73	148	27	6	1
Dall's Porpoise	California/Oregon/Washington	155	433	185	1	.....	975	2,787	1,214	1	.....
Harbor Porpoise	Morro Bay	.....	13	11	0	.....	.....	76	71	0	.....
Harbor Porpoise	San Francisco/Russian River	.....	22	24	.....	.....	.....	153	164	.....	.....
California Sea Lion	U.S.	3,254	4,576	313	43	4	20,202	29,753	2,048	282	22
Guadalupe Fur Seal	Mexico	50	60	4	1	1	312	361	25	7	1
Northern Fur Seal	Eastern Pacific	1	2	1	0	.....	1	14	1	0	.....
Northern Fur Seal	California	1	2	1	0	.....	1	11	1	0	.....
Steller Sea Lion	Eastern	5	8	2	.....	.....	31	50	12	.....	.....
Harbor Seal	California	1,510	2,050	214	6	1	9,224	12,668	1,343	42	7
Hawaiian Monk Seal	Hawaii	14	21	3	1	0	89	136	17	1	0
Northern Elephant Seal	California Breeding	147	229	31	1	.....	936	1,505	201	1	.....

Note: The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 49—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM EXPLOSIVES DURING NAVY TESTING ACTIVITIES (INCLUDES SMALL SHIP SHOCK TRIALS)

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Gray Whale	Eastern North Pacific	123	56	5	0	-	713	353	30	0	-
Gray Whale	Western North Pacific	2	1	0	-	-	9	1	0	-	-
Blue Whale	Eastern North Pacific	21	25	2	-	-	135	96	14	-	-
Bryde's Whale	Eastern Tropical Pacific	3	3	1	-	-	16	20	1	-	-
Bryde's Whale	Hawaii	1	1	0	-	-	1	6	0	-	-
Fin Whale	Hawaii	1	0	-	-	-	2	0	-	-	-
Fin Whale	California/Oregon/Washington	76	69	6	0	-	451	284	39	0	-
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	13	11	1	-	-	80	67	5	-	-
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	31	29	1	1	-	187	172	5	1	-
Humpback Whale	Hawaii	40	32	2	-	-	275	224	11	-	-
Minke Whale	Hawaii	1	1	0	-	-	3	1	0	-	-
Minke Whale	California/Oregon/Washington	9	10	1	-	0	58	63	6	-	0
Sei Whale	Hawaii	0	0	-	-	-	0	0	-	-	-
Sei Whale	Eastern North Pacific	2	2	1	-	-	11	8	1	-	-
Sperm Whale	Hawaii	0	1	-	-	-	0	1	-	-	-
Sperm Whale	California/Oregon/Washington	2	1	1	-	-	12	7	1	-	-
Dwarf Sperm Whale	Hawaii	86	107	27	0	0	548	669	135	0	0
Dwarf Sperm Whale	California/Oregon/Washington	20	33	17	-	0	127	205	96	-	0
Pygmy Sperm Whale	Hawaii	97	114	28	0	-	614	718	142	0	-
Pygmy Sperm Whale	California/Oregon/Washington	22	33	18	-	-	145	200	109	-	-
Baird's Beaked Whale	California/Oregon/Washington	1	1	0	-	-	5	2	0	-	-
Blainville's Beaked Whale	Hawaii	0	-	-	-	-	0	-	-	-	-
Goose-Beaked Whale	Hawaii	1	1	0	-	-	4	1	0	-	-
Goose-Beaked Whale	California/Oregon/Washington	8	3	1	0	-	50	16	2	0	-

Longman's Beaked Whale	Hawaii	0	0	-	-	-	0	0	-	-	-
Mesoplodont Beaked Whale	California/Oregon/Washington	6	3	1	0	0	35	21	4	0	0
False Killer Whale	Main Hawaiian Islands Insular	1	1	-	-	-	3	3	-	-	-
False Killer Whale	Hawaii Pelagic	0	0	0	-	-	0	0	0	-	-
False Killer Whale	Baja California Peninsula Mexico*	0	1	0	0	-	0	3	0	0	-
Killer Whale	Eastern North Pacific Offshore	2	1	1	0	-	8	6	2	0	-
Melon-Headed Whale	Hawaiian Islands	1	1	1	0	-	4	2	1	0	-
Pygmy Killer Whale	Hawaii	1	0	0	0	-	1	0	0	0	-
Pygmy Killer Whale	California—Baja California Peninsula Mexico*.	-	1	0	0	-	-	1	0	0	-
Short-Finned Pilot Whale	Hawaii	4	3	1	-	-	26	20	3	-	-
Short-Finned Pilot Whale	California/Oregon/Washington	2	2	1	-	-	14	11	1	-	-
Bottlenose Dolphin	Maui Nui	2	2	-	-	-	13	14	-	-	-
Bottlenose Dolphin	Hawaii Pelagic	51	32	4	1	-	354	222	27	5	-
Bottlenose Dolphin	Kaua'i/Ni'ihau	0	0	0	-	-	0	0	0	-	-
Bottlenose Dolphin	O'ahu	-	1	0	0	-	-	1	0	0	-
Bottlenose Dolphin	California Coastal	-	1	0	0	-	-	2	0	0	-
Bottlenose Dolphin	California/Oregon/Washington Offshore.	6	7	1	0	-	40	48	6	0	-
Fraser's Dolphin	Hawaii	0	0	0	-	-	0	0	0	-	-
Long-Beaked Common Dolphin	California	72	83	27	6	1	472	525	168	31	2
Northern Right Whale Dolphin	California/Oregon/Washington	9	9	3	1	1	59	55	20	3	1
Pacific White-Sided Dolphin	California/Oregon/Washington	25	31	6	1	1	168	204	36	5	1
Pantropical Spotted Dolphin	Maui Nui	19	8	1	0	-	131	54	7	0	-
Pantropical Spotted Dolphin	Hawaii Island	1	1	1	-	-	3	2	1	-	-
Pantropical Spotted Dolphin	Hawaii Pelagic	12	4	1	1	0	78	27	2	1	0
Pantropical Spotted Dolphin	O'ahu	-	1	0	-	-	-	1	0	-	-
Pantropical Spotted Dolphin	Baja California Peninsula Mexico*	25	19	1	1	1	171	128	4	1	1
Risso's Dolphin	Hawaii	1	1	1	-	-	2	1	1	-	-
Risso's Dolphin	California/Oregon/Washington	11	10	4	1	0	71	62	21	1	0
Rough-Toothed Dolphin	Hawaii	42	23	3	1	1	289	160	19	3	1
Short-Beaked Common Dolphin	California/Oregon/Washington	428	492	103	21	5	2,819	3,129	601	112	16
Spinner Dolphin	Hawaii Pelagic	0	1	0	0	-	0	1	0	0	-
Spinner Dolphin	Hawaii Island	0	-	-	-	-	0	-	-	-	-
Spinner Dolphin	Kaua'i/Ni'ihau	0	1	1	-	-	0	1	1	-	-
Spinner Dolphin	O'ahu/4 Islands Region	1	1	-	-	-	5	3	-	-	-
Striped Dolphin	Hawaii Pelagic	2	1	1	0	-	9	5	1	0	-
Striped Dolphin	California/Oregon/Washington	16	22	4	1	0	108	147	23	3	0
Dall's Porpoise	California/Oregon/Washington	438	631	304	1	0	2,808	3,857	1,748	4	0
Harbor Porpoise	Monterey Bay	0	-	-	-	-	0	-	-	-	-
Harbor Porpoise	Morro Bay	74	159	75	1	0	495	1,091	516	2	0
Harbor Porpoise	San Francisco/Russian River	3	3	1	-	-	15	18	4	-	-
California Sea Lion	U.S.	842	1,046	161	14	1	5,409	6,705	1,008	87	5
Guadalupe Fur Seal	Mexico	73	90	12	2	0	483	599	76	9	0
Northern Fur Seal	Eastern Pacific	19	28	7	1	0	117	177	42	2	0
Northern Fur Seal	California	15	22	6	1	0	93	140	35	3	0
Steller Sea Lion	Eastern	0	1	0	-	-	0	2	0	-	-
Harbor Seal	California	170	158	14	1	0	1,030	977	90	2	0
Hawaiian Monk Seal	Hawaii	10	11	1	-	-	65	74	6	-	-
Northern Elephant Seal	California Breeding	220	332	55	1	0	1,427	2,096	332	1	0

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 50—ANNUAL ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM SMALL SHIP SHOCK TRIALS OVER A MAXIMUM YEAR OF NAVY TESTING

[One event]

Species	Stock	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality
Blue Whale	Eastern North Pacific	12	-	-	-
Fin Whale	California/Oregon/Washington	24	0	-	-
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	1	0	-	-
Humpback Whale	Mainland Mexico—California/Oregon/Washington	2	0	0	-
Minke Whale	California/Oregon/Washington	1	0	-	-
Sei Whale	Eastern North Pacific	0	-	-	-
Sperm Whale	California/Oregon/Washington	0	0	-	-
Dwarf Sperm Whale	California/Oregon/Washington	2	2	-	-
Pygmy Sperm Whale	California/Oregon/Washington	2	2	-	-
Baird's Beaked Whale	California/Oregon/Washington	0	0	-	-
Goose-Beaked Whale	California/Oregon/Washington	1	0	0	-
Mesoplodont Beaked Whale	California/Oregon/Washington	0	0	0	0
Short-Finned Pilot Whale	California/Oregon/Washington	0	-	-	-
Bottlenose Dolphin	California/Oregon/Washington Offshore	0	0	0	-
Long-Beaked Common Dolphin	California	4	1	1	1
Northern Right Whale Dolphin	California/Oregon/Washington	0	0	0	0
Pacific White-Sided Dolphin	California/Oregon/Washington	1	-	0	0
Pantropical Spotted Dolphin	Baja California Peninsula Mexico*	1	0	0	0
Risso's Dolphin	California/Oregon/Washington	1	0	0	0
Short-Beaked Common Dolphin	California/Oregon/Washington	17	5	3	3
Striped Dolphin	California/Oregon/Washington	0	0	0	-
Dall's Porpoise	California/Oregon/Washington	39	34	-	0
California Sea Lion	U.S	6	1	0	0
Guadalupe Fur Seal	Mexico	0	-	-	-
Northern Elephant Seal	California Breeding	6	4	0	0

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. The estimated takes in this table are included in table 48 and not additional to table 48.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 51—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM EXPLOSIVES DURING COAST GUARD TRAINING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Gray Whale	Eastern North Pacific	0	1	-	-	-	0	1	-	-	-
Blue Whale	Eastern North Pacific	1	-	-	-	-	1	-	-	-	-
Fin Whale	California/Oregon/Washington	0	0	0	-	-	0	0	0	-	-
Humpback Whale	Central America/Southern Mexico—California/Oregon/Washington.	0	0	-	-	-	0	0	-	-	-
Humpback Whale	Mainland Mexico—California/Oregon/Washington.	1	0	-	-	-	1	0	-	-	-
Minke Whale	California/Oregon/Washington	0	0	-	-	-	0	0	-	-	-
Sei Whale	Hawaii	-	0	-	-	-	-	0	-	-	-
Sperm Whale	California/Oregon/Washington	0	-	-	-	-	0	-	-	-	-
Dwarf Sperm Whale	Hawaii	1	1	1	-	-	6	5	1	-	-
Dwarf Sperm Whale	California/Oregon/Washington	1	1	1	-	-	1	1	1	-	-
Pygmy Sperm Whale	Hawaii	1	1	1	-	-	7	3	1	-	-
Pygmy Sperm Whale	California/Oregon/Washington	1	1	0	-	-	1	1	0	-	-
Goose-Beaked Whale	California/Oregon/Washington	0	-	-	-	-	0	-	-	-	-
Mesoplodont Beaked Whale	California/Oregon/Washington	1	-	0	-	-	1	-	0	-	-
False Killer Whale	Baja California Peninsula Mexico*	1	-	1	-	-	1	-	1	-	-
Melon-Headed Whale	Hawaiian Islands	1	-	-	-	-	1	-	-	-	-
Bottlenose Dolphin	California/Oregon/Washington Offshore	1	1	-	-	-	1	1	-	-	-
Fraser's Dolphin	Hawaii	1	0	-	-	-	1	0	-	-	-
Long-Beaked Common Dolphin	California	1	1	0	-	-	1	1	0	-	-
Northern Right Whale Dolphin	California/Oregon/Washington	0	0	-	-	-	0	0	-	-	-
Pacific White-Sided Dolphin	California/Oregon/Washington	0	0	-	-	-	0	0	-	-	-
Pantropical Spotted Dolphin	Hawaii Island	0	0	-	-	-	0	0	-	-	-
Pantropical Spotted Dolphin	Hawaii Pelagic	-	1	-	-	-	-	1	-	-	-
Pantropical Spotted Dolphin	Baja California Peninsula Mexico*	-	1	-	-	-	-	1	-	-	-
Risso's Dolphin	California/Oregon/Washington	0	1	-	-	-	0	1	-	-	-
Rough-Toothed Dolphin	Hawaii	0	-	-	-	-	0	-	-	-	-
Short-Beaked Common Dolphin	California/Oregon/Washington	3	2	1	-	-	17	14	2	-	-
Striped Dolphin	Hawaii Pelagic	-	0	0	-	-	-	0	0	-	-
Striped Dolphin	California/Oregon/Washington	-	1	-	-	-	-	1	-	-	-
Dall's Porpoise	California/Oregon/Washington	2	2	1	-	-	11	9	3	-	-
Harbor Porpoise	San Francisco/Russian River	0	0	0	-	-	0	0	0	-	-
California Sea Lion	U.S	2	2	0	0	-	10	8	0	0	-
Guadalupe Fur Seal	Mexico	1	-	-	-	-	2	-	-	-	-
Northern Fur Seal	Eastern Pacific	0	1	-	-	-	0	1	-	-	-
Northern Fur Seal	California	0	0	-	-	-	0	0	-	-	-
Harbor Seal	California	1	0	-	-	-	1	0	-	-	-
Northern Elephant Seal	California Breeding	2	2	1	-	-	8	11	1	-	-

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 52—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM EXPLOSIVES DURING ARMY TRAINING ACTIVITIES

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Bryde's Whale	Hawaii	1	1	-	-	-	2	1	-	-	-
Humpback Whale	Hawaii	3	1	-	-	-	15	7	-	-	-
Minke Whale	Hawaii	1	-	-	-	-	3	-	-	-	-
Dwarf Sperm Whale	Hawaii	51	46	12	-	-	355	322	84	-	-
Pygmy Sperm Whale	Hawaii	57	51	15	-	-	399	356	101	-	-
Blainville's Beaked Whale	Hawaii	-	1	-	-	-	-	1	-	-	-
Goose-Beaked Whale	Hawaii	1	1	0	-	-	3	3	0	-	-

TABLE 52—ANNUAL AND 7-YEAR ESTIMATED TAKE OF MARINE MAMMAL STOCKS FROM EXPLOSIVES DURING ARMY TRAINING ACTIVITIES—Continued

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Longman's Beaked Whale	Hawaii	1	1	-	-	-	2	1	-	-	-
Melon-Headed Whale	Hawaiian Islands	1	1	1	-	-	5	3	1	-	-
Melon-Headed Whale	Kohala Resident (Hawaii)	1	1	-	-	-	4	3	-	-	-
Pygmy Killer Whale	Hawaii	1	-	-	-	-	3	-	-	-	-
Short-Finned Pilot Whale	Hawaii	2	1	1	1	-	9	6	2	1	-
Bottlenose Dolphin	Hawaii Pelagic	2	1	1	0	-	10	4	1	0	-
Fraser's Dolphin	Hawaii	2	3	1	1	-	12	15	5	1	-
Pantropical Spotted Dolphin	Maui Nui	-	1	-	-	-	-	1	-	-	-
Pantropical Spotted Dolphin	Hawaii Pelagic	2	1	1	1	0	8	6	1	1	0
Risso's Dolphin	Hawaii	-	-	1	0	-	-	-	1	0	-
Rough-Toothed Dolphin	Hawaii	3	2	1	1	-	17	14	1	1	-
Striped Dolphin	Hawaii Pelagic	1	2	1	1	-	7	10	1	1	-
Hawaiian Monk Seal	Hawaii	1	-	-	-	-	3	-	-	-	-

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

Estimated Take From Vessel Strike by Serious Injury or Mortality

Vessel strikes from commercial, recreational, and military vessels are known to affect large whales and have resulted in serious injury and fatalities to cetaceans (Abramson *et al.,* 2011; Berman-Kowalewski *et al.,* 2010a; Calambokidis, 2012; Douglas *et al.,* 2008; Laggner, 2009; Lammers *et al.,* 2003; Van der Hoop *et al.,* 2013; Van der Hoop *et al.,* 2012). Records of vessel strikes of large whales date back to the early 17th century, and the worldwide number of vessel strikes of large whales appears to have increased steadily during recent decades (Laist *et al.,* 2001; Ritter 2012).

Numerous studies of interactions between surface vessels and marine mammals have demonstrated that free-ranging marine mammals often, but not always (*e.g.,* McKenna *et al.,* 2015), engage in avoidance behavior when surface vessels move toward them. It is not clear whether these responses are caused by the physical presence of a surface vessel, the underwater noise generated by the vessel, or an interaction between the two (Amaral and Carlson, 2005; Au and Green, 2000; Bain *et al.,* 2006; Bauer 1986; Bejder *et al.,* 1999; Bejder and Lusseau, 2008; Bejder *et al.,* 2009; Bryant *et al.,* 1984; Corkeron, 1995; Erbe, 2002; Félix, 2001; Goodwin and Cotton, 2004; Greig *et al.,* 2020; Guilpin *et al.,* 2020; Keen *et al.,* 2019; Lemon *et al.,* 2006; Lusseau, 2003; Lusseau, 2006; Magalhaes *et al.,* 2002; Nowacek *et al.,* 2001; Redfern *et al.,* 2020; Richter *et al.,* 2003; Scheidat *et al.,* 2004; Simmonds, 2005; Szesciorka *et al.,* 2019; Watkins, 1986; Williams *et al.,* 2002; Wursig *et al.,* 1998). Several authors suggest that the noise generated during motion is probably an important factor (Blane and Jaakson, 1994; Evans *et al.,* 1992; Evans *et al.,* 1994). These studies suggest that the behavioral responses of marine mammals to surface vessels are similar to their behavioral responses to predators. Avoidance behavior is expected to be even stronger in the subset of instances during which the Action Proponents are conducting military readiness activities using active sonar or explosives.

The marine mammals most vulnerable to vessel strikes are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* sperm whales). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel strikes (Nowacek *et al.,* 2004). These species are primarily large, slow moving whales. There are 8 species (17 stocks) of large whales that are known to occur within the HCTT Study Area (table 14): gray whale, blue whale, Bryde's whale, fin whale, humpback whale, minke whale, sei whale, and sperm whale.

Some researchers have suggested the relative risk of a vessel strike can be assessed as a function of animal density and the magnitude of vessel traffic (*e.g.,* Fonnesbeck *et al.,* 2008; Vanderlaan *et al.,* 2008). Differences among vessel types also influence the probability of a vessel strike. The ability of any vessel to detect a marine mammal and avoid a collision depends on a variety of factors, including environmental conditions, vessel design, size, speed, and ability and number of personnel observing, as well as the behavior of the animal. Vessel speed, size, and mass are all important factors in determining if injury or death of a marine mammal is likely due to a vessel strike. For large vessels, speed and angle of approach can influence the severity of a strike. Large whales also do not have to be at the water's surface to be struck. Silber *et al.* (2010) found that when a whale is below the surface (about one to two times the vessel draft), under certain circumstances (vessel speed and location of the whale relative to the ship's centerline), there is likely to be a pronounced propeller suction effect. This suction effect may draw the whale into the hull of the ship, increasing the probability of propeller strikes.

There are some key differences between the operation of military and non-military vessels which make the likelihood of a military vessel striking a whale lower than some other vessels (*e.g.,* commercial merchant vessels). Key differences include:

- Military vessels have personnel assigned to stand watch at all times, day and night, when moving through the water (*i.e.,* when the vessel is underway). Watch personnel undertake extensive training and are certified to stand watch only after demonstrating competency in all necessary skills. While on watch, personnel employ visual search and reporting procedures in accordance with the U.S. Navy Lookout Training Handbook, the Coast Guard's Shipboard Lookout Manual, or civilian equivalent.
- The bridges of many military vessels are positioned closer to the bow, offering better visibility ahead of the vessel (compared to a commercial merchant vessel);
- Military readiness activities often involve aircraft (which can serve as part of the Lookout team), that can more readily detect cetaceans in the vicinity of a vessel or ahead of a vessel's present course, often before crew on the vessel would be able to detect them;
- Military vessels are generally more maneuverable than commercial merchant vessels, and are therefore capable of changing course more quickly in the event cetaceans are spotted in the vessel's path;
- Military vessels operate at the slowest speed practical consistent with operational requirements. While minimum speed is intended as a fuel conservation measure particular to a certain ship class, secondary benefits include a better ability to detect and avoid objects in the water, including marine mammals;
- Military ships often operate within a defined area for a period of time, in contrast to point-to-point commercial shipping over greater distances;
- The crew size on military vessels is generally larger than merchant vessels, allowing for stationing more trained Lookouts on the bridge. At all times when the Action Proponents' vessels are underway, trained Lookouts and bridge navigation teams are used to detect objects on the surface of the water ahead of the ship, including cetaceans. Some events may have additional personnel (beyond the minimum number of required Lookouts) who are already standing watch in or on the platform conducting the event or additional participating platforms and would have eyes on the water for all or part of an event. These additional personnel serve as members of the Lookout team; and
- When submerged, submarines are generally slow moving (to avoid detection); as a result, marine mammals at depth with a submarine are likely able to avoid collision with the submarine. When a submarine is transiting on the surface, the Navy posts Lookouts serving the same function as they do on surface vessels.

Vessel strike to marine mammals is not associated with any specific military readiness activity. Rather, vessel strike is a limited and sporadic, but possible, accidental result of military vessel movement within the HCTT Study Area or while in transit.

There were two recorded U.S. Navy vessel strikes of large whales in the HSTT (now HCTT) Study Area in 2009. There were no known strikes from June 2009 until May 2021, a period of approximately 12 years. (Of note, between 2009–2024, the Navy documented 384 U.S. Navy vessel movements in HSTT to avoid marine mammals during MTEs.) Since 2021 there have been five strikes of large whales in SOCAL attributed to naval vessels, three by the U.S. Navy and two by the Royal Australian Navy. As stated

previously, the U.S. Navy struck a large whale in waters off Southern California in May 2023. Based on available photos and video, NMFS and the Navy have determined this whale was either a fin whale or sei whale. The U.S. Navy struck two unidentified large whales during the months of June and July 2021, and prior to that, on May 7, 2021, the Royal Australian Navy HMAS Sydney, a 147.5 m (161.3 yd) Hobart Class Destroyer, struck and killed two fin whales (a mother and her calf) while operating within SOCAL. Please see the *Authorized Take From Vessel Strikes and Explosives by Serious Injury or Mortality* section of the 2025 HSTT final rule (90 FR 4944, January 16, 2025) for detailed descriptions of the naval vessel strikes that occurred in 2021 and 2023.

In March 2024 a dead fin whale was discovered off of Pier 10 in Naval Station San Diego within the Navy's security barrier. The security barrier, which consists of a series of connected floating sections, is intended to discourage unauthorized boat entry to the piers. The necropsy indicated that vessel strike was the most likely cause of death. Given the location the whale was discovered, this could have been the result of a military vessel strike. However, the Navy reviewed its vessel activity during that time frame and available observations of those vessels coming and going to port, as well as at port, and determined it was unlikely that the whale was carried into port by a Navy vessel. Based on this and other information from Navy's investigation, we cannot determine whether this whale was struck by a Navy vessel during HSTT activities or was struck by a commercial or other vessel and drifted into the Navy pier area.

There has been one recorded Coast Guard vessel strike of a large whale (humpback) in the HCTT Study Area since 2009. The strike occurred in 2020 off Maui, HI. There have been no known strikes within the California portion of the HCTT Study Area. However, there were two Coast Guard strikes outside of and inshore of the California portion of the HCTT Study Area, a humpback whale in 2023 and a gray whale in 2024. The vessels involved in the 2023 and 2024 strikes were moving at slow speed less than 6 kn and no obvious injury to the whales were observed after the strikes.

In light of the key differences between the operation of military and non-military vessels discussed above, it is highly unlikely that a military vessel would strike any type of marine mammal without detecting it. Specifically, Lookouts posted on or near the ship's bow can visually detect a strike in the absence of other indications that a strike has occurred. The Action Proponents' internal procedures and mitigation requirements include reporting of any vessel strikes of marine mammals, and the Action Proponents' discipline, extensive training (not only for detecting marine mammals, but for detecting and reporting any potential navigational obstruction), and strict chain of command give NMFS a high level of confidence that all strikes are reported. Accordingly, NMFS is confident that the Navy and Coast Guard's reported strikes are accurate and appropriate for use in the analysis.

When generally compared to mysticetes, odontocetes are more capable of physically avoiding a vessel strike and since some species occur in large groups, they are more easily seen when they are closer to the water surface. The smaller size and maneuverability of dolphins, small whales (not including large whale calves), porpoises, and pinnipeds generally make vessel strike very unlikely. For as long as records have been kept, neither the Navy nor the Coast Guard have any record of any small whales or pinnipeds being struck by a vessel as a result of military readiness activities. Over the same time period, NMFS, the Navy, and the Coast Guard have only one record of a dolphin being struck by a vessel as a result of Navy or Coast Guard activities. The dolphin was accidentally struck by a Navy small boat in fall 2021 in Saint Andrew's Pass, Florida. Other than this one reported strike of a dolphin in 2021, NMFS has never received any reports from other LOA or IHA holders indicating that these species have been struck by vessels. Worldwide vessel strike records show little evidence of strikes of these groups or marine mammals from the shipping sector and larger vessels (though for many species, records do exist (*e.g.,* West *et al.* 2024, Van Waerebeek *et al.,* 2007)), and the majority of the Action Proponents' activities involving faster-moving vessels (that could be considered more likely to hit a marine mammal) are located in offshore areas where smaller delphinid, porpoise, and pinniped densities are lower.

In order to account for the accidental nature of vessel strike to large whales in general, and the potential risk from vessel movement within the HCTT Study Area within the 7-year period of this proposed authorization, the Action Proponents requested incidental takes based on probabilities derived from a Poisson distribution. A Poisson distribution is often used to describe random occurrences when the probability of an occurrence is small. Count data, such as cetacean sighting data, or in this case strike data, are often described as a Poisson or over-dispersed Poisson distribution. The Poisson distribution was calculated using vessel strike data between 2009–2024 in the HCTT Study Area, historical at-sea days in the HCTT Study Area for the Navy and the Coast Guard (described in detail in section 6 of the application), and estimated potential at-sea days for both Action Proponents during the 7-year period from 2025–2032 covered by the requested regulations. The analysis incorporates data beginning in 2009 as that was the start of the Navy's Marine Species Awareness Training and adoption of additional mitigation measures to address vessel strike, which will remain in place along with additional and modified mitigation measures during the 7 years of this proposed rulemaking. The analysis for the period of 2025 to 2032 is described in detail below and in section 6.3.2 (Probability of Vessel Strike of Large Whale Species) of the application.

Between 2009 and early 2024, there were a total of 35,006 Navy at-sea days for Navy manned vessels greater than 127 m (418 ft, or Littoral Combat Ship size and above) in the HCTT Study Area, an average 2,188 days per year. This estimate is based on positional tracking data records from the Navy's Authoritative Maritime Services database for the years 2016–2023. The Navy used the average of the 2016–2023 annual values as a surrogate for annual at-sea days for each year between 2009 and 2015. Given variation in vessel traffic from year to year, the Navy anticipates that the annual average from this period is a sufficient prediction of future at-sea days for manned surface ships for the period of this proposed rule (*i.e.,* 2025–2032) (*i.e.,* 2,188 days per year). In addition, this vessel strike analysis considers the potential for larger sized USVs (longer than 61 m (200 ft)) to strike a large whale, as these vessels would be used for military readiness activities during the proposed effective period of this proposed rule. While there have been no known vessel strikes from USVs, this analysis incorporates an estimated 728 at-sea days for large USVs, for a predicted total of 2,916 annual at-sea days from large, manned vessels and large USVs from 2025–2032 (*i.e.,* 20,412 at-sea days over the 7-year period).

Between 2009 and early 2024, there were a total of 4,179 Coast Guard at-sea days for vessels larger than 100 m (328 ft) in the HCTT Study Area, an average of 262 days per year. To account for limitations in data availability particular

to Coast Guard vessel size classes, future new vessel or repositioning home port assignments, in consideration of documented strikes from Coast Guard medium sized vessels <100 m, and out of an abundance of caution, the Coast Guard predicted that there could be up to 60 additional at-sea days per year for the 2025–2032 period, for a predicted total of 322 annual at-sea days for vessels that may strike a large whale from 2025–2032 (*i.e.,* 2,254 at-sea days over the 7-year period).

As described above, during the same 2009 to 2024 period, there were five Navy vessel strikes of large whales and one Coast Guard vessel strike of a large whale. To calculate a vessel strike rate for each Action Proponent for the period of 2009 through 2024, the Action Proponents used the respective number of past vessel strikes of large whales and the respective number of at-sea days. Navy at-sea days (for vessels greater than 65 ft (19.8 m)) from 2009 through 2024 was estimated to be 35,006 days. Dividing the five known Navy strikes during that period by the at-sea days (*i.e.,* 5 strikes/35,006 at-sea days) results in a strike rate of 0.000143 strikes per at-sea day. Coast Guard at-sea days from 2009 through 2024 was estimated to be 4,179 days. Dividing the one known Coast Guard strike during that period by the at-sea days (*i.e.,* 1 strike/4,179 at-sea days) results in a strike rate of 0.000239 strikes per day.

As described above, the Action Proponents estimated that 20,412 Navy and 2,254 Coast Guard at-sea days would occur over the 7-year period associated with the requested authorization. Given a strike rate of 0.000143 Navy strikes per at-sea day, and 0.000239 Coast Guard strikes per at-sea day, the predicted number of vessel strikes over a 7-year period would be 2.9 strikes by the Navy and 0.5 strikes by the Coast Guard.

Using this predicted number of strikes, the Poisson distribution predicted the probabilities of a specific number of strikes (n = 0, 1, 2, *etc.*) from 2025 through 2032 for each Action Proponent. The probability analysis concluded that there is a 95 percent chance that a Navy vessel would strike at least one whale over the 7-year period, and a 79, 56, 34, 17, or 8 percent chance that more than one, two, three, four, or five whales, respectively, would be struck by the Navy over the 7-year period.

The probability analysis concluded that there is a 42 percent chance that a Coast Guard vessel would strike at least one whale over the 7-year period, and a 10 or 1 percent chance that more than one or two whales, respectively, would be struck by the Coast Guard over the 7-year period.

Based on this analysis, the Navy is requesting authorization to take five large whales by serious injury or mortality by vessel strike incidental to Navy training and testing activities, and the Coast Guard is requesting authorization to take two large whales by serious injury or mortality by vessel strike incidental to Coast Guard training activities. NMFS concurs that take by serious injury or mortality by vessel strike of up to five large whales by the Navy and two large whales by the Coast Guard (seven large whales total) could occur over the 7-year regulations and, based on the information provided earlier in this section, NMFS concurs with the Action Proponents' assessment and recognizes the potential for incidental take by vessel strike of large whales only (*i.e.,* no dolphins, small whales (not including large whale calves), porpoises, or pinnipeds) over the course of the 7-year regulations from military readiness activities.

While the Poisson distribution allows the Action Proponents and NMFS to determine the likelihood of vessel strike of all large whales, it does not indicate the likelihood of each strike occurring to a particular species or stock. As described above, the Action Proponents have not always been able to identify the species of large whale struck during previous known vessel strikes. However, based on the information available, the Navy requested authorization for take by serious injury or mortality by vessel strike of five whales, and of those five, no more than the following numbers from these stocks: one blue whale (Eastern North Pacific stock), four fin whales (California/Oregon/Washing (CA/OR/WA) stock), two gray whales (Eastern North Pacific stock), two humpback whale (one each of the Mainland Mexico-CA/OR/WA stock and the Central North Pacific stock), and one sperm whale (Hawaii stock). The Coast Guard requested authorization for take by serious injury or mortality by vessel strike of two whales, and of those two, no more than the following numbers from these stocks: one blue whale (Eastern North Pacific stock), two fin whales (CA/OR/WA stock), two gray whales (Eastern Pacific stock), and two humpback whales (one each of the Mainland Mexico-CA/OR/WA stock and Central North Pacific stock).

After concurring that take of up to seven large whales could occur (five takes by Navy, two by Coast Guard), and in consideration of the Action Proponents' request, NMFS considered which species could be among the seven large whales struck. NMFS conducted an analysis that considered several factors, in addition to the overlap of Navy activities with stock distribution: (1) the relative likelihood of striking one stock versus another based on available strike data from all vessel types as denoted in the SARs, and (2) whether each Action Proponent has ever struck an individual from a particular species or stock in the HCTT Study Area, and if so, how many times.

To address number (1) above, for SOCAL, NMFS compiled information from the 2023 SARs (Carretta *et al.,* 2024, Young *et al.,* 2024) on detected annual rates of large whale M/SI from vessel strike (table 53). (Of note, these data include the strike of two fin whales by the Royal Australian Navy in 2021, but do not include Navy strikes in 2021 and 2023 because the species struck is not known.) The M/SI in the 2023 SAR considers modeled takes (accounting for undetected vessel strike mortality) for some, but not most species and stocks (*i.e.,* M/SI for humpback whale includes modeled takes from Rockwood *et al.* (2017)). Using known strike data for all species and stocks allows NMFS to consider similar metrics for this comparative analysis. (Note that we rely on the M/SI estimates from the 2023 SAR (or draft 2024 SAR, where relevant) in our negligible impact analysis.) We also consider modeled takes of species from Rockwood *et al.* (2017) in table 53. The annual rates of large whale serious injury or mortality from vessel strike reported in the SARs help inform the relative susceptibility of large whale species to vessel strike in HCTT Study Area as recorded systematically over the five-year period used for the SARs. We summed the annual rates of serious injury or mortality from vessel strikes as reported in the SARs (excluding strikes that the SAR indicates occurred outside of the Study Area (*e.g.,* in Alaska)) and then divided each species' annual rate by this sum to get the percentage of total annual strikes for each species/stock (table 53).

TABLE 53—SUMMARY OF FACTORS CONSIDERED IN DETERMINING THE NUMBER OF INDIVIDUALS IN EACH STOCK POTENTIALLY STRUCK BY A VESSEL

Species	Stock	Total known U.S. Navy or Coast Guard strikes in HCTT study area	Rockwood *et al.* (2017) modeled vessel strikes [a]	Annual rate of M/SI from vessel strike [b]	Percentage of total annual strikes	Percent likelihood of 1 strike over 7 years	Percent likelihood of 2 strikes over 7 years	Percent likelihood of 3 strikes over 7 years
Blue whale	Eastern North Pacific.	Navy 2004	18	0.6	6.06	5.76	0.33	0.02
Fin whale	California/Oregon/Washington.	Navy 2009; Navy 2009; Navy 2023 (fin or sei).	43	1.6	16.16	15.35	2.36	0.36
Humpback whale	Mainland Mexico-California-Oregon-Washington.	Coast Guard 2016 (northern California) [c].	22	2.6	26.26	24.95	6.22	1.55
Humpback whale	Central America/Southern Mexico-California-Oregon-Washington.							
Sperm whale	Hawaii	Navy 2007		0.0	0.00	UNK	UNK	UNK
Gray whale	Eastern North Pacific.	Navy 1993; Navy 1998; Navy 1998.		1.8	18.18	17.27	2.98	0.52
Humpback whale	Hawaii	Navy 1998; Navy 2003; Coast Guard 2020.		3.3	33.33	31.67	10.03	3.18
Sei whale	Eastern North Pacific.	Navy 2023 (fin or sei).		0.0	0.0	0.00	0.00	0.00
Sei whale	Hawaii			0.0	0.0	0.00	0.00	0.00
Sperm whale	California/Oregon/Washington.			0.0	0.0	0.00	0.00	0.00
Bryde's whale	Eastern Tropical Pacific.			0.0	0.0	0.00	0.00	0.00
Bryde's whale	Hawaii			0.0	0.0	0.00	0.00	0.00
Minke whale	Hawaii			0.0	0.0	0.00	0.00	0.00
Minke whale	California/Oregon/Washington.			0.0	0.0	0.00	0.00	0.00

[a] Rockwood *et al.* (2017) modeled likely annual vessel strikes off the West Coast for these three species only.
[b] Values are from the most recent stock assessment report (Carretta *et al.,* 2024).
[c] The strike by the Coast Guard in 2016 was in San Francisco Bay, CA, outside the boundary of the HCTT Study Area.

To inform the likelihood of a single action proponent striking a particular species of large whale, we multiplied the percent of total annual strikes for a given species in table 53 by the total percent likelihood of a single action proponent striking at least one whale (*i.e.,* 95 and 42 percent for the Navy and Coast Guard, respectively, as described by the probability analysis above). We also calculated the percent likelihood of a single action proponent striking a particular species of large whale two or three times by squaring or cubing, respectively, the value estimated for the probability of striking a particular species of whale once (*i.e.,* to calculate the probability of an event occurring twice, multiply the probability of the first event by the second). The results of these calculations are reflected in the last three columns of table 53. We note that these probabilities vary from year to year as the average annual mortality changes depending on the specific range of time considered; however, over the years and through updated data in the SARs, stocks tend to consistently maintain a relatively higher or relatively lower likelihood of being struck.

The percent likelihood calculated (as described above) are then considered in combination with the information indicating the known species that the Navy or Coast Guard has struck in the HCTT Study Area since 1991 (since they started tracking consistently) (see table 53). We note that for the lethal take of species specifically denoted in table 53, 47 percent of those struck by the Navy (8 of 17 in the Pacific) remained unidentified (including the May 2023 strike, which as stated above, NMFS and the Navy have determined was of either a fin whale or sei whale), and 20 percent of those struck by the Coast Guard (1 of 5 in the Pacific) remained unidentified. However, given the information on known stocks struck, the analysis below remains appropriate. We also note that Rockwood *et al.* (2017) modeled the likelihood of vessel strike of blue whales, fin whales, and humpback whales on the U.S. West Coast (discussed in more detail in the *Serious Injury or Mortality* subsection of the Preliminary Analysis and Negligible Impact Determination section), and those numbers help inform the relative likelihood that the Navy or Coast Guard could strike those stocks.

Accordingly, stocks that have no record of ever having been struck by any vessel are considered to have a zero percent likelihood of being struck by the Navy or Coast Guard in the 7-year period of the proposed rule. Marine mammal stocks that have never been struck by the Navy or Coast Guard, have rarely been struck by other vessels, and have a low percent likelihood based on the historical vessel strike calculation are also considered to have a zero percent likelihood to be struck by the Navy or Coast Guard during the 7-year rule. We note that while vessel strike records have not differentiated between Eastern North Pacific and Western North Pacific gray whales, given their small population size and the comparative rarity with which individuals from the Western North Pacific stock are detected off the U.S. West Coast, it is highly unlikely that they would be encountered, much less struck. This rules out all but eight stocks. This leaves the following stocks for further analysis: blue whale (Eastern North Pacific stock), fin whale (CA/OR/WA stock), gray whale (Eastern North Pacific stock), humpback whale (Mainland Mexico-CA/OR/WA, Central America/Southern Mexico-CA/OR/WA, and Hawaii stocks), sei whale (Eastern North Pacific stock), and sperm whale (Hawaii stock).

As stated previously, based on available photos and video of the whale struck by the U.S. Navy in Southern

California in 2023, NMFS and the Navy have determined this whale was either a fin whale or sei whale. While the species of the two whales struck by the U.S. Navy in 2021 are unknown, given the following factors, NMFS expects these strikes may have been CA/OR/WA fin whales or Eastern North Pacific gray whales, or some combination of these two stocks. These species have the highest annual rates of M/SI from vessel collision in California (1.6, 1.8, respectively, as noted above). Additionally, gray whale and fin whale have the most recorded vessel strike incidents by military vessels in California and are the only stocks known to have been hit more than one time by naval or Coast Guard vessels in the California portion of the study area (three gray whale strikes by the U.S. Navy (1993, 1998), two or three fin whale strikes by the U.S. Navy (2009, potentially 2023), and two fin whale strikes by the Royal Australian Navy (2021)). Further, accounting for undocumented vessel strikes, Rockwood *et al.* (2021) estimated that in their study area off Southern California from 2012–2018, on average 8.9 blue, 4.6 humpback, and 9.7 fin whales were killed by civilian vessel strikes from June to November each year. In addition, they estimated that, on average, 5.7 humpback whales were killed by civilian vessel strike from January–April per year (Rockwood *et al.* 2021). For fin whales in particular, model-predicted densities of large whales in the Southern California Bight from May to July 2021 (the time period during which the 2021 strikes of two unidentified whales by the U.S. Navy occurred) estimated fin whale abundance as being nearly an order of magnitude higher than either blue or humpback whale abundance during this time period (Becker *et al.* 2020b; Zickel *et al.* 2021). Ship-whale encounter models for the U.S. West Coast Exclusive Economic Zone also indicated that vessel strike mortality estimates for fin whales were significantly higher than for blue whales and humpback whales (Rockwood *et al.* 2017). The comparatively higher modeled vessel strike rates for fin whales result from both the larger population as well as the more offshore distribution that overlaps significantly with several major shipping routes for a much greater spatial extent (Rockwood *et al.* 2017). Based on 1,243 visual boat-based sightings of 2,638 fin whales from 1991–2011, Calambokidis *et al.* (2015) found fin whale concentration areas included the San Clemente Basin where the 2021 Navy vessel strikes occurred. Tanner and Cortes Banks area and the shelf edge west of SNI were also reported as fin whale concentration areas. There are two different populations of fin whales that occur in the Southern California Bight: a seasonal population, and a population that occurs year-round with offshore/inshore movements (Campbell *et al.* 2015; Falcone *et al.* 2022). This would likely make fin whales more susceptible to vessel strike year-round, as compared to other large whale species that may occur seasonally within SOCAL. Therefore, we find that, of the five total takes by serious injury or mortality by vessel strike of large whales proposed for authorization for the Navy over the course of the 7-year rule, up to three of those takes could be of the CA/OR/WA stock of fin whale and up to two could be of the Eastern North Pacific stock of gray whale given that the two strikes of unidentified large whales in 2021 could have been of either stock. Further, we expect that, of the five total takes by serious injury or mortality by vessel strike of large whales proposed for authorization for the Navy, up to two of those takes could occur in Hawaii, and therefore be of individuals of the Hawaii stock of humpback whale. NMFS expects that, of the two total takes by serious injury or mortality by vessel strike of large whales proposed for authorization for the Coast Guard, one of those takes could be of the CA/OR/WA stock of fin whale, Eastern North Pacific stock of gray whale, or Hawaii stock of humpback whale. (Coast Guard struck a humpback whale in Hawaii in 2020.)

For U.S. Navy vessel strikes in California, based on the information summarized in table 53 and the fact that there is the potential for up to five large whales to be struck by the Navy over the 7-year rule, one individual from the Eastern North Pacific stock of blue whale, Mainland Mexico-CA/OR/WA and Central America/Southern Mexico CA/OR/WA stocks of humpback whale, or Eastern North Pacific stock of sei whale could be among the five whales struck. The total strikes of Eastern North Pacific blue whales and the percent likelihood of striking one based on the historic strike calculation above can both be considered moderate compared to other stocks, and the Navy struck a blue whale in 2004 (based on the historic strike calculation, the likelihood of striking two blue whales is well below one percent (table 52)). Therefore, we consider it reasonably likely that the Navy could strike one individual over the course of the 7-year proposed rule. The total strikes of Eastern North Pacific sei whales are low (*i.e.,* 0) compared to other stocks, but NMFS and the Navy think it is possible that the Navy may have struck a sei whale in SOCAL in 2023. Therefore, we consider it reasonably likely that the Navy could strike a sei whale over the period of the rule. The Navy has not struck a humpback whale in the California portion of the HCTT Study Area. However, in 2016 a U.S. Coast Guard vessel struck a humpback whale heading out of San Francisco Bay, and as a species, humpbacks have a high number of total strikes and percent likelihood of being struck. The likelihood of Central America/Southern Mexico-CA/OR/WA (Central America DPS) or Mainland Mexico-CA/OR/WA (Mexico DPS) humpback whales being struck by any vessel type is moderate to high relative to other stocks, and NMFS anticipates that the Navy could strike one individual humpback whale from the Mainland Mexico-CA/OR/WA stock (Mexico DPS) and/or one individual from the Central America/Southern Mexico- CA/OR/WA (Central America DPS) over the 7-year duration of the rule.

For Coast Guard vessel strikes in California, NMFS anticipates that the Coast Guard may potentially strike the same species as listed above for the Navy. Based on the information summarized in table 53 and the fact that there is the potential for up to two large whales to be struck by the Coast Guard over the 7-year rule, one individual from the Eastern North Pacific stock of blue whale, CA/OR/WA stock of fin whale, Mainland Mexico-CA/OR/WA and Central America/Southern Mexico CA/OR/WA stocks of humpback whale, Eastern North Pacific stock of gray whale, or Eastern North Pacific stock of sei whale could be among the two whales struck. While, as noted above, NMFS anticipates that the U.S. Navy is more likely to strike a fin whale than some other stocks, NMFS does not anticipate that the same is true for the Coast Guard, as its vessel traffic is not concentrated in the area where previous known Navy vessel strikes of fin whales have occurred. Given the lower potential total number of vessel strikes by the Coast Guard, NMFS does not anticipate that the Coast Guard is likely to strike more than one of any given species.

For Hawaii stocks, given that all known vessel strikes between 2015 and 2021 were of humpback whales, we anticipate that any vessel strike of a large whale in Hawaii would likely be of the Hawaii stock of humpback whale. Given that this stock has the highest percentage of total annual strikes (33.3 percent) and a 10.3 percent chance of

being struck twice over the effective period of the rule, NMFS is proposing to authorize two lethal takes of Hawaii humpback whales for the Navy and one for the Coast Guard. NMFS also anticipates that the Navy may strike up to one Hawaii sperm whale given the 2007 sperm whale strike. Given the already lower likelihood of striking the Hawaii stock of sperm whales, the relatively lower vessel activity in the Hawaii portion of the HCTT Study Area, and the relatively lower Coast Guard vessel traffic compared to Navy vessel traffic, NMFS neither anticipates, nor proposes to authorize, a Coast Guard strike of this stock.

As described above, the Navy's analysis suggests and NMFS' analysis concurs that the likelihood of vessel strikes to the stocks below is discountable due to the stocks' relatively low occurrence in the HCTT Study Area, particularly in core HCTT training and testing subareas, and the fact that the stocks have not been struck by the Navy and are rarely, if ever, recorded struck by other vessels. Therefore, NMFS is not authorizing lethal take for the following stocks: blue whale (Central North Pacific stock), Bryde's whale (Eastern Tropical Pacific stock and Hawaii stock), fin whale (Hawaii stock), gray whale (Western North Pacific stock), minke whale (CA/OR/WA stock and Hawaii stock), sei whale (Hawaii stock), and sperm whale (CA/OR/WA stock).

Also of note, while information on past Navy vessel strikes can serve as a reasonable indicator of future vessel strike risk, future conditions may differ from the past in ways that could influence the likelihood of a large whale vessel strike occurring. In general, the magnitude of vessel strike risk may be increasing over time as many whale populations are gradually recovering from centuries of commercial whaling (Redfern *et al.* 2020). Increased vessel strike risk off California in recent decades has been associated with increases in the abundance of fin and humpback whale populations in the North Pacific (Redfern *et al.* 2020). It has also been suggested that the blue whale population in the Eastern North Pacific, inclusive of the California portion of the HCTT Study Area, is at carrying capacity and recovered to pre-whaling levels (Monnahan *et al.* 2014). In addition, the magnitude of risk may also be affected by shifts in whale distributions over time in response to environmental factors including marine heatwaves and associated changes in prey distribution.

Historically, military vessel strikes of large whales within the HCTT Study Area have been rare events with only eight such strikes occurring over the past 14 years, five U.S. Navy strikes, one Coast Guard strike, and two Royal Australian Navy strikes. However, the fact that four of these strikes occurred within a 3-month period (May–July) in 2021, and two occurred within a 4-month period (February–May) in 2009, suggests that military vessel strikes in California can be both highly episodic and clustered. The four large whale strikes in 2021 (two strikes of unidentified large whales by the U.S. Navy and two fin whale strikes by the Royal Australian Navy) appear to be outliers in the time series of military vessel strikes in SOCAL for that period. Particularly in consideration of the 2023 U.S. Navy strike, these strikes could also represent an early indicator of an increased military vessel strike risk within SOCAL based on the factors discussed above. Results from a survey of whale watching vessel operators and crew in Southern California, combined with remote sensing data in the area, suggest that the number of large whales may have been greater in May through July of 2021 compared with previous years in certain high military vessel traffic and ''core'' use HCTT areas off southern California, particularly farther offshore as well as closer to shore off San Diego Bay (Zickel *et al.,* 2021).

In conclusion, while take by vessel strike across any given year is sporadic, based on the information and analysis above, including consideration of the 2021 and 2023 strikes by the U.S. Navy, NMFS anticipates no more than seven takes of large whales by M/SI could occur over the 7-year period of the rule (no more than five by Navy, no more than two by Coast Guard). Of those seven whales over the 7-years, no more than four may come from the CA/OR/WA stock of fin whale. No more than three may come from the following stocks: gray whale (Eastern North Pacific stock); and humpback whale (Hawaii stock). No more than two may come from the following stocks: blue whale (Eastern North Pacific stock); sei whale (Eastern North Pacific); and humpback whale (Mainland Mexico-CA/OR/WA and Central America/Southern Mexico-CA/OR/WA stocks (Mexico and Central America DPSs, respectively)). No more than one may come from the Hawaii stock of sperm whale. (Note that these species and stock conclusions vary slightly from that requested by Navy and Coast Guard.) Accordingly, NMFS has evaluated under the negligible impact standard the M/SI of 0.14, 0.29, 0.43, or 0.57 whales annually from each of these species or stocks (*i.e.,* one, two, three, or four takes, respectively, divided by 7 years to get the annual number), along with the expected incidental takes by harassment.

Summary of Requested Take From Military Readiness Activities

Table 54 and table 55 summarize the Action Proponents' take proposed by harassment type and effect type, respectively.

TABLE 54—TOTAL ANNUAL AND 7-YEAR INCIDENTAL TAKE PROPOSED BY STOCK DURING ALL ACTIVITIES BY HARASSMENT TYPE

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-Year total Level B harassment	7-Year total Level A harassment	7-Year total mortality
Gray Whale	Eastern North Pacific	16,711	167	0.43	87,292	1,010	3
Gray Whale	Western North Pacific	169	2	0	852	5	0
Blue Whale	Central North Pacific	92	1	0	524	2	0
Blue Whale	Eastern North Pacific	4,571	27	0.29	24,808	150	2
Bryde's Whale	Eastern Tropical Pacific	322	5	0	1,874	14	0
Bryde's Whale	Hawaii	409	3	0	2,356	11	0
Fin Whale	Hawaii	86	1	0	487	1	0
Fin Whale	California/Oregon/Washington	13,501	55	0.57	68,558	300	4
Humpback Whale	Central America/Southern Mexico-California/Oregon/Washington.	1,888	19	0.29	9,898	96	2
Humpback Whale	Mainland Mexico-California/Oregon/Washington.	4,449	44	0.29	23,370	220	2
Humpback Whale	Hawaii	3,034	24	0.43	18,945	151	3
Minke Whale	Hawaii	296	3	0	1,698	13	0

TABLE 54—TOTAL ANNUAL AND 7-YEAR INCIDENTAL TAKE PROPOSED BY STOCK DURING ALL ACTIVITIES BY HARASSMENT TYPE—Continued

Species	Stock	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	7-Year total Level B harassment	7-Year total Level A harassment	7-Year total mortality
Minke Whale	California/Oregon/Washington	2,993	32	0	16,116	193	0
Sei Whale	Hawaii	253	2	0	1,437	5	0
Sei Whale	Eastern North Pacific	302	3	0.29	1,611	9	2
Sperm Whale	Hawaii	1,649	1	0.14	9,619	1	1
Sperm Whale	California/Oregon/Washington	3,891	3	0	20,606	5	0
Dwarf Sperm Whale	Hawaii	45,224	915	0	262,401	5,103	0
Dwarf Sperm Whale	California/Oregon/Washington	5,664	94	0	30,093	517	0
Pygmy Sperm Whale	Hawaii	45,787	936	0	265,322	5,221	0
Pygmy Sperm Whale	California/Oregon/Washington	5,615	107	0	29,868	609	0
Baird's Beaked Whale	California/Oregon/Washington	10,174	0	0	56,149	0	0
Blainville's Beaked Whale	Hawaii	7,542	0	0	46,004	0	0
Goose-Beaked Whale	Hawaii	30,359	0	0	185,039	0	0
Goose-Beaked Whale	California/Oregon/Washington	166,816	2	0	939,012	4	0
Longman's Beaked Whale	Hawaii	18,316	1	0	112,152	4	0
Mesoplodont Beaked Whale	California/Oregon/Washington	92,839	2	0	520,938	6	0
False Killer Whale	Main Hawaiian Islands Insular	169	0	0	1,009	0	0
False Killer Whale	Northwest Hawaiian Islands	191	0	0	1,165	0	0
False Killer Whale	Hawaii Pelagic	1,670	1	0	9,865	1	0
False Killer Whale	Baja California Peninsula Mexico	2,537	2	0	13,888	2	0
Killer Whale	Hawaii	127	0	0	733	0	0
Killer Whale	Eastern North Pacific Offshore	1,023	4	0	6,089	23	0
Killer Whale	West Coast Transient	55	0	0	261	0	0
Melon-Headed Whale	Hawaiian Islands	31,456	13	0	183,773	68	0
Melon-Headed Whale	Kohala Resident (Hawaii)	56	0	0	332	0	0
Pygmy Killer Whale	Hawaii	8,895	3	0	52,059	8	0
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	795	0	0	4,358	0	0
Short-Finned Pilot Whale	Hawaii	17,304	7	0	104,772	26	0
Short-Finned Pilot Whale	California/Oregon/Washington	4,279	11	0.57	24,532	56	4
Bottlenose Dolphin	Maui Nui	326	0	0	2,151	0	0
Bottlenose Dolphin	Hawaii Island	9	0	0	44	0	0
Bottlenose Dolphin	Hawaii Pelagic	43,313	25	0.29	287,119	163	2
Bottlenose Dolphin	Kaua'i/Ni'ihau	1,460	0	0	9,314	0	0
Bottlenose Dolphin	O'ahu	7,232	6	0.14	50,375	30	1
Bottlenose Dolphin	California Coastal	1,350	7	0	8,761	42	0
Bottlenose Dolphin	California/Oregon/Washington Offshore.	28,058	15	0	157,628	83	0
Fraser's Dolphin	Hawaii	35,480	8	0	210,526	34	0
Long-Beaked Common Dolphin	California	296,878	152	2.43	1,804,793	952	17
Northern Right Whale Dolphin	California/Oregon/Washington	45,514	21	0.14	224,039	96	1
Pacific White-Sided Dolphin	California/Oregon/Washington	69,210	42	0.29	361,049	242	2
Pantropical Spotted Dolphin	Maui Nui	2,373	4	0	15,192	18	0
Pantropical Spotted Dolphin	Hawaii Island	6,024	7	0	35,584	25	0
Pantropical Spotted Dolphin	Hawaii Pelagic	44,390	19	0	262,155	81	0
Pantropical Spotted Dolphin	O'ahu	6,426	6	0	44,200	23	0
Pantropical Spotted Dolphin	Baja California Peninsula Mexico	97,626	47	0.29	535,681	239	2
Risso's Dolphin	Hawaii	6,558	4	0	38,040	5	0
Risso's Dolphin	California/Oregon/Washington	43,833	21	0	240,847	125	0
Rough-Toothed Dolphin	Hawaii	96,873	36	0.29	587,819	196	2
Short-Beaked Common Dolphin	California/Oregon/Washington	2,169,554	877	15.29	11,804,423	5,075	107
Spinner Dolphin	Hawaii Pelagic	4,544	2	0	26,539	4	0
Spinner Dolphin	Hawaii Island	110	1	0	644	1	0
Spinner Dolphin	Kaua'i/Ni'ihau	4,446	2	0	28,334	6	0
Spinner Dolphin	O'ahu/4 Islands Region	1,201	1	0	8,205	2	0
Striped Dolphin	Hawaii Pelagic	37,782	12	0	219,594	52	0
Striped Dolphin	California/Oregon/Washington	133,399	44	0.14	724,174	231	1
Dall's Porpoise	California/Oregon/Washington	59,619	1,237	0	305,432	6,786	0
Harbor Porpoise	Monterey Bay	2,179	0	0	10,934	0	0
Harbor Porpoise	Morro Bay	4,373	88	0	26,316	590	0
Harbor Porpoise	Northern California/Southern Oregon	481	0	0	2,339	0	0
Harbor Porpoise	San Francisco/Russian River	9,960	26	0	48,900	169	0
California Sea Lion	U.S.	1,899,749	723	3.86	10,628,139	4,572	27
Guadalupe Fur Seal	Mexico	347,553	54	0.14	1,900,834	300	1
Northern Fur Seal	Eastern Pacific	33,195	12	0	158,796	55	0
Northern Fur Seal	California	22,098	10	0	106,298	47	0
Steller Sea Lion	Eastern	999	3	0	5,346	13	0
Harbor Seal	California	71,463	261	1.00	391,189	1,642	7
Hawaiian Monk Seal	Hawaii	1,104	6	0	7,380	25	0
Northern Elephant Seal	California Breeding	118,514	111	0	626,540	645	0

Note: The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

TABLE 55—TOTAL ANNUAL AND 7-YEAR INCIDENTAL TAKE PROPOSED BY STOCK DURING ALL ACTIVITIES BY EFFECT TYPE

Species	Stock	Maximum annual behavioral	Maximum annual TTS	Maximum annual AUD INJ	Maximum annual non-auditory injury	Maximum annual mortality	Maximum 7-year behavioral	Maximum 7-year TTS	Maximum 7-year AUD INJ	Maximum 7-year non-auditory injury	Maximum 7-year mortality
Gray Whale	Eastern North Pacific	7,151	9,560	167	0	0.43	43,599	43,693	1,010	0	3
Gray Whale	Western North Pacific	72	97	2	0	0	434	418	5	0	0
Blue Whale	Central North Pacific	17	75	1	0	0	92	432	2	0	0
Blue Whale	Eastern North Pacific	1,447	3,124	27	0	0.29	8,513	16,295	150	0	2
Bryde's Whale	Eastern Tropical Pacific	111	211	5	0	0	664	1,210	14	0	0
Bryde's Whale	Hawaii	68	341	3	0	0	392	1,964	11	0	0
Fin Whale	Hawaii	21	65	1	0	0	113	374	1	0	0
Fin Whale	California/Oregon/Washington	3,704	9,797	54	1	0.57	21,366	47,192	299	1	4
Humpback Whale	Central America/Southern Mexico-California/Oregon/Washington.	547	1,341	19	0	0.29	3,305	6,593	96	0	2
Humpback Whale	Mainland Mexico-California/Oregon/Washington.	1,274	3,175	43	1	0.29	7,701	15,669	219	1	2
Humpback Whale	Hawaii	1227	1,807	24	0	0.43	7,828	11,117	151	0	3
Minke Whale	Hawaii	44	252	3	0	0	259	1,439	13	0	0
Minke Whale	California/Oregon/Washington	942	2,051	32	0	0	5,735	10,381	193	0	0
Sei Whale	Hawaii	38	215	2	0	0	227	1,210	5	0	0
Sei Whale	Eastern North Pacific	83	219	3	0	0.29	487	1,124	9	0	2
Sperm Whale	Hawaii	1237	412	1	0	0.14	7,313	2,306	1	0	1
Sperm Whale	California/Oregon/Washington	2,999	892	3	0	0	16,304	4,302	5	0	0
Dwarf Sperm Whale	Hawaii	10,880	34,344	914	1	0	67,933	194,468	5,102	1	0
Dwarf Sperm Whale	California/Oregon/Washington	1,505	4,159	94	0	0	8,583	21,510	517	0	0
Pygmy Sperm Whale	Hawaii	10,954	34,833	935	1	0	68,237	197,085	5,220	1	0
Pygmy Sperm Whale	California/Oregon/Washington	1549	4,066	107	0	0	8,830	21,038	609	0	0
Baird's Beaked Whale	California/Oregon/Washington	10,112	62	0	0	0	55,858	291	0	0	0
Blainville's Beaked Whale	Hawaii	7,508	34	0	0	0	45,810	194	0	0	0
Goose-Beaked Whale	Hawaii	30230	129	0	0	0	184,319	720	0	0	0
Goose-Beaked Whale	California/Oregon/Washington	166,204	612	2	0	0	936,000	3,012	4	0	0
Longman's Beaked Whale	Hawaii	18,219	97	1	0	0	111,612	540	4	0	0
Mesoplodont Beaked Whale	California/Oregon/Washington	92,419	420	2	0	0	518,892	2,046	6	0	0
False Killer Whale	Main Hawaiian Islands Insular	105	64	0	0	0	637	372	0	0	0
False Killer Whale	Northwest Hawaiian Islands	128	63	0	0	0	775	390	0	0	0
False Killer Whale	Hawaii Pelagic	936	734	1	0	0	5,719	4,146	1	0	0
False Killer Whale	Baja California Peninsula Mexico *.	1,710	827	2	0	0	9,540	4,348	2	0	0
Killer Whale	Hawaii	57	70	0	0	0	337	396	0	0	0
Killer Whale	Eastern North Pacific Offshore	830	193	4	0	0	5,053	1,036	23	0	0
Killer Whale	West Coast Transient	27	28	0	0	0	137	124	0	0	0
Melon-Headed Whale	Hawaiian Islands	16187	15,269	13	0	0	98,220	85,553	68	0	0
Melon-Headed Whale	Kohala Resident (Hawaii)	41	15	0	0	0	250	82	0	0	0
Pygmy Killer Whale	Hawaii	4,654	4,241	3	0	0	28,302	23,757	8	0	0
Pygmy Killer Whale	California-Baja California Peninsula Mexico *.	622	173	0	0	0	3,499	859	0	0	0
Short-Finned Pilot Whale	Hawaii	11626	5,678	6	1	0	72,315	32,457	25	1	0
Short-Finned Pilot Whale	California/Oregon/Washington	3,353	926	9	2	0.57	19,691	4,841	44	12	4
Bottlenose Dolphin	Maui Nui	309	17	0	0	0	2,049	102	0	0	0
Bottlenose Dolphin	Hawaii Island	5	4	0	0	0	27	17	0	0	0
Bottlenose Dolphin	Hawaii Pelagic	37284	6,029	23	2	0.29	251,065	36,054	151	12	2
Bottlenose Dolphin	Kaua'i/Ni'ihau	1,221	239	0	0	0	7,657	1,657	0	0	0
Bottlenose Dolphin	O'ahu	7,108	124	5	1	0.14	49,565	810	27	3	1
Bottlenose Dolphin	California Coastal	1,306	44	6	1	0	8,502	259	41	1	0
Bottlenose Dolphin	California/Oregon/Washington Offshore.	21232	6,826	14	1	0	122,030	35,598	80	3	0
Fraser's Dolphin	Hawaii	19,854	15,626	6	2	0	122,248	88,278	32	2	0
Long-Beaked Common Dolphin	California	253,952	42,926	128	24	2.43	1,588,795	215,998	804	148	17
Northern Right Whale Dolphin	California/Oregon/Washington	23867	21,647	19	2	0.14	125,984	98,055	90	6	1
Pacific White-Sided Dolphin	California/Oregon/Washington	45,571	23,639	38	4	0.29	254,280	106,769	218	24	2
Pantropical Spotted Dolphin	Maui Nui	2,191	182	4	0	0	14,107	1,085	18	0	0
Pantropical Spotted Dolphin	Hawaii Island	2902	3,122	6	1	0	17,820	17,764	23	2	0

Pantropical Spotted Dolphin	Hawaii Pelagic	24231	20,159	16	3	0	148,329	113,826	77	4	0
Pantropical Spotted Dolphin	O'ahu	6,255	171	5	1	0	43,081	1,119	22	1	0
Pantropical Spotted Dolphin	Baja California Peninsula Mexico*	60,809	36,817	45	2	0.29	341,397	194,284	232	7	2
Risso's Dolphin	Hawaii	3,564	2,994	4	0	0	21,364	16,676	5	0	0
Risso's Dolphin	California/Oregon/Washington	33,191	10,642	17	4	0	188,061	52,786	107	18	0
Rough-Toothed Dolphin	Hawaii	57947	38,926	31	5	0.29	367,021	220,798	175	21	2
Short-Beaked Common Dolphin	California/Oregon/Washington	1,499,861	669,693	806	71	15.29	8,473,412	3,331,011	4,634	441	107
Spinner Dolphin	Hawaii Pelagic	2,177	2,367	2	0	0	13,145	13,394	4	0	0
Spinner Dolphin	Hawaii Island	60	50	1	0	0	362	282	1	0	0
Spinner Dolphin	Kaua'i/Ni'ihau	3,561	885	2	0	0	22,186	6,148	6	0	0
Spinner Dolphin	O'ahu/4 Islands Region	1,156	45	1	0	0	7,942	263	2	0	0
Striped Dolphin	Hawaii Pelagic	18,620	19162	10	2	0	112,710	106,884	48	4	0
Striped Dolphin	California/Oregon/Washington	81,046	52,353	42	2	0.14	453,209	270,965	222	9	1
Dall's Porpoise	California/Oregon/Washington	13,394	46,225	1,235	2	0	76,921	228,511	6,781	5	0
Harbor Porpoise	Monterey Bay	2,179	0	0	0	0	10,934	0	0	0	0
Harbor Porpoise	Morro Bay	4,152	221	87	1	0	24,909	1,407	588	2	0
Harbor Porpoise	Northern California/Southern Oregon.	481	0	0	0	0	2,339	0	0	0	0
Harbor Porpoise	San Francisco/Russian River	9,898	62	26	0	0	48,554	346	169	0	0
California Sea Lion	U.S	1,638,285	261464	666	57	3.86	9,421,167	1,206,972	4,203	369	27
Guadalupe Fur Seal	Mexico	266199	81,354	51	3	0.14	1,491,214	409,620	284	16	1
Northern Fur Seal	Eastern Pacific	23105	10,090	11	1	0	114,217	44,579	53	2	0
Northern Fur Seal	California	15853	6,245	9	1	0	78,553	27,745	44	3	0
Steller Sea Lion	Eastern	837	162	3	0	0	4,601	745	13	0	0
Harbor Seal	California	52,154	19,309	254	7	1.00	286,337	104,852	1,598	44	7
Hawaiian Monk Seal	Hawaii	906	198	5	1	0	6,149	1231	24	1	0
Northern Elephant Seal	California Breeding	65,095	53,419	109	2	0	379,380	247,160	643	2	0

Note: Zero (0) impacts indicate total less than 0.5 and a dash (-) is a true zero. In some cases where the estimated take within a cell is equal to 1, that value has been rounded up from a value that is less than 0.5 to avoid underestimating potential impacts to a species or stock based on the 7-year rounding rules discussed in section 2.4 of appendix E (Explosive and Acoustic Analysis Report) of the 2024 HCTT Draft EIS/OEIS.

*The Baja California Peninsula Mexico and California—Baja California Peninsula Mexico populations of false killer whale, pantropical spotted dolphin, and pygmy killer whales are not recognized stocks in NMFS Pacific stock assessment report (Carretta *et al.,* 2024), but separate density estimates were derived to support the Navy's analysis.

Proposed Mitigation Measures

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable adverse impact on the species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for subsistence uses (''least practicable adverse impact''). NMFS does not have a regulatory definition for least practicable adverse impact. The 2004 NDAA amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that a determination of ''least practicable adverse impact'' shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. For additional discussion of NMFS' interpretation of the least practicable adverse impact standard, see the Mitigation Measures section of the Gulf of Alaska Study Area final rule (88 FR 604, January 4, 2023).

Implementation of Least Practicable Adverse Impact Standard

Here, we discuss how we determine whether a measure or set of measures meets the ''least practicable adverse impact'' standard. Our separate analysis of whether the take anticipated to result from the Action Proponents' activities meets the ''negligible impact'' standard appears in the Preliminary Analysis and Negligible Impact Determination section below.

Our evaluation of potential mitigation measures includes consideration of two primary factors: (1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, or their availability for subsistence uses (where relevant). This analysis considers such things as the nature of the potential adverse impact (*e.g.,* likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation. (2) The practicability of the measure(s) for applicant implementation. Practicability of implementation may consider such things as cost, impact on activities, and, in the case of a military readiness activity, specifically considers personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks, we recognize that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS' analysis focuses on measures that are designed to avoid or minimize impacts on individual marine mammals that are more likely to increase the probability or severity of population-level effects.

While direct evidence of impacts to species or stocks from a specified activity is rarely available, and additional study is still needed to understand how specific disturbance events affect the fitness of individuals of certain species, there have been improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or degree of impacts on species or stocks may often be inferred given a detailed understanding of the activity, the environment, and the affected species or stocks—and the best available science has been used here. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects (or the risk thereof) to species or stocks. We also acknowledge that there is always the potential that new information, or a new recommendation, could become available in the future and necessitate reevaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability) and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species, consideration of personnel safety, practicality of implementation, and consideration of the impact on effectiveness of military readiness activities are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability in terms of these considerations, can vary widely. For example, a time/area restriction could be of very high value for decreasing population-level impacts (*e.g.,* avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (*e.g.,* decreased disturbance in an area of high productivity but of less biological importance). Regarding practicability, a measure might involve restrictions in an area or time that impede the Navy's ability to certify a strike group (higher impact on mission effectiveness), or it could mean delaying a small in-port training event by 30 minutes to avoid exposure of a marine mammal to injurious levels of sound (*i.e.,* lower impact). A responsible evaluation of ''least practicable adverse impact'' will consider the factors along these realistic scales. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the species or stock or its habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. We discuss consideration of these factors in greater detail below.

1. Reduction of adverse impacts to marine mammal species or stocks and their habitat.

The emphasis given to a measure's ability to reduce the impacts on a species or stock considers the degree, likelihood, and context of the anticipated reduction of impacts to individuals (and how many individuals) as well as the status of the species or stock.

The ultimate impact on any individual from a disturbance event (which informs the likelihood of adverse species- or stock-level effects) is dependent on the circumstances and associated contextual factors, such as duration of exposure to stressors. Though any proposed mitigation needs to be evaluated in the context of the specific activity and the species or stocks affected, measures with the following types of effects have greater value in reducing the likelihood or severity of adverse species- or stock-level impacts: avoiding or minimizing injury or mortality; limiting interruption of known feeding, breeding, mother/young, or resting behaviors; minimizing the abandonment of important habitat (temporally and spatially); minimizing the number of individuals subjected to these types of disruptions; and limiting

degradation of habitat. Mitigating these types of effects is intended to reduce the likelihood that the activity will result in energetic or other types of impacts that are more likely to result in reduced reproductive success or survivorship. It is also important to consider the degree of impacts that are expected in the absence of mitigation in order to assess the added value of any potential measures. Finally, because the least practicable adverse impact standard gives NMFS discretion to weigh a variety of factors when determining appropriate mitigation measures and because the focus of the standard is on reducing impacts at the species or stock level, the least practicable adverse impact standard does not compel mitigation for every kind of take, or every individual taken, if that mitigation is unlikely to meaningfully contribute to the reduction of adverse impacts on the species or stock and its habitat, even when practicable for implementation by the applicant.

The status of the species or stock is also relevant in evaluating the appropriateness of potential mitigation measures in the context of least practicable adverse impact. The following are examples of factors that may, alone or in combination, result in greater emphasis on the importance of a mitigation measure in reducing impacts on a species or stock: the stock is known to be decreasing or status is unknown, but believed to be declining; the known annual mortality (from any source) is approaching or exceeding the PBR level (as defined in MMPA section 3(20)); the affected species or stock is a small, resident population; or the stock is involved in a UME or has other known vulnerabilities (*e.g.,* recovering from an oil spill).

Habitat mitigation, particularly as it relates to rookeries, mating grounds, and areas of similar significance, is also relevant to achieving the standard and can include measures such as reducing impacts of the activity on known prey utilized in the activity area or reducing impacts on physical habitat. As with species- or stock-related mitigation, the emphasis given to a measure's ability to reduce impacts on a species or stock's habitat considers the degree, likelihood, and context of the anticipated reduction of impacts to habitat. Because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat.

We consider available information indicating the likelihood of any measure to accomplish its objective. If evidence shows that a measure has not typically been effective nor successful, then either that measure should be modified or the potential value of the measure to reduce effects should be lowered.

2. Practicability.

Factors considered may include cost, impact on activities, and, in the case of a military readiness activity, will include personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (see 16 U.S.C. 1371(a)(5)(A)(iii)).

Assessment of Mitigation Measures for the HCTT Study Area

NMFS has fully reviewed the specified activities and the mitigation measures included in the application and the 2024 HCTT Draft EIS/OEIS to determine if the mitigation measures would result in the least practicable adverse impact on marine mammals and their habitat. NMFS worked with the Action Proponents in the development of their initially proposed measures, which are informed by years of implementation and monitoring. A complete discussion of the Action Proponents' evaluation process used to develop, assess, and select mitigation measures, which was informed by input from NMFS, can be found in chapter 5 (Mitigation) and appendix K (Geographic Mitigation Assessment) of the 2024 HCTT Draft EIS/OEIS. The process described in chapter 5 (Mitigation) and appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS robustly supported NMFS' independent evaluation of whether the mitigation measures would meet the least practicable adverse impact standard. The Action Proponents would be required to implement the mitigation measures identified in this proposed rule for the full 7 years to avoid or reduce potential impacts from acoustic, explosive, and physical disturbance and strike stressors.

As a general matter, where an applicant proposes measures that are likely to reduce impacts to marine mammals, the fact that they are included in the application indicates that the measures are practicable, and it is not necessary for NMFS to conduct a detailed analysis of the measures the applicant proposed (rather, they are simply included). However, it is still necessary for NMFS to consider whether there are additional practicable measures that would meaningfully reduce the probability or severity of impacts that could affect reproductive success or survivorship.

The Action Proponents have agreed to mitigation measures that would reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources or explosives, vessel strike, and impacts to marine mammal habitat. Specifically, the Action Proponents would use a combination of delayed starts, powerdowns, and shutdowns to avoid mortality or serious injury, minimize the likelihood or severity of AUD INJ or non-auditory injury, and reduce instances of TTS or more severe behavioral disturbance caused by acoustic sources or explosives. The Action Proponents would also implement multiple time/area restrictions that would reduce take of marine mammals in areas or at times where they are known to engage in important behaviors (*e.g.,* calving, where the disruption of those behaviors would have a higher probability of resulting in impacts on reproduction or survival of individuals that could lead to population-level impacts.

The Action Proponents assessed the practicability of the proposed measures in the context of personnel safety, practicality of implementation, and their impacts on the Action Proponents' ability to meet their Congressionally mandated requirements and found that the measures are supportable. As described in more detail below, NMFS has independently evaluated the measures the Action Proponents proposed in the manner described earlier in this section (*i.e.,* in consideration of their ability to reduce adverse impacts on marine mammal species and their habitat and their practicability for implementation). We have determined that the measures would significantly reduce impacts on the affected marine mammal species and stocks and their habitat and, further, be practicable for implementation by the Action Proponents. We have preliminarily determined that the mitigation measures assure that the Action Proponents' activities would have the least practicable adverse impact on the species or stocks and their habitat.

The Action Proponents also evaluated numerous measures in the 2024 HCTT Draft EIS/OEIS that were not included in the application, and NMFS independently reviewed and preliminarily concurs with the Action Proponents' analysis that their inclusion was not appropriate under the least practicable adverse impact standard based on our assessment. The Action Proponents considered these additional potential mitigation measures in the context of the potential benefits to marine mammals and whether they are practical or impractical.

Section 5.9 (Measures Considered but Eliminated) of chapter 5 (Mitigation) of the 2024 HCTT Draft EIS/OEIS, includes

an analysis of an array of different types of mitigation that have been recommended over the years by non-governmental organizations or the public, through scoping or public comment on environmental compliance documents. These recommendations generally fall into three categories, discussed below: reduction of activity; activity-based operational measures; and time/area limitations.

As described in section 5.9 (Measures Considered but Eliminated) of the 2024 HCTT Draft EIS/OEIS, the Action Proponents considered reducing the overall amount of training, reducing explosive use, modifying sound sources, completely replacing live training with computer simulation, and including time of day restrictions. Many of these mitigation measures could potentially reduce the number of marine mammals taken via direct reduction of the activities or amount of sound energy put in the water. However, as described in chapter 5 (Mitigation) of the 2024 HCTT Draft EIS/OEIS, the Action Proponents need to train in the conditions in which they fight—and these types of modifications fundamentally change the activity in a manner that would not support the purpose and need for the training (*i.e.,* are entirely impracticable) and therefore are not considered further. NMFS finds the Action Proponents' explanation of why adoption of these recommendations would unacceptably undermine the purpose of the training persuasive. After independent review, NMFS finds the Action Proponents' judgment on the impacts of these potential mitigation measures to personnel safety, practicality of implementation, and the effectiveness of training persuasive, and for these reasons, NMFS finds that these measures do not meet the least practicable adverse impact standard because they are not practicable.

In chapter 5 (Mitigation) of the 2024 HCTT Draft EIS/OEIS, the Action Proponents also evaluated additional potential activity—based mitigation measures, including increased mitigation zones, ramp-up measures, additional passive acoustic and visual monitoring, and decreased vessel speeds. Some of these measures have the potential to incrementally reduce take to some degree in certain circumstances, though the degree to which this would occur is typically low or uncertain. However, as described in the Action Proponents' analysis, the measures would have significant direct negative effects on mission effectiveness and are considered impracticable. NMFS independently reviewed the Action Proponents' evaluation and concurs with this assessment, which supports NMFS' preliminary findings that the impracticability of this additional mitigation would greatly outweigh any potential minor reduction in marine mammal impacts that might result; therefore, these additional mitigation measures are not warranted.

Lastly, chapter 5 (Mitigation) of the 2024 HCTT Draft EIS/OEIS also describes a comprehensive analysis of potential geographic mitigation that includes consideration of both a biological assessment of how the potential time/area limitation would benefit the species and its habitat (*e.g.,* is a key area of biological importance or would result in avoidance or reduction of impacts) in the context of the stressors of concern in the specific area and an operational assessment of the practicability of implementation (*e.g.,* including an assessment of the specific importance of an area for training, considering proximity to training ranges and emergency landing fields and other issues). In some cases, potential benefits to marine mammals were non-existent, while in others the consequences on mission effectiveness were too great.

NMFS has reviewed the Action Proponents' analysis in chapter 5 (Mitigation) and appendix A (Activity Descriptions) of the 2024 HCTT Draft EIS/OEIS, which consider the same factors that NMFS considers to satisfy the least practicable adverse impact standard, and concurs with the analysis and conclusions. Therefore, NMFS is not proposing to include any of the measures that the Action Proponents ruled out in the 2024 HCTT Draft EIS/OEIS. Below are the mitigation measures that NMFS has preliminarily determined would ensure the least practicable adverse impact on all affected species and their habitat, including the specific considerations for military readiness activities. Table 56 describes the information designed to aid Lookouts and other applicable personnel with their observation, environmental compliance, and reporting responsibilities. The following sections describe the mitigation measures that would be implemented in association with the activities analyzed in this document. The mitigation measures are organized into two categories: activity-based mitigation and geographic mitigation areas.

Of note, according to the U.S. Navy, consistent with customary international law, when a foreign military vessel participates in a U.S. Navy exercise within the U.S. territorial sea (*i.e.,* 0 to 12 nmi (0 to 22.2 km) from shore), the U.S. Navy will request that the foreign vessel follow the U.S. Navy's mitigation measures for that particular event. When a foreign military vessel participates in a U.S. Navy exercise beyond the U.S. territorial sea but within the U.S. Exclusive Economic Zone, the U.S. Navy will encourage the foreign vessel to follow the U.S. Navy's mitigation measures for that particular event (Navy 2022a; Navy 2022b). In either scenario (*i.e.,* both within and beyond the territorial sea), U.S. Navy personnel will provide the foreign vessels participating with a description of the mitigation measures to follow.

TABLE 56—ENVIRONMENTAL AWARENESS AND EDUCATION

Stressor or Activity: All training and testing activities, as applicable.
Requirements: Navy personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specified activities must complete one or more modules of the U.S. Navy Afloat Environmental Compliance Training Series, as identified in their career path training plan. Modules include: • Introduction to Afloat Environmental Compliance Training Series. The introductory module provides information on environmental laws (*e.g.,* ESA, MMPA) and the corresponding responsibilities that are relevant to military readiness activities. The material explains why environmental compliance is important in supporting the Action Proponents' commitment to environmental stewardship. • Marine Species Awareness Training. All bridge watch personnel, Commanding Officers, Executive Officers, maritime patrol aircraft aircrews, anti-submarine warfare and mine warfare rotary-wing aircrews, Lookouts, and equivalent civilian personnel must successfully complete the Marine Species Awareness Training prior to standing watch or serving as a Lookout. The Marine Species Awareness Training provides information on sighting cues, visual observation tools and techniques, and sighting notification procedures. Navy biologists developed Marine Species Awareness Training to improve the effectiveness of visual observations for biological resources, focusing on marine mammals and sea turtles, and including floating vegetation, jellyfish aggregations, and flocks of seabirds. • Protective Measures Assessment Protocol. This module provides the necessary instruction for accessing mitigation requirements during the event planning phase using the Protective Measures Assessment Protocol (PMAP) software tool.

TABLE 56—ENVIRONMENTAL AWARENESS AND EDUCATION—Continued

• Sonar Positional Reporting System and Marine Mammal Incident Reporting. This module provides instruction on the procedures and activity reporting requirements for the Sonar Positional Reporting System and marine mammal incident reporting.

Activity-Based Mitigation

Activity-based mitigation is mitigation that the Action Proponents would implement whenever and wherever an applicable military readiness activity takes place within the HCTT Study Area. Previously referred to as ''Procedural Mitigation,'' the primary objective of activity-based mitigation is to reduce overlap of marine mammals with stressors that have the potential to cause injury or mortality in real time. Activity-based mitigations are fundamentally consistent across stressor activity, although specific variations account for differences in platform configuration, event characteristics, and stressor types. The Action Proponents customize mitigation for each applicable activity category or stressor. Activity-based mitigation generally involves: (1) the use of one or more trained Lookouts to diligently observe for marine mammals and other specific biological resources (*e.g.,* indicator species like floating vegetation, jelly aggregations, large schools of fish, and flocks of seabirds) within a mitigation zone; (2) requirements for Lookouts to immediately communicate sightings of marine mammals and other specific biological resources to the appropriate watch station for information dissemination; and (3) requirements for the watch station to implement mitigation (*e.g.,* halt an activity) until certain recommencement conditions have been met. The remainder of the mitigation measures are activity-based mitigation measures (table 57 through table 76) organized by stressor type and activity category and include acoustic stressors (*i.e.,* active sonar, air guns, pile driving, weapons firing noise), explosive stressors (*i.e.,* bombs, gunnery, underwater demolition, mine counter-measure and neutralization activities, missiles and rockets, sonobuoys and research-based sub-surface explosives, ship shock trials, and sinking exercises), and physical disturbance and strike stressors (*i.e.,* aerial-deployed mines and non-explosive bombs, non-explosive gunnery, non-explosive torpedoes missiles and rockets, vessel movement, towed in-water devices, and net deployment).

The Action Proponents must implement the proposed mitigation measures described in table 57 through table 76, as appropriate, in response to an applicable sighting within, or entering into, the relevant mitigation zone for acoustic stressors, explosives, and non-explosive munitions. Each table describes the activities that the requirements apply to, the required mitigation zones in which the action proponents must take a mitigation action, the required number of Lookouts and observation platform, the required mitigation actions that the action proponents must take before, during, and/or after an activity, and a required wait period prior to commencing or recommencing an activity after a delay, power down, or shutdown of an activity.

The Action Proponents proposed wait periods because events cannot be delayed or ceased indefinitely for the purpose of mitigation due to impacts on safety, sustainability, and the ability to meet mission requirements. Wait periods are designed to allow animals the maximum amount of time practical to resurface (*i.e.,* become available to be observed) before activities resume. The action proponents factored in an assumption that mitigation may need to be implemented more than once when developing wait period durations. Wait periods are 10 minutes, 15 minutes, or 30 minutes depending on the fuel constraints of the platform and feasibility of implementation. NMFS concurs with these proposed wait periods.

If an applicable species (identified in the relevant mitigation tables) is observed within a required mitigation zone prior to the initial start of the activity, the Action Proponents must: (1) relocate the event to a location where applicable species are not observed; or (2) delay the initial start of the event (or stressor use) until one of the ''Mitigation Zone All-Clear Conditions'' (defined below) has been met. If an applicable stressor is observed within a required mitigation zone during the event (*i.e.,* during use of the indicated source) the Action Proponents must take the action described in the ''Mitigation Zones'' section of the table until one of the Mitigation Zone All-Clear Conditions has been met.

For all activities, an activity may not commence or recommence until one of the following ''Mitigation Zone All-Clear Conditions'' have been met: (1) a Lookout observes the applicable species exiting the mitigation zone; (2) a Lookout concludes that the animal has exited the mitigation zone based on its observed course, speed, and movement relative to the mitigation zone; (3) a Lookout affirms the mitigation zone has been clear from additional sightings for a designated ''wait period''; or (4) for mobile events, the stressor has transited a distance equal to double the mitigation zone size beyond the location of the last sighting.

Activity-Based Mitigation for Active Acoustic Stressors

Mitigation measures for acoustic stressors are provided below and include active acoustic sources (table 57), pile driving and extraction (table 58), and weapons firing noise (table 59). For this proposed action, the following ranges apply to the use of small, medium, and large caliber: small is up to and including 50 caliber machine gun rounds; medium is greater than 50 caliber and less than 57 millimeter (mm; 2.24 inch); and large is 57 mm (2.24 inch) and larger. Small caliber items are solid projectiles (*i.e.,* bullets). Medium caliber items are 30–57 mm (1.18–2.24 inch) and can have both inert non-explosive rounds and high explosive rounds. High caliber items are greater than or equal to 57 mm (2.24 inch) and can have both inert non-explosive rounds and high explosive rounds. Activity-based mitigation for acoustic stressors does not apply to:

- sources not operated under positive control (*e.g.,* moored oceanographic sources);
- sources used for safety of navigation (*e.g.,* fathometers);
- sources used or deployed by aircraft operating at high altitudes (*e.g.,* bombs deployed from high altitude (since personnel cannot effectively observe the surface of the water));
- sources used, deployed, or towed by unmanned platforms except when escort vessels are already participating in the event and have positive control over the source;
- sources used by submerged submarines (*e.g.,* sonar (since they cannot conduct visual observation));
- de minimis sources (*e.g.,* those >200 kHz); and
- vessel-based, unmanned vehicle-based, or towed in-water sources when marine mammals (*e.g.,* dolphins) are determined to be intentionally swimming at the bow or alongside or

directly behind the vessel, vehicle, or device (*e.g.,* to bow-ride or wake-ride).

TABLE 57—MITIGATION FOR ACTIVE ACOUSTIC SOURCES

Stressor or Activity: Active acoustic sources with power down and shut down capabilities:
- Low-frequency active sonar ≥200 dB.
- Mid-frequency active sonar sources that are hull mounted on a surface ship (including surfaced submarines).
- Broadband and other active acoustic sources >200 dB.

- Mitigation Zones:
  - 1,000 yd (914.4 m) from active acoustic sources (power down of 6 dB total).
  - 500 yd (457.2 m) from active acoustic sources (power down of 10 dB total).
  - 200 yd (182.9 m) from active acoustic sources (shut down).
- Mitigation Requirements:
  - One Lookout in/on one of the following:
    - Aircraft.
    - Pierside, moored, or anchored vessel
    - Underway vessel with space/crew restrictions (including small boats).
    - Underway vessel already participating in the event that is escorting (and has positive control over sources used, deployed, or towed by) an unmanned platform.
  - Two Lookouts on an underway vessel without space/crew restrictions.
  - Lookouts would use information from passive acoustic detections to inform visual observations when passive acoustic devices are already being used in the event.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of using active acoustic sources (*e.g.,* while maneuvering on station).
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals during use of active acoustic sources.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

Stressor or Activity: Active acoustic sources with shut down (but not power down) capabilities:
- Low-frequency active sonar <200 dB.
- Mid-frequency active sonar sources that are not hull mounted on a surface ship (*e.g.,* dipping sonar, towed arrays).
- High-frequency active sonar.
- Air guns.
- Broadband and other active acoustic sources <200 dB.

- Mitigation Zones:
  - 200 yd (182.9 m) from active acoustic sources (shut down).
- Mitigation Requirements:
  - One Lookout in/on one of the following:
    - Aircraft.
    - Pierside, moored, or anchored vessel.
    - Underway vessel with space/crew restrictions (including small boats).
    - Underway vessel already participating in the event that is escorting (and has positive control over sources used, deployed, or towed by) an unmanned platform.
  - Two Lookouts on an underway vessel without space/crew restrictions.
  - Lookouts would use information from passive acoustic detections to inform visual observations when passive acoustic devices are already being used in the event.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of using active acoustic sources (*e.g.,* while maneuvering on station).
  - Action Proponent personnel must observe the mitigation zone for marine mammals during use of active acoustic sources.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 58—MITIGATION FOR PILE DRIVING AND EXTRACTION

Stressor or Activity: Vibratory and impact pile driving and extraction.

- Mitigation Zone:
  - 5 yd (4.6 m) from piles being driven or extracted (cease pile driving or extraction).
- Mitigation Requirements:
  - One Lookout on one of the following:
    - Shore.
    - Pier.
    - Small boat.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation for 15 minutes prior to the initial start of pile driving or pile extraction.
  - Action Proponent personnel must observe the mitigation zone for marine mammals during pile driving or extraction.
- Wait Period:
  - 15 minutes.

TABLE 59—MITIGATION FOR WEAPONS FIRING NOISE

Stressor or Activity: Explosive and non-explosive large-caliber gunnery firing noise (surface-to-surface and surface-to-air).

- Mitigation Zone:
  - 30 degrees on either side of the firing line out to 70 yd (64 m) from the gun muzzle (cease fire).
- Mitigation Requirements:
  - One Lookout on a vessel.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of large-caliber gun firing (*e.g.,* during target deployment).
  - Action Proponent personnel must observe the mitigation zone for marine mammals during large-caliber gun firing.
- Wait Period:
  - 30 minutes.

Activity-Based Mitigation for Explosive Stressors

Mitigation measures for explosive stressors are provided below and include explosive bombs (table 60), explosive gunnery (table 61), explosive underwater demolition multiple charge—mat weave and obstacle loading (table 62), explosive mine countermeasure and neutralization without divers (table 63), explosive mine neutralization with divers (table 64), explosive missiles and rockets (table 65), explosive sonobuoys and research-based sub-surface explosives (table 66), explosive torpedoes (table 67), ship shock trials (table 68), and SINKEX (table 69). After the event, the Action Proponents must observe the area for marine mammals. Post-event observations are intended to aid incident reporting requirements for marine mammals. Practicality and the duration of post-event observations will be determined on site by fuel restrictions and mission-essential follow-on commitments. For example, it is more challenging to remain on-site for extended periods of time for some activities due to factors such as range from the target or altitude of an aircraft. For all activities involving explosives, if a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately. Activity-based mitigation for explosive stressors does not apply to explosives:

- deployed by aircraft operating at high altitudes;
- deployed by submerged submarines, except for explosive torpedoes;
- deployed against aerial targets;
- during vessel- or shore-launched missile or rocket events;
- used at or below the de minimis threshold; and
- deployed by unmanned platforms except when escort vessels are already participating in the event and have positive control over the explosive.

TABLE 60—MITIGATION FOR EXPLOSIVE BOMBS

Stressor or Activity: Any NEW.

- Mitigation Zone:
  - 2,500 yd (2,286 m) from the intended target (cease fire).
- Mitigation Requirements:
  - One Lookout in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of bomb delivery (*e.g.,* when arriving on station).
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals during bomb delivery.
  - After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 10 minutes.

TABLE 61—MITIGATION FOR EXPLOSIVE GUNNERY

Stressor or Activity: Air-to-surface medium-caliber, surface-to-surface medium-caliber, surface-to-surface large-caliber.

- Mitigation Zones:
  - Air-to-surface medium-caliber:
    - 200 yd (182.9 m) from the intended impact location (cease fire).
  - Surface-to-surface medium-caliber:
    - 600 yd (548.6 m) from the intended impact location (cease fire).
  - Surface-to-surface large-caliber:
    - 1,000 yd (914.4 m) from the intended impact location (cease fire).
- Mitigation Requirements:
  - One Lookout on a vessel or in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of gun firing (*e.g.,* while maneuvering on station).
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals during gunnery fire.

TABLE 61—MITIGATION FOR EXPLOSIVE GUNNERY—Continued

- After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 62—MITIGATION FOR EXPLOSIVE UNDERWATER DEMOLITION MULTIPLE CHARGE—MAT WEAVE AND OBSTACLE LOADING

Stressor or Activity: Any NEW.

- Mitigation Zones:
  - 700 yd (640 m) from the detonation site (cease fire).
- Mitigation Requirements:
  - Two Lookouts: one on a small boat and one on shore from an elevated platform.
- Mitigation Requirement Timing:
  - The Lookout positioned on a small boat must observe the mitigation zone for marine mammals and floating vegetation for 30 minutes prior to the first detonation.
  - The Lookout positioned onshore must use binoculars to observe for marine mammals for 10 minutes prior to the first detonation.
  sbull; Action Proponent personnel must observe the mitigation zone for marine mammals during detonations.
  - After the event, when practical, Action Proponent personnel must observe the detonation vicinity for 30 minutes for marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 10 minutes (determined by the shore observer).

TABLE 63—MITIGATION FOR EXPLOSIVE MINE COUNTERMEASURE AND NEUTRALIZATION

[No divers]

Stressor or Activity: 0.1–5 lb (0.05–2.3 kg) NEW, >5 lb (2.3 kg) NEW.

- Mitigation Zones:
  - 0.1–5 lb (0.05–2.3 kg) NEW:
    - 600 yd (548.6 m) from the detonation site (cease fire).
  - >5 lb (2.3 kg) NEW:
    - 2,100 yd (1,920.2 m) from the detonation site (cease fire).
- Mitigation Requirements:
  - 0.1–5 lb (0.05–2.3 kg) NEW:
    - One Lookout on a vessel or in an aircraft.
  - >5 lb (2.3 kg) NEW:
    - Two Lookouts: one on a small boat and one in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of detonations (*e.g.,* while maneuvering on station; typically, 10 or 30 minutes depending on fuel constraints).
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals, concentrations of seabirds, and individual foraging seabirds (in the water and not on shore) during detonations or fuse initiation.
  - After the event, when practical, Action Proponent personnel must observe the detonation vicinity for 10 or 30 minutes (depending on fuel constraints) for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 64—MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION

[With divers]

Stressor or Activity: 0.1–20 lb (0.05–9.1 kg) NEW (positive control), 0.1–29 lb (0.05–13.2 kg) NEW (time-delay), >20–60 lb (9.1–27.2 kg) NEW (positive control).

- Mitigation Zones:
  - 0.1–20 lb (0.05–9.1 kg) NEW (positive control).
    - 500 yd (457.2 m) from the detonation site (cease fire).
  - 0.1–29 lb (0.05–13.2 kg) NEW (time-delay), >20–60 lb (9.1–27.2 kg) NEW (positive control).
    - 1,000 yd (914.4 m) from the detonation site (cease fire).
- Mitigation Requirements:
  - 0.1–20 lb (0.05–9.1 kg) NEW (positive control).
    - Lookouts in two small boats (one Lookout per boat), or one small boat and one rotary-wing aircraft (with one Lookout each), and one Lookout on shore for shallow-water events during 0.1–20 lb (0.05–9.1 kg) NEW (positive control) use.
  - 0.1–29 lb (0.05–13.2 kg) NEW (time-delay), >20–60 lb (9.1–27.2 kg) NEW (positive control).
    - Four Lookouts in two small boats (two Lookouts per boat), and one additional Lookout in an aircraft if used in the event.
- Mitigation Requirement Timing:

TABLE 64—MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION—Continued

[With divers]

- Time-delay devices must be set not to exceed 10 minutes.
- Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of detonations or fuse initiation for positive control events (*e.g.,* while maneuvering on station) or for 30 minutes prior for time-delay events.
- Action Proponent personnel must observe the applicable mitigation zone for marine mammals, concentrations of seabirds, and individual foraging seabirds (in the water and not on shore) during detonations or fuse initiation.
- When practical based on mission, safety, and environmental conditions:
  - Boats must observe from the mitigation zone radius mid-point.
  - When two boats are used, boats must observe from opposite sides of the mine location.
  - Platforms must travel a circular pattern around the mine location.
  - Boats must have one Lookout observe inward toward the mine location and one Lookout observe outward toward the mitigation zone perimeter.
  - Divers must be part of the Lookout Team.
- After the event, when practical, Action Proponent personnel must observe the detonation vicinity for 30 minutes for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 65—MITIGATION FOR EXPLOSIVE MISSILES AND ROCKETS

Stressor or Activity: 0.6–20 lb (0.3–9.1 kg) NEW (air-to-surface), >20–500 lb (9.1–226.8 kg) NEW (air-to-surface).

- Mitigation Zones:
  - 0.6–20 lb (0.3–9.1 kg) NEW (air-to-surface).
    - 900 yd (823 m) from the intended impact location (cease fire).
  - >20–500 lb (9.1–226.8 kg) NEW (air-to-surface).
    - 2,000 yd (1,828.8 m) from the intended impact location (cease fire).
- Mitigation Requirements:
  - One Lookout in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of missile or rocket delivery (*e.g.,* during a fly-over of the mitigation zone).
  - Action Proponent personnel must observe the applicable mitigation zone for marine mammals during missile or rocket delivery.
  - After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 66—MITIGATION FOR EXPLOSIVE SONOBUOYS AND RESEARCH-BASED SUB-SURFACE EXPLOSIVES

Stressor or Activity: Any NEW of sonobuoys, 0.1–5 lb (0.05–2.3 kg) NEW for other types of sub-surface explosives used in research applications.

- Mitigation Zone:
  - 600 yd (548.6 m) from the device or detonation sites (cease fire).
- Mitigation Requirements:
  - One Lookout on a small boat or in an aircraft.
  - Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of detonations (*e.g.,* during sonobuoy deployment, which typically lasts 20–30 minutes).
  - Action Proponent personnel must observe the mitigation zone for marine mammals during detonations.
  - After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 67—MITIGATION FOR EXPLOSIVE TORPEDOES

Stressor or Activity: Any NEW.

- Mitigation Zone:
  - 2,100 yd (1,920.2 m) from the intended impact location (cease fire).
- Mitigation Requirements:
  - One Lookout in an aircraft.
  - Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations.
- Mitigation Requirement Timing:

TABLE 67—MITIGATION FOR EXPLOSIVE TORPEDOES—Continued

- Action Proponent personnel must observe the mitigation zone for marine mammals, floating vegetation, and jellyfish aggregations immediately prior to the initial start of detonations (*e.g.,* during target deployment).
- Action Proponent personnel must observe the mitigation zone for marine mammals during torpedo launches.
- After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 68—MITIGATION FOR SHIP SHOCK TRIALS

Stressor or Activity: Any NEW.

- Mitigation Zone:
  - 3.5 nmi (6.5 km) from the target ship hull (cease fire).
- Mitigation Requirements:
  - On the day of the event, 10 observers (Lookouts and third-party observers combined), spread between aircraft or multiple vessels as specified in the event-specific mitigation plan.
- Mitigation Requirement Timing:
  - Action Proponent personnel must develop a detailed, event-specific monitoring and mitigation plan in the year prior to the event and provide it to NMFS for review.
  - Beginning at first light on days of detonation, until the moment of detonation (as allowed by safety measures) Action Proponent personnel must observe the mitigation zone for marine mammals, floating vegetation, jellyfish aggregations, large schools of fish, and flocks of seabirds.
  - If any dead or injured marine mammals are observed after an individual detonation, Action Proponent personnel must follow established incident reporting procedures and halt any remaining detonations until Action Proponent personnel or third-party observers can consult with NMFS and review or adapt the event-specific mitigation plan, if necessary.
  - During the 2 days following the event (minimum) and up to 7 days following the event (maximum), and as specified in the event-specific mitigation plan, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals.
- Wait Period:
  - 30 minutes.

TABLE 69—MITIGATION FOR SINKING EXERCISES (SINKEX)

Stressor or Activity: Any NEW.

- Mitigation Zone:
  - 2.5 nmi (4.6 km) from the target ship hull (cease fire).
- Mitigation Requirements:
  - Two Lookouts: one on a vessel and one in an aircraft.
  - Lookouts would use information from passive acoustic detections to inform visual observations when passive acoustic devices are already being used during weapon firing.
- Mitigation Requirement Timing:
  - During aerial observations for 90 minutes prior to the initial start of weapon firing, Action Proponent personnel must observe the mitigation zone for marine mammals, floating vegetation, and jellyfish aggregations.
  - From the vessel during weapon firing, and from the aircraft and vessel immediately after planned or unplanned breaks in weapon firing of more than 2 hours, Action Proponent personnel must observe the mitigation zone for marine mammals.
  - Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals for 2 hours after sinking the vessel or until sunset, whichever comes first. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.
- Wait Period:
  - 30 minutes.

Activity-Based Mitigation for Non-Explosive Ordnance

Mitigation measures for non-explosive ordnance are provided below and include aerial-deployed mines and non-explosive bombs (table 70), non-explosive gunnery (table 71), and non-explosive missiles and rockets (table 72). Explosive aerial-deployed mines do not detonate upon contact with the water surface and are therefore considered non-explosive when mitigating the potential for a mine shape to strike a marine mammal at the water surface. Activity-based mitigation for non-explosive ordnance does not apply to non-explosive ordnance:

- deployed by aircraft operating at high altitudes;
- deployed against aerial targets and land-based targets;
- deployed during vessel- or shore-launched missile or rocket events; and
- deployed by unmanned platforms except when escort vessels are already participating in the event and have positive control over ordnance deployment.

TABLE 70—MITIGATION FOR AERIAL-DEPLOYED MINES AND NON-EXPLOSIVE BOMBS

Stressor or Activity: Explosive aerial-deployed mines, non-explosive aerial-deployed mines and non-explosive bombs.

- Mitigation Zone:

TABLE 70—MITIGATION FOR AERIAL-DEPLOYED MINES AND NON-EXPLOSIVE BOMBS—Continued

- 1,000 yd (914.4 m) from the intended target (cease fire).
- Mitigation Requirements:
  - One Lookout in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of mine or bomb delivery (*e.g.,* when arriving on station).
  - Action Proponent personnel must observe the mitigation zone for marine mammals during mine or bomb delivery.
- Wait Period:
  - 10 minutes.

TABLE 71—MITIGATION FOR NON-EXPLOSIVE GUNNERY

Stressor or Activity: Non-explosive surface-to-surface large-caliber ordnance, non-explosive surface-to-surface and air-to-surface medium-caliber ordnance, non-explosive surface-to-surface and air-to-surface small-caliber ordnance.

- Mitigation Zone:
  - 200 yd (182.9 m) from the intended impact location (cease fire).
- Mitigation Requirements:
  - One Lookout on a vessel or in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the start of gun firing (*e.g.,* while maneuvering on station).
  - Action Proponent personnel must observe the mitigation zone for marine mammals during gunnery firing.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

TABLE 72—MITIGATION FOR NON-EXPLOSIVE MISSILES AND ROCKETS

Stressor or Activity: Non-explosives (air-to-surface).

- Mitigation Zone:
  - 900 yd (823 m) from the intended impact location (cease fire).
- Mitigation Requirements:
  - One Lookout in an aircraft.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the start of missile or rocket delivery (*e.g.,* during a fly-over of the mitigation zone).
  - Action Proponent personnel must observe the mitigation zone for marine mammals during missile or rocket delivery.
- Wait Period:
  - 10 or 30 minutes (depending on fuel constraints of the platform).

Activity-Based Mitigation for Physical Disturbance and Strike Stressors

Mitigation measures for physical disturbance and strike stressors are provided below and include crewed surface vessels (table 73), unmanned vehicles (table 74), towed in-water devices (table 75), and net deployment (table 76). Activity-based mitigation for physical disturbance and strike stressors will not be implemented:

- by submerged submarines;
- by unmanned vehicles except when escort vessels are already participating in the event and have positive control over the unmanned vehicle movements;
- when marine mammals (*e.g.,* dolphins) are determined to be intentionally swimming at the bow, alongside the vessel or vehicle, or directly behind the vessel or vehicle (*e.g.,* to bow-ride or wake-ride);
- when pinnipeds are hauled out on man-made navigational structures, port structures, and vessels;
- by manned surface vessels and towed in-water devices actively participating in cable laying during Modernization & Sustainment of Ranges activities; and
- when impractical based on mission requirements (*e.g.,* during certain aspects of amphibious exercises).

TABLE 73—MITIGATION FOR MANNED SURFACE VESSELS

Stressor or Activity: Manned surface vessels, including surfaced submarines.

- Mitigation Zones:
  - Underway manned surface vessels must maneuver themselves (which may include reducing speed) to maintain the following distances as mission and circumstances allow:
    - 500 yd (457.2 m) from whales.
    - 200 yd (182.9 m) from other marine mammals.
- Mitigation Requirements:
  - One or more Lookouts on manned underway surface vessels in accordance with the most recent navigation safety instruction.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals immediately prior to manned surface vessels getting underway and while underway.

TABLE 74—MITIGATION FOR UNMANNED VEHICLES

Stressor or Activity: Unmanned Surface Vehicles and Unmanned Underwater Vehicles already being escorted (and operated under positive control) by a manned surface support vessel.

- Mitigation Zones:
  - A surface support vessel that is already participating in the event, and has positive control over the unmanned vehicle, must maneuver the unmanned vehicle (which may include reducing its speed) to ensure it maintains the following distances as mission and circumstances allow:
    - 500 yd (457.2 m) from whales.
    - 200 yd (182.9 m) from other marine mammals.
- Mitigation Requirements:
  - One Lookout on a surface support vessel that is already participating in the event and has positive control over the unmanned vehicle.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals immediately prior to unmanned vehicles getting underway and while underway.

TABLE 75—MITIGATION FOR TOWED IN-WATER DEVICES

Stressor or Activity: In-water devices towed by an aircraft, a manned surface vessel, or an Unmanned Surface Vehicle or Unmanned Underwater Vehicle already being escorted (and operated under positive control) by a manned surface vessel.

- Mitigation Zone:
  - Manned towing platforms, or surface support vessels already participating in the event that have positive control over an unmanned vehicle that is towing an in-water device, must maneuver itself or the unmanned vehicle (which may include reducing speed) to ensure towed in-water devices maintain the following distances as mission and circumstances allow:
    - 250 yd (228.6 m) from marine mammals.
- Mitigation Requirements:
  - One Lookout on the manned towing vessel or aircraft, or on a surface support vessel that is already participating in the event and has positive control over an unmanned vehicle that is towing an in-water device.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals immediately prior to and while in-water devices are being towed.

TABLE 76—MITIGATION FOR NET DEPLOYMENT

Stressor or Activity: Nets deployed for testing of an Unmanned Underwater Vehicle.

- Mitigation Zone:
  - If a marine mammal is sighted within 500 yd of the deployment location, the support vessel must:
    - Delay deployment of nets until the mitigation zone has been clear for 15 minutes.
    - Recover nets if they are deployed.
- Mitigation Requirements:
  - One Lookout on the support vessel.
- Mitigation Requirement Timing:
  - Action Proponent personnel must observe the mitigation zone for marine mammals for 15 minutes prior to the deployment of nets and while the nets are deployed.
  - Nets must be deployed during daylight hours only.

Geographic Mitigation Areas

In addition to activity-based mitigation, the Action Proponents would implement mitigation measures within mitigation areas to avoid or minimize potential impacts on marine mammals (see figures 11–1 and 11–2 of the application). A full technical analysis of the mitigation areas that the Action Proponents considered for marine mammals is provided in appendix K (Geographic Mitigation Assessment) of the 2024 HCTT Draft EIS/OEIS. The Action Proponents took into account public comments received on the 2017 HSTT Draft EIS/OEIS, the best available science, and the practicability of implementing additional mitigation measures and has enhanced its mitigation areas and mitigation measures beyond those that were included in the 2018–2025 regulations to further reduce impacts to marine mammals.

Information on the mitigation measures that the Action Proponents propose to implement within mitigation areas is provided in table 77 through table 86. The mitigation applies year-round unless specified otherwise in the tables.

NMFS conducted an independent analysis of the mitigation areas that the Action Proponent proposed, which are described below. NMFS preliminarily concurs with the Action Proponents' analysis, which indicates that the measures in these mitigation areas are both practicable and will reduce the likelihood, magnitude, or severity of adverse impacts to marine mammals or their habitat in the manner described in the Action Proponents' analysis and this proposed rule. NMFS is heavily reliant on the Action Proponents' description of operational practicability, since the Action Proponents are best equipped to describe the degree to which a given mitigation measure affects personnel safety or mission effectiveness, and how practical it is to implement. The Action Proponents consider the measures in this proposed rule to be practicable, and NMFS concurs. We further discuss the manner in which the Geographic Mitigation Areas in the proposed rule will reduce the likelihood, magnitude,

or severity of adverse impacts to marine mammal species or their habitat in the Preliminary Analysis and Negligible Impact Determination section.

Geographic Mitigation Areas in Hawaii

Table 77 details geographic mitigation related to the use of active sonar and explosives off Hawaii Island. The mitigation is a continuation from Phase III.

TABLE 77—HAWAII ISLAND MARINE MAMMAL MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Acoustic	The Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of helicopter dipping sonar (a mid-frequency active sonar source) annually within the mitigation area.	Mitigation in this area is designed to reduce exposure of numerous small and resident marine mammal populations (including Blainville's beaked whales, bottlenose dolphins, goose-beaked whales, dwarf sperm whales, false killer whales, melon-headed whales, pantropical spotted dolphins, pygmy killer whales, rough-toothed dolphins, short-finned pilot whales, and spinner dolphins), humpback whales within important seasonal reproductive habitat, and Hawaiian monk seals within critical habitat, to levels of sound that have the potential to cause injurious or behavioral impacts.
Explosives	The Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) within the mitigation area.	Mitigation in this area is designed to prevent exposure of the species listed above to explosives that have the potential to cause injury, mortality, or behavioral disturbance.

Table 78 details geographic mitigation related to the use of active sonar and explosives off Molokaʻi, Maui, Lānaʻi, and Kahoʻolawe Islands. The mitigation is a continuation from Phase III.

TABLE 78—HAWAII 4-ISLANDS MARINE MAMMAL MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Acoustic	From November 15–April 15, the Action Proponents must not use MF1 surface ship hull-mounted mid-frequency active sonar within the mitigation area.	Mitigation in this area is designed to minimize exposure of humpback whales in high-density seasonal reproductive habitats (*e.g.,* north of Maui and Molokaʻi) and Main Hawaiian Islands insular false killer whales in high seasonal occurrence areas to levels of sound that have the potential to cause injurious or behavioral impacts.
Explosives	The Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) within the mitigation area (year-round).	Mitigation in this area is designed to prevent exposure of humpback whales in high-density seasonal reproductive habitats (*e.g.,* north of Maui and Molokaʻi), Main Hawaiian Islands insular false killer whales in high seasonal occurrence areas, and numerous small and resident marine mammal populations that occur year-round (including bottlenose dolphins, pantropical spotted dolphins, and spinner dolphins, and Hawaiian monk seals) to explosives that have the potential to cause injury, mortality, or behavioral disturbance.

Table 79 details special reporting requirements related to the use of active sonar off Oʻahu, Molokaʻi, and Hawaii Island. The mitigation is a continuation from Phase III with a modified geographic extent based on based available science.

TABLE 79—HAWAII HUMPBACK WHALE SPECIAL REPORTING MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Acoustic	The Action Proponents must report the total hours of MF1 surface ship hull-mounted mid-frequency active sonar used from November through May in the mitigation area in their training and testing activity reports submitted to NMFS.	Special reporting requirements are designed to aid NMFS' and the Action Proponents' analysis of potential impacts in the mitigation area, which contains the Hawaiian Islands Humpback Whale National Marine Sanctuary plus a 5-km (2.7 nmi) sanctuary buffer (excluding the PMRF).

Table 80 details awareness notification message requirements for the Hawaii Range Complex. The mitigation is a continuation from Phase III.

TABLE 80—HAWAII HUMPBACK WHALE AWARENESS MESSAGES

Category	Mitigation requirements	Mitigation benefits
Acoustic, Explosives, Physical disturbance and strike.	The Action Proponents must broadcast awareness messages to alert applicable assets (and their Lookouts) transiting and training or testing in the Hawaii Range Complex to the possible presence of concentrations of humpback whales from November through May. Lookouts must use that knowledge to help inform their visual observations during military readiness activities that involve vessel movements, active sonar, in-water explosives (including underwater explosives and explosives deployed against surface targets), or the deployment of non-explosive ordnance against surface targets in the mitigation area.	Mitigation in this area is designed to minimize potential humpback whale vessel interactions and exposure to acoustic, explosive, and physical disturbance and strike stressors that have the potential to cause mortality, injury, or behavioral disturbance during the reproductive season. The Hawaii Humpback Whale Awareness Messages apply to the entire Hawaii Range Complex; therefore, the mitigation described in table 77, table 78, and table 79 is in addition to the requirements described for this overlapping area.

Geographic Mitigation Areas in California

Table 81 details geographic mitigation related to the use of active sonar off the coast of northern California. The mitigation is new for this phase.

TABLE 81—NORTHERN CALIFORNIA LARGE WHALE MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Acoustic	From June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Central California Large Whale Mitigation Area, and the Southern California Blue Whale Mitigation Area.	Mitigation in this area is designed to reduce exposure of blue whales, fin whales, gray whales, and humpback whales in important seasonal foraging, migratory, and calving habitats to levels of sound that have the potential to cause injurious or behavioral impacts.

Table 82 details geographic mitigation related to the use of active sonar off the coast of Central California. The mitigation is a continuation from Phase III with a modified geographic extent based on best available science.

TABLE 82—CENTRAL CALIFORNIA LARGE WHALE MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Acoustic	From June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Northern California Large Whale Mitigation Area, and the Southern California Blue Whale Mitigation Area.	Mitigation in this area is designed to reduce exposure of blue whales, fin whales, gray whales, and humpback whales in important seasonal foraging, migratory, and calving habitats to levels of sound that have the potential to cause injurious or behavioral impacts.

Table 83 details geographic mitigation related to the use of active sonar and explosives off the coast of Southern California. The mitigation is a continuation from Phase III.

TABLE 83—SOUTHERN CALIFORNIA BLUE WHALE MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Acoustic	From June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Northern California Large Whale Mitigation Area, and the Central California Large Whale Mitigation Area.	Mitigation in this area is designed to reduce exposure of blue whales within important seasonal foraging habitats to levels of sound that have the potential to cause injurious or behavioral impacts.

TABLE 83—SOUTHERN CALIFORNIA BLUE WHALE MITIGATION AREA—Continued

Category	Mitigation requirements	Mitigation benefits
Explosives	From June 1–October 31, the Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) during large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) training and testing.	Mitigation in this area is designed to reduce exposure of blue whales within important seasonal foraging habitats to explosives that have the potential to cause injury, mortality, or behavioral disturbance.

Table 84 details awareness notification message requirements for the SOCAL Range Complex. The mitigation is a continuation from Phase III.

TABLE 84—CALIFORNIA LARGE WHALE AWARENESS MESSAGES

Category	Mitigation requirements	Mitigation benefits
Acoustic, Explosives, Physical disturbance and strike.	The Action Proponents must broadcast awareness messages to alert applicable assets (and their Lookouts) transiting and training or testing off the U.S. West Coast to the possible presence of concentrations of large whales, including gray whales (November–March), fin whales (November–May), and mixed concentrations of blue, humpback, and fin whales that may occur based on predicted oceanographic conditions for a given year (*e.g.,* May–November, April–November). Awareness messages may provide the following types of information which could vary annually: • While blue whales tend to be more transitory, some fin whales are year-round residents that can be expected in nearshore waters within 10 nmi (18.5 km) of the California mainland and offshore operating areas at any time. • Fin whales occur in groups of one to three individuals, 90 percent of the time, and in groups of four or more individuals, 10 percent of the time. • Unique to fin whales offshore southern California (including the Santa Barbara Channel and PMSR area), there could be multiple individuals and/or separate groups scattered within a relatively small area (1–2 nmi; 1.9–2.7 km) due to foraging or social interactions. • When a large whale is observed, this may be an indicator that additional marine mammals are present and nearby, and the vessel should take this into consideration when transiting. • Lookouts must use that knowledge to help inform their visual observations during military readiness activities that involve vessel movements, active sonar, in-water explosives (including underwater explosives and explosives deployed against surface targets), or the deployment of non-explosive ordnance against surface targets in the mitigation area.	Mitigation in this area is designed to minimize potential blue whale, gray whale, and fin whale vessel interactions and exposure to acoustic stressors, explosives, and physical disturbance and strike stressors that have the potential to cause mortality, injury, or behavioral disturbance during the foraging and migration seasons, and to resident whales.

Table 85 details real-time notification requirements for a designated area within the SOCAL Range Complex. The mitigation is a continuation from the 2025 HSTT Final Rule (90 FR 4944, January 16, 2025).

TABLE 85—CALIFORNIA LARGE WHALE REAL-TIME NOTIFICATION MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
Physical disturbance and strike.	The Action Proponents must issue real-time notifications to alert Action Proponent vessels operating in the vicinity of large whale aggregations (four or more whales) sighted within 1 nmi (1.9 km) of an Action Proponent vessel within an area of the Southern California Range Complex (between 32–33 degrees North and 117.2–119.5 degrees West).	The real-time notification area encompasses the locations of recent (2009, 2021, 2023) vessel strikes, and historic strikes where precise latitude and longitude were known.

TABLE 85—CALIFORNIA LARGE WHALE REAL-TIME NOTIFICATION MITIGATION AREA—Continued

Category	Mitigation requirements	Mitigation benefits
	The four whales that make up a defined ''aggregation'' would not all need to be from the same species, and the aggregation could consist either of a single group of four (or more) whales, or any combination of smaller groups totaling four (*e.g.,* two groups of two whales each or a group of three whales and a solitary whale) within the 1 nmi (1.9 km) zone. Lookouts must use the information from the real-time notifications to inform their visual observations of applicable mitigation zones. If Lookouts observe a large whale aggregation within 1 nmi (1.9 km) of the event vicinity within the area between 32–33 degrees North and 117.2–119.5 degrees West, the watch station must initiate communication with the designated point of contact to contribute to the Navy's real-time sighting notification system.	

Table 86 details geographic mitigation related to in-air vehicle launch noise and associated monitoring for pinniped haulout locations on San Nicolas Island, California. The mitigation is an adaptation of procedural mitigation for the same activities in the 2022 PMSR final rule (87 FR 40888, July 8, 2022).

TABLE 86—SAN NICOLAS ISLAND PINNIPED HAULOUT MITIGATION AREA

Category	Mitigation requirements	Mitigation benefits
In-air vehicle launch noise.	Navy personnel must not enter pinniped haulout or rookery areas. Personnel may be adjacent to pinniped haulouts and rookery prior to and following a launch for monitoring purposes. Missiles and targets must not cross over pinniped haulout areas at altitudes less than 305 m (1,000 ft), except in emergencies or for real-time security incidents. For unmanned aircraft systems (UAS), the following minimum altitudes will be maintained over pinniped haulout areas and rookeries: Class 0–2 UAS will maintain a minimum altitude of 92 m (300 ft); Class 3 UAS will maintain a minimum altitude of 153 m (500 ft); Class 4 or 5 UAS will not be flown below 305 m (1,000 ft). The Navy may not conduct more than 40 launch events annually. The Navy may not conduct more than 10 launch events at night annually. Launch events must be scheduled to avoid the peak pinniped pupping seasons (from January through July) to the maximum extent practicable. The Navy must implement a monitoring plan using video and acoustic monitoring of up to three pinniped haulout areas and rookeries during launch events that include missiles or targets that have not been previously monitored for at least three launch events. The Navy will review the launch procedure and monitoring methods, in cooperation with NMFS, if any incidents of injury or mortality of a pinniped are discovered during post-launch surveys, or if surveys indicate possible effects to the distribution, size, or productivity of the affected pinniped populations as a result of the specified activities. If necessary, appropriate changes will be made through modification to the Authorization prior to conducting the next launch of the same vehicle.	Mitigation is designed to minimize in-air launch noise and physical disturbance to pinnipeds hauled out on beaches, as well as to continue assessing baseline pinniped distribution/abundance and potential changes in pinniped use of these beaches after launch events.

Mitigation Conclusions

NMFS has carefully evaluated the Action Proponents' proposed mitigation measures—many of which were developed with NMFS' input during the previous phases of HCTT (formerly HSTT) authorizations but several of which are new since implementation of the 2018 to 2025 regulations—and considered a broad range of other measures (*i.e.,* the measures considered but eliminated in the 2024 HCTT Draft EIS/OEIS, which reflect many of the comments that have arisen from public input or through discussion with NMFS in past years) in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: the manner in

which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce the likelihood and/or magnitude of adverse impacts to marine mammal species and their habitat; the proven or likely efficacy of the measures; and the practicability of the measures for applicant implementation, including consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Based on our evaluation of the Action Proponents' proposed measures, as well as other measures considered by the Action Proponents and NMFS (see section 5.9 (Measures Considered but Eliminated) of chapter 5 (Mitigation) of the 2024 HCTT Draft EIS/OEIS), NMFS has preliminarily determined that these proposed mitigation measures are appropriate means of effecting the least practicable adverse impact on marine mammal species and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and considering specifically personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. Additionally, an adaptive management component helps further ensure that mitigation is regularly assessed and provides a mechanism to improve the mitigation, based on the factors above, through modification as appropriate.

The proposed rule comment period provides the public an opportunity to submit recommendations, views, and/or concerns regarding the Action Proponents' activities and the proposed mitigation measures. While NMFS has preliminarily determined that the Action Proponents' proposed mitigation measures would effect the least practicable adverse impact on the affected species and their habitat, NMFS will consider all public comments to help inform our final determination. Consequently, proposed mitigation measures may be refined, modified, removed, or added prior to the issuance of the final rule based on public comments received and, as appropriate, analysis of additional potential mitigation measures.

Proposed Monitoring

Section 101(a)(5)(A) of the MMPA states that in order to authorize incidental take for an activity, NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present.

Although the Navy has been conducting research and monitoring for over 20 years in areas where it has been training, it developed a formal marine species monitoring program in support of the HCTT Study Area MMPA and ESA processes in 2009. Across all Navy training and testing study areas, the robust marine species monitoring program has resulted in hundreds of technical reports and publications on marine mammals that have informed Navy and NMFS analyses in environmental planning documents, rules, and Biological Opinions. The reports are made available to the public on the Navy's marine species monitoring website (*https://www.navymarinespeciesmonitoring.us*) and the data on the Ocean Biogeographic Information System Spatial Ecological Analysis of Megavertebrate Populations (OBIS–SEAMAP) (*https://seamap.env.duke.edu/*).

The Navy would continue collecting monitoring data to inform our understanding of the occurrence of marine mammals in the HCTT Study Area, the likely exposure of marine mammals to stressors of concern in the HCTT Study Area, the response of marine mammals to exposures to stressors, the consequences of a particular marine mammal response to their individual fitness and, ultimately, populations, and the effectiveness of implemented mitigation measures. Taken together, mitigation and monitoring comprise the Navy's integrated approach for reducing environmental impacts from the specified activities. The Navy's overall monitoring approach seeks to leverage and build on existing research efforts whenever possible.

As agreed upon between the Action Proponents and NMFS, the monitoring measures presented here, as well as the mitigation measures described above, focus on the protection and management of potentially affected marine mammals. A well-designed monitoring program can provide important feedback for validating assumptions made in analyses and allow for adaptive management of marine mammals and their habitat, and other marine resources. Monitoring is required under the MMPA, and details of the monitoring program for the specified activities have been developed through coordination between NMFS and the Action Proponents through the regulatory process for previous Navy at-sea training and testing activities.

Navy Marine Species Research and Monitoring Strategic Framework

The initial structure for the U.S. Navy's marine species monitoring efforts was developed in 2009 with the Integrated Comprehensive Monitoring Program (ICMP). The intent of the ICMP was to provide an overarching framework for coordination of the Navy's monitoring efforts during the early years of the program's establishment. A Strategic Planning Process (U.S. Department of the Navy, 2013) was subsequently developed and together with the ICMP framework serves as a planning tool to focus marine species monitoring priorities defined by ESA and MMPA requirements, and to coordinate monitoring efforts across regions based on a set of common objectives. Using an underlying conceptual framework incorporating a progression of knowledge from occurrence to exposure/response, and ultimately consequences, the Strategic Planning Process was developed as a tool to help guide the investment of resources to address top level objectives and goals of the monitoring program most efficiently. The Strategic Planning Process identifies Intermediate Scientific Objectives (see *https://www.navymarinespeciesmonitoring.us/about/strategic-planning-process/*), which form the basis of evaluating, prioritizing, and selecting new monitoring projects or investment topics and serve as the basis for developing and executing new monitoring projects across the Navy's training and testing ranges (both Atlantic and Pacific).

Monitoring activities relating to the effects of military readiness activities on marine species are generally designed to address one or more of the following top-level goals:

- An increase in the understanding of the likely occurrence of marine mammals and ESA-listed marine species in the vicinity of the action (*i.e.,* presence, abundance, distribution, and density);
- An increase in the understanding of the nature, scope, or context of the likely exposure of marine mammals and ESA-listed species to any of the potential stressors associated with the action (*e.g.,* sound, explosive detonation, or military expended materials), through better understanding of one or more of the following:
  - the nature of the action and its surrounding environment (*e.g.,* sound-source characterization, propagation, and ambient noise levels),

○ the affected species (*e.g.,* life history or dive patterns),

○ the likely co-occurrence of marine mammals and ESA-listed marine species with the action (in whole or part), or

○ the likely biological or behavioral context of exposure to the stressor for the marine mammal and ESA-listed marine species (*e.g.,* age class of exposed animals or known pupping, calving, or feeding areas).

• An increase in the understanding of how individual marine mammals or ESA-listed marine species respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible (*e.g.,* at what distance or received level)).

• An increase in the understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either:

○ the long-term fitness and survival of an individual; or

○ the population, species, or stock (*e.g.,* through impacts on annual rates of recruitment or survival).

• An increase in the understanding of the effectiveness of mitigation and monitoring measures.

• A better understanding and record of the manner in which the authorized entity complies with the Incidental Take Authorization and Incidental Take Statement.

• An increase in the probability of detecting marine mammals (through improved technology or methods), both specifically within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals; and

• Ensuring that adverse impact of activities remains at the least practicable level.

The Navy's Marine Species Monitoring Program investments are evaluated through the Adaptive Management Review process to: (1) assess overall progress; (2) review goals and objectives; and (3) make recommendations for refinement and evolution of the monitoring program's focus and direction. The Marine Species Monitoring Program has developed and matured significantly since its inception and now supports a portfolio of several dozen active projects across a range of geographic areas and protected species taxa addressing both regional priorities (*i.e.,* particular species of concern), and Navy-wide needs such as the behavioral response of beaked whales to training and testing activities.

A Research and Monitoring Summit was held in early 2023 to evaluate the current state of the Marine Species Monitoring Program in terms of progress, objectives, priorities, and needs, and to solicit valuable input from meeting participants including NMFS, Marine Mammal Commission, Navy, and scientific experts. The overarching goal of the summit was to facilitate updating the ICMP framework for guiding marine species research and monitoring investments, and to identify data gaps and priorities to be addressed over the next 5–10 years across a range of basic research through applied monitoring. One of the outcomes of this summit meeting is a refreshed strategic framework effectively replacing the ICMP which will provide increased coordination and synergy across the Navy's protected marine species investment programs (see section 13.1 of the application). This will contribute to the collective goal of supporting improved assessment of effects from training and testing activities through development of first in class science and data.

For over a decade, the Navy has implemented the PMAP software tool, which provides operators with notification of the required mitigation and a visual display of the planned training or testing activity location overlaid with relevant environmental data. This module was developed by civilian marine biologists employed by the Navy and was reviewed and approved by NMFS. It provides information on marine species sighting cues, visual observation tools and techniques, and sighting notification procedures. It is a video-based complement to the U.S. Navy Lookout Training Handbook or equivalent. Since 2007, this module has been required for commanding officers, executive officers, equivalent civilian personnel, and personnel who will stand watch as a Lookout.

Additionally, the U.S. Navy Lookout Training Handbook was updated in 2022 to include a more robust chapter on environmental compliance, mitigation, and marine species observation tools and techniques. Environmental awareness and education training is also provided to Navy personnel through the Afloat Environmental Compliance Training program or equivalent. Training is designed to help personnel gain an understanding of their personal environmental compliance roles and responsibilities (including mitigation implementation). Finally, the Navy's current generation of land-based ship bridge simulators now incorporate marine mammal response in team training scenarios for bridge watch standers and Lookouts.

Past and Current Action Proponent Monitoring in the HCTT Study Area

The Navy's monitoring program has undergone significant changes since the first rules were issued for the HRC and SOCAL Study Areas in 2009 through the process of adaptive management. The monitoring program developed for the first cycle of environmental compliance documents (*e.g.,* U.S. Department of the Navy, 2008a, 2008b) utilized effort-based compliance metrics that were somewhat limiting. Through adaptive management discussions, the Navy designed and conducted monitoring studies according to scientific objectives and eliminated specific effort requirements.

Progress has also been made on the conceptual framework categories from the Scientific Advisory Group for Navy Marine Species Monitoring (U.S. Department of the Navy, 2011), ranging from occurrence of animals, to their exposure, response, and population consequences. The Navy continues to manage the Atlantic and Pacific program as a whole, with monitoring in each range complex taking a slightly different but complementary approach. The Navy has continued to use the approach of layering multiple simultaneous components in many of the range complexes to leverage an increase in return of the progress toward answering scientific monitoring questions. For example, in later Phase I HRC monitoring through Phase III HSTT monitoring, several monitoring efforts coincided on the instrumented Navy training range off PMRF during an actual anti-submarine warfare training exercise. This included: (1) deploying civilian marine mammal observers aboard a Navy destroyer employing mid-frequency active sonar; (2) a civilian marine mammal aerial survey aircraft orbiting the destroyer during the course of the exercise; (3) Navy acousticians monitoring the exercise participants and animals via the hydrophones of the instrumented range during the exercise; and (4) having satellite tagging of animals performed on the training range just prior to the exercise.

Numerous publications, dissertations, and conference presentations have resulted from research conducted under the marine species monitoring program (*https://www.navymarinespecies monitoring.us/reading-room/*), leading to a significant contribution to the body of marine mammal science. Publications on occurrence, distribution, and density

have fed the modeling input, and publications on exposure and response have informed Navy and NMFS analysis of behavioral response and consideration of mitigation measures.

Furthermore, collaboration between the monitoring program and the Navy's research and development (*e.g.,* the ONR) and demonstration-validation (*e.g.,* Living Marine Resources (LMR)) programs has been strengthened, leading to research tools and products that have already transitioned to the monitoring program. These include Marine Mammal Monitoring on Ranges, controlled exposure experiment behavioral response studies, acoustic sea glider surveys, and global positioning system-enabled satellite tags. Recent progress has been made with better integration with monitoring across all Navy at-sea study areas, including the HCTT Study Area and various other ranges. Publications from the LMR and ONR programs have also resulted in significant contributions to hearing, acoustic criteria used in effects modeling, exposure, and response, as well as in developing tools to assess biological significance (*e.g.,* consequences).

NMFS and the Navy also consider data collected during mitigations as monitoring. Data are collected by shipboard personnel on hours spent training and hours of sonar use. Additionally, during MTEs, data are collected when marine mammals are observed within the mitigation zones when mitigations are implemented. These data are provided to NMFS in both classified and unclassified annual exercise reports, which would continue under this proposed rule.

NMFS has received multiple years' worth of annual exercise and monitoring reports addressing active sonar use and explosive detonations within the HCTT Study Area and other Navy range complexes. The data and information contained in these reports have been considered in developing mitigation and monitoring measures for the proposed military readiness activities within the HCTT Study Area. The Navy's annual exercise and monitoring reports may be viewed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities* and *https://www.navymarinespeciesmonitoring.us/reporting/.*

The Navy's marine species monitoring program supports several monitoring projects in the HCTT Study Area at any given time. Additional details on the scientific objectives for each project can be found at: *https://www.navymarinespeciesmonitoring.us/regions/pacific/current-projects/.* Some projects may only require one or two years of field effort. Other projects could entail multi-year field efforts (2–5 years). Most current HCTT projects are multi-year ongoing studies such as odontocete tagging and behavioral response to sonar in Hawaii, and beaked whale distribution and response to sonar in California.

Specific monitoring under the 2018–2025 regulations included the following projects:

- Pacific Marine Assessment Program for Protected Species (PACMAPPS) survey;
- Effectiveness of Navy Lookout Teams in Detecting Cetaceans;
- Long Term Acoustic Monitoring of Marine Mammals Utilizing the Instrumented Range at Pacific Missile Range Facility (PMRF) (ongoing);
- Pacific Islands comprehensive stranding investigations (ongoing);
- North Pacific Humpback Whale Tagging;
- Estimation of Received Levels of MFAS and Behavioral Response of Marine Mammals at PMRF (ongoing);
- Marine Mammal Monitoring on Navy Ranges (ongoing);
- Marine Mammal Sightings During CalCOFI Cruises (ongoing);
- Blue and Fin Whale Satellite Tagging;
- Guadalupe Fur Seal Satellite Tracking;
- Passive Acoustic Monitoring of Marine Mammals in SOCAL Range Complex (ongoing); and
- Cuvier's Beaked Whale and Fin Whale Population Dynamics and Impact Assessment at the Southern California Offshore Antisubmarine Warfare Range (SOAR) (ongoing).

Future monitoring efforts by the Action Proponents in the HCTT Study Area are anticipated to continue along the same objectives: establish the baseline habitat uses and movement patterns; establish the baseline behavior (*e.g.,* foraging, dive patterns, *etc.*); and evaluate potential exposure and behavioral responses of marine mammals exposed to training and testing activities.

Currently planned monitoring projects and their Intermediate Scientific Objective for the 2025–2032 rule are listed below, many of which are continuations of projects currently underway. Other than those ongoing projects, monitoring projects are typically planned one year in advance; therefore, this list does not include all projects that will occur over the entire period of the rule.

- Long Term Acoustic Monitoring of Marine Mammals Utilizing the Instrumented Range at Pacific Missile Range Facility (PMRF) (ongoing)—The objectives are: (1) determine what species and populations of marine mammals and ESA-listed species are present in Navy range complexes, testing ranges, and in specific training and testing areas; (2) establish the baseline habitat uses, seasonality, and movement patterns of marine mammals and ESA-listed species where Navy training and testing activities occur; (3) evaluate potential exposure of marine mammals and ESA-listed species to Navy training and testing activities; (4) establish the regional baseline vocalization behavior, including seasonality and acoustic characteristics, of marine mammals where Navy training and testing activities occur; (5) apply passive acoustic tools and techniques for detecting, classifying, locating, and tracking marine mammals; (6) apply analytic methods to evaluate exposure and/or behavioral response of marine mammals to Navy training and testing activities; (7) evaluate acoustic exposure levels associated with behavioral responses of marine mammals to support development and refinement of acoustic risk functions; (8) evaluate trends in distribution and abundance for populations of marine mammals and ESA-listed species that are regularly exposed to Navy training and testing activities; and (9) leverage existing data with newly developed analysis tools and techniques.
- Pacific Islands comprehensive stranding investigations (ongoing)—The objectives are to: (1) determine what species and populations of marine mammals and ESA-listed species are present in Navy range complexes, testing ranges, and in specific training and testing areas; and (2) establish the baseline habitat uses, seasonality, and movement patterns of marine mammals and ESA-listed species where Navy training and testing activities occur.
- Estimation of Received Levels of MFAS and Behavioral Response of Marine Mammals at PMRF (ongoing)—The objectives are to: (1) determine what species and populations of marine mammals and ESA-listed species are exposed to U.S. Navy training and testing activities; (2) establish the baseline habitat uses, seasonality, and movement patterns of marine mammals and ESA-listed species where Navy training and testing activities occur; (3) establish the regional baseline vocalization behavior, including seasonality and acoustic characteristics, of marine mammals where Navy training and testing activities occur; (4) determine what behaviors can most effectively be assessed for potential

response to Navy training and testing activities; (5) evaluate behavioral responses of marine mammals exposed to Navy training and testing activities to support PCoD development and application; (6) application of passive acoustic tools and techniques for detecting, classifying, locating, and tracking marine mammals; (7) evaluate trends in distribution and abundance for populations of marine mammals and ESA-listed species that are regularly exposed to Navy training and testing activities; and (8) leverage existing data with newly developed analysis tools and techniques.

- Marine Mammal Monitoring on Navy Ranges (ongoing)—The objectives are to: (1) estimate the distribution, abundance, and density of marine mammals and ESA-listed species in Navy range complexes, testing ranges, and in specific training and testing areas; (2) establish the regional baseline vocalization behavior, including seasonality and acoustic characteristics, of marine mammals where Navy training and testing activities occur; (3) application of passive acoustic tools and techniques for detecting, classifying, locating, and tracking marine mammals; (4) application of analytic methods to evaluate exposure and/or behavioral response of marine mammals to Navy training and testing activities; and (5) evaluate trends in distribution and abundance for populations of marine mammals and ESA-listed species that are regularly exposed to Navy training and testing activities.
- Marine Mammal Sightings During CalCOFI Cruises (ongoing)—The objectives are to: (1) determine what species and populations of marine mammals and ESA-listed species are present in Navy range complexes, testing ranges, and in specific training and testing areas; (2) estimate the distribution, abundance, and density of marine mammals and ESA-listed species in Navy range complexes, testing ranges, and in specific training and testing areas; and (3) establish the baseline habitat uses, seasonality, and movement patterns of marine mammals and ESA-listed species where Navy training and testing activities occur.
- Passive Acoustic Monitoring of Marine Mammals in SOCAL Range Complex (ongoing)—The objectives are to: (1) determine what species and populations of marine mammals and ESA-listed species are present in Navy range complexes, testing ranges, and in specific training and testing areas; (2) establish the baseline habitat uses, seasonality, and movement patterns of marine mammals and ESA-listed species where Navy training and testing activities occur; (3) establish the regional baseline vocalization behavior, including seasonality and acoustic characteristics, of marine mammals where Navy training and testing activities occur; and (4) apply passive acoustic tools and techniques for detecting, classifying, locating, and tracking marine mammals.
- Cuvier's Beaked Whale and Fin Whale Population Dynamics and Impact Assessment at the Southern California Offshore Antisubmarine Warfare Range (SOAR) (ongoing)—The objectives are to: (1) determine what species and populations of marine mammals and ESA-listed species are present in Navy range complexes, testing ranges, and in specific training and testing areas; (2) establish the baseline habitat uses, seasonality, and movement patterns of marine mammals and ESA-listed species where Navy training and testing activities occur; (3) establish the regional baseline vocalization behavior, including seasonality and acoustic characteristics, of marine mammals where Navy training and testing activities occur, (4) determine what behaviors can most effectively be assessed for potential response to Navy training and testing activities; (5) apply passive acoustic tools and techniques for detecting, classifying, locating, and tracking marine mammals; (6) evaluate behavioral responses of marine mammals exposed to Navy training and testing activities to support PCoD development and application; (7) evaluate trends in distribution and abundance for populations of marine mammals and ESA-listed species that are regularly exposed to Navy training and testing activities; and (8) leverage existing data with newly developed analysis tools and techniques.

Adaptive Management

The proposed regulations governing the take of marine mammals incidental to military readiness activities in the HCTT Study Area contain an adaptive management component. Our understanding of the effects of military readiness activities (*e.g.,* acoustic and explosive stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of 7-year regulations.

The reporting requirements associated with this proposed rule are designed to provide NMFS with monitoring data from the previous year to allow NMFS to consider whether any changes to existing mitigation and monitoring requirements are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Action Proponents regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring and if the measures are practicable. If the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS would publish a notice of the planned LOAs in the **Federal Register** and solicit public comment.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) results from monitoring and exercise reports, as required by MMPA authorizations; (2) compiled results of Navy-funded research and development studies; (3) results from specific stranding investigations; (4) results from general marine mammal and sound research; and (5) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs. The results from monitoring reports and other studies may be viewed at: *https://www.navymarinespeciesmonitoring.us.*

Proposed Reporting

In order to issue incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring. Reports from individual monitoring events, results of analyses, publications, and periodic progress reports for specific monitoring projects will be posted to the Navy's Marine Species Monitoring web portal at: *https://www.navymarinespeciesmonitoring.us.*

There are several different reporting requirements for the Navy pursuant to the current regulations. All of these reporting requirements would be continued for the Navy under this proposed rule for the 7-year period.

Special Reporting for Geographic Mitigation Areas

The Action Proponents must report the total hours of MF1 surface ship hull-mounted mid-frequency active sonar used from November through May in

the Hawaii Humpback Whale Special Reporting Mitigation Area in their annual training and testing activity reports. Special reporting for this area is designed to aid the Action Proponents and NMFS in continuing to analyze potential impacts of training and testing in the mitigation areas. In addition to the mitigation area-specific requirement, for all mitigation areas, should national security require the Action Proponents to exceed the activity restrictions in a given mitigation area, Action Proponent personnel must provide NMFS with advance notification and include the information (*e.g.,* sonar hours, explosives usage, or restricted area use) in its annual activity reports submitted to NMFS.

Notification of Injured, Live Stranded, or Dead Marine Mammals

The Action Proponents would consult the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when injured, live stranded, or dead marine mammals are detected. The Notification and Reporting Plan is available for review at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

Annual HCTT Study Area Marine Species Monitoring Report

The Action Proponents would submit an annual report of the HCTT Study Area marine species monitoring, which would be included in a Pacific-wide monitoring report, describing the implementation and results from the previous calendar year. Data collection methods will be standardized across range complexes and the HCTT Study Area to allow for comparison in different geographic locations. The draft report must be submitted to the Director of the Office of Protected Resources of NMFS annually as specified in the LOAs. NMFS will submit comments or questions on the report, if any, within 3 months of receipt. The report will be considered final after the Action Proponents have addressed NMFS' comments, or 3 months after submittal of the draft if NMFS does not provide comments on the draft report. The report would describe progress of knowledge made with respect to intermediate scientific objectives within the HCTT Study Area associated with the ICMP. Similar study questions would be treated together so that progress on each topic can be summarized across all Navy ranges. The report need not include analyses and content that do not provide direct assessment of cumulative progress on the monitoring plan study questions.

Annual HCTT Training and Testing Reports

In the event that the analyzed sound levels were exceeded, the Action Proponents would submit a preliminary report(s) detailing the exceedance within 21 days after the anniversary date of issuance of the LOAs. Regardless of whether analyzed sound levels were exceeded, the Navy would submit a detailed report (HCTT Annual Training Exercise Report and Testing Activity Report) and Coast Guard and Army would each submit a detailed report (HCTT Annual Training Exercise Report) to NMFS annually as specified in the LOAs. NMFS will submit comments or questions on the reports, if any, within 1 month of receipt. The reports will be considered final after the Action Proponents have addressed NMFS' comments, or 1 month after submittal of the drafts if NMFS does not provide comments on the draft reports. The annual report shall contain information on MTEs, ship shock trials, SINKEX events, and a summary of all sound sources used (total hours or quantity (per the LOA)) of each bin of sonar or other non-impulsive source; total annual number of each type of explosive exercises; and total annual expended/detonated rounds (*e.g.,* missiles, bombs, sonobuoys, *etc.*) for each explosive bin). The annual reports will also contain cumulative sonar and explosive use quantity from previous years' reports through the current year. Additionally, if there were any changes to the sound source allowance in the reporting year, or cumulatively, the reports would include a discussion of why the change was made and include analysis to support how the change did or did not affect the analysis in the 2024 HCTT Draft EIS/OEIS and MMPA final rule. The annual reports would also include the details regarding specific requirements associated with specific mitigation areas. The analysis in the detailed report would be based on the accumulation of data from the current year's report and data collected from previous annual reports. The detailed reports shall also contain special reporting for the Hawaii Humpback Whale Special Reporting Mitigation Area, as described in the LOAs.

The final annual reports at the conclusion of the authorization period (year 7) will also serve as the comprehensive close-out reports and include both the final year annual use compared to annual authorization as well as a cumulative 7-year annual use compared to 7-year authorization. NMFS must submit comments on the draft close-out report, if any, within 3 months of receipt. The reports will be considered final after the Action Proponents have addressed NMFS' comments, or 3 months after submittal of the drafts if NMFS does not provide comments.

Other Reporting and Coordination

The Action Proponents would continue to report and coordinate with NMFS for the following:

- Annual marine species monitoring technical review meetings that also include researchers and the Marine Mammal Commission; and
- Annual Adaptive Management meetings that also include the Marine Mammal Commission (and could occur in conjunction with the annual marine species monitoring technical review meetings).

Preliminary Analysis and Negligible Impact Determination

General Negligible Impact Analysis

Introduction

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be taken by Level A harassment or Level B harassment (as presented in table 37, table 38, table 39, and table 40), NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration) and the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, other ongoing

sources of human-caused mortality, and ambient noise levels).

In the Estimated Take of Marine Mammals section, we identified the subset of potential effects that would be expected to qualify as take under the MMPA both annually and over the 7-year period covered by this proposed rule, and then identified the maximum number of takes we believe could occur (mortality) or are reasonably expected to occur (harassment) based on the methods described. The impact that any given take will have is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.,* the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-level impacts on individuals, *etc.*). For this proposed rule we evaluated the likely impacts of the enumerated maximum number of harassment takes that are proposed for authorization and reasonably expected to occur, in the context of the specific circumstances surrounding these predicted takes. We also include a specific assessment of M/SI takes that could occur, as well as consideration of the traits and statuses of the affected species and stocks. Last, we collectively evaluated this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific assessments that support our negligible impact conclusions for each stock or species. Because all of the Action Proponents' specified activities would occur within the ranges of the marine mammal stocks identified in the rule, all negligible impact analyses and determinations are at the stock level (*i.e.,* additional species-level determinations are not needed).

Harassment

The specified activities reflect representative levels of military readiness activities. The Description of the Proposed Activity section describes annual activities. There may be some flexibility in the exact number of hours, items, or detonations that may vary from year to year, but take totals would not exceed the maximum annual totals and 7-year totals indicated in table 37, table 38, table 39, and table 40. We base our analysis and negligible impact determination on the maximum number of takes that would be reasonably expected to occur annually and are proposed to be authorized, although, as stated before, the number of takes are only one part of the analysis, which includes extensive qualitative consideration of other contextual factors that influence the degree of impact of the takes on the affected individuals. To avoid repetition, we provide some general analysis immediately below that applies to all the species listed in table 37, table 38, table 39, and table 40, given that some of the anticipated effects of the Action Proponents' military readiness activities on marine mammals are expected to be relatively similar in nature. Below that, we provide additional information specific to mysticetes, odontocetes, and pinnipeds and, finally, break our analysis into species (and/or stocks), or groups of species (and the associated stocks) where relevant similarities exist, to provide more specific information related to the anticipated effects on individuals of a specific stock or where there is information about the status or structure of any species that would lead to a differing assessment of the effects on the species or stock. Organizing our analysis by grouping species or stocks that share common traits or that will respond similarly to effects of the Action Proponents' activities and then providing species- or stock-specific information allows us to avoid duplication while assuring that we have analyzed the effects of the specified activities on each affected species or stock.

The Action Proponents' harassment take request is based on one model for pile driving, a second model for land-based missile and target launches, and a third model (NAEMO) for all other acoustic stressors, which NMFS reviewed and concurs appropriately estimates the maximum amount of harassment that is reasonably likely to occur. As described in more detail above, NAEMO calculates sound energy propagation from sonar and other transducers, air guns, and explosives during military readiness activities; the sound or impulse received by animat dosimeters representing marine mammals distributed in the area around the modeled activity; and whether the sound or impulse energy received by a marine mammal exceeds the thresholds for effects. Assumptions in the Navy models intentionally err on the side of overestimation when there are unknowns. The effects of the specified activities are modeled as though they would occur regardless of proximity to marine mammals, meaning that no activity-based mitigation is considered (*e.g.,* no power down or shut down). However, the modeling does quantitatively consider the possibility that marine mammals would avoid continued or repeated sound exposures to some degree, based on a species' sensitivity to behavioral disturbance. NMFS provided input to, independently reviewed, and concurred with the Action Proponents on this process. The Action Proponents' analysis, which is described in detail in section 6 of the application, was used to quantify harassment takes for this proposed rule.

The Action Proponents and NMFS anticipate more severe effects from takes resulting from exposure to higher received levels (though this is in no way a strictly linear relationship for behavioral effects throughout species, individuals, or circumstances) and less severe effects from takes resulting from exposure to lower received levels. However, there is also growing evidence of the importance of distance in predicting marine mammal behavioral response to sound, *i.e.,* sounds of a similar level emanating from a more distant source have been shown to be less likely to elicit a response of equal magnitude (DeRuiter 2012). The estimated number of takes by Level A harassment and Level B harassment does not equate to the number of individual animals the Action Proponents expect to harass (which is lower), but rather to the instances of take (*i.e.,* exposures above the Level A harassment and Level B harassment threshold) that are anticipated to occur over the 7-year period. These instances may represent either brief exposures (*i.e.,* seconds or minutes) or, in some cases, longer durations of exposure within a day. In some cases, an animal that incurs a single take by AUD INJ or TTS may also experience a direct behavioral harassment from the same exposure. Some individuals may experience multiple instances of take (meaning over multiple days) over the course of the year, which means that the number of individuals taken is smaller than the total estimated takes. Generally speaking, the higher the number of takes as compared to the population abundance, the more repeated takes of individuals are likely, and the higher the actual percentage of individuals in the population that are likely taken at least once in a year. We look at this comparative metric (number of takes to population abundance) to give us a relative sense of where a larger portion of a species is being taken by the specified activities, where there is a likelihood that the same individuals are being taken across multiple days, and whether the number of days might be higher or more likely sequential. Where the number of instances of take is less than 100 percent of the abundance, and there is no information to specifically suggest that some subset of animals is known to congregate in an area in which

activities are regularly occurring (*e.g.,* a small resident population, takes occurring in a known important area such as a BIA, or a large portion of the takes occurring in a certain region and season), the overall likelihood and number of repeated takes is generally considered low, as it could, on one extreme, mean that every take represents a separate individual in the population being taken on one day (a minimal impact to an individual) or, more likely, that some smaller number of individuals are taken on one day annually and some are taken on a few, not likely sequential, days annually, and of course some are not taken at all.

In the ocean, the use of sonar and other active acoustic sources is often transient and is unlikely to repeatedly expose the same individual animals within a short period, for example within one specific exercise. However, for some individuals of some species, repeated exposures across different activities could occur over the year, especially where events occur in generally the same area with more resident species. In short, for some species, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some would be exposed multiple times, but based on the nature of the specified activities and the movement patterns of marine mammals, it is unlikely that individuals from most stocks would be taken over more than a few days within a given year. This means that even where repeated takes of individuals are likely to occur, they are more likely to result from non-sequential exposures from different activities, and, even if sequential, individual animals are not predicted to be taken for more than several days in a row, at most. As described elsewhere, the nature of the majority of the exposures would be expected to be of a less severe nature, and based on the numbers, it is likely that any individual exposed multiple times is still only taken on a small percentage of the days of the year. The greater likelihood is that not every individual is taken, or perhaps a smaller subset is taken with a slightly higher average and larger variability of highs and lows, but still with no reason to think that, for most species or stocks, any individuals would be taken a significant portion of the days of the year.

Behavioral Response

The estimates calculated using the BRF do not differentiate between the different types of behavioral responses that qualify as Level B harassment. As described in the application, the Action Proponents identified, with NMFS' input, that moderate behavioral responses, as characterized in Southall *et al.* (2021), would be considered a take. The behavioral responses predicted by the BRFs are assumed to be moderate severity exposures (*e.g.,* altered migration paths or dive profiles, interrupted nursing, breeding or feeding, or avoidance) that may last for the duration of an exposure. The Action Proponents then compiled the available data indicating at what received levels and distances those responses have occurred, and used the indicated literature to build biphasic behavioral response curves and cut-off conditions that are used to predict how many instances of Level B behavioral harassment occur in a day (see the Criteria and Thresholds Technical Report). Take estimates alone do not provide information regarding the potential fitness or other biological consequences of the responses on the affected individuals. We therefore consider the available activity-specific, environmental, and species-specific information to determine the likely nature of the modeled behavioral responses and the potential fitness consequences for affected individuals.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to individual animals from sonar and other active sound sources during military readiness activities would be primarily from anti-submarine warfare events. It is important to note although anti-submarine warfare is one of the warfare areas of focus during MTEs, there are significant periods when active anti-submarine warfare sonars are not in use. Nevertheless, behavioral responses are assumed more likely to be significant during MTEs than during other anti-submarine warfare activities due to the duration (*i.e.,* multiple days), scale (*i.e.,* multiple sonar platforms), and use of high-power hull-mounted sonar in the MTEs. In other words, in the range of potential behavioral effects that might be expected as part of a response that qualifies as an instance of Level B behavioral harassment (which by nature of the way it is modeled/counted, occurs within 1 day), the less severe end might include exposure to comparatively lower levels of a sound, at a detectably greater distance from the animal, for a few or several minutes, and that could result in a behavioral response such as avoiding an area that an animal would otherwise have chosen to move through or feed in for some amount of time or breaking off one or a few feeding bouts. More severe effects could occur when the animal gets close enough to the source to receive a comparatively higher level, is exposed continuously to one source for a longer time, or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

To help assess this, for sonar (LFAS/MFAS/HFAS) used in the HCTT Study Area, the Action Proponents provided information estimating the instances of take by Level B harassment by behavioral disturbance under each BRF that would occur within 6-dB increments (discussed below in the *Group and Species-Specific Analyses* section), and by distance in 5-km bins in section 2.3.3 of appendix A of the application. As mentioned above, all else being equal, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to lead to adverse effects, which could more likely accumulate to impacts on reproductive success or survivorship of the animal, but other contextual factors (*e.g.,* distance, duration of exposure, and behavioral state of the animals) are also important (Di Clemente *et al.,* 2018; Ellison *et al.,* 2012; Moore and Barlow, 2013; Southall *et al.,* 2019; Wensveen *et al.,* 2017, *etc.*). The majority of takes by Level B harassment are expected to be in the form of comparatively milder responses (*i.e.,* lower-level exposures that still qualify as take under the MMPA, but would likely be less severe along the continuum of responses that qualify as take) of a generally shorter duration. We anticipate more severe effects from takes when animals are exposed to higher received levels of sound or at closer proximity to the source. Because species belonging to taxa that share common characteristics are likely to respond and be affected in similar ways, these discussions are presented within each species group below in the *Group and Species-Specific Analyses* section. As noted previously in this proposed rule, behavioral response is likely highly variable between species, individuals within a species, and context of the exposure. Specifically, given a range of behavioral responses that may be classified as Level B harassment, to the degree that higher received levels of sound are expected to result in more severe behavioral responses, only a smaller percentage of the anticipated Level B harassment from the specified

activities might result in more severe responses (see the *Group and Species-Specific Analyses* section below for more detailed information).

Physiological Stress Response

Some of the lower level physiological stress responses (*e.g.,* orientation or startle response, change in respiration, change in heart rate) discussed earlier would likely co-occur with the predicted harassments, although these responses are more difficult to detect and fewer data exist relating these responses to specific received levels of sound. Level B harassment takes, then, may have a stress-related physiological component as well; however, we would not expect the Action Proponents' generally short-term, intermittent, and (typically in the case of sonar) transitory activities to create conditions of long-term continuous noise leading to long-term physiological stress responses in marine mammals that could affect reproduction or survival.

Diel Cycle

Many animals perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hour cycle). Behavioral responses to noise exposure, when taking place in a biologically important context, such as disruption of critical life functions, displacement, or avoidance of important habitat, are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Henderson *et al.* (2016) found that ongoing smaller scale events had little to no impact on foraging dives for Blainville's beaked whale, while multi-day training events may decrease foraging behavior for Blainville's beaked whale (Manzano-Roth *et al.,* 2016). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multiple-day substantive behavioral responses and multiple-day anthropogenic activities. For example, just because an at-sea exercise lasts for multiple days does not necessarily mean that individual animals are either exposed to those exercises for multiple days or, further, exposed in a manner resulting in a sustained multiple day substantive behavioral response. Large multi-day Navy exercises, such as anti-submarine warfare activities, typically include vessels moving faster than while in transit (typically 10–15 kn (18.5–27.8 km/hr) or higher) and generally cover large areas that are relatively far from shore (typically more than 3 nmi (5.6 km) from shore) and in waters greater than 600 ft (182.9 m) deep. Marine mammals are moving as well, which would make it unlikely that the same animal could remain in the immediate vicinity of the ship for the entire duration of the exercise. Further, the Action Proponents do not necessarily operate active sonar the entire time during an exercise. While it is certainly possible that these sorts of exercises could overlap with individual marine mammals multiple days in a row at levels above those anticipated to result in a take, because of the factors mentioned above, it is considered unlikely for the majority of takes. However, it is also worth noting that the Action Proponents conduct many different types of noise-producing activities over the course of the year and it is likely that some marine mammals will be exposed to more than one activity and taken on multiple days, even if they are not sequential.

Durations of Navy activities utilizing tactical sonar sources and explosives vary and are fully described in chapter 2 of the 2024 HCTT Draft EIS/OEIS. Sonar used during anti-submarine warfare would impart the greatest amount of acoustic energy of any category of sonar and other transducers analyzed in the application and include hull-mounted, towed, line array, sonobuoy, helicopter dipping, and torpedo sonars. Most anti-submarine warfare sonars are MFAS (1–10 kHz); however, some sources may use higher or lower frequencies. Anti-submarine warfare training and testing activities using hull-mounted sonar proposed for the HCTT Study Area generally last for only a few hours. However, anti-submarine warfare testing activities range from several hours, to days, to more than 10 days for large integrated anti-submarine warfare MTEs (see table 2, table 3, and table 7). For these multi-day exercises there will typically be extended intervals of non-activity in between active sonar periods. Because of the need to train in a large variety of situations, the Navy conducts anti-submarine warfare activities in varying locations. Given the average length and dynamic nature of anti-submarine warfare activities (times of sonar use) and typical vessel speed, combined with the fact that the majority of the cetaceans would not likely remain in proximity to the sound source, it is unlikely that an animal would be exposed to LFAS/MFAS/HFAS at levels or durations likely to result in a substantive response that would then be carried on for more than one day or on successive days.

Most planned explosive events are instantaneous or scheduled to occur over a short duration (less than 2 hours) and the explosive component of these activities only lasts for minutes. Although explosive activities may sometimes be conducted in the same general areas repeatedly, because of their short duration and the fact that they are in the open ocean and animals can easily move away, it is similarly unlikely that animals would be exposed for long, continuous amounts of time, or demonstrate sustained behavioral responses. Although SINKEXs may last for up to 48 hours (4–8 hours typically, possibly 1–2 days), they are almost always completed in a single day and only a maximum of one event is planned annually for SOCAL and 2–3 annually in Hawaii (see table 3). They are stationary and conducted in deep, open water (where fewer marine mammals would typically be expected to be randomly encountered), and they have rigorous monitoring (see table 69) and shutdown procedures all of which make it unlikely that individuals would be exposed to the exercise for extended periods or on consecutive days, though some individuals may be exposed on multiple days.

Assessing the Number of Individuals Taken and the Likelihood of Repeated Takes

As described previously, Navy modeling uses the best available science to predict the instances of exposure above certain acoustic thresholds, which are equated, as appropriate, to harassment takes. As further noted, for active acoustics it is more challenging to parse out the number of individuals taken by Level B harassment and the number of times those individuals are taken from this larger number of instances, though factors such as movement ecology (*e.g.,* is the species resident and more likely to remain in closer proximity to ongoing activities, versus nomadic or migratory; Keen *et al.* (2021)) or whether there are known BIAs where animals are known to congregate can help inform this. One method that NMFS uses to help better understand the overall scope of the impacts is to compare these total instances of take against the abundance of that species (or stock if applicable). For example, if there are 100 harassment takes in a population of 100, one can assume either that every individual was exposed above acoustic thresholds once per year, or that some smaller number were exposed a few times per year, and a few were not exposed at all. Where the

instances of take exceed 100 percent of the population, multiple takes of some individuals are predicted and expected to occur within a year. Generally speaking, the higher the number of takes as compared to the population abundance, the more multiple takes of individuals are likely, and the higher the actual percentage of individuals in the population that are likely taken at least once in a year. We look at this comparative metric to give us a relative sense of where larger portions of the species are being taken by the Action Proponents' activities and where there is a higher likelihood that the same individuals are being taken across multiple days and where that number of days might be higher. It also provides a relative picture of the scale of impacts on each species.

In the ocean, unlike a modeling simulation with static animals, the transient nature of sonar use makes it unlikely to repeatedly expose the same individual animals within a short period, for example, within one specific exercise. However, some repeated exposures across different activities could occur over the year with more resident species. In short, we expect the total anticipated takes represent exposures of a smaller number of individuals of which some could be exposed multiple times, but based on the nature of the Action Proponents' activities and the movement patterns of marine mammals, it is unlikely that any particular subset would be taken over more than several sequential days (with a few possible exceptions discussed in the species-specific conclusions). In other cases, such as activities that overlap habitat of small and resident populations, repeated exposures of the same individuals may be more likely given the likelihood that a smaller number of animals would routinely use the affected habitat.

When calculating the proportion of a population taken (*e.g.,* the number of takes divided by population abundance), which can also be helpful in estimating the number of days over which some individuals may be taken, it is important to choose an appropriate population estimate against which to make the comparison. Herein, NMFS considers two potential abundance estimates, the SARs and the NMSDD abundance estimates. The SARs, where available, provide the official population estimate for a given species or stock in U.S. waters in a given year. These estimates are typically generated from the most recent shipboard and/or aerial surveys conducted, and in some cases, the estimates show substantial year-to-year variability. When the stock is known to range well outside of U.S. Exclusive Economic Zone (EEZ) boundaries, population estimates based on surveys conducted only within the U.S. EEZ are known to be underestimates. The NMSDD-derived abundance estimates are abundances for within the boundaries described for the density database for the California and Hawaii Study Areas only and, therefore, differ from some SAR abundance estimates. For the California Study Area, the NMSDD abundances are based on the extent of the west coast density models, which include areas off the Baja California peninsula of Mexico to the south but are truncated to the north and west of the California portion of the Study Area as shown in the Density Technical Report. For some species, the NMSDD abundances are based on density models that extend up to the northern extent of the west coast U.S. EEZ, beyond the HCTT Study Area. These are noted in the table. In some instances, even this larger extent does not cover the full range of a species or stock. For the Hawaii Study Area, the NMSDD abundances are based on a buffer around the Hawaiian island chain. Thus, island-associated species are encompassed, but abundances of wider-ranging species may be underestimated.

The SAR and NMSDD abundance estimates can differ substantially because these estimates may be based on different methods and data sources. For example, the SARs only consider data from the past 8 year period, whereas the NMSDD considers a longer data history. Further, the SARs estimate the number of animals in a population but not spatial densities. NMSDD uses predictive density models to estimate species presence, even where sighting data is limited or lacking altogether. Each density model is limited to the variables and assumptions considered by the original data source provider. NMFS considered these factors and others described in the Density Technical Report when comparing the estimated takes to current population abundances for each species or stock.

In consideration of the factors described above, to estimate repeated impacts across large areas relative to species geographic distributions, comparing the impacts predicted in NAEMO to abundances predicted using the NMSDD models is usually preferable. By comparing estimated take to the NMSDD abundance estimates, impacts and abundance estimates are based on the same underlying assumptions about a species' presence. NMFS has compared the estimated take to the NMSDD abundance estimates herein for all stocks, with the exception of stocks where the abundance information fits into one of the following scenarios, in which case NMFS concluded that comparison to the SAR abundance estimate is more appropriate: (1) a species' or stocks' range extends beyond the U.S. EEZ and the SAR abundance estimate is greater than the NMSDD abundance. For highly migratory species (*e.g.,* large whales) or those whose geographic distribution extends beyond the boundaries of the HCTT Study Area (*e.g.,* Alaska stocks), comparisons to the SAR are appropriate. Many of the stocks present in the HCTT Study Area have ranges significantly larger than the HCTT Study Area, and that abundance is captured by the SAR. Therefore, comparing the estimated takes to an abundance, in this case the SAR abundance, which represents the total population, may be more appropriate than modeled abundances for only the HCTT Study Area; and (2) when the current minimum population estimate in the SAR is greater than the NMSDD abundance, regardless of whether the stock range extends beyond the EEZ. The NMSDD and SAR abundance estimates are both included in table 89, table 91, table 93, table 95, table 97, and table 99, and each table indicates which stock abundance estimate was selected for comparison to the take estimate for each species or stock.

Temporary Threshold Shift

NMFS and the Navy have estimated that all species of marine mammals may incur some level of TTS from active sonar. As mentioned previously, in general, TTS can last from a few minutes to days, be of varying degree, and occur across various frequency bandwidths, all of which determine the severity of the impacts on the affected individual, which can range from minor to more severe. Table 41 through table 51 indicate the number of takes by TTS that may be incurred by different species from exposure to active sonar, air guns, pile driving, and explosives. The TTS incurred by an animal is primarily characterized by three characteristics:

1. Frequency—Available data suggest that most TTS occurs in the frequency range of the source up to one octave higher than the source (with the maximum TTS at ½ octave above) (Finneran 2015; Southall *et al.,* 2019). The Navy's MF anti-submarine warfare sources, which are the highest power and most numerous sources and the ones that cause the most take by TTS, utilize the 1–10 kHz frequency band, which suggests that if TTS were to be

induced by any of these MF sources it would be in a frequency band somewhere between approximately 1 and 20 kHz, which is in the range of communication calls for many odontocetes, but below the range of the echolocation signals used for foraging. There are fewer hours of HF source use and the sounds would attenuate more quickly, plus they have lower source levels, but if an animal were to incur TTS from these sources, it would cover a higher frequency range (sources are between 10 and 100 kHz, which means that TTS could range up to the highest frequencies audible to VHF cetaceans, approaching 200 kHz), which could overlap with the range in which some odontocetes communicate or echolocate. However, HF systems are typically used less frequently and for shorter time periods than surface ship and aircraft MF systems, so TTS from HF sources is less likely than from MF sources. There are fewer LF sources and the majority are used in the more readily mitigated testing environment, and TTS from LF sources would most likely occur below 2 kHz, which is in the range where many mysticetes communicate and also where other auditory cues are located (waves, snapping shrimp, fish prey). Also of note, the majority of sonar sources from which TTS may be incurred occupy a narrow frequency band, which means that the TTS incurred would also be across a narrower band (*i.e.,* not affecting the majority of an animal's hearing range).

2. Degree of the shift (*i.e.,* by how many dB the sensitivity of the hearing is reduced)—Generally, both the degree of TTS and the duration of TTS will be greater if the marine mammal is exposed to a higher level of energy (which would occur when the peak SPL is higher or the duration is longer). The threshold for the onset of TTS was discussed previously in this proposed rule. An animal would have to approach closer to the source or remain in the vicinity of the sound source appreciably longer to increase the received SEL, which would be difficult considering the Lookouts and the nominal speed of an active sonar vessel (10–15 kn (18.5–27.8 km/hr)) and the relative motion between the sonar vessel and the animal. In the TTS studies discussed in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section, some using exposures of almost an hour in duration or up to 217 SEL, most of the TTS induced was 15 dB or less, though Finneran *et al.* (2007) induced 43 dB of TTS with a 64-second exposure to a 20 kHz source measured via auditory steady-state response (auditory evoked potential measurement). The SQS–53 (MFAS) hull-mounted sonar (MF1) nominally emits a short (*i.e.,* 1-second) ping typically every 50 seconds, incurring those levels of TTS due to this source is highly unlikely. Sources with higher duty cycles, such as MF1C (high duty cycle hull-mounted sonar) produce longer ranges to effects and contribute to auditory effects from this action. Since most hull-mounted sonar, such as the SQS–53, engaged in anti-submarine warfare training would be moving at between 10 and 15 kn (18.5 to 27.8 km/hr) and nominally pinging every 50 seconds, the vessel will have traveled a minimum distance of approximately 843.2 ft (257 m) during the time between those pings. For a Navy vessel moving at a nominal 10 kn (18.5 km/hr), it is unlikely a marine mammal would track with the ship and could maintain speed parallel to the ship to receive adequate energy over successive pings to suffer TTS. In general, there is a higher potential for TTS associated with sources with higher duty cycles, like continuous hull-mounted sonars, compared to those sources that are intermittent or have lower duty cycles (Kastelein *et al.,* 2015). Though high duty cycle or continuous hull-mounted sonars make up a small percentage of the Navy's overall MFAS activities.

In short, given the anticipated duration and levels of sound exposure, we would not expect marine mammals to incur more than relatively low levels of TTS in most cases for sonar exposure. To add context to this degree of TTS, individual marine mammals may regularly experience variations of 6 dB differences in hearing sensitivity in their lifetime (Finneran *et al.,* 2000; Finneran *et al.,* 2002; Schlundt *et al.,* 2000).

3. Duration of TTS (recovery time)—As discussed in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section, TTS laboratory studies using exposures of up to an hour in duration or up to 217 dB SEL, most individuals recovered within 1 day (or less, often in minutes) (Kastelein, 2020b). One study resulted in a recovery that took 4 days (Finneran *et al.,* 2015; Southall *et al.,* 2019). However, there is evidence that repeated exposures resulting in TTS could potentially lead to residual threshold shifts that persist for longer durations and can result in PTS (Reichmuth *et al.,* 2019).

Compared to laboratory studies, marine mammals are likely to experience lower SELs from sonar used in the HCTT Study Area due to movement of the source and animals, and because of the lower duty cycles typical of higher power sources (though some of the Navy MF1C sources have higher duty cycles). Therefore, TTS resulting from MFAS would likely be of lesser magnitude and duration compared to laboratory studies. Also, for the same reasons discussed in the Preliminary Analysis and Negligible Impact Determination—Diel Cycle section, and because of the short distance between the source and animals needed to reach high SELs, it is unlikely that animals would be exposed to the levels necessary to induce TTS in subsequent time periods such that hearing recovery is impeded. Additionally, though the frequency range of TTS that marine mammals might incur would overlap with some of the frequency ranges of their vocalization types, the frequency range of TTS from MFAS would not usually span the entire frequency range of one vocalization type, much less span all types of vocalizations or other critical auditory cues.

As a general point, the majority of the TTS takes are the result of exposure to hull-mounted MFAS, with fewer from explosives (broad-band lower frequency sources), and even fewer from LFAS or HFAS sources (narrower band). As described above, we expect the majority of these takes to be in the form of mild, short-term (minutes to hours), narrower band (only affecting a portion of the animal's hearing range) TTS. This means that for one to several times per year, for several minutes, maybe a few hours, or at most in limited circumstances a few days, a taken individual will have diminished hearing sensitivity (*i.e.,* more than natural variation, but nowhere near total deafness). More often than not, such an exposure would occur within a narrower mid- to higher frequency band that may overlap part (but not all) of a communication, echolocation, or predator range, but sometimes across a lower or broader bandwidth. The significance of TTS is also related to the auditory cues that are germane within the time period that the animal incurs the TTS. For example, if an odontocete has TTS at echolocation frequencies, but incurs it at night when it is resting and not feeding, it may not be as impactful. In short, the expected results of any one of these limited number of mild TTS occurrences could be that: (1) it does not overlap signals that are pertinent to that animal in the given time period; (2) it overlaps parts of signals that are important to the animal, but not in a manner that impairs interpretation; or (3) it reduces detectability of an important signal to a small degree for a

short amount of time—in which case the animal may be aware and be able to compensate (but there may be slight energetic cost), or the animal may have some reduced opportunities (*e.g.,* to detect prey) or reduced capabilities to react with maximum effectiveness (*e.g.,* to detect a predator or navigate optimally). However, it is unlikely that individuals would experience repeated or high degree TTS overlapping in frequency and time with signals critical for behaviors that would impact overall fitness.

Auditory Masking or Communication Impairment

The ultimate potential impacts of masking on an individual (if it were to occur) are similar to those discussed for TTS, but an important difference is that masking only occurs during the time of the signal, versus TTS, which continues beyond the duration of the signal. Fundamentally, masking is referred to as a chronic effect because one of the key harmful components of masking is its duration—the fact that an animal would have reduced ability to hear or interpret critical cues becomes much more likely to cause a problem the longer it occurs. Also inherent in the concept of masking is the fact that the potential for the effect is only present during the times that the animal and the source are in close enough proximity for the effect to occur (and further, this time period would need to coincide with a time that the animal was utilizing sounds at the masked frequency). As our analysis has indicated, because of the relative movement of vessels and the sound sources primarily involved in this proposed rule, we do not expect the exposures with the potential for masking to be of a long duration.

Masking is fundamentally more of a concern at lower frequencies, because low frequency signals propagate significantly farther than higher frequencies and because they are more likely to overlap both the narrower LF calls of mysticetes, as well as many non-communication cues such as fish and invertebrate prey, and geologic sounds that inform navigation. Masking is also more of a concern from continuous sources (versus intermittent sonar signals) where there is no quiet time between pulses and detection and interpretation of auditory signals is likely more challenging. For these reasons, dense aggregations of, and long exposure to, continuous LF activity are much more of a concern for masking, whereas comparatively short-term exposure to the predominantly intermittent pulses of often narrow frequency range MFAS or HFAS, or explosions are not expected to result in a meaningful amount of masking. While the Action Proponents occasionally use LF and more continuous sources, it is not in the contemporaneous aggregate amounts that would be expected to accrue to degrees that would have the potential to affect reproductive success or survival. Additional detail is provided below.

Standard hull-mounted MFAS typically pings every 50 seconds. Some hull-mounted anti-submarine sonars can also be used in an object detection mode known as ''Kingfisher'' mode (*e.g.,* used on vessels when transiting to and from port) where pulse length is shorter but pings are much closer together in both time and space since the vessel goes slower when operating in this mode, and during which an increased likelihood of masking in the vicinity of vessel could be expected. For the majority of other sources, the pulse length is significantly shorter than hull-mounted active sonar, on the order of several microseconds to tens of milliseconds. Some of the vocalizations that many marine mammals make are less than 1 second long, so, for example with hull-mounted sonar, there would be a 1 in 50 chance (only if the source was in close enough proximity for the sound to exceed the signal that is being detected) that a single vocalization might be masked by a ping. However, when vocalizations (or series of vocalizations) are longer than the 1 second pulse of hull-mounted sonar, or when the pulses are only several microseconds long, the majority of most animals' vocalizations would not be masked.

Most anti-submarine warfare sonars and countermeasures use MF frequencies and a few use LF and HF frequencies. Most of these sonar signals are limited in the temporal, frequency, and spatial domains. The duration of most individual sounds is short, lasting up to a few seconds each. A few systems operate with higher duty cycles or nearly continuously, but they typically use lower power, which means that an animal would have to be closer, or in the vicinity for a longer time, to be masked to the same degree as by a higher level source. Nevertheless, masking could occasionally occur at closer ranges to these high-duty cycle and continuous active sonar systems, but, as described previously, it would be expected to be of a short duration. While data are lacking on behavioral responses of marine mammals to continuously active sonars, mysticete species are known to habituate to novel and continuous sounds (Nowacek *et al.,* 2004), suggesting that they are likely to have similar responses to high-duty cycle sonars. Furthermore, most of these systems are hull-mounted on surface ships with the ships moving at least 10 kn (18.5 km/hr), and it is unlikely that the ship and the marine mammal would continue to move in the same direction and the marine mammal subjected to the same exposure due to that movement. Most anti-submarine warfare activities are geographically dispersed and last for only a few hours, often with intermittent sonar use even within this period. Most anti-submarine warfare sonars also have a narrow frequency band (typically less than one-third octave). These factors reduce the likelihood of sources causing significant masking. HF signals (above 10 kHz) attenuate more rapidly in the water due to absorption than do lower frequency signals, thus producing only a very small zone of potential masking. If masking or communication impairment were to occur briefly, it would more likely be in the frequency range of MFAS (the more powerful source), which overlaps with some odontocete vocalizations (but few mysticete vocalizations); however, it would likely not mask the entirety of any particular vocalization, communication series, or other critical auditory cue, because the signal length, frequency, and duty cycle of the MFAS/HFAS signal does not perfectly resemble the characteristics of any single marine mammal species' vocalizations.

Other sources used in the Action Proponents' training and testing that are not explicitly addressed above, many of either higher frequencies (meaning that the sounds generated attenuate even closer to the source) or used less frequently, would be expected to contribute to masking over far smaller areas and/or times. For the reasons described here, any limited masking that could potentially occur would be minor and short-term.

In conclusion, masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as from vessels; however, the duration of temporal and spatial overlap with any individual animal and the spatially separated sources that the Action Proponents use would not be expected to result in more than short-term, low impact masking that would not affect reproduction or survival.

Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives

Table 41 through table 51 indicate the number of takes of each species by Level A harassment in the form of auditory injury resulting from exposure to active sonar and/or explosives is estimated to

occur, and table 54 indicates the totals across all activities. The number of takes estimated to result from auditory injury annually from sonar, air guns, and explosives for each species/stock from all activities combined ranges from 0 to 1,235 (the 1,235 is for the CA/OR/WA stock of Dall's porpoise). Thirty-two stocks have the potential to incur non-auditory injury from explosives, and the number of individuals from any given stock from all activities combined ranges from 1 to 71 (the 71 is for the CA/OR/WA stock of short-beaked common dolphin). As described previously, the Navy's model likely overestimates the number of injurious takes to some degree. Nonetheless, these Level A harassment take numbers represent the maximum number of instances in which marine mammals would be reasonably expected to incur auditory and/or non-auditory injury, and we have analyzed them accordingly.

If a marine mammal is able to approach a surface vessel within the distance necessary to incur auditory injury in spite of the mitigation measures, the likely speed of the vessel (nominally 10–15 kn (18.5–27.8 km/hr)) and relative motion of the vessel would make it very difficult for the animal to remain in range long enough to accumulate enough energy to result in more than a mild case of auditory injury. As discussed previously in relation to TTS, the likely consequences to the health of an individual that incurs auditory injury can range from mild to more serious and is dependent upon the degree of auditory injury and the frequency band associated with auditory injury. The majority of any auditory injury incurred as a result of exposure to Navy sources would be expected to be in the 2–20 kHz range (resulting from the most powerful hull-mounted sonar) and could overlap a small portion of the communication frequency range of many odontocetes, whereas other marine mammal groups have communication calls at lower frequencies. Because of the broadband nature of explosives, auditory injury incurred from exposure to explosives would occur over a lower, but wider, frequency range. Permanent loss of some degree of hearing is a normal occurrence for older animals, and many animals are able to compensate for the shift, both in old age or at younger ages as the result of stressor exposure. While a small loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale it would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival.

The Action Proponents implement mitigation measures (described in the Proposed Mitigation Measures section) during explosive activities, including delaying detonations when a marine mammal is observed in the mitigation zone. Nearly all explosive events would occur during daylight hours thereby improving the sightability of marine mammals and mitigation effectiveness. Observing for marine mammals during the explosive activities would include visual and passive acoustic detection methods (the latter when they are available and part of the activity) before the activity begins, in order to cover the mitigation zones that can range from 200 yd (183 m) to 2,500 yd (2,286 m) depending on the source (*e.g.,* explosive sonobuoy, explosive torpedo, explosive bombs), and 2.5 nmi (4.6 km) for sinking exercises (see table 60 through table 69).

The type and amount of take by Level A harassment are indicated for all species and species groups in table 89, table 91, table 93, table 95, table 97, and table 99. Generally speaking, non-auditory injuries from explosives could range from minor lung injuries (which is the most sensitive organ and first to be affected) that consist of some short-term reduction of health and fitness immediately following the injury that heals quickly and will not have any discernible long-term effects, up to more impactful permanent injuries across multiple organs that may cause health problems and negatively impact reproductive success (*i.e.,* increase the time between pregnancies or even render reproduction unlikely) but fall just short of a ''serious injury'' by virtue of the fact that the animal is not expected to die. Nonetheless, due to the Navy's mitigation and detection capabilities, we would not expect marine mammals to typically be exposed to a more severe blast located closer to the source—so the impacts likely would be less severe. In addition, most non-auditory injuries and mortalities or serious injuries are predicted for stocks with medium to large group sizes, mostly delphinids, which increases sightability. It is still difficult to evaluate how these injuries may or may not impact an animal's fitness; however, these effects are only seen in limited numbers (single digits for all but three stocks) and mostly in species of moderate, high, and very high abundances. In short, it is unlikely that any, much less all, of the limited number of injuries accrued to any one stock would result in reduced reproductive success of any individuals; even if a few injuries did result in reduced reproductive success of individuals, the status of the affected stocks are such that it would not be expected to adversely impact rates of reproduction (and auditory injury of the low severity anticipated here is not expected to affect the survival of any individual marine mammals).

Serious Injury and Mortality

NMFS is authorizing a very limited number of serious injuries or mortalities that could occur in the event of a vessel strike or as a result of marine mammal exposure to explosive detonations. We note here that the takes from potential vessel strikes or explosive exposures enumerated below could result in non-serious injury, but their worst potential outcome (*i.e.,* mortality) is analyzed for the purposes of the negligible impact determination.

The MMPA requires that PBR be estimated in SARs and that it be used in applications related to the management of take incidental to commercial fisheries (*i.e.,* the take reduction planning process described in section 118 of the MMPA and the determination of whether a stock is ''strategic'' as defined in section 3 of the MMPA). While nothing in the statute requires the application of PBR outside the management of commercial fisheries interactions with marine mammals, NMFS recognizes that as a quantitative metric, PBR may be useful as a consideration when evaluating the impacts of other human-caused activities on marine mammal stocks. Outside the commercial fishing context, and in consideration of all known human-caused mortality, PBR can help inform the potential effects of M/SI requested to be authorized under section 101(a)(5)(A) of the MMPA. As noted by NMFS and the U.S. FWS in our implementing regulations for the 1986 amendments to the MMPA (54 FR 40341, September 29, 1989), the Services consider many factors, when available, in making a negligible impact determination, including, but not limited to, the status of the species or stock relative to OSP (if known); whether the recruitment rate for the species or stock is increasing, decreasing, stable, or unknown; the size and distribution of the population; and existing impacts and environmental conditions. In this multi-factor analysis, PBR can be a useful indicator for when, and to what extent, the agency should take an especially close look at the circumstances associated with the potential mortality, along with any other factors that could influence annual rates of recruitment or survival.

Below we describe how PBR is considered in NMFS M/SI analysis. Please see the 2020 Northwest Training and Testing Final Rule (85 FR 72312, November 12, 2020) for a background discussion of PBR and how it was adopted for use authorizing incidental take under MMPA section 101(a)(5)(A) for specified activities such as the Action Proponent's training and testing in the HCTT Study Area.

When considering PBR during evaluation of effects of M/SI under MMPA section 101(a)(5)(A), we utilize a two-tiered analysis for each stock for which M/SI is proposed for authorization:

Tier 1: Compare the total human-caused average annual M/SI estimate from all sources, including the M/SI proposed for authorization from the specific activity, to PBR. If the total M/SI estimate is less than or equal to PBR, then the specific activity is considered to have a negligible impact on that stock. If the total M/SI estimate (including from the specific activity) exceeds PBR, conduct the Tier 2 analysis.

Tier 2: Evaluate the estimated M/SI from the specified activity relative to the stock's PBR. If the M/SI from the specified activity is less than or equal to 10 percent of PBR and other major sources of human-caused mortality have mitigation in place, then the individual specified activity is considered to have a negligible impact on that stock. If the estimate exceeds 10 percent of PBR, then, absent other mitigating factors, the specified activity could be considered likely to have a non-negligible impact on that stock and additional analysis is necessary.

Additional detail regarding the two tiers of the evaluation are provided below.

As indicated above, the goal of the Tier 1 assessment is to determine whether total annual human-caused mortality, including from the specified activity, would exceed PBR. To aid in the Tier 1 evaluation and get a clearer picture of the amount of annual M/SI that remains without exceeding PBR, for each species or stock, we first calculate a ''residual PBR,'' which equals PBR minus the ongoing annual human-caused M/SI (*i.e.,* Residual PBR = PBR − (annual M/SI estimate from the SAR + other M/SI authorized under section 101(a)(5)(A) of the MMPA). If the ongoing human-caused M/SI from other sources does not exceed PBR, then residual PBR is a positive number, and we consider how the proposed authorized incidental M/SI from the specified activities being evaluated compares to residual PBR using the Tier 1 framework in the following paragraph. If the ongoing anthropogenic mortality from other sources already exceeds PBR, then residual PBR is a negative number and we move to the Tier 2 discussion further below to consider the M/SI from the specific activities.

To reiterate, the Tier 1 analysis overview in the context of residual PBR, if the M/SI from the specified activity does not exceed PBR, the impacts of the authorized M/SI on the species or stock are generally considered to be negligible. As a simplifying analytical tool in the Tier 1 evaluation, we first consider whether the M/SI from the specified activities could cause incidental M/SI that is less than 10 percent of residual PBR, which we consider an ''insignificance threshold.'' If so, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI for the marine mammal stock in question that alone will clearly not adversely affect annual rates of recruitment and survival and for which additional analysis or discussion of the anticipated M/SI is not required because the negligible impact standard clearly will not be exceeded on that basis alone.

When the M/SI from the specified activity is above the insignificance threshold in the Tier 1 evaluation, it does not indicate that the M/SI associated with the specified activities is necessarily approaching a level that would exceed negligible impact. Rather, it is used as a cue to look more closely if and when the M/SI for the specified activity approaches residual PBR, as it becomes increasingly necessary (the closer the M/SI from the specified activity is to 100 percent residual PBR) to carefully consider whether there are other factors that could affect reproduction or survival, such as take by Level A and/or Level B harassment that has been predicted to impact reproduction or survival of individuals, or other considerations such as information that illustrates high uncertainty involved in the calculation of PBR for some stocks. Recognizing that the impacts of harassment of any authorized incidental take (by Level A or Level B harassment from the specified activities) would not combine with the effects of the authorized M/SI to adversely affect the stock through effects on recruitment or survival, if the proposed authorized M/SI for the specified activity is less than residual PBR, the M/SI, alone, would be considered to have a negligible impact on the species or stock. If the proposed authorized M/SI is greater than residual PBR, then the assessment should proceed to Tier 2.

For the Tier 2 evaluation, recognizing that the total annual human-caused M/SI exceeds PBR, we consider whether the incremental effects of the proposed authorized M/SI for the specified activity, specifically, would be expected to result in a negligible impact on the affected species or stocks. For the Tier 2 assessment, consideration of other factors (positive or negative), including those described above (*e.g.,* the certainty in the data underlying PBR and the impacts of any harassment authorized for the specified activity), as well as the mitigation in place to reduce M/SI from other activities is especially important to assessing the impacts of the M/SI from the specified activity on the species or stock. PBR is a conservative metric and not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. For example, in some cases stock abundance (which is one of three key inputs into the PBR calculation) is underestimated because marine mammal survey data within the U.S. EEZ are used to calculate the abundance even when the stock range extends well beyond the U.S. EEZ. An underestimate of abundance could result in an underestimate of PBR. Alternatively, we sometimes may not have complete M/SI data beyond the U.S. EEZ to compare to PBR, which could result in an overestimate of residual PBR. The accuracy and certainty around the data that feed any PBR calculation, such as the abundance estimates, must be carefully considered to evaluate whether the calculated PBR accurately reflects the circumstances of the particular stock.

As referenced above, in some cases the ongoing human-caused mortality from activities other than those being evaluated already exceeds PBR and, therefore, residual PBR is negative. In these cases, any additional mortality, no matter how small, and no matter how small relative to the mortality caused by other human activities, would result in greater exceedance of PBR. PBR is helpful in informing the analysis of the effects of mortality on a species or stock because it is important from a biological perspective to be able to consider how the total mortality in a given year may affect the population. However, section 101(a)(5)(A) of the MMPA indicates that NMFS shall authorize the requested incidental take from a specified activity if we find that ''the total of such taking [*i.e.,* from the specified activity] will have a negligible impact on such species or stock.'' In other words, the task under

the statute is to evaluate the impact of the applicant's anticipated take on the species or stock, not the impact of take by other entities. Neither the MMPA nor NMFS' implementing regulations call for consideration of other unrelated activities and their impacts on the species or stock.

Accordingly, we may find that the impacts of the taking from the specified activity may (alone) be negligible even when total human-caused mortality from all activities exceeds PBR (in the context of a particular species or stock). Specifically, where the authorized M/SI would be less than or equal to 10 percent of PBR and management measures are being taken to address M/SI from the other contributing activities (*i.e.,* other than the specified activities covered by the incidental take authorization under consideration), the impacts of the authorized M/SI would be considered negligible. In addition, we must also still determine that any impacts on the species or stock from other types of take (*i.e.,* harassment) caused by the applicant do not combine with the impacts from mortality or serious injury addressed here to result in adverse effects on the species or stock through effects on annual rates of recruitment or survival.

As noted above, while PBR is useful in informing the evaluation of the effects of M/SI in MMPA section 101(a)(5)(A) determinations, it is one consideration to be assessed in combination with other factors and is not determinative. For example, as explained above, the accuracy and certainty of the data used to calculate PBR for the species or stock must be considered. And we reiterate the considerations discussed above for why it is not appropriate to consider PBR an absolute cap in the application of this guidance. Accordingly, we use PBR as a trigger for concern while also considering other relevant factors to provide a reasonable and appropriate means of evaluating the effects of potential mortality on rates of recruitment and survival, while acknowledging that it is possible for total human-caused M/SI to exceed PBR (or for the M/SI from the specified activity to exceed 10 percent of PBR in the case where other human-caused mortality is exceeding PBR, as described in the last paragraph) by some small amount and still make a negligible impact determination under MMPA section 101(a)(5)(A).

We note that on June 17, 2020, NMFS finalized Procedure 02–204–02, Criteria for Determining Negligible Impact under MMPA section 101(a)(5)(E) (see *https://www.fisheries.noaa.gov/national/laws-policies/protected-resources-policy-directives*). The guidance explicitly notes the differences in the negligible impact determinations required under section 101(a)(5)(E), as compared to sections 101(a)(5)(A) and 101(a)(5)(D), and specifies that the procedure in that document is limited to how the agency conducts negligible impact analyses for commercial fisheries under section 101(a)(5)(E). In this proposed rule, NMFS has described its method for considering PBR to evaluate the effects of potential mortality in the negligible impact analysis. NMFS has reviewed the 2020 guidance and determined that our consideration of PBR in the evaluation of mortality as described above and in the proposed rule remains appropriate for use in the negligible impact analysis for the Action proponent's activities under section 101(a)(5)(A).

Our evaluation of the M/SI for each of the species and stocks for which mortality or serious injury could occur follows.

We first consider maximum potential incidental M/SI from the vessel strike analysis for the affected large whales (table 87) and from the Action Proponents' explosive detonations for the affected small cetaceans and pinnipeds (table 88) in consideration of NMFS' threshold for identifying insignificant M/SI take. By considering the maximum potential incidental M/SI in relation to PBR and ongoing sources of anthropogenic mortality, as described above, we begin our evaluation of whether the potential incremental addition of M/SI through vessel strikes and explosive detonations may affect the species' or stocks' annual rates of recruitment or survival. We also consider the interaction of those mortalities with incidental taking of that species or stock by harassment pursuant to the specified activity.

Based on the methods discussed previously, NMFS is proposing to authorize seven mortalities of large whales due to vessel strike over the course of the 7-year rule, five by the Navy and two by the Coast Guard (table 87). Across the 7-year duration of the rule, four takes by mortality (annual average of 0.57 takes) of fin whale (CA/OR/WA stock) could occur and are proposed for authorization; three takes by mortality (annual average of 0.43 takes) of gray whale (Eastern North Pacific stock) and humpback whale (Hawaii stock) could occur and are proposed for authorization; two takes by mortality (annual average of 0.29 takes) of blue whale (Eastern North Pacific stock), sei whale (Eastern North Pacific), and humpback whale (Mainland Mexico-CA/OR/WA and Central America/Southern Mexico-CA/OR/WA stocks (Mexico and Central America DPSs, respectively)) could occur and are proposed for authorization; one take by mortality (annual average of 0.14 takes) of the Hawaii stock of sperm whale could occur and is proposed for authorization. To calculate the annual average of M/SI by vessel strike, we divided the 7-year proposed take by serious injury or mortality by seven.

TABLE 87—SUMMARY INFORMATION RELATED TO MORTALITIES REQUESTED FOR VESSEL STRIKE, 2025–2032

Common name	Stock	Stock abundance	Total annual M/SI [a]	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions	Annual M/SI due to vessel collision	NWTT authorized take (annual)	Potential biological removal (PBR)	Residual PBR (PBR minus annual M/SI)	Recent UME (Y/N); number of strandings, year declared (since 2014)	Annual proposed authorized take (Navy)	7-Year proposed authorized take (Navy)	Annual proposed authorized take (Coast Guard)	7-Year proposed authorized take (Coast Guard)	Total annual proposed authorized take	Total 7-year proposed authorized take
Blue whale	Eastern North Pacific*.	3,233	≥18.6	Y; ≥0.61	0.6	0	4.1	−14.5	N	0.14	1	0.14	1	0.29	2
Fin whale	California/Oregon/Washington*.	12,304	≥43.4	Y; ≥0.41	6.45	0.29	80	36.31	N	0.43	3	0.14	1	0.57	4
Humpback whale ..	Mainland Mexico—California-Oregon-Washington* [b].	3,741	22	Y; 11.4	2.6	0.29 b	43	20.71	N	0.14	1	0.14	1	0.29	2
Humpback whale ..	Central America/Southern Mexico—California-Oregon-Washington* [c].	1,603	14.9	Y; 8.1	6.45	0.29 c	3.5	−11.69	N	0.14	1	0.14	1	0.29	2
Sperm whale	Hawai'iHawai'i*	6,062	0	N; 0	UNK	0	18	18	N	0.14	1	0.00	0	0.14	1
Gray whale	Eastern North Pacific.	26,960	131	Y; 9.3	1.8	0.14	801	669.86	Y; 690; 2019	0.29	2	0.14	1	0.43	3
Humpback whale ..	Hawai'i [b]	11,278	27.09	Y; 8.39	5.4	0.29 b	127	99.62	Y; 52; 2015	0.29	2	0.14	1	0.43	3
Sei whale	Eastern North Pacific.	864	0	Unk	0	0	1.25	1.25	N	0.14	1	0.14	1	0.29	2

Note: Unk = Unknown. N/A = Not Applicable. NMFS is proposing to authorize seven takes by serious injury or mortality by vessel strike total across the 7-year duration of the proposed rule, five takes by the Navy and two takes by the Coast Guard.

* Stock abundance from NMSDD.

[a] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock as indicated in the SAR and includes M/SI from fisheries interactions and other sources.

[b] In 2022, the Central North Pacific stock of humpback whale was split into the Mainland Mexico-California-Oregon-Washington and Hawaii stocks. The 2020 NWTT final rule (85 FR 72312, November 12, 2020) authorized two takes of the Central North Pacific stock. Given the stock structure change, NMFS has assumed that the two strikes could occur to either the Mainland Mexico—CA/OR/WA stock or the Hawaii stock.

[c] The 2020 NWTT final rule (85 FR 72312, November 12, 2020) authorized two takes of the CA/OR/WA stock of humpback whale. Given the stock structure change, NMFS has assumed that the two strikes could occur to the Central America/Southern Mexico- CA/OR/WA stock.

The Action Proponents also requested a limited number of takes by M/SI from explosives. Across the 7-year duration of the rule, NMFS is proposing to authorize 107 takes by M/SI (annual average of 15.29 takes) of short-beaked common dolphin (CA/OR/WA stock), 27 takes by M/SI (annual average of 3.86 takes) of California sea lion (U.S. stock), 17 takes by M/SI (annual average of 2.43 takes) of long-beaked common dolphin (California stock), 7 takes by M/SI (annual average of 1 take) of harbor seal (California stock), 4 takes by M/SI (annual average of 0.57 takes) of short-finned pilot whale (CA/OR/WA stock), 2 takes by M/SI (annual average of 0.29 takes) of bottlenose dolphin (Hawaii pelagic stock), Pacific white-sided dolphin (CA/OR/WA stock), pantropical spotted dolphin (Baja California Peninsula Mexico population), and rough-toothed dolphin (Hawaii stock), and 1 take by M/SI (annual average of 0.14 takes) of bottlenose dolphin (Oʻahu stock), Northern right whale dolphin (CA/OR/WA stock), striped dolphin (CA/OR/WA stock), and Guadalupe fur seal (Mexico stock) (table 88). To calculate the annual average of M/SI from explosives, we divided the 7-year proposed take by serious injury or mortality by seven (table 88), the same method described for vessel strikes.

TABLE 88—SUMMARY INFORMATION RELATED TO HCTT SERIOUS INJURY OR MORTALITY FROM EXPLOSIVES
[2025–2032]

Species	Stock	Stock abundance	Total annual M/SI [a]	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions	SWFSC authorized take (annual) [b]	NWTT authorized take (annual) [b]	PBR	Residual PBR (PBR minus annual M/SI) [c]	Recent UME (Y/N); number of strandings, year declared (since 2014)	Annual proposed take by serious injury or mortality (all action proponents) [d]	7-Year proposed take by serious injury or mortality (all action proponents)	Population trend
Short-finned pilot whale.	California/Oregon/Washington.	836	1.2	Y; 1.2	0.40	0	4.5	2.90	N	0.57	4	Unk.
Bottlenose dolphin	Hawaii Pelagic*	25,120	0	N; 0	0	0	158	158	N	0.29	2	Unk.
Bottlenose dolphin	O'ahu*	113	Unk	Unk	0	0	1	Unk	N	0.14	1	Unk.
Long-beaked common dolphin.	California*	209,100	≥29.7	Y; ≥26.5	2.8	0	668	635.5	N	2.43	17	Unk.
Northern right whale dolphin.	California/Oregon/Washington*.	68,935	≥6.6	Y; ≥6.6	2.20	0	163	154.20	N	0.14	1	Unk.
Pacific white-sided dolphin.	California/Oregon/Washington*.	107,775	7	Y; 4	[c] 8.2	0	279	263.8	N	0.29	2	Unk.
Pantropical spotted dolphin.	Baja California Peninsula Mexico*.	70,889	Unk	Unk	0	0	Unk	Unk	N	0.29	2	Unk.
Rough-toothed dolphin	Hawaii*	106,193	3.2	Y; 3.2	0	0	511	507.8	N	0.29	2	Unk.
Short-beaked common dolphin.	California/Oregon/Washington*.	1,049,117	≥30.5	Y; ≥30.5	2.8	0	8,889	8,856	N	15.29	107	Unk, possibly increasing.
Striped dolphin	California/Oregon/Washington*.	160,551	≥4	Y; ≥4.0	2.8	0	225	218.2	N	0.14	1	Unk.
California sea lion	U.S.	257,606	>321	Y; ≥197	6	0	14,011	13,684	N	3.86	27	Stable.
Guadalupe fur seal	Mexico	63,850	≥10.0	Y; ≥7.2	0	0	1,959	1,949	Y; 715; 2015	0.14	1	Increasing.
Harbor seal	California	30,968	43	Y; 30	[d] 2.8	0	1,641	1,595	N	1	7	Decreasing.

Note: Unk = Unknown.
*Stock abundance from NMSDD.
[a] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock as indicated in the SAR and includes M/SI from fisheries interactions and other sources.
[b] These columns represents the annual authorized take by mortality in the 2021 LOA for Southwest Fisheries Science Center (SWFSC) Fisheries and Ecosystem Research Activities and the 2020 LOAs for U.S. Navy Northwest Training and Testing (NWTT) Study Area.
[c] The SWFSC final rule (86 FR 3840, January 15, 2021) authorizes 41 takes by M/SI of Pacific white-sided dolphin over the 5-year duration of the final rule (*i.e.,* 8.2 annually). These takes could be of multiple stocks; however, NMFS has conservatively assumed that all of the takes would occur to the CA/OR/WA stock.
[d] The SWFSC final rule (86 FR 3840, January 15, 2021) authorizes 14 takes by M/SI of harbor seals over the 5-year duration of the final rule (*i.e.,* 2.8 annually). These takes could be of multiple stocks; however, NMFS has conservatively assumed that all of the takes would occur to the California stock.

As described above, NMFS M/SI analysis includes two Tiers and our discussion is organized into sections that mirror that framework, as applicable. Specifically, we standardly first address stocks analyzed within Tier 1 (*i.e.,* those for which total known human-caused M/SI is below PBR (*i.e.,* the M/SI from the specified activity is below residual PBR)), considering those with proposed M/SI both below and above the insignificance threshold. Then, if applicable, we discuss stocks for which total mortality exceeds PBR in a Tier 2 analysis in which we compare the proposed M/SI of the specified activity alone against PBR and consider other factors as necessary. Of note, for some stocks total M/SI is not known, in which case a Tier 1 analysis is not possible and, therefore, we move directly to a Tier 2 analysis. In rare cases, PBR itself cannot be calculated, in which case we consider other known factors and/or surrogate stocks to inform the NID analysis.

Stocks With Total Average Annual Human-Caused M/SI Below PBR (Tier 1) and Proposed M/SI Is Below the Insignificance Threshold—

As noted above, for a species or stock with M/SI proposed for authorization less than 10 percent of residual PBR, we consider M/SI from the specified activities to represent a clearly insignificant incremental increase in ongoing anthropogenic M/SI that alone (*i.e.,* in the absence of any other take and barring any other unusual circumstances) will clearly not adversely affect annual rates of recruitment and survival. In this case, as shown in table 87 and table 88, the following species or stocks have potential or estimated take by M/SI from vessel strike and explosives, respectively, and proposed for authorization below their insignificance threshold: fin whale (CA/OR/WA stock); humpback whale (Mainland Mexico-CA/OR/WA and Hawaii stocks); gray whale (Eastern North Pacific stock); sperm whale (Hawaii stock); bottlenose dolphin (Hawaii pelagic stock); long-beaked common dolphin (California stock); northern right whale dolphin (CA/OR/WA stock); Pacific white-sided dolphin (CA/OR/WA stock); rough-toothed dolphin (Hawaii stock); short-beaked common dolphin (CA/OR/WA stock); striped dolphin (CA/OR/WA stock); California sea lion (U.S. stock); Guadalupe fur seal (Mexico stock); and harbor seal (California stock). For the stocks with authorized M/SI below the insignificance threshold, there are no other known factors, information, or unusual circumstances that indicate anticipated M/SI below the insignificance threshold could have adverse effects on annual rates of recruitment or survival and they are not discussed further.

Stocks With Total Average Annual Human-Caused M/SI Below PBR (Tier 1) and Proposed Authorized M/SI Is Above the Insignificance Threshold—

Sei Whale (Eastern North Pacific Stock)

For sei whales (Eastern North Pacific stock), PBR is currently set at 1.25. The total annual M/SI is 0, yielding a residual PBR of 1.25. NMFS is proposing to authorize one M/SI for the Navy and one for the Coast Guard over the 7-year duration of the rule (two total; indicated as 0.29 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival), which leaves a PBR remainder of 0.96.

As described above, if the total M/SI estimate is less than or equal to PBR, which is the case here, then the specific activity is considered to have a negligible impact on that stock. Although the M/SI from take proposed here for the specified activity is above the insignificance threshold, as described above, that does not indicate that the M/SI associated with the specified activities is necessarily approaching a level that would exceed negligible impact. Rather, it is used as a cue to look more closely if and when the M/SI for the specified activity approaches residual PBR, as it becomes increasingly necessary (the closer the M/SI from the specified activity is to 100 percent residual PBR) to carefully consider whether there are other factors that could affect reproduction or survival. Here, the M/SI is not closely approaching residual PBR (PBR remainder is 0.96) and there are no other factors that would suggest that the authorized mortality (alone) would have more than a negligible impact on this stock.

As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

Additionally of note, management measures are in place to address M/SI caused by other activities. The Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around the Vessel Speed Reduction (VSR) zones and the Channel Islands NMS region. The seasonally established Southern California VSR zone spans from Point Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from May 1 through December 15, 2025 are recommended to exercise caution and voluntarily reduce speed to 10 kn (18.5 km per hour) or less. While the VSR zone is aimed at reducing risk of fatal vessel strike of blue, humpback, and fin whales, this measure is also anticipated to reduce risk to sei whales (note, this is an expanded timeframe from the Whale Advisory Zone discussed in the 2020 HSTT final rule, which spanned June through November, though the effective period could change in future years). Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and U.S. Navy chartered aircraft. Information on seasonal presence, movement, and general distribution patterns of large whales is shared with mariners, NMFS Office of Protected Resources, U.S. Coast Guard, California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of Southern California, and whale scientists. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database.

As stated in the 2023 SAR, the California swordfish drift gillnet fishery is the most likely U.S. fishery to interact with Eastern North Pacific sei whales, though there are zero estimated annual takes from this fishery given no observed entanglements from 1990–2021 across 9,246 observed fishing sets (Carretta *et al.* (2022)). NMFS established the Pacific Offshore Cetacean Take Reduction Team (POCTRT) in 1996 and prepared an associated Plan to reduce the risk of M/SI via fisheries interactions incidental to the California/Oregon thresher shark/swordfish drift gillnet fishery. In 1997, NMFS published final regulations formalizing the requirements of the Plan, including the use of pingers following several specific provisions and the employment of Skipper education workshops. While the POCTRT is still active, the fishery is expected to be phased out entirely by 2027 following passage of the Driftnet Modernization and Bycatch Reduction Act by the U.S. Congress in 2022. As such, within 2 years of the effective period of this proposed rule, NMFS

does not anticipate mortality from this fishery.

Short-Finned Pilot Whale (CA/OR/WA Stock)

For the CA/OR/WA stock of short-finned pilot whale, PBR is currently set at 4.5, the total annual M/SI is estimated at 1.2, and the total annual authorized take from SWFSC Fisheries and Ecosystem Research Activities in the California Current is 0.4, yielding a residual PBR of 2.9. NMFS is proposing to authorize four M/SIs (U.S. Navy only) over the 7-year duration of the rule (indicated as 0.57 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival), which leaves a PBR remainder of 2.33.

As described above, if the total M/SI estimate is less than or equal to PBR, which is the case here, then the specific activity is considered to have a negligible impact on that stock. Although the M/SI from take proposed here for the specified activity is above the insignificance threshold, as described above, that does not indicate that the M/SI associated with the specified activities is necessarily approaching a level that would exceed negligible impact. Rather, it is used as a cue to look more closely if and when the M/SI for the specified activity approaches residual PBR, as it becomes increasingly necessary (the closer the M/SI from the specified activity is to 100 percent residual PBR) to carefully consider whether there are other factors that could affect reproduction or survival. Here, the M/SI is not closely approaching residual PBR (PBR remainder is 2.33) and there are no other factors that would suggest that the authorized mortality (alone) would have more than a negligible impact on this stock.

As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

As reported in the SAR, the total annual M/SI of this stock (1.2) is from the CA/OR thresher shark/swordfish drift gillnet fishery. NMFS established the POCTRT in 1996 and prepared an associated Plan to reduce the risk of M/SI via fisheries interactions incidental to the California/Oregon thresher shark/swordfish drift gillnet fishery. In 1997, NMFS published final regulations formalizing the requirements of the Plan, including the use of pingers following several specific provisions and the employment of Skipper education workshops. While the POCTRT is still active, the fishery is expected to be phased out entirely by 2027 following passage of the Driftnet Modernization and Bycatch Reduction Act by the U.S. Congress in 2022. As such, within 2 years of the effective period of this proposed rule, NMFS does not anticipate additional mortality from this fishery.

Stocks With Total Average Annual Human-Caused Mortality Above PBR (Tier 2)—

Blue Whale (Eastern North Pacific Stock)

For blue whales (Eastern North Pacific stock), PBR is currently set at 4.1 and the total annual M/SI is estimated at greater than or equal to 18.6, yielding a residual PBR of −14.5. NMFS is proposing to authorize one M/SI for the Navy and one for the Coast Guard over the 7-year duration of the rule (two total; indicated as 0.29 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival), which leaves a PBR remainder of −14.79. However, given that the negligible impact determination is based on the assessment of take of the activity being analyzed, when total annual mortality from human activities is higher, but the impacts from the specific activity being analyzed are very small, NMFS may still find the incremental impact of the authorized take from a specified activity is negligible even if total human-caused mortality exceeds PBR. Specifically, for example, if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.,* other than the specified activities covered by the incidental take authorization in consideration). When those considerations are applied here, the lethal take proposed for authorization (0.29 annually) of blue whales from the Eastern North Pacific stock is less than 10 percent of PBR (which is 4.1), and there are management measures in place to address M/SI from activities other than those the Action Proponents are conducting (as discussed below). Immediately below, we explain the information that supports our finding that the Action Proponents' M/SI proposed for authorization is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

The 2018 draft SAR and the more recent SARs incorporate a method to estimate annual deaths by vessel strike utilizing an encounter theory model that combined species distribution models of whale density, vessel traffic characteristics, and whale movement patterns obtained from satellite-tagged animals in the region to estimate encounters that would result in mortality (Rockwood *et al.* 2017). The model predicts 18 annual mortalities of blue whales from vessel strikes, which, with the additional M/SI of 1.54 from fisheries interactions, results in the current estimate of residual PBR being −15.4. Although NMFS' Permits and Conservation Division in the Office of Protected Resources has independently reviewed the vessel strike model and its results and agrees that it is appropriate for estimating blue whale mortality by vessel strike on the U.S. West Coast, for analytical purposes we also note that if the historical method were used to predict vessel strike (*i.e.,* using observed mortality by vessel strike, or 0.6, instead of 18), then total human-caused mortality including the Action Proponents' potential take would not exceed PBR. We further note that the authors (Rockwood *et al.* 2017) do not suggest that vessel strike suddenly increased to 18 recently. In fact, the model is not specific to a year, but rather offers a generalized prediction of vessel strike off the U.S. West Coast. Therefore, if the Rockwood *et al.* (2017) model is an accurate representation of vessel strike, then similar levels of vessel strike have been occurring in past years as well. Put another way, if the model is correct, for some number of years total-human-caused mortality has been significantly underestimated and PBR has been similarly exceeded by a notable amount, and yet, the Eastern North Pacific stock of blue whales remains stable, nevertheless.

NMFS' 2023 SAR states that the current population trend is unknown, though there may be evidence of a population size increase since the 1990s. The SAR further cites to Monnahan *et al.* (2015), which used a population dynamics model to estimate that the Eastern North Pacific blue whale population was at 97 percent of carrying capacity in 2013 and to suggest

that the observed lack of a population increase since the early 1990s was explained by density dependence, not impacts from vessel strike. This would mean that this stock of blue whales shows signs of stability and is not increasing in population size because the population size is at or nearing carrying capacity for its available habitat. In fact, we note that this population has maintained this status throughout the years that the Navy has consistently tested and trained at similar levels (with similar vessel traffic) in areas that overlap with blue whale occurrence, which would be another indicator of population stability.

Monnahan *et al.* (2015) modeled vessel numbers, vessel strikes, and the population of the Eastern North Pacific blue whale population from 1905 out to 2050 using a Bayesian framework to incorporate informative biological information and assign probability distributions to parameters and derived quantities of interest. The authors tested multiple scenarios with differing assumptions, incorporated uncertainty, and further tested the sensitivity of multiple variables. Their results indicated that there is no immediate threat (*i.e.,* through 2050) to the population from any of the scenarios tested, which included models with 10 and 35 strike mortalities per year. Broadly, the authors concluded that, unlike other blue whale stocks, the Eastern North Pacific blue whales have recovered from 70 years of whaling and are in no immediate threat from vessel strikes. They further noted that their conclusion conflicts with the depleted and strategic designation under the MMPA as well as PBR specifically.

As discussed, we also take into consideration management measures in place to address M/SI caused by other activities. The Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around the VSR zones and the Channel Islands NMS region. Redfern *et al.* (2013) note that the most risky area for blue whales is the Santa Barbara Channel, where shipping lanes intersect with common feeding areas. The seasonally established Southern California VSR zone spans from Point Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from May 1 through December 15, 2025 are recommended to exercise caution and voluntarily reduce speed to 10 kn (18.5 km per hour) or less for blue, humpback, and fin whales. Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and U.S. Navy chartered aircraft. Information on seasonal presence, movement, and general distribution patterns of large whales is shared with mariners, NMFS Office of Protected Resources, U.S. Coast Guard, California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of Southern California, and whale scientists. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database. In addition to management measures for vessel strike, NMFS is in the process of developing a new Take Reduction Team to address the incidental M/SI of humpback and blue whales in several trap/pot fisheries along the West Coast of the U.S. The Team is expected to be in place by November 30, 2025. Additional information is available on NMFS' website at: *https://www.fisheries.noaa.gov/west-coast/marine-mammal-protection/west-coast-take-reduction-team*

The loss of a male would have far less, if any, effect on population rates and, absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that each of the two strikes proposed for authorization by this proposed rulemaking would be a male, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the likely absence of M/SI in 5 or 6 of the 7 years and the fact that each of the strikes could be a male.

Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. As noted above, Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that ''[e]stimating incidental mortality in 1 year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated.'' The information included here indicates that the current population trend of this blue whale stock is unknown but likely approaching carrying capacity and has leveled off because of density-dependence, not human-caused mortality, in spite of what might be otherwise indicated from the calculated PBR. Further, potential M/SI proposed for authorization is below 10 percent of PBR and management actions are in place to minimize vessel strike from other vessel activity in one of the highest-risk areas for strikes. Based on the presence of the factors described above, we do not expect lethal take from Action Proponents' activities, alone, to adversely affect Eastern North Pacific blue whales through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality exceeds PBR necessitates close attention to the remainder of the impacts (*i.e.,* harassment) on the Eastern North Pacific stock of blue whales from the Navy's activities to ensure that the total takes proposed for authorization have a negligible impact on the species or stock. Therefore, this information will be considered in combination with our assessment of the impacts of harassment takes proposed for authorization in the *Group and Species-Specific Analyses* section that follows.

Humpback Whale (Central America/Southern Mexico CA/OR/WA Stock)

For humpback whales (Central America/Southern Mexico CA/OR/WA stock), PBR is currently set at 3.5, the total annual M/SI is estimated at greater than or equal to 14.9, and the 2020 NWTT final rule authorizes 0.29 takes by mortality annually, yielding a residual PBR of −11.69. NMFS is proposing to authorize one M/SI for the Navy and one for the Coast Guard over the 7-year duration of the rule (two total; indicated as 0.29 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival), which leaves a PBR remainder of −11.98.

However, given that the negligible impact determination is based on the assessment of take of the activity being analyzed, when total annual mortality from human activities is higher, but the impacts from the specific activity being analyzed are very small, NMFS may still find the incremental impact of the authorized take from a specified activity is negligible even if total human-caused mortality exceeds PBR. Specifically, for example, if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.,* other than the specified activities covered by the incidental take authorization in consideration). When those

considerations are applied here, the lethal take proposed for authorization (0.29 annually) of humpback whales from the Central America/Southern Mexico CA/OR/WA stock is less than 10 percent of PBR (which is 3.5), and there are management measures in place to address M/SI from activities other than those the Action Proponents are conducting (as discussed below). Immediately below, we explain the information that supports our finding that the Action Proponents' M/SI proposed for authorization is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

The 2018 draft SAR and the more recent SARs rely on a new method to estimate annual deaths by vessel strike utilizing an encounter theory model that combined species distribution models of whale density, vessel traffic characteristics, and whale movement patterns obtained from satellite-tagged animals in the region to estimate encounters that would result in mortality (Rockwood *et al.* 2017). The model predicts 22 annual mortalities of humpback whales from vessel strikes, and the SAR attributes 6.45 of those strikes to the Central America/Southern Mexico-CA/OR/WA stock. With the additional M/SI of 8.1 from fisheries interactions, 0.35 from marine debris, recreational, and tribal fisheries, and 0.29 from vessel strike authorized in the NWTT final rule, results in the current estimate of residual PBR being −11.69. Although NMFS' Permits and Conservation Division in the Office of Protected Resources has independently reviewed the vessel strike model and its results and agrees that it is appropriate for estimating humpback whale mortality by vessel strike on the U.S. West Coast, for analytical purposes we also note that if the historical method were used to predict vessel strike (*i.e.,* using observed mortality by vessel strike, or 0.6, instead of 18), then total human-caused mortality including the Action Proponents' potential take would not exceed PBR. We further note that the authors (Rockwood *et al.* 2017) do not suggest that vessel strike suddenly increased to 22 recently. In fact, the model is not specific to a year, but rather offers a generalized prediction of vessel strike off the U.S. West Coast. Therefore, if the Rockwood *et al.* (2017) model is an accurate representation of vessel strike, then similar levels of vessel strike have been occurring in past years as well. Put another way, if the model is correct, for some number of years total-human-caused mortality has been significantly underestimated and PBR has been similarly exceeded by a notable amount, and yet, the Central America/Southern Mexico-CA/OR/WA stock of humpback whales is increasing nevertheless.

As discussed, we also take into consideration management measures in place to address M/SI caused by other activities. The Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around the VSR zones and the Channel Islands NMS region. The seasonally established Southern California VSR zone spans from Point Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from May 1 through December 15, 2025 are recommended to exercise caution and voluntarily reduce speed to 10 kn (18.5 km per hour) or less for blue, humpback, and fin whales. Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and U.S. Navy chartered aircraft. Information on seasonal presence, movement, and general distribution patterns of large whales is shared with mariners, NMFS Office of Protected Resources, U.S. Coast Guard, California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of Southern California, and whale scientists. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database. In addition to management measures for vessel strike, NMFS is in the process of developing a new Take Reduction Team to address the incidental M/SI of humpback and blue whales in several trap/pot fisheries along the West Coast of the U.S. The Team is expected to be in place by November 30, 2025. Additional information is available on NMFS' website at: *https://www.fisheries.noaa.gov/west-coast/marine-mammal-protection/west-coast-take-reduction-team.*

The loss of a male would have far less, if any, effect on population rates and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that each of the two strikes proposed for authorization by this proposed rulemaking would be a male, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the likely absence of M/SI in 5 or 6 of the 7 years and the fact that each of the strikes could be a male.

Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. As noted above, Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that ''[e]stimating incidental mortality in 1 year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated.'' Further, potential M/SI proposed for authorization is below 10 percent of PBR and management actions are in place to minimize vessel strike from other vessel activity and efforts are underway to minimize M/SI from trap/pot fisheries along the U.S. West Coast. Based on the presence of the factors described above, we do not expect lethal take from Action Proponents' activities, alone, to adversely affect Central America/Southern Mexico-CA/OR/WA humpback whales through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality exceeds PBR necessitates close attention to the remainder of the impacts (*i.e.,* harassment) on the Central America/Southern Mexico-CA/OR/WA stock of humpback whales from the Action Proponents' activities to ensure that the total takes proposed for authorization have a negligible impact on the species or stock. Therefore, this information will be considered in combination with our assessment of the impacts of harassment takes proposed for authorization in the *Group and Species-Specific Analyses* section that follows.

Stocks for Which Total Average Annual Mortality Is Not Known—

Bottlenose Dolphin (O'ahu Stock)

For bottlenose dolphin (O'ahu stock), PBR is currently set at 1. The total annual M/SI is unknown, and therefore a residual PBR cannot be calculated. NMFS is proposing to authorize one M/SI over the 7-year duration of the rule

(indicated as 0.14 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival).

Given that the negligible impact determination is based on the assessment of take of the activity being analyzed, even if total annual mortality from human activities is higher, but the impacts from the specific activity being analyzed are very small, NMFS may still find the incremental impact of the authorized take from a specified activity is to be negligible even if total human-caused mortality exceeds PBR. As such, the incremental impact of the authorized take from a specified activity may also be negligible where total annual M/SI is unknown. An unknown total annual M/SI is a cue to look more closely if and when the M/SI for the specified activity approaches PBR (*e.g.,* consider whether there are mitigation measures in place for other potential sources of M/SI), as it becomes increasingly necessary (the closer the M/SI from the specified activity is to PBR) to carefully consider whether there are other factors that could affect reproduction or survival. Here, the M/SI proposed for authorization is 0.14 annually, which does not closely approach PBR (PBR is 1.0), there are management measures in place to address M/SI from activities other than those the Action Proponents are conducting (as discussed below), and there are no other factors that would suggest that the authorized mortality (alone) would have more than a negligible impact on this stock. Immediately below, we explain the information that supports our finding that the Action Proponents' M/SI proposed for authorization is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

As reported in the SAR, while information about fishery-related mortality is limited for this stock, Hawaii fisheries use gear types that cause mortality and serious injury to marine mammals in other U.S. fisheries, including gillnets and hook-and-line, and mortality reports indicate that nearshore fisheries are a risk for bottlenose dolphins in Hawaii. However, gillnetting around Maui and much of O'ahu is banned by state regulation, and in areas where gillnetting is permitted, fishermen are required to monitor their gillnets for bycatch every 30 minutes.

In this case, 0.14 M/SI means one mortality in 1 of the 7 years and zero mortalities in 6 of those 7 years. Therefore, the Action Proponents would not be contributing to the total human-caused mortality at all in 6 of the 7, or 85.7 percent, of the years covered by this proposed rulemaking. That means that even if an O'ahu bottlenose dolphin were to be lethally taken from explosives, in 6 of the 7 years, there could be no effect on annual rates of recruitment or survival from Navy-caused M/SI. Additionally, the loss of a male would have far less, if any, effect on population rates and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that the single mortality proposed for authorization by this proposed rulemaking would be a male, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of M/SI in 6 of the 7 years and the fact that the single mortality could be a male. Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. This is especially important given the minor difference between zero and one across the 7-year period covered by this proposed rulemaking, which is the smallest distinction possible when considering mortality. As noted above, Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that ''[e]stimating incidental mortality in 1 year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated.'' Further, management actions are in place that minimize fishery interactions. Based on the presence of the factors described above, we do not expect lethal take from the Action Proponents' activities, alone, to adversely affect O'ahu bottlenose dolphins through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality is unknown, and PBR is low, necessitates close attention to the remainder of the impacts (*i.e.,* harassment) on the O'ahu stock of bottlenose dolphins from the Action Proponents' activities to ensure that the total takes proposed for authorization have a negligible impact on the species or stock. Therefore, this information will be considered in combination with our assessment of the impacts of authorized harassment takes in the *Group and Species-Specific Analyses* section that follows.

Stocks for Which PBR Is Unknown—

Pantropical Spotted Dolphin (Baja California Peninsula Mexico Population)

The Baja California Peninsula Mexico population of pantropical spotted dolphins are not a NMFS-managed stock, and therefore, PBR and annual M/SI metrics are not available. NMFS is proposing to authorize two M/SIs over the 7-year duration of the rule (indicated as 0.29 annually for the purposes of evaluating overall effects on annual rates of recruitment and survival).

Immediately below, we explain the information that supports our finding that the Action Proponents' M/SI proposed for authorization is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

Given that this is not a NMFS-managed stock, some metrics are not available for this population, including PBR. PBR values are calculated by NMFS as the level of annual removal from a stock that will allow that stock to equilibrate within OSP at least 95 percent of the time, and is the product of factors relating to the minimum population estimate of the stock (N_{min}), the productivity rate of the stock at a small population size, and a recovery factor. The productivity rate is estimated as one-half of the estimated or theoretical maximum rate of population growth for the stock if it were small. In this case, NMFS estimates the productivity rate to be one half the default maximum net growth rate for cetaceans (one half of 4 percent). Recovery factors range from 0.1 to 1, with smaller factors applied to more at-risk species. Given the unknowns of this population NMFS used 0.1. N_{min} is not

available, and therefore, NMFS relies on the NMSDD abundance estimate of 70,889 to estimate PBR. As such, using the NMSDD abundance estimate, PBR is estimated to be 141.78 (70,889 × (0.5 × 4 percent) × (0.1). (Of note, if PBR was calculating using an estimated N_{min} of half of the NMSDD abundance estimate (35,445), PBR would be 70.89.)

Given that the negligible impact determination is based on the assessment of take of the activity being analyzed, even if total annual mortality from human activities is higher, but the impacts from the specific activity being analyzed are very small, NMFS may still find the incremental impact of the authorized take from a specified activity is to be negligible even if total human-caused mortality exceeds PBR. As such, the incremental impact of the authorized take from a specified activity may also be negligible where total annual M/SI is unknown. An unknown total annual M/SI is a cue to look more closely if and when the M/SI for the specified activity approaches PBR (*e.g.,* consider whether there are mitigation measures in place for other potential sources of M/SI), as it becomes increasingly necessary (the closer the M/SI from the specified activity is to PBR) to carefully consider whether there are other factors that could affect reproduction or survival. Here, the M/SI proposed for authorization is 0.29 annually, which does not closely approach our PBR estimate above (PBR is estimated as 141.78, potentially as low as 70.89), and there are no other factors that would suggest that the authorized mortality (alone) would have more than a negligible impact on this stock. Immediately below, we explain the information that supports our finding that the Action Proponents' M/SI proposed for authorization is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the *Group and Species-Specific Analyses* section.

The loss of a male would have far less, if any, effect on population rates and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that any single mortality proposed for authorization by this proposed rulemaking would be a male, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of M/SI in 5 or 6 of the 7 years and the fact that any single mortality could be a male.

Based on the presence of the factors described above, we do not expect lethal take from the Action Proponents' activities, alone, to adversely affect the Baja California Peninsula Mexico population of pantropical spotted dolphins through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality is unknown necessitates close attention to the remainder of the impacts (*i.e.,* harassment) on the Baja California Peninsula Mexico population of pantropical spotted dolphins from the Action Proponents' activities to ensure that the total takes proposed for authorization have a negligible impact on the species or stock. Therefore, this information will be considered in combination with our assessment of the impacts of authorized harassment takes in the *Group and Species-Specific Analyses* section that follows.

Group and Species-Specific Analyses

In this section, we build on the general analysis that applies to all marine mammals in the HCTT Study Area from the previous sections. We first include information and analysis that applies to mysticetes or, separately, odontocetes or pinnipeds, and then within those three sections, more specific information that applies to smaller groups, where applicable, and the affected species or stocks. The specific authorized take numbers are also included in the analyses below, and so here we provide some additional context and discussion regarding how we consider the authorized take numbers in those analyses.

The maximum amount and type of incidental take of marine mammals reasonably likely to occur and therefore proposed to be authorized from exposures to sonar and other active acoustic sources and explosions during the 7-year activity period are shown in table 37, table 38, table 39, and table 40, and the subset attributable to ship shock trials is included in table 49.

In the discussions below, the estimated takes by Level B harassment represent instances of take, not the number of individuals taken (the much lower and less frequent Level A harassment takes are far more likely to be associated with separate individuals), and in some cases individuals may be taken more than one time. As part of our evaluation of the magnitude and severity of impacts to marine mammal individuals and the species, and specifically in an effort to better understand the degree to which the modeled and estimated takes likely represent repeated takes of the individuals of a given species/stock, we consider the total annual numbers of take by harassment (auditory injury, non-auditory injury, TTS, and behavioral disturbance) for species or stocks as compared to their associated abundance estimates—specifically, take numbers higher than the stock abundance clearly indicate that some number of individuals are being taken on more than one day in the year, and broadly higher or lower ratios of take to abundance may reasonably be considered to equate to higher or lower likelihood of repeated takes, respectively, other potentially influencing factors being equal. In addition to the mathematical consideration of estimated take compared to abundance, we also consider other factors or circumstances that may influence the likelihood of repeated takes, where known, such as circumstances where activities resulting in take are focused in an area and time (*e.g.,* instrumented ranges or a homeport, or long-duration activities such as MTEs) and/or where the same individual marine mammals are known to congregate over longer periods of time (*e.g.,* pinnipeds at a haulout, mysticetes in a known foraging area, or resident odontocetes with smaller home ranges). Similarly, and all else being equal, estimated takes that are largely focused in one region and/or season (see table 89, table 91, table 93, table 95, table 97, and table 99) may indicate a higher likelihood of repeated takes of the same individuals.

Occasional, milder behavioral responses are unlikely to cause long-term consequences for individual animals or populations, and even if some smaller subset of the takes are in the form of a longer (several hours or a day) and more severe response, if they are not expected to be repeated over a comparatively longer duration of sequential days, impacts to individual fitness are not anticipated. Nearly all studies and experts agree that infrequent exposures of a single day or less are unlikely to impact an individual's overall energy budget (Farmer *et al.,* 2018b; Harris *et al.,* 2018; King *et al.,* 2015; NAS, 2017; New *et al.,* 2014; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015; Hoekendijk *et al.,* 2018; Wisniewska *et al.,* 2018; Czapanskiy *et al.,* 2021; Pirotta, 2022). Generally speaking, and in the case of most

species impacted by the proposed activities, in the cases where some number of individuals may reasonably be expected to be taken on more than one day within a year, that number of days would be comparatively small and also with no reason to expect that those takes would occur on sequential days. In the rarer cases of species where individuals might be expected to be taken on a comparatively higher number of days of the year and there are reasons to think that these days might be sequential or clumped together, the likely impacts of this situation are discussed explicitly in the species discussions.

To assist in understanding what this analysis means, we clarify a few issues related to estimated takes and the analysis here. An individual that incurs AUD INJ or TTS may sometimes, for example, also be subject to behavioral disturbance at the same time. As described above in this section, the degree of auditory injury, and the degree and duration of TTS, expected to be incurred from the Navy's activities are not expected to impact marine mammals such that their reproduction or survival could be affected. Similarly, data do not suggest that a single instance in which an animal accrues auditory injury or TTS and is also subjected to behavioral disturbance would result in impacts to reproduction or survival. Alternately, we recognize that if an individual is subjected to behavioral disturbance repeatedly for a longer duration and on consecutive days, effects could accrue to the point that reproductive success is impacted. Accordingly, in analyzing the number of takes and the likelihood of repeated and sequential takes, we consider the total takes, not just the takes by Level B harassment by behavioral disturbance, so that individuals potentially exposed to both threshold shift and behavioral disturbance are appropriately considered. The number of takes by Level A harassment by auditory injury are so low (and zero in some cases) compared to abundance numbers that it is considered highly unlikely that any individual would be taken at those levels more than once.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to most marine mammal stocks from sonar and other active sound sources during the specified military readiness activities would be primarily from anti-submarine warfare events. On the less severe end, exposure to comparatively lower levels of sound at a detectably greater distance from the animal, for a few or several minutes, could result in a behavioral response such as avoiding an area that an animal would otherwise have moved through or fed in, or breaking off one or a few feeding bouts. More severe behavioral effects could occur when an animal gets close enough to the source to receive a comparatively higher level of sound, is exposed continuously to one source for a longer time or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently. In addition to the proximity to the source, the type of activity and the season and location during which an animal is exposed can inform the impacts. These factors, including the numbers and types of effects that are estimated in areas known to be biologically important for certain species are discussed in the group and species-specific sections, below.

As described in the Proposed Mitigation Measures section, this proposed rule includes mitigation measures that would reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources or explosives, vessel strike, and impacts to marine mammal habitat. Specifically, the Action Proponents would use a combination of delayed starts, powerdowns, and shutdowns to avoid mortality or serious injury, minimize the likelihood or severity of AUD INJ or non-auditory injury, and reduce instances of TTS or more severe behavioral disturbance caused by acoustic sources or explosives. The Action Proponents would also implement multiple time/area restrictions that would reduce take of marine mammals in areas or at times where they are known to engage in important behaviors, such as calving, where the disruption of those behaviors would have a higher probability of resulting in impacts on reproduction or survival of individuals that could lead to population-level impacts.

These time/area restrictions include a Hawaii Island Marine Mammal Mitigation Area, a Hawaii 4-Islands Marine Mammal Mitigation Area, Northern California Large Whale Mitigation Area, Central California Large Whale Mitigation Area, Southern California Blue Whale Mitigation Area, California Large Whale Real-Time Notification Mitigation Area, and San Nicolas Island Pinniped Haulout Mitigation Area as well as Hawaii Humpback Whale Awareness Messages and California Large Whale Awareness Messages. The Southern California Blue Whale Mitigation Area is discussed in the blue whale section below. However, it is important to note that measures in that area, while developed to protect blue whales, would also benefit other marine mammals in those areas. Therefore, they are discussed here also.

Within the Hawaii Island Marine Mammal Mitigation Area, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of helicopter dipping sonar (a mid-frequency active sonar source) annually and must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets). Mitigation in this area is designed to reduce exposure of numerous small and resident marine mammal populations (including Blainville's beaked whales, bottlenose dolphins, goose-beaked whales, dwarf sperm whales, false killer whales, melon-headed whales, pantropical spotted dolphins, pygmy killer whales, rough-toothed dolphins, short-finned pilot whales, and spinner dolphins), humpback whales within important seasonal reproductive habitat, and Hawaiian monk seals within critical habitat, to levels of sound that have the potential to cause injurious or behavioral impacts.

Within the Hawaii 4-Islands Marine Mammal Mitigation Area, from November 15–April 15, the Action Proponents must not use MF1 surface ship hull-mounted mid-frequency active sonar. The Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) within the mitigation area (year-round). This mitigation would prevent exposure of humpback whales in high-density seasonal reproductive habitats (*e.g.,* north of Maui and Moloka'i), Main Hawaiian Islands insular false killer whales in high seasonal occurrence areas, and numerous small and resident marine mammal populations that occur year-round (including bottlenose dolphins, pantropical spotted dolphins, and spinner dolphins, and Hawaiian monk seals) to explosives that have the potential to cause injury, mortality, or behavioral disturbance, and would minimize exposure of humpback whales in high-density seasonal reproductive habitats (*e.g.,* north of Maui and Moloka'i) and Main Hawaiian Islands insular false killer whales in high seasonal occurrence areas to levels of sound that have the potential to cause injurious or behavioral impacts.

Within the Northern California Large Whale Mitigation Area, Central California Large Whale Mitigation Area, and Southern California Blue Whale Mitigation Area, from June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within these three areas. This measure would reduce exposure of blue whales, fin whales, gray whales, and humpback whales in important seasonal foraging, migratory, and calving habitats to levels of sound that have the potential to cause injurious or behavioral impacts. Additionally, during the same June 1–October 31 period, within the portion of the mitigation area off San Diego, the Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) during large-caliber (≥57 mm (2.24 inch)) gunnery, torpedo, bombing, and missile (including 2.75-inch (7 cm) rockets) training and testing. This measure would reduce exposure of large whales within important seasonal foraging habitats to explosives that have the potential to cause injury, mortality, or behavioral disturbance.

Within the California Large Whale Real-Time Notification Mitigation Area, the Action Proponents would issue real-time notifications to alert Action Proponent vessels operating in the vicinity of large whale aggregations (four or more whales) sighted within 1 nmi (1.9 km) of an Action Proponent vessel within an area of the Southern California Range Complex (between 32–33 degrees North and 117.2–119.5 degrees West). Lookouts must use the information from the real-time notifications to inform their visual observations of applicable mitigation zones. The real-time notification area encompasses the locations of recent (2009, 2021, 2023) vessel strikes, and historic strikes where precise latitude and longitude were known.

Within the San Nicolas Island Pinniped Haulout Mitigation Area, Navy personnel must implement multiple measures that would minimize in-air launch noise and physical disturbance to pinnipeds hauled out on beaches, as well as to continue assessing baseline pinniped distribution/abundance and potential changes in pinniped use of these beaches after launch events.

Last, the Hawaii Humpback Whale Awareness Messages and California Large Whale Awareness Messages would alert applicable assets (and their Lookouts) transiting and training or testing in the Hawaii Range Complex or on the U.S. West Coast to the possible presence of concentrations of large whales during certain periods of the year. Lookouts must use that knowledge to help inform their visual observations during military readiness activities that involve vessel movements, active sonar, in-water explosives (including underwater explosives and explosives deployed against surface targets), or the deployment of non-explosive ordnance against surface targets in the mitigation area. These messages would minimize potential large whale vessel interactions and exposure to acoustic, explosive, and physical disturbance and strike stressors that have the potential to cause mortality, injury, or behavioral disturbance during reproductive seasons, foraging and migration seasons, and to resident whales.

In addition to the nature and context of the disturbance, including whether take occurs in a known BIA, species-specific factors affect the severity of impacts to individual animals and population consequences of disturbance. Keen *et al.* (2021) identifies three population consequences of disturbance themes: life history traits, environmental conditions, and disturbance source characteristics. Life history traits considered in Keen *et al.* (2021) include movement ecology (whether animals are resident, nomadic, or migratory), reproductive strategy (capital breeders, income breeders, or mixed), body size (based on size and life stage), and pace of life (slow or fast).

Regarding movement ecology, resident animals that have small home ranges relative to the size and duration of an impact zone would have a higher risk of repeated exposures to an ongoing activity. Animals that are nomadic over a larger range may have less predictable risk of repeated exposure. For resident and nomadic populations, overlap of a stressor with feeding or reproduction depends more on time of year rather than location in their habitat range. In contrast, migratory animals may have higher or reduced potential for exposure during feeding and reproduction based on both location, time of the year, and duration of an activity. The risk of repeated exposure during individual events may be lower during migration as animals maintain directed transit through an area.

Reproduction is energetically expensive for female marine mammals, and reproductive strategy can influence an animal's sensitivity to disturbance. Mysticetes and phocids are capital breeders. Capital breeders rely on their capital, or energy stores, to migrate, maintain pregnancy, and nurse a calf. Capital breeders would be more resilient to short-term foraging disruption due to their reliance on built-up energy reserves, but are vulnerable to prolonged foraging impacts during gestation. Otariids and most odontocetes are income breeders, which rely on some level of income, or regular foraging, to give birth and nurse a calf. Income breeders would be more sensitive to the consequences of disturbances that impact foraging during lactation. Some species exhibit traits of both, such as beaked whales.

Smaller animals require more food intake per unit body mass than large animals. They must consume food on a regular basis and are likely to be non-migratory and income breeders. The smallest odontocetes, the porpoises, must maintain high metabolisms to maintain thermoregulation and cannot rely on blubber stores for long periods of time, whereas larger odontocetes can more easily thermoregulate. The larger size of other odontocetes is an adaptation for deep diving that allows them to access high quality mesopelagic and bathypelagic prey. Both small and large odontocetes have lower foraging efficiency than the large whales. The filter-feeding large whales (*i.e.,* mysticetes) consume most of their food within several months of the year and rely on extensive lipid reserves for the remainder of the year. The metabolism of mysticetes allows for fasting while seeking prey patches during foraging season and prolonged periods of fasting outside of foraging season (Goldbogen *et al.,* 2023). Their energy stores support capital breeding and long migrations. The effect of a temporary feeding disturbance is likely to have inconsequential impacts to a mysticete, but may be consequential for small cetaceans. Despite their relatively smaller size, amphibious pinnipeds have lower thermoregulatory requirements because they spend a portion of time on land. For purposes of this assessment, marine mammals were generally categorized as small (less than 10 ft (3.05 m)), medium (10–30 ft (3.05–9.1 m)), or large (more than 30 ft (9.1 m)) based on length.

Populations with a fast pace of life are characterized by early age of maturity, high birth rates, and short life spans, whereas populations with a slow pace of life are characterized by later age of maturity, low birth rates, and long life spans. The consequences of disturbance in these populations differ. Although reproduction in populations with a fast pace of life are more sensitive to foraging disruption, these populations are quick to recover. Reproduction in populations with a slow pace of life is

resilient to foraging disruption, but late maturity and low birth rates mean that long-term impacts to breeding adults have a longer-term effect on population growth rates. Pace of life was categorized for each species in this analysis by comparing age at sexual maturity, birth rate interval, life span, body size, and feeding and reproductive strategy.

Southall *et al.* (2023) also identified factors that inform a population's vulnerability. The authors describe a framework to assess risk to populations from specific industry impact scenarios at different locations or times of year. While this approach may not be suitable for many military readiness activities, for which alternate spatial or seasonal scenarios are not usually feasible, the concepts considered in that framework's population vulnerability assessment are useful in this analysis, including population status (endangered or threatened), population trend (decreasing, stable, or increasing), population size, and chronic exposure to other anthropogenic or environmental stressors (*e.g.,* fisheries interactions, pollution, *etc.*). These factors are also considered when assessing the overall vulnerability of a stock to repeated effects from acoustic and explosive stressors.

In consideration of the factors outlined above, if impacts to individuals increase in magnitude or severity such that repeated and sequential higher severity impacts occur (the probability of this goes up for an individual the higher total number of takes it has) or the total number of moderate to more severe impacts increases substantially, especially if occurring across sequential days, then it becomes more likely that the aggregate effects could potentially interfere with feeding enough to reduce energy budgets in a manner that could impact reproductive success via longer cow-calf intervals, terminated pregnancies, or calf mortality. It is important to note that these impacts only accrue to females, which only comprise approximately 50 percent of the population. Based on energetic models, it takes energetic impacts of a significantly greater magnitude to cause the death of an adult marine mammal, and females will always terminate a pregnancy or stop lactating before allowing their health to deteriorate. Also, the death of an adult female has significantly more impact on population growth rates than reductions in reproductive success, while the death of an adult male has very little effect on population growth rates. However, as previously explained, such severe impacts from the specified activities would be very infrequent and not considered likely to occur at all for most species and stocks. We note that the negligible impact analysis is inherently a two-tiered assessment that first evaluates the anticipated impacts of the activities on marine mammals individuals, and then if impacts are expected to reproduction or survival of any individuals further evaluates the effects of those individual impacts on rates of reproduction and survival of the species or stock, in the context of the status of the species or stock. The analyses below in some cases address species collectively if they occupy the same functional hearing group (*i.e.,* very-low, low, high, and very high-frequency cetaceans), share similar life history strategies, and/or are known to behaviorally respond similarly to acoustic stressors. Because some of these groups or species share characteristics that inform the impact analysis similarly, it would be duplicative to repeat the same analysis for each species. In addition, similar species typically have the same hearing capabilities and behaviorally respond in the same manner.

Thus, our analysis below considers the effects of the specified activities on each affected species or stock even where discussion is organized by functional hearing group and/or information is evaluated at the group level. Where there are meaningful differences between a species or stock that would further differentiate the analysis, they are either described within the section or the discussion for those species or stocks is included as a separate part of each section. Specifically, we first give broad descriptions of the mysticete, odontocete, and pinniped groups and then differentiate into further groups as appropriate below.

Mysticetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status and life history of the stocks to support the negligible impact determinations for each stock. We have already described above why we believe the incremental addition of the limited number of low-level auditory injury takes will not have any meaningful effect towards inhibiting reproduction or survival. We have also described in this section above the unlikelihood of any masking or habitat impacts having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Action Proponents' activities. For mysticetes, there is no predicted non-auditory injury from explosives for any stocks except the CA/OR/WA stock of fin whale and the Mainland Mexico-CA/OR/WA stock of humpback whale. Regarding the severity of individual takes by Level B harassment by behavioral disturbance for mysticetes, the majority of these responses are anticipated to occur at received levels below 172 dB, and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Much of the discussion below focuses on the behavioral effects and the mitigation measures that reduce the probability or severity of effects in biologically important areas or other habitat. Because there are multiple stock-specific factors in relation to the status of the species, as well as mortality take due to vessel strike for several stocks, at the end of the section we break out stock-specific findings.

In table 89 below for mysticetes, we indicate the total annual mortality, Level A harassment, and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

In table 90 below, we indicate the status, life history traits, important habitats, and threats that inform our analysis of the potential impacts of the estimated take on the affected mysticete stocks.

TABLE 89—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR MYSTICETES IN THE HCTT STUDY AREA

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassment as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater
Gray Whale	Eastern North Pacific.	26,960	10,863	16,711	167	0.43	16,878	63	Cold (99 percent).	SOCAL (98 percent).
Gray Whale	Western North Pacific.	290	110	169	2	0	171	59	Cold (100 percent).	SOCAL (97 percent).
Blue Whale	Central North Pacific.	133	170	92	1	0	93	55	Cold (70 percent).	HRC (95 percent).
Blue Whale	Eastern North Pacific.	1,898	3,233	4,571	27	0.29	4,598	142	Warm (56 percent).	SOCAL (87 percent).
Bryde's Whale	Eastern Tropical Pacific.	UNK	69	322	5	0	327	474	Cold (56 percent).	SOCAL (89 percent).
Bryde's Whale	Hawaii	791	766	409	3	0	412	52	Cold (57 percent).	HRC (93 percent).
Fin Whale	Hawaii	203	226	86	1	0	87	38	Cold (75 percent).	HRC (97 percent).
Fin Whale	California/Oregon/Washington.	11,065	12,304	13,501	55	0.57	13,557	110	Warm (70 percent).	SOCAL (52 percent).
Humpback Whale.	Central America/Southern Mexico—California-Oregon-Washington.	1,496	1,603	1,888	19	0.29	1,907	119	Cold (71 percent).	SOCAL (56 percent).
Humpback Whale.	Mainland Mexico—California-Oregon-Washington.	3,477	3,741	4,449	44	0.29	4,493	120	Cold (71 percent).	SOCAL (58 percent).
Humpback Whale.	Hawaii	11,278	9,806	3,034	24	0.43	3,058	27	Cold (99 percent).	HRC (98 percent).
Minke Whale ...	Hawaii	438	509	296	3	0	299	59	Cold (70 percent).	HRC (96 percent).
Minke Whale ...	California/Oregon/Washington.	915	1,342	2,993	32	0	3,025	225	N/A	SOCAL (75 percent).
Sei Whale	Hawaii	391	452	253	2	0	255	56	Cold (69 percent).	HRC (95 percent).
Sei Whale	Eastern North Pacific.	864	155	302	3	0.29	305	35	Cold (58 percent).	SOCAL (72 percent).

Note: N/A = Not Applicable, UNK = Unknown. NMSDD abundances are averages only within the U.S. EEZ.

*Indicates which abundance estimate was used to calculate the maximum annual take as a percentage of abundance, either the NMFS SARs (Carretta *et al.,* 2024; Young, 2024) or the NMSDD (table 2.4–1 in appendix A of the application). Please refer to the Mysticetes section for details on which abundance estimate was selected.

TABLE 90—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO DOLPHINS IN THE HCTT STUDY AREA

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.*, 2023) and West Coast (Calambokidis *et al.*, 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
Gray Whale ..	Eastern North Pacific.	Not listed	Not depleted, not strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise, subsistence hunting.	No	No	Yes: F–BIA Parent and Core; M–BIA Parent and Child; R–BIA.	Increasing	801	131
Gray Whale ..	Western North Pacific.	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise, subsistence hunting.	No	No	No	Unk	0.12	UNK
Blue Whale ...	Central North Pacific.	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	No	Unk	0.1	0
Blue Whale ...	Eastern North Pacific.	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	Yes: F–BIA Parent and Core.	Unk, possibly increasing.	4.1	≥18.6

Bryde's Whale.	Eastern Tropical Pacific.	Not listed	Not depleted, not strategic.	Unknown, likely migratory.	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	No	Unk	UND	UNK
Bryde's Whale.	Hawaii	Not listed	Not depleted, not strategic.	Unknown, likely migratory.	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	No	Unk	6.2	0
Fin Whale	Hawaii	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	No	Unk	0.2	0
Fin Whale	California/Oregon/ Washington.	Endangered ..	Depleted, Strategic.	Migratory-resident (SOCAL).	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	Yes: F–BIA Parent and Core.	Unk	80	≥43.4
Humpback Whale.	Central America/Southern Mexico—California-Oregon-Washington.	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	Yes	Yes: F–BIA Parent and Core.	Increasing	3.5	14.9

TABLE 90—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO DOLPHINS IN THE HCTT STUDY AREA—Continued

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.*, 2023) and West Coast (Calambokidis *et al.*, 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
Humpback Whale.	Mainland Mexico—California-Oregon-Washington.	Threatened ...	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	Yes	Yes: F–BIA Parent and Core.	Unk	43	22
Humpback Whale.	Hawaii	Not listed	Not depleted, not strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise.	No	No	Yes: R–BIA MHI and MHI-Core Parent and Child.	Unk	127	27.09
Minke Whale	Hawaii	Not listed	Not depleted, not strategic.	Migratory ..	Med-Large.	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance.	No	No	No	Unk	2.1	0
Minke Whale	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Migratory-resident.	Med-Large.	Capital	Slow	Vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance.	No	No	No	Unk	4.1	≥0.19
Sei Whale	Hawaii	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, ocean noise.	No	No	No	Unk	0.4	0.2

Sei Whale	Eastern North Pacific.	Endangered ..	Depleted, Strategic.	Migratory ..	Large	Capital	Slow	Vessel strikes, fisheries interactions, ocean noise.	No	No	No	Unk	1.25	UNK

Note: N/A = Not Applicable, UND = Undetermined, Unk = Unknown.

Gray Whale (Eastern North Pacific and Western North Pacific Stocks)—

Gray whales from the Eastern North Pacific stock are not listed under the ESA and are not considered as depleted or strategic under the MMPA, while gray whales from the Western North Pacific stock are listed as endangered under the ESA and depleted and strategic under the MMPA. Both stocks are migratory and most likely to be in the California Study Area during their migrations from winter to spring within 10 km (5.4 nmi) of the coast. Some gray whales transit further offshore in Southern California when making straight line transits south of Point Conception to and from Mexico. Gray whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, ocean noise, and subsistence hunting, among others.

The current stock abundance estimate of the Eastern North Pacific stock of gray whale is 26,960 animals and for the Western North Pacific stock is 290 animals. There are no UMEs or other factors that cause particular concern for these stocks. As described in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the HCTT Study Area overlaps eight BIAs for the Eastern North Pacific stock, including three feeding, four migratory, and one reproductive for the nearshore migratory corridor used by cow/calf pairs. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment are 167 and 16,711, respectively. As indicated, the rule also allows for up to three takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section.

There are no known biologically important areas for the Western North Pacific stock of gray whale in the HCTT Study Area, though the Western North Pacific stock may use the same migratory areas as the Eastern North Pacific stock while migrating to wintering areas in Mexico (Calambokidis *et al.,* 2024). As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment are 2 and 169, respectively. No mortality is anticipated or proposed for authorization, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with gray whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Gray whales are large-bodied capital breeders with a slow pace of life and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of take, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the number of takes by harassment as compared to the stock/species abundance (see table 89), and the fact that a portion of the takes of the Eastern North Pacific occur in BIAs, it is likely that some portion of the individuals taken are taken repeatedly over a limited number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Given the magnitude and severity of the impacts discussed above to the Western North Pacific stock (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are unlikely to result in impacts on the reproduction or survival of any individuals and, thereby, unlikely to affect annual rates of recruitment or survival. For the Eastern North Pacific stock, as analyzed and described in the Serious Injury and Mortality section, given the status of the stock and in consideration of other ongoing anthropogenic mortality (fisheries interactions, vessel strike), the M/SI proposed for authorization (three over the course of the 7-year rule, or 0.43 annually) would not, alone, nor in combination with the impacts of the take by harassment discussed above (which is not expected to impact the reproduction or survival of any individuals), be expected to adversely affect rates of recruitment and survival for any of this stock. For these reasons, we have determined that the total take (considering annual maxima and across 7 years) anticipated and proposed for authorization would have a negligible impact on the Eastern North Pacific and Western North Pacific stocks of gray whale.

Blue Whale (Central North Pacific and Eastern North Pacific Stocks)—

Blue whales are listed as endangered under the ESA and as both depleted and strategic under the MMPA. Both stocks of blue whales are migratory populations that can occur near the coast, over the continental shelf, and in oceanic waters. Blue whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strike, fisheries interactions, habitat degradation, pollution, vessel disturbance, and ocean noise, among others.

The Navy's NMSDD estimates the Central North Pacific stock abundance as 170, and the Eastern North Pacific stock abundance as 3,233. The Central North Pacific stock's primary range is outside of the HCTT Study Area. There are no UMEs or other factors that cause

particular concern for this stock, and there are no known biologically important areas for the Central North Pacific stock of blue whales in the HCTT Study Area. This stock migrates from their feeding grounds in the Gulf of Alaska to Hawaii in winter. While they occur in the Hawaii Study Area, they are not sighted frequently or year-round. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 1 and 92, respectively. No mortality is anticipated or proposed for authorization, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

For the Eastern North Pacific stock, there are no UMEs or other factors that cause additional concern for this stock. As described in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the HCTT Study Area overlaps a feeding BIA for the Eastern North Pacific stock (Calambokidis *et al.,* 2024). The Eastern North Pacific stock of blue whales is a migratory population that can occur near the coast, over the continental shelf, and in deep oceanic waters from the northern Gulf of Alaska to the eastern tropical Pacific. This stock forages in their hierarchical feeding BIAs off California in warmer months (June-November). In recent years, the Eastern North Pacific stock has been reported to spend more time (averaging over 8 months) on feeding grounds in the Southern California Bight. The highest densities of blue whales are predicted along nearshore southern California where most impacts would occur, so blue whales may be impacted while foraging in the designated BIAs. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A Harassment and Level B harassment is 27 and 4,571, respectively. As indicated, the rule also allows for up to two takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with blue whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Blue whales are large-bodied capital breeders with a slow pace of life, and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, for the Central North Pacific stock, given the lower number of takes by harassment as compared to the stock/species abundance (see table 89), their migratory movement pattern, and the absence of take concentrated in areas in which animals are known to congregate, it is unlikely that any individual blue whales from the Central North Pacific stock would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival. For the Eastern North Pacific stock, given the number of takes by harassment as compared to the stock/species abundance (see table 89) and the fact that a portion of the takes occur in BIAs, it is likely that some portion of the individuals taken are taken repeatedly over a limited number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas (*i.e.,* not concentrated within a specific region and season), and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Given the magnitude and severity of the impacts discussed above to the Central North Pacific stock of blue whales (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For the Eastern North Pacific stock, as analyzed and described in the Serious Injury and Mortality section, given the status of the stock, and in consideration of other ongoing anthropogenic mortality (fisheries interactions, vessel strike), the M/SI proposed for authorization (two over the course of the 7-year rule, or 0.29 annually) would not, alone, nor in combination with the impacts of the take by harassment discussed above (which is not expected to impact the reproduction or survival of any individuals), be expected to adversely affect rates of recruitment and survival for any of this stock. For these reasons, we have determined that the total take (considering annual maxima and across 7 years) anticipated and proposed for authorization would have a negligible impact on the Eastern North Pacific and Central North Pacific stocks of blue whale.

Bryde's Whale (Eastern Tropical Pacific and Hawaii Stocks)—

Little is known about the movements of Bryde's whales in the Study Area, but seasonal shifts in their distribution occur toward and away from the equator in winter and summer. Therefore, both populations of Bryde's whales are at least somewhat migratory populations that travel within their tropical and subtropical ranges year-round. There are no known biologically important areas for Bryde's whales in the HCTT Study Area. Bryde's whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strike, fisheries interactions,

habitat degradation, pollution, vessel disturbance, and ocean noise, among others.

Bryde's whales in the Eastern Tropical Pacific have not been designated as a stock under the MMPA, are not ESA-listed, and there is no current reported population trend. The Navy's NMSDD estimates the Eastern Tropical Pacific Bryde's whale is 69 animals. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 5 and 322, respectively. No mortality is anticipated or proposed for authorization, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

The Hawaii stock of Bryde's whale is not listed as threatened or endangered under the ESA and is not considered depleted or strategic under the MMPA. The current stock abundance estimate of the Hawaii stock of Bryde's whale is 791 animals. The stock's primary range extends outside of the HCTT Study Area. There are no UMEs or other factors that cause particular concern for this stock. Bryde's whales are the only baleen whale found in Hawaiian waters year-round, and the only mysticete in Hawaii that does not undergo predictable north-south seasonal migrations. However, Bryde's whales occur mostly in offshore waters of the North Pacific. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 3 and 409, respectively. No mortality is anticipated or proposed for authorization, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with Bryde's whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Bryde's whales are large-bodied capital breeders with a slow pace of life, and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts to the Hawaii stock through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the number of takes by harassment as compared to the stock/species abundance (see table 89), it is likely that some portion of the individuals taken from the Eastern Tropical Pacific stock are taken repeatedly over a moderate number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted. For the Hawaii stock, given the lower number of takes by harassment as compared to the stock/species abundance (see table 89), their migratory movement pattern, and the absence of take concentrated in areas in which animals are known to congregate, it is unlikely that any individual Bryde's whales from the Hawaii stock would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival.

Given the magnitude and severity of the impacts discussed above to Bryde's whales in the Eastern Tropical Pacific (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take anticipated and proposed for authorization would have a negligible impact on the Eastern Tropical Pacific and Hawaii stocks of Bryde's whale.

Fin Whale (Hawaii and CA/OR/WA Stocks)—

Fin whales are listed as endangered under the ESA and depleted and strategic under the MMPA. Fin whales have higher abundances in temperate and polar waters, and are not frequently seen in warm, tropical waters. Fin whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strike, fisheries interactions, habitat degradation, pollution, vessel disturbance, and ocean noise, among others.

The Navy's NMSDD estimates the abundance of the Hawaii stock of fin whale is 226 and the CA/OR/WA stock of fin whale is 12,304. There are no UMEs or other factors that cause particular concern for these stocks, and there are no known biologically important areas for the Hawaii stock of fin whale in the HCTT Study Area. The Hawaii stock of fin whales are not sighted frequently or year-round, and likely only migrate to the Hawaii portion of the HCTT Study Area during fall and winter. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A Harassment and Level B harassment is 1 and 86, respectively. No mortality is anticipated or proposed for authorization, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

For the CA/OR/WA stock, as described in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the HCTT Study Area overlaps a feeding BIA (Parent and Child) for this stock (Calambokidis *et al.,* 2024). This stock of fin whales is a migratory-resident population that travels along the entire U.S. west coast and may be present

throughout the year in southern and central California. There are generally higher densities farther offshore in the summer and fall, and closer to shore in winter and spring. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A Harassment and Level B harassment is 55 and 13,501, respectively. The rule allows for a limited number of takes by non-auditory injury (1 animal). As indicated, the rule also allows for up to four takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with fin whale communication and other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness. The rule also allows for a limited number of takes by non-auditory injury (*i.e.,* 1 animal) for this stock. As described above in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these non-auditory injuries are unlikely to be of a nature or level that would impact reproduction or survival.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Fin whales are large-bodied capital breeders with a slow pace of life and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the number of takes by harassment as compared to the stock/species abundance (see table 89) and the fact that a portion of the takes occur in BIAs for the CA/OR/WA stock, it is likely that some portion of the individuals of each stock are taken repeatedly over a limited number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Fin whales have the largest hierarchal feeding BIAs spanning the coast of California from June to November, which overlap more with PMSR and SOCAL compared to NOCAL, as the core BIAs are generally farther offshore in northern California. Impacts would be attributable to various activities in summer and fall (warm season), with most impacts occurring in southern California year-round. However, this stock is migratory and Navy activities are not anticipated to overlap a large portion of the BIAs, leaving large areas of important foraging habitat available.

Given the magnitude and severity of the impacts discussed above to the Hawaii stock of fin whales (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are unlikely to result in impacts on the reproduction or survival of any individuals and, thereby, unlikely to affect annual rates of recruitment or survival. For the CA/OR/WA stock, as analyzed and described in the Serious Injury and Mortality section, given the status of the stock and in consideration of other ongoing anthropogenic mortality (fisheries interactions, vessel strike), the M/SI proposed for authorization (three over the course of the 7-year rule, or 0.57 annually) would not, alone, nor in combination with the impacts of the take by harassment discussed above (which is not expected to impact the reproduction or survival of any individuals), be expected to adversely affect rates of recruitment and survival for any of this stock. For these reasons, we have determined that the total take (considering annual maxima and across 7 years) anticipated and proposed for authorization would have a negligible impact on the CA/OR/WA and Hawaii stocks of fin whale.

Humpback Whale (Central America/Southern Mexico—CA/OR/WA, Mainland Mexico—CA/OR/WA, and Hawaii Stocks)—

Humpback whales occur throughout the HCTT Study Area, and the two stocks (Central America/Southern Mexico—CA/OR/WA and Mainland Mexico—CA/OR/WA) found in the California portion of the Study Area most abundant in shelf and slope waters which are areas of high productivity and often sighted near shore, while also frequently moving through deep offshore waters during migration. In the Hawaii portion of the Study Area, the Hawaii of humpback whales occur seasonally in nearshore waters surrounding the main Hawaiian Islands during breeding season (typically December through May). The HCTT Study Area overlaps ESA-designated critical habitat for the endangered Central America DPS and the Mexico DPS of humpback whales along the west coast (86 FR 21082, April 21, 2021), as described in the Description of Marine Mammals in the Area of Specified Activities section. There are no UMEs or other factors that cause particular concern for these stocks. The HCTT Study Area overlaps a feeding BIA (Parent and Core) for the two stocks found in California (Calambokidis *et al.,* 2024), and a reproductive BIA (Parent and Child) for the Hawaii stock (Kratofil *et al.,* 2023). Humpback whales face several anthropogenic and non-anthropogenic risk factors, including vessel strikes, fisheries interactions, habitat degradation, pollution, vessel disturbance, and ocean noise, among others.

The Central America/Southern Mexico—CA/OR/WA stock (Central America DPS) of humpback whale is listed as endangered under the ESA and as both depleted and strategic under the MMPA. The Navy's NMSDD estimates this stock size is 1,603. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 19 and 1,888, respectively. As indicated, the rule also allows for up to two takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section.

The Mainland Mexico—CA/OR/WA stock (part of the Mexico DPS) of humpback whale is listed as threatened under the ESA and as both depleted and strategic under the MMPA. The Navy's NMSDD estimates this stock size is 3,741. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 44 and 4,449 respectively. The rule allows for a limited number of takes by non-auditory injury (*i.e.,* 1 animal). As described above, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these injuries are unlikely to impact reproduction or survival. As indicated, the rule also allows for up to two takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section.

The Hawaii stock of humpback whale is not listed as endangered under the ESA and as neither depleted nor strategic under the MMPA. The current stock abundance estimate of the Hawaii stock (Hawaii DPS) is 11,278. The stock's primary range extends outside of the HCTT Study Area. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 24 and 3,034, respectively. As indicated, the rule also allows for up to three takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section. The total take allowable for each stock across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness. The rule also allows for one take by non-auditory injury for the Mainland Mexico-CA/OR/WA stock. As described above, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, this non-auditory injury is unlikely to be of a nature or level that would impact reproduction or survival.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Humpback whales are large-bodied capital breeders with a slow pace of life and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat. In particular, for the Mainland Mexico-CA/OR/WA stock, this proposed rulemaking includes the Northern California Large Whale Mitigation Area and Central California Large Whale Mitigation Area. Within this area from June 1-October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Central California Large Whale Mitigation Area, and the Southern California Blue Whale Mitigation Area. These restrictions would reduce exposure of humpback whales in important seasonal foraging, migratory, and calving habitats to levels of sound that have the potential to cause injurious or behavioral impacts.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, for the Mainland Mexico-CA/OR/WA and Central America/Southern Mexico-CA/OR/WA stocks, given the number of takes by harassment as compared to the stock/species abundance (see table 89) and the fact that a portion of the takes of both stocks occur in BIAs, it is likely that some portion of the individuals taken are taken repeatedly over a limited number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted. Further, these stocks are migratory, and although some impacts to these stocks would occur in critical habitat and BIAs important for foraging off the coast of California, there are large areas available outside of the Study Area that contain high-quality foraging habitat for both stocks. Further, the majority of impacts to these stocks are anticipated to occur during the cold season, a portion of which (December to February) the BIAs for feeding are not considered to be active.

For the Hawaii stock, given the lower number of takes by harassment as compared to the stock/species abundance (see table 89), their migratory movement pattern, and the absence of take concentrated in areas in which animals are known to congregate, it is unlikely that any individual humpback whales from the Hawaii stock would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival.

For all three stocks, as described in the Serious Injury and Mortality section, given the status of the stocks, and in consideration of other ongoing

anthropogenic mortality, the amount of allowed M/SI take proposed here would not, alone, nor in combination with the impacts of the take by harassment discussed above (which is not expected to impact the reproduction or survival of any individuals), be expected to adversely affect rates of recruitment and survival. For these reasons, we have determined that the total take (considering annual maxima and across 7 years) anticipated and proposed for authorization would have a negligible impact on the Central America/Southern Mexico-CA/OR/WA, Mainland Mexico-CA/OR/WA, and Hawaii stocks of humpback whales.

Minke Whale (Hawaii and CA/OR/WA Stocks)—

Minke whales in the HCTT Study Area are not listed as threatened or endangered under the ESA, and neither the Hawaii stock nor the CA/OR/WA stock are considered depleted or strategic under the MMPA. There are no UMEs or other factors that cause particular concern for either stock and there are no known biologically important areas for minke whales in the HCTT Study Area. Minke whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strike, fisheries interactions, habitat degradation, pollution, vessel disturbance, and disease, among others.

The Navy's NMSDD estimates the abundance of the Hawaii stock of minke whale is 509 animals and the CA/OR/WA stock of minke whale is 1,342 animals. The stock's primary range extends outside of the HCTT Study Area. The Hawaii stock generally congregates in Hawaiian water in the colder months (fall to spring) and migrates to more productive areas in winter. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 3 and 296, respectively. The CA/OR/WA stock can be found year-round in southern California, generally congregating in nearshore waters over the continental shelf off California, and has low variability in annual distribution patterns. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 32 and 2,993, respectively. No mortality is anticipated or proposed for authorization for either stock, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration, and mostly not in a frequency band that would be expected to interfere with minke whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Minke whales are medium-to-large-bodied capital breeders with a slow pace of life and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, for the Hawaii stock, given the lower number of takes by harassment as compared to the stock/species abundance (see table 89), their migratory movement pattern, and the absence of take concentrated in areas in which animals are known to congregate, it is unlikely that any individual minke whales from the Hawaii stock would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival. For the CA/OR/WA stock, given the number of takes by harassment as compared to the stock/species abundance (see table 89), it is likely that some portion of the individuals taken are taken repeatedly over a limited to moderate number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Given the magnitude and severity of the impacts discussed above to the CA/OR/WA and Hawaii stocks of minke whale (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed for authorization would have a negligible impact on the Hawaii and CA/OR/WA stocks of minke whales.

Sei Whale (Hawaii and Eastern North Pacific Stocks)—

Sei whales are listed as endangered under the ESA and as both depleted and strategic under the MMPA. Sei whales generally have higher abundances in the cold and deep water of the open ocean. There are no UMEs or other factors that cause particular concern for either stock, and there are no known biologically important areas for sei whales in the HCTT Study Area. Sei whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strike, fisheries interactions, and ocean noise, among others.

The Navy's NMSDD estimates the abundance of the Hawaii stock is 452 and the Eastern North Pacific stock is 864 animals. The Hawaii stock's primary range is outside of the HCTT Study Area. This stock is migratory and not frequently detected in Hawaii, traveling from their cold subpolar latitudes to Hawaii in the winter, where they are more likely to be on the Hawaii Range Complex in the cold season. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 2 and 253, respectively. No mortality of the Hawaii

stock is anticipated or proposed for authorization, nor is any non-auditory injury.

The Eastern North Pacific stock occurs year-round in deep offshore waters of California and is likely to occur in the Transit Corridor of the HCTT Study Area. The Eastern North Pacific stock seasonally migrates, though to a lesser extent compared to other large whales. As shown in table 89, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 3 and 302, respectively. As indicated, the rule also allows for up to two takes by serious injury or mortality over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section. The total take allowable across all 7 years of the rule for both stocks is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with sei whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Sei whales are large-bodied capital breeders with a slow pace of life and are therefore generally less susceptible to impacts from shorter duration foraging disruptions. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the lower number of takes by harassment as compared to the stock/species abundance (see table 89), their migratory movement pattern, and the absence of take concentrated in areas in which animals are known to congregate, it is unlikely that any individual from either stock would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival.

Given the magnitude and severity of the impacts discussed above to the Hawaii stock of sei whales (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For the CA/OR/WA stock, as analyzed and described in the Serious Injury and Mortality section above, given the status of the stock, the M/SI proposed for authorization for CA/OR/WA sei whales (two over the course of the 7-year rule, or 0.29 annually) would not, alone, be expected to adversely affect the stock through rates of recruitment or survival. Given the magnitude and severity of the take by harassment discussed above and any anticipated habitat impacts, and in consideration of the required mitigation measures and other information presented, the take by harassment proposed for authorization is unlikely to result in impacts on the reproduction or survival of any individuals and, thereby, unlikely to affect annual rates of recruitment or survival either alone or in combination with the M/SI proposed for authorization. For these reasons, we have determined that the take by harassment anticipated and proposed for authorization would have a negligible impact on the Hawaii and CA/OR/WA stocks of sei whales.

Odontocetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status and life history of the stocks to support the negligible impact determinations for each stock. We have already described above why we believe the incremental addition of the limited number of low-level auditory injury takes will not have any meaningful effect towards inhibiting reproduction or survival. We have also described above in this section the unlikelihood of any masking or habitat impacts having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Action Proponents' activities. Some odontocete stocks have predicted non-auditory injury from explosives, discussed further below. Regarding the severity of individual takes by Level B harassment by behavioral disturbance for odontocetes, the majority of these responses are anticipated to occur at received levels below 178 dB for most odontocete species and below 154 dB for sensitive species (*i.e.,* beaked whales and harbor porpoises, for which a lower behavioral disturbance threshold is applied), and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Much of the discussion below focuses on the behavioral effects and the mitigation measures that reduce the probability or severity of effects in biologically important areas or other habitats. Because there are multiple stock-specific factors in relation to the status of the species, as well as mortality take for several stocks, at the end of the section we break out stock- or group-specific findings.

In table 91 (sperm whales, dwarf sperm whales, and pygmy sperm whales), table 93 (beaked whales), table 95 (dolphins and small whales), table 97 (porpoises), and table 99 (pinnipeds) below, we indicate the total annual mortality, Level A harassment, and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

In table 92 (sperm whales, dwarf sperm whales, and pygmy sperm whales), table 94 (beaked whales), table 96 (dolphins and small whales), table 98 (porpoises), and table 100 (pinnipeds), below, we indicate the status, life history traits, important habitats, and threats that inform our analysis of the potential impacts of the estimated take on the affected odontocete stocks.

TABLE 91—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR PACIFIC STOCKS OF SPERM WHALE, DWARF SPERM WHALE, AND PYGMY SPERM WHALE IN THE HCTT STUDY

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassment as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater
Sperm Whale	Hawaii	5,707	6,062	1,649	1	0.14	1,650	27	Cold (55 percent).	HRC (94 percent).
Sperm Whale	California/Oregon/Washington.	2,606	4,549	3,891	3	0	3,894	86	Cold (55 percent).	SOCAL (70 percent).
Dwarf Sperm Whale.	Hawaii	UNK	43,246	45,224	915	0	46,139	107	Cold (54 percent).	HRC (93 percent).
Dwarf Sperm Whale.	California/Oregon/Washington.	UNK	2,462	5,664	94	0	5,758	234	Cold (57 percent).	SOCAL (75 percent).
Pygmy Sperm Whale.	Hawaii	42,083	48,589	45,787	936	0	46,723	96	Cold (54 percent).	HRC (93 percent).
Pygmy Sperm Whale.	California/Oregon/Washington.	4,111	2,462	5,615	107	0	5,722	139	Cold (59 percent).	SOCAL (74 percent).

Note: N/A = Not Applicable, UNK = Unknown. NMSDD abundances are averages only within the U.S. EEZ.

* Indicates which abundance estimate was used to calculate the maximum annual take as a percentage of abundance, either the NMFS SARs (Carretta *et al.*, 2024; Young, 2024) or the NMSDD (table 2.4–1 in appendix A of the application). Please refer to the Odontocetes section for details on which abundance estimate was selected.

TABLE 92—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO SPERM WHALE, DWARF SPERM WHALE, AND PYGMY SPERM WHALE IN THE HCTT STUDY AREA

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.*, 2023) and West Coast (Calambokidis *et al.*, 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
Sperm Whale.	Hawaii	Endangered ..	Depleted, Strategic.	Resident-migratory.	Large	Income	Slow	Vessel strikes, fisheries interactions, ocean noise, marine debris, disease.	No	No	No	Unk	18	0
Sperm Whale.	California/Oregon/Washington.	Endangered ..	Depleted, Strategic.	Migratory-resident.	Large	Income	Slow	Vessel strikes, fisheries interactions, ocean noise, marine debris, disease.	No	No	No	Stable	4	0.52
Dwarf Sperm Whale.	Hawaii	Not listed	Not depleted, not strategic.	Migratory, nomadic, resident.	Small-Med ..	Income	Fast	Fisheries interactions, marine debris, ocean noise.	No	No	Yes: S–BIA Parent and Child HI-Core.	Unk	UND	0
Dwarf Sperm Whale.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Migratory, nomadic, resident.	Small-Med ..	Income	Fast	Fisheries interactions, marine debris, ocean noise.	No	No	No	Unk	UND	0
Pygmy Sperm Whale.	Hawaii	Not listed	Not depleted, not strategic.	Migratory, nomadic, resident.	Small-Med ..	Income	Fast	Fisheries interactions, marine debris, ocean noise.	No	No	Yes: S–BIA O MN HI.	Unk	257	0
Pygmy Sperm Whale.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Migratory, nomadic, resident.	Small-Med ..	Income	Fast	Fisheries interactions, marine debris, ocean noise.	No	No	No	Unk	19.2	0

Note: N/A = Not Applicable, UND = Undetermined, Unk = Unknown.

Sperm Whales, Dwarf Sperm Whales, and Pygmy Sperm Whales—

Sperm Whale (Hawaii and CA/OR/WA Stocks)

Sperm whales are listed as endangered under the ESA and are considered depleted and strategic under the MMPA. The Navy's NMSDD estimate for the Hawaii stock is 6,062 animals and for the CA/OR/WA stock is 4,549 animals. There are no UMEs or other factors that cause particular concern for these stocks, and there are no known biologically important areas for the sperm whales in the HCTT Study Area. Sperm whales generally have higher abundances in deep water and areas of high productivity and are somewhat migratory, but their movement ecology is demographically dependent. The Hawaii stock is residential and occurs in Hawaiian waters year-round, while the CA/OR/WA stock is somewhat migratory, with some individuals leaving warm waters in summer to travel north to their arctic feeding grounds and returning south in the fall and winter. Sperm whales face several chronic anthropogenic and non-anthropogenic risk factors, including vessel strike, fisheries interactions, pollution, ocean noise, and disease, among others.

As shown in table 91, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B harassment is 1 (Hawaii stock) and 3 (CA/OR/WA stock), and 1,649 (Hawaii stock) to 3,891 (CA/OR/WA stock), respectively. As indicated, the rule also allows for up to one take by serious injury or mortality of Hawaii sperm whales over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section. The total take allowable for each stock across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 178 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Sperm whales are large-bodied income breeders with a slow pace of life and are likely more resilient to missed foraging opportunities due to acoustic disturbance than smaller odontocetes. However, they may be more susceptible to impacts due to lost foraging opportunities during reproduction, especially if they occur during lactation (Farmer *et al.,* 2018b). Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. For both stocks of sperm whales, given the lower number of takes by harassment as compared to the stock/species abundance (see table 91), and the absence of take concentrated in areas in which animals are known to congregate, it is unlikely that any individual sperm whales would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival.

Given the magnitude and severity of the impacts discussed above to sperm whales (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the proposed take by harassment is not expected to impact the reproduction or survival of any individuals nor, as described previously, is the mortality proposed for authorization expected to adversely affect the species or stock. For these reasons, we have determined that the take anticipated and proposed for authorization would have a negligible impact on the Hawaii and CA/OR/WA stocks of sperm whale.

Dwarf Sperm Whale (Hawaii and CA/OR/WA Stocks) and Pygmy Sperm Whale (Hawaii and CA/OR/WA Stocks)

Neither dwarf sperm whales nor pygmy sperm whales are listed under the ESA, and none of the stocks are considered depleted or strategic under the MMPA. The current stock abundance of the CA/OR/WA stock of pygmy sperm whale is 4,111 animals, and the stock abundances from Navy's NMSDD are 2,426 (CA/OR/WA stock of dwarf sperm whale), 43,246 (Hawaii stock of dwarf sperm whale), and 48,589 (Hawaii stock of pygmy sperm whale). There are no UMEs or other factors that cause particular concern for these stocks. As described in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the HCTT Study Area overlaps two known BIAs for small and resident populations of the Hawaii stocks of dwarf and pygmy sperm whale. Dwarf and pygmy sperm whales face several chronic anthropogenic and non-anthropogenic risk factors, including fisheries interactions, marine debris, and ocean noise, among others.

As shown in table 91, the maximum annual allowable instances of take under this proposed rule by Level A Harassment and Level B harassment is: 915 and 45,224 for the Hawaii stock of dwarf sperm whale, respectively; 94 and 5,664 for the CA/OR/WA stock of dwarf sperm whale, respectively; 936 and 45,787 for the Hawaii stock of pygmy sperm whale, respectively; and 107 and 5,615 for the CA/OR/WA stock of pygmy sperm whale, respectively. No mortality is anticipated or proposed for authorization. The rule allows for a limited number of takes by non-auditory injury (one each for the Hawaii stocks of dwarf and pygmy sperm whales). As described above, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these injuries are unlikely to impact reproduction or survival. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be

lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with dwarf and pygmy sperm whale communication, overlap more than a relatively narrow portion of the vocalization range of any single species or stock, or preclude detection or interpretation of important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness. The rule also allows for a limited number of takes by non-auditory injury (one per stock) for the Hawaii stocks of dwarf and pygmy sperm whales. As described above in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these non-auditory injuries are unlikely to be of a nature or level that would impact reproduction or survival for either of the Hawaii stocks of dwarf and pygmy sperm whales.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 178 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Dwarf and pygmy sperm whales are small-to-medium-bodied income breeders with a fast pace of life. They are generally more sensitive to missed foraging opportunities than larger odontocetes, especially during lactation, but would be quick to recover given their fast pace of life. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat. In particular, this proposed rulemaking includes a Hawaii Island Marine Mammal Mitigation Area, within which the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of helicopter dipping sonar (a mid-frequency active sonar source) annually and must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets). These restrictions would reduce exposure of numerous small and resident marine mammal populations, including dwarf and pygmy sperm whales, to levels of sound from sonar or explosives that have the potential to cause injury or mortality, thereby reducing the likelihood of those effects and, further, minimizing the severity of behavioral disturbance.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the number of takes by harassment as compared to the stock/species abundance (see table 91) and the fact that a portion of the takes occur in BIAs for the Hawaii stocks, it is likely that some portion of the individuals taken are taken repeatedly over a limited to moderate number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Given the magnitude and severity of the impacts discussed above to dwarf and pygmy sperm whale stocks in the HCTT Study Area (considering annual take maxima and the total across 7 years) and their habitats, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take anticipated and proposed for authorization would have a negligible impact on the Hawaii and CA/OR/WA stocks of dwarf and pygmy sperm whales.

Beaked Whales—

This section builds on the broader odontocete discussion above (*i.e.,* that information applies to beaked whales as well), and brings together the discussion of the different types and amounts of take that different beaked whale species and stocks will likely incur, any additional applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock.

TABLE 93—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR BEAKED WHALES IN THE HCTT STUDY AREA

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassmen as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater
Baird's Beaked Whale.	California/Oregon/Washington.	1,363	871	10,174	0	0	10,174	746	Cold (54 percent).	SOCAL (58 percent).
Blainville's Beaked Whale.	Hawaii	1,132	1,300	7,542	0	0	7,542	580	Cold (55 percent).	HRC (94 percent).
Goose-Beaked Whale.	Hawaii	4,431	5,116	30,359	0	0	30,359	593	Cold (55 percent).	HRC (94 percent).
Goose-Beaked Whale.	California/Oregon/Washington.	5,454	13,531	166,816	2	0	166,818	1233	Cold (54 percent).	SOCAL (82 percent).

TABLE 93—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR BEAKED WHALES IN THE HCTT STUDY AREA—Continued

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassmen as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater
Longman's Beaked Whale.	Hawaii	2,550	2,940	18,316	1	0	18,317	623	Cold (56 percent).	HRC (94 percent).
Mesoplodont Beaked Whale.	California/Oregon/Washington.	3,044	7,534	92,839	2	0	92,841	1232	Cold (55 percent).	SOCAL (76 percent).

Note: N/A = Not Applicable, UNK = Unknown. NMSDD abundances are averages only within the U.S. EEZ.

* Indicates which abundance estimate was used to calculate the maximum annual take as a percentage of abundance, either the NMFS SARs (Carretta *et al.,* 2024; Young, 2024) or the NMSDD (table 2.4–1 in appendix A of the application). Please refer to the Odontocetes section for details on which abundance estimate was selected.

TABLE 94—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO BEAKED WHALES IN THE HCTT STUDY AREA

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.,* 2023) and West Coast (Calambokidis *et al.,* 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
Baird's Beaked Whale.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic, resident.	Large	Mixed	Slow	Fisheries interactions, ocean noise.	No	No	No	Stable, possibly increasing.	8.9	≥0.2
Blainville's Beaked Whale.	Hawaii	Not listed	Not depleted, not strategic.	Nomadic, resident.	Med	Mixed	Med	Fisheries interactions, ocean noise.	No	No	Yes: S–BIA Parent and Child O MN HI.	Unk	5.6	0
Goose-Beaked Whale.	Hawaii	Not listed	Not depleted, not strategic.	Nomadic, resident.	Med	Mixed	Med	Fisheries interactions, ocean noise.	No	No	Yes: S–BIA Parent and Child HI-Core.	Unk	32	0
Goose-Beaked Whale.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic, resident.	Med	Mixed	Med	Fisheries interactions, ocean noise.	No	No	No	Unk	42	<0.1
Longman's Beaked Whale.	Hawaii	Not listed	Not depleted, not strategic.	Nomadic-resident.	Med	Mixed	Med	Fisheries interactions, ocean noise.	No	No	No	Unk	15	0
Mesoplodont Beaked Whale.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Resident-nomadic.	Med	Mixed	Med	Fisheries interactions, ocean noise.	No	No	No	Unk, possibly increasing.	20	0.1

Note: N/A = Not Applicable, Unk = Unknown.

These stocks are not listed as endangered or threatened under the ESA, and they are not considered depleted or strategic under the MMPA. The stock abundance estimates range from 1,300 (Hawaii stock of Blainville's beaked whale, NMSDD) to 13,531 (CA/OR/WA stock of goose-beaked whale, NMSDD). There are no UMEs or other factors that cause particular concern for these stocks in the HCTT Study Area. As described in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the HCTT Study Area overlaps two known biologically important areas for small and resident populations for the Hawaii stocks of Blainville's and goose-beaked whales. Beaked whales face several chronic anthropogenic and non-anthropogenic risk factors, including fisheries interactions, and ocean noise, among others.

As shown in table 93, the maximum annual allowable instances of take under this proposed rule by Level A harassment and Level B Harassment range from 0 to 2, and 7,542 and 166,816, respectively. No mortality is anticipated or proposed for authorization, nor is any non-auditory injury. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with echolocation, overlap more than a relatively narrow portion of the vocalization range of any single species or stock, or preclude detection or interpretation of important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness on the CA/OR/WA stocks of goose- and mesoplodont beaked whales and the Hawaii stock of Longman's beaked whales.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 154 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Beaked whales are medium-to-large-bodied odontocetes with a medium pace of life and likely moderately resilient to missed foraging opportunities due to acoustic disturbance. They are mixed breeders (*i.e.,* behaviorally income breeders), and they demonstrate capital breeding strategies during gestation and lactation (Keen *et al.,* 2021), so they may be more vulnerable to prolonged loss of foraging opportunities during gestation. Further, as described in the *Group and Species-Specific Analyses* section above and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat. In particular, this proposed rulemaking includes a Hawaii Island Marine Mammal Mitigation Area, within which the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of helicopter dipping sonar (a mid-frequency active sonar source) annually and must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets). These restrictions would reduce exposure of numerous small and resident marine mammal populations, including the Hawaii stocks of Blainville's and goose-beaked whales, to levels of sound from sonar or explosives that have the potential to cause injury or mortality, thereby reducing the likelihood of those effects and, further, minimizing the severity of behavioral disturbance.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the number of takes by harassment as compared to the stock/species abundance (see table 93), it is likely that some portion of the individuals taken are taken repeatedly over a moderate number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Given the magnitude and severity of the impacts discussed above to beaked whale stock/species (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take anticipated and proposed for authorization would have a negligible impact on the CA/OR/WA stocks of Baird's, goose-, and mesoplodont beaked whales, and the Hawaii stocks of Blainville's, goose-, and Longman's beaked whale stocks.

Dolphins and Small Whales—

Of the 39 stocks of dolphins and small whales (Delphinidae) for which incidental take is proposed for authorization (see table 95), one is listed as endangered under the ESA and depleted and strategic under the MMPA: the Main Hawaiian Islands Insular stock of false killer whale. While not ESA-listed, the Hawaii Pelagic stock of false killer whale is considered strategic under the MMPA. As shown in table 95 and table 96, these delphinids vary in stock abundance, body size, and movement ecology from, for example, the small-bodied, nomadic CA/OR/WA stock of short-beaked common dolphin with NMSDD abundance estimate of 1,049,117, to the medium-sized small and resident Main Hawaiian Islands Insular stock of false killer whale with an estimated abundance of 138. The HCTT Study Area overlaps ESA-designated critical habitat for the Main Hawaiian Islands Insular stock of false killer whale (83 FR 35062, July 24, 2018), as well as BIAs for the following small and resident populations: false killer whale (Main Hawaiian Islands Insular and Northwest Hawaiian Islands stocks), melon-headed whale (Hawaiian Islands and Kohala Resident stocks), short-finned pilot whale (Hawaii stock), bottlenose dolphin (Maui Nui, Hawaii Island, Kauaʻi/Niʻihau, and Oʻahu stocks), pantropical spotted dolphins (Maui Nui, Hawaii Island, and Oʻahu stocks), rough-toothed dolphin (Hawaii stock), and spinner dolphin (Hawaii Island, Kauaʻi/Niʻihau, and Oʻahu/4

Islands Region stocks). These areas are described in the Description of Marine Mammals and Their Habitat in the Area of Specified Activities section. Delphinids face a number of chronic anthropogenic and non-anthropogenic risk factors including fishery interactions, biotoxins, chemical contaminants, illegal feeding/harassment, ocean noise, oil spills and energy exploration, vessel strikes, and swim with dolphin programs, the impacts of which vary depending whether the stock is more coastal (*e.g.,* swim with dolphin programs occur mostly with coastally-distributed spinner dolphins), more or less deep-diving (*e.g.,* entanglement more common in deep divers like pygmy killer whales and pilot whales), and other behavioral differences (*e.g.,* vessels strikes more concern for killer whales). There are no known UMEs or other factors that cause particular concern for these stocks.

TABLE 95—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR DOLPHINS IN THE HCTT STUDY AREA

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassment as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater	Greatest degree any individual expected to be taken repeatedly across multiple days
False Killer Whale	Main Hawaiian Islands Insular.	138	98	169	0	0	169	122	Warm (53 percent), Cold (46 percent).	HRC (100 percent).	Limited number of days.
False Killer Whale	Northwest Hawaiian Islands.	477	477	191	0	0	191	40	Cold (68 percent).	HRC (100 percent).	Limited number of days.
False Killer Whale	Hawaii Pelagic	5,528	2,400	1,670	1	0	1,671	30	Cold (52 percent).	HRC (95 percent).	Zero to limited number of days.
False Killer Whale	Baja California Peninsula Mexico.	N/A	1,990	2,537	2	0	2,539	128	Cold (58 percent).	SOCAL (100 percent).	Limited number of days.
Killer Whale	Hawaii	161	198	127	0	0	127	64	Cold (51 percent).	HRC (95 percent).	Zero to limited number of days.
Killer Whale	Eastern North Pacific Offshore.	300	155	1,023	4	0	1,027	342	Cold (61 percent).	SOCAL (88 percent).	Limited to moderate number of days.
Killer Whale	West Coast Transient	349	26	55	0	0	55	16	Warm (56 percent).	NOCAL (58 percent).	Zero to limited number of days.
Melon-Headed Whale	Hawaiian Islands	40,647	46,949	31,456	13	0	31,469	67	Cold (53 percent).	HRC (96 percent).	Limited number of days.
Melon-Headed Whale	Kohala Resident (Hawaii)	UNK	447	56	0	0	56	13	Warm (77 percent).	HRC (100 percent).	Zero to limited number of days.
Pygmy Killer Whale	Hawaii	10,328	11,928	8,895	3	0	8,898	75	N/A	HRC (95 percent).	Zero to limited number of days.
Pygmy Killer Whale	California—Baja California Peninsula Mexico.	N/A	874	795	0	0	795	91	Warm (100 percent).	SOCAL (84 percent).	Zero to limited number of days.
Short-Finned Pilot Whale	Hawaii	19,242	23,117	17,304	7	0	17,311	75	Cold (53 percent).	HRC (97 percent).	Limited number of days.
Short-Finned Pilot Whale	California/Oregon/Washington.	836	831	4,279	11	0.57	4,291	513	Cold (60 percent).	SOCAL (85 percent).	Moderate number of days.
Bottlenose Dolphin	Maui Nui	64	65	326	0	0	326	502	N/A	HRC (100 percent).	Moderate number of days.
Bottlenose Dolphin	Hawaii Island	136	138	9	0	0	9	7	Cold (80 percent).	HRC (100 percent).	Zero to limited number of days.
Bottlenose Dolphin	Hawaii Pelagic	24,669	25,120	43,313	25	0.29	43,338	173	Cold (52 percent).	HRC (100 percent).	Limited number of days.
Bottlenose Dolphin	Kaua'i/Ni'ihau	112	113	1,460	0	0	1,460	1,292	Cold (59 percent).	HRC (100 percent).	High number of days.
Bottlenose Dolphin	O'ahu	112	113	7,232	6	0.14	7,238	6,405	Cold (54 percent).	HRC (100 percent).	High number of days.
Bottlenose Dolphin	California Coastal	453	182	1,350	7	0	1,357	300	Cold (60 percent).	SOCAL (98 percent).	Limited to moderate number of days.
Bottlenose Dolphin	California/Oregon/Washington Offshore.	3,477	42,395	28,058	15	0	28,073	66	Warm (65 percent).	SOCAL (93 percent).	Zero to limited number of days.
Fraser's Dolphin	Hawaii	40,960	47,288	35,480	8	0	35,488	75	Cold 51 percent).	HRC (97 percent).	Zero to limited number of days.
Long-Beaked Common Dolphin.	California	83,379	209,100	296,878	152	2.43	297,032	142	Warm (54 percent).	SOCAL (82 percent).	Limited number of days.
Northern Right Whale Dolphin.	California/Oregon/Washington.	29,285	68,935	45,514	21	0.14	45,535	66	Cold (75 percent).	NOCAL (41 percent).	Zero to limited number of days.
Pacific White-Sided Dolphin.	California/Oregon/Washington.	34,999	107,775	69,210	42	0.29	69,252	64	Cold (59 percent).	SOCAL (53 percent).	Zero to limited number of days.
Pantropical Spotted Dolphin.	Maui Nui	UNK	2,674	2,373	4	0	2,377	89	N/A	HRC (100 percent).	Limited number of days.
Pantropical Spotted Dolphin.	Hawaii Island	UNK	8,674	6,024	7	0	6,031	70	Warm (51 percent).	HRC (100 percent).	Limited number of days.

TABLE 95—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR DOLPHINS IN THE HCTT STUDY AREA—Continued

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassment as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater	Greatest degree any individual expected to be taken repeatedly across multiple days
Pantropical Spotted Dolphin.	Hawaii Pelagic	67,313	62,395	44,390	19	0	44,409	71	Cold (55 percent).	HRC (97 percent).	Zero to limited number of days.
Pantropical Spotted Dolphin.	O'ahu	UNK	1,491	6,426	6	0	6,432	431	Warm (51 percent).	HRC (100 percent).	Moderate number of days.
Pantropical Spotted Dolphin.	Baja California Peninsula Mexico.	N/A	70,889	97,626	47	0.29	97,673	138	Cold (55 percent).	SOCAL (100 percent).	Limited number of days.
Risso's Dolphin	Hawaii	6,979	8,649	6,558	4	0	6,562	76	N/A	HRC (95 percent).	Zero to limited number of days.
Risso's Dolphin	California/Oregon/Washington.	6,336	19,357	43,833	21	0	43,854	227	Cold (54 percent).	SOCAL (87 percent).	Limited to moderate number of days.
Rough-Toothed Dolphin	Hawaii	83,915	106,193	96,873	36	0.29	96,909	91	Cold (53 percent).	HRC (97 percent).	Limited number of days.
Short-Beaked Common Dolphin.	California/Oregon/Washington.	1,056,308	1,049,117	2,169,554	877	15.29	2,170,446	207	Warm (53 percent).	SOCAL (82 percent).	Limited to moderate number of days.
Spinner Dolphin	Hawaii Pelagic	N/A	6,807	4,544	2	0	4,546	67	Cold (54 percent).	HRC (95 percent).	Zero to limited number of days.
Spinner Dolphin	Hawaii Island	665	670	110	1	0	111	17	Warm (60 percent).	HRC (100 percent).	Zero to limited number of days.
Spinner Dolphin	Kaua'i/Ni'ihau	N/A	606	4,446	2	0	4,448	734	Cold (65 percent).	HRC (100 percent).	Moderate number of days.
Spinner Dolphin	O'ahu/4 Islands Region	N/A	355	1,201	1	0	1,202	339	Warm (63 percent).	HRC (100 percent).	Limited to moderate number of days.
Striped Dolphin	Hawaii Pelagic	64,343	68,909	37,782	12	0	37,794	55	Cold (53 percent).	HRC (95 percent).	Zero to limited number of days.
Striped Dolphin	California/Oregon/Washington.	29,988	160,551	133,399	44	0.14	133,443	83	Warm (55 percent).	SOCAL (87 percent).	Zero to limited number of days.

Note: N/A = Not Applicable, UNK = Unknown. NMSDD abundances are averages only within the U.S. EEZ.

*Indicates which abundance estimate was used to calculate the maximum annual take as a percentage of abundance, either the NMFS SARs (Carretta *et al.,* 2024; Young, 2024) or the NMSDD (table 2.4–1 in appendix A of the application). Please refer to the Odontocetes section for details on which abundance estimate was selected.

TABLE 96—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO DOLPHINS IN THE HCTT STUDY AREA

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.,* 2023) and West Coast (Calambokidis *et al.,* 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
False Killer Whale.	Main Hawaiian Islands Insular.	Endangered	Depleted, Strategic.	Resident-nomadic.	Med	Income	Med	Fisheries interactions, contaminants.	No	Yes	Yes: S–BIA Parent and Child MHI-Core.	Decreasing	0.3	0.1
False Killer Whale.	Northwest Hawaiian Islands.	Not listed	Not depleted, not strategic.	Resident, nomadic.	Med	Income	Med	Fisheries interactions, contaminants.	No	No	Yes: S–BIA	Unk	1.43	0.16

False Killer Whale.	Hawaii Pelagic	Not listed	Not depleted, Strategic.	Nomadic	Med	Income	Med	Fisheries interactions, contaminants.	No	No	No	Unk	36	47
False Killer Whale.	Baja California Peninsula Mexico.	N/A	N/A	Unk	Med	Income	Med	Fisheries interactions, contaminants.	No	No	No	Unk		
Killer Whale	Hawaii	Not listed	Not depleted, not strategic.	Nomadic	Large	Income	Slow	Fisheries interactions.	No	No	No	Unk	0.8	0
Killer Whale	Eastern North Pacific Offshore.	Not listed	Not depleted, not strategic.	Nomadic	Large	Income	Slow	Fisheries interactions, vessel strikes, ocean noise.	No	No	No	Stable	2.8	0
Killer Whale	West Coast Transient.	Not listed	Not depleted, not strategic.	Nomadic	Large	Income	Slow	Fisheries interactions, vessel strikes, ocean noise.	No	No	No	Unk	3.5	0.4
Melon-Headed Whale.	Hawaiian Islands.	Not listed	Not depleted, not strategic.	Resident-nomadic.	Small	Income	Med	Fisheries interactions, ocean noise.	No	No	Yes: S–BIA	Unk	233	0
Melon-Headed Whale.	Kohala Resident (Hawaii).	Not listed	Not depleted, not strategic.	Resident	Small	Income	Med	Fisheries interactions, ocean noise.	No	No	Yes: S–BIA	Unk	UND	0
Pygmy Killer Whale.	Hawaii	Not listed	Not depleted, not strategic.	Resident, nomadic.	Small	Income	Med	Fisheries interactions, ocean noise.	No	No	No	Unk	59	0
Pygmy Killer Whale.	California—Baja California Peninsula Mexico.	N/A	N/A	Unk	Small	Income	Med	Fisheries interactions, ocean noise.	No	No	No	Unk		
Short-Finned Pilot Whale.	Hawaii	Not listed	Not depleted, not strategic.	Nomadic	Med	Income	Slow	Fisheries interactions.	No	No	Yes: S–BIA Parent and Child MHI-Western community, Central community, Eastern community.	Unk	159	0.2
Short-Finned Pilot Whale.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Med	Income	Slow	Fisheries interactions.	No	No	No	Unk	4.5	1.2
Bottlenose Dolphin.	Maui Nui	Not listed	Not depleted, not strategic.	Resident	Small-Med.	Income	Med	Entanglement	No	No	Yes: S–BIA Parent and Child.	Unk	0.6	UNK
Bottlenose Dolphin.	Hawaii Island	Not listed	Not depleted, not strategic.	Resident	Small-Med.	Income	Med	Fisheries interactions.	No	No	Yes: S–BIA	Unk	1	>0.2

TABLE 96—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO DOLPHINS IN THE HCTT STUDY AREA—Continued

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.*, 2023) and West Coast (Calambokidis *et al.*, 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
Bottlenose Dolphin.	Hawaii Pelagic	Not listed	Not depleted, not strategic.	Nomadic	Small-Med.	Income	Med	Fisheries interactions.	No	No	No	Unk	158	0
Bottlenose Dolphin.	Kaua'i/Ni'ihau ..	Not listed	Not depleted, not strategic.	Resident	Small-Med.	Income	Med	Fisheries interactions.	No	No	Yes: S–BIA Parent and Child.	Unk	0.9	UNK
Bottlenose Dolphin.	O'ahu	Not listed	Not depleted, not strategic.	Resident	Small-Med.	Income	Med	Entanglement ..	No	No	Yes: S–BIA Parent and Child.	Unk	1	UNK
Bottlenose Dolphin.	California Coastal.	Not listed	Not depleted, not strategic.	Nomadic	Small-Med.	Income	Med	Biotoxins, chemical contaminants, fisheries interactions, habitat alteration, illegal feeding and harassment, ocean noise, oil spills and energy exploration, vessel strikes.	No	No	No	Stable, possibly increasing.	2.7	≥2.0
Bottlenose Dolphin.	California/Oregon/Washington Offshore.	Not listed	Not depleted, not strategic.	Nomadic	Small-Med.	Income	Med	Fisheries interactions.	No	No	No	Unk	19.7	≥0.82
Fraser's Dolphin	Hawaii	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Fast	Fisheries interactions.	No	No	No	Unk	241	0
Long-Beaked Common Dolphin.	California	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Fisheries interactions, exposure to underwater detonations in coastal waters.	No	No	No	Unk	668	≥29.7
Northern Right Whale Dolphin.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Fisheries interactions.	No	No	No	Unk	163	≥6.6

Pacific White-Sided Dolphin.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Entanglement, fisheries interactions.	No	No	No	Unk	279	7
Pantropical Spotted Dolphin.	Maui Nui	Not listed	Not depleted, not strategic.	Resident	Small	Income	Med	Fisheries interactions.	No	No	Yes: S–BIA Parent and Child.	Unk	UND	UNK
Pantropical Spotted Dolphin.	Hawaii Island	Not listed	Not depleted, not strategic.	Resident	Small	Income	Med	Fisheries interactions.	No	No	Yes: S–BIA Parent and Child.	Unk	UND	UNK
Pantropical Spotted Dolphin.	Hawaii Pelagic	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Fisheries interactions.	No	No	No	Unk	538	0
Pantropical Spotted Dolphin.	O'ahu	Not listed	Not depleted, not strategic.	Resident	Small	Income	Med	Fisheries interactions.	No	No	Yes: S–BIA Parent and Child.	Unk	UND	UNK
Pantropical Spotted Dolphin.	Baja California Peninsula Mexico.	N/A	N/A	Nomadic	Small	Income	Med	Fisheries interactions.	No	No	No	Unk	UNK	UNK
Risso's Dolphin	Hawaii	Not listed	Not depleted, not strategic.	Nomadic	Small-Med.	Income	Med	Fisheries interactions.	No	No	No	Unk	53	0
Risso's Dolphin	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Small-Med.	Income	Med	Fisheries interactions.	No	No	No	Unk	46	≥3.7
Rough-Toothed Dolphin.	Hawaii	Not listed	Not depleted, not strategic.	Resident, nomadic.	Small	Income	Med	Fisheries interactions.	No	No	Yes: S–BIA MNHI, Parent and Child KN O.	Unk	511	3.2
Short-Beaked Common Dolphin.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Fisheries interactions, exposure to underwater detonations in coastal waters.	No	No	No	Unk, possibly increasing.	8,889	≥30.5
Spinner Dolphin	Hawaii Pelagic	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Fast	Fisheries interactions, ocean noise.	No	No	No	Unk	UND	0
Spinner Dolphin	Hawaii Island	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Fast	Swim with the dolphin programs, ocean noise, fisheries interactions.	No	No	Yes: S–BIA	Unk	6.2	≥1.0

TABLE 96—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO DOLPHINS IN THE HCTT STUDY AREA—Continued

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.*, 2023) and West Coast (Calambokidis *et al.*, 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
Spinner Dolphin	Kaua'i/Ni'ihau ..	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Fast	Swim with the dolphin programs, ocean noise, fisheries interactions.	No	No	Yes: S–BIA ...	Unk	UND	UNK
Spinner Dolphin	O'ahu/4 Islands Region.	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Fast	Swim with the dolphin programs, ocean noise, fisheries interactions.	No	No	Yes: S–BIA ...	Unk	UND	≥0.4
Striped Dolphin ..	Hawaii Pelagic	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Fisheries interactions.	No	No	No	Unk	511	0
Striped Dolphin ..	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Med	Fisheries interactions.	No	No	No	Unk	225	≥4

Note: N/A = Not Applicable, UND = Undetermined, Unk = Unknown.

As shown in table 95, the maximum annual allowable instances of take by Level B harassment for delphinid stocks ranges from 9 (Hawaii Island stock of bottlenose dolphin) to 2,169,554 for the CA/OR/WA stock of short-beaked common dolphin, with 14 stocks below 2,000, five stocks above 70,000, and the remainder between 2,000 and 70,000. Take by Level A harassment is 0 for 9 of the 39 stocks, between 1 and 15 for 20 stocks, and above 15 for 10 stocks. As indicated, the rule also allows for take by M/SI for 10 stocks (the CA/OR/WA stocks of short-finned pilot whale, northern right whale dolphin, Pacific white-sided dolphin, short-beaked common dolphin, and striped dolphin; the Hawaii Pelagic and Oʻahu stocks of bottlenose dolphin; the California stock of long-beaked common dolphin; the Baja California Peninsula Mexico population of pantropical spotted dolphin; and the Hawaii stock of rough-toothed dolphin), the impacts of which are discussed above in the Serious Injury and Mortality section. The total take allowable across all 7 years of the rule is indicated in table 54.

All delphinid stocks are expected to incur some number of takes in the form of TTS. As described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, these temporary hearing impacts are expected to be lower-level, of short duration (from minutes to at most several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with delphinid echolocation, overlap more than a relatively narrow portion of the vocalization range of any single species or stock, or preclude detection or interpretation of important low-frequency cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. About three-quarters of the affected delphinid stocks will incur some number of takes by AUD INJ, over half of those stocks will incur take in the single digits, with only two stocks exceeding 45 (long- and short-beaked common dolphin). For reasons similar to those discussed for TTS, while auditory injury impacts last longer, given the anticipated effectiveness of mitigation measures and the likelihood that individuals are expected to avoid higher levels associated with more severe impacts, the lower anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to affect the fitness of any individuals. Two stocks are projected to incur notably higher numbers of take by AUD INJ (128 for the California stock of long-beaked common dolphin and 806 for the CA/OR/WA stock of short-beaked common dolphin) and while the conclusions above are still applicable, it is further worth noting that these two stocks have relatively large abundances and limited annual mortality as compared to PBR. The rule also allows for a limited number of takes by non-auditory injury (*i.e.,* 1–71) for 19 stocks (less than 5 takes for all stocks except for the California stock of long-beaked common dolphin and the CA/OR/WA stock of short-beaked common dolphin). As described above in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these non-auditory injuries are unlikely to be of a nature or level that would impact reproduction or survival, with the exception of long- and short-beaked common dolphins.

Due to the larger number of long- and short-beaked common dolphin individuals predicted to be exposed annually to levels associated with non-auditory injury (24 and 71, respectively), it is more likely that some subset of these individuals could potentially be injured in a manner that would result in them foregoing reproduction for a year (up to 4 long-beaked and 13 short-beaked common dolphins). A year of foregone reproduction for a male is generally meaningless to population rates unless the animal ultimately dies. M/SI have been modeled for this activity separately, and NMFS does not anticipate that these non-auditory injuries would result in mortality, for young or adults. Neither stock is considered depleted or strategic. While the population trends of these stocks are not known (though the SAR notes that the CA/OR/WA stock of short-beaked common dolphin is possibly increasing), they are not considered depleted or strategic, and total annual mortality is well below PBR for each stock. Importantly, the increase in a calving interval by a year would have far less of an impact on a population rate than a mortality would and, accordingly, the number of instances of foregone reproduction predicted here would not be expected to adversely affect this stock through effects on annual rates of recruitment or survival.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 178 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Delphinids are income breeders with a medium pace of life, meaning that while they can be sensitive to the consequences of disturbances that impact foraging during lactation, from a population standpoint, they can be moderately quick to recover. Further, as described in the *Group and Species-Specific Analyses* section (and the Proposed Mitigation Measures section), mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in higher value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In the case of over half of the delphinid stocks (see the ''Greatest degree any individual expected to be taken repeatedly across multiple days'' column in table 95), given the low number of takes by harassment as compared to the stock/species abundance alone, and also in consideration of their nomadic movement pattern and whether take is concentrated in areas in which animals are known to congregate, it is unlikely that these individual delphinids would be taken on more than a limited number of days within a year and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival. In the case of the rest of the stocks, given the number of takes by harassment as compared to the stock/species abundance, it is likely that some portion of the individuals taken are taken repeatedly over a small to moderate number of days (as indicated in the ''Greatest degree any individual expected to be taken repeatedly across multiple days'' column in table 95), with two stocks (Kauaʻi/Niʻihau and Oʻahu stocks of bottlenose dolphins) likely to be taken over a high number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at

different times and in different areas, and the fact that many result from transient activities conducted at sea, for all stocks except Kauaʻi/Niʻihau and Oʻahu stocks of bottlenose dolphins (addressed below), it is unlikely that the anticipated small to moderate number of repeated takes for a given individual would occur clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals are likely to be impacted. Further, many of these stocks are nomadic and, apart from the small resident populations, there are no known foraging areas or other areas within which delphinids are known to congregate for important behaviors, and for most stocks, the takes are not concentrated within a specific region and season.

Regarding the magnitude of repeated takes for the Kauaʻi/Niʻihau and Oʻahu stocks of bottlenose dolphins, given the number of takes by harassment as compared to the stock/species abundance and the small resident populations, it is more likely that some number of individuals would experience a comparatively higher number of repeated takes over a potentially fair number of sequential days. Due to the higher number of repeated takes focused within the stocks' limited ranges, it is thereby more likely that a portion of the individuals (approximately 50 percent of which would be female) could be repeatedly interrupted during foraging in a manner and amount such that impacts to the energy budgets of a limited number of females (from either losing feeding opportunities or expending considerable energy moving away from sound sources or finding alternative feeding options) could cause them to forego reproduction for a year (noting that bottlenose dolphin calving intervals are typically 3 or more years). Energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal, male or female. The population trends of these stocks are unknown, and neither are considered depleted or strategic. Importantly, the increase in a calving interval by a year would have far less of an impact on a population rate than a mortality would and, accordingly, a limited number of instances of foregone reproduction would not be expected to adversely affect these stocks through effects on annual rates of recruitment or survival (noting also that no mortality is predicted or authorized for the Kauaʻi/Niʻihau stock, and 0.14 annual mortality is authorized for the Oʻahu stock). Further, of note, use of in-water explosives (including underwater explosives and explosives deployed against surface targets) is prohibited within the Hawaii 4-Islands Marine Mammal Mitigation Area. This measure would be prevent exposure of these stocks to explosives that have the potential to cause injury, mortality or behavioral disturbance within that area. Further, within the same area, mitigation from November 15 to April 15 prohibiting use of MF1 surface ship hull-mounted mid-frequency active sonar would reduce exposure of these stocks to levels of sound that have the potential to cause injurious or behavioral impacts.

Given the magnitude and severity of the take by harassment discussed above and any anticipated habitat impacts, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are unlikely to result in impacts on the reproduction or survival of any individuals of delphinid stocks, with the exception of the 10 stocks for which takes by M/SI are predicted and the 1 stock for which an increased calving interval could potentially occur. Regarding the Kauaʻi/Niʻihau and Oʻahu stocks of bottlenose dolphins, as described above, we do not anticipate the relatively limited number of individuals that might be taken over repeated days within the year in a manner that results in a year of foregone reproduction to adversely affect the stock through effects on rates of recruitment or survival, given the status of the stocks. Regarding the CA/OR/WA stock of short-finned pilot whale, Hawaii Pelagic and Oʻahu stocks of bottlenose dolphin, California stock of long-beaked common dolphin, CA/OR/WA stock of Northern right whale dolphin, CA/OR/WA stock of Pacific white-sided dolphin, Baja California Peninsula Mexico population of pantropical spotted dolphin, Hawaii stock of rough-toothed dolphin, CA/OR/WA stock of short-beaked common dolphin, and CA/OR/WA stock of striped dolphin, as described in the Serious Injury and Mortality section, given the status of the stocks and in consideration of other ongoing anthropogenic mortality (where known), the amount of allowed M/SI take proposed here would not alone, nor in combination with the impacts of the take by harassment discussed above (which are not expected to impact the reproduction or survival of any individuals for those stocks), be expected to adversely affect rates of recruitment and survival. For these reasons, we have determined that the total take (considering annual maxima and across 7 years) anticipated and proposed for authorization would have a negligible impact on all delphinid species and stocks.

Porpoises—

Neither Dall's porpoise nor harbor porpoise are listed as endangered or threatened under the ESA, and none of the porpoise stocks are considered depleted or strategic under the MMPA. The Navy's NMSDD estimate for the CA/OR/WA stock of Dall's porpoise is 61,840, and the stock abundances of harbor porpoises range from 3,885 (Navy's NMSDD) to 15,303 (SAR). There are no UMEs or other factors that cause particular concern for this stock. As described in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the HCTT Study Area overlaps two small and resident population BIAs for the Monterey Bay and Morro Bay stocks of harbor porpoise (Calambokidis *et al.,* 2015). There is no ESA-designated critical habitat for Dall's or harbor porpoise as neither species is ESA-listed. Dall's porpoises can be found from Baja California, Mexico, to the northern Bering Sea. They shift their distribution southward during cooler-water periods on both interannual and seasonal time scales. They primarily congregate in shelf and slope waters and decrease substantially in waters warmer than 17°C (63 °F). Harbor porpoises generally have higher abundances in shallow waters (less than 200 m (656 ft)) and near shore, but they sometimes move into deeper offshore waters. However, this species has no overlap with nearshore or offshore areas in the SOCAL Range Complex (*e.g.,* San Diego, SOAR) or the southern nearshore portions of PMSR (*e.g.,* Port Hueneme). Dall's and harbor porpoises face several chronic anthropogenic and non-anthropogenic risk factors, including fishing gear, fisheries interactions, and ocean noise (including acoustic deterrent devices or ''seal bombs'' in the case of harbor porpoises), among others.

TABLE 97—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR PORPOISES IN THE HCTT STUDY AREA

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual level B harassment	Maximum annual level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassment as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater
Dall's Porpoise	California/Oregon/Washington.	16,498	61,840	59,619	1,237	0	60,856	98	Cold (82 percent)	SOCAL (48 percent)
Harbor Porpoise	Monterey Bay	3,760	4,530	2,179	0	0	2,179	48	Cold (71 percent)	NOCAL (100 percent)
Harbor Porpoise	Morro Bay	4,191	3,885	4,373	88	0	4,461	115	Cold (74 percent)	PMSR (99 percent)
Harbor Porpoise	Northern California/Southern Oregon.	15,303	1,961	481	0	0	481	3	Cold (68 percent)	NOCAL (100 percent)
Harbor Porpoise	San Francisco/Russian River.	7,777	9,974	9,960	26	0	9,986	100	Cold (61 percent)	NOCAL (100 percent)

Note: N/A = Not Applicable, UNK = Unknown. NMSDD abundances are averages only within the U.S. EEZ.
*Indicates which abundance estimate was used to calculate the maximum annual take as a percentage of abundance, either the NMFS SARs (Carretta *et al.,* 2024; Young, 2024) or the NMSDD (table 2.4–1 in appendix A of the application). Please refer to the Odontocetes section for details on which abundance estimate was selected.

TABLE 98—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO PORPOISES IN THE HCTT STUDY AREA

Marine Mammal Species	Stock	ESA Status	MMPA Status	Movement Ecology	Body Size	Reproductive Strategy	Pace of Life	Chronic Risk Factors	UME, Oil Spill, Other	ESA-Designated Critical Habitat	BIAs II for Hawaii (Kratofil *et al.,* 2023) and West Coast (Calambokidis *et al.,* 2024)	Population Trend	PBR	Annual Mortality/Serious Injury (from other human activities)
Dall's Porpoise.	California/Oregon/Washington.	Not listed	Not depleted, not strategic.	Nomadic	Small	Income	Fast	Fishing gear fisheries interactions.	No	No	No	Unk	99	≥0.66
Harbor Porpoise.	Monterey Bay	Not listed	Not depleted, not strategic.	Resident	Small	Income	Fast	Fisheries interactions, ocean noise (including acoustic deterrent devices or "seal bombs").	No	No	Yes: S–BIA	Increasing	35	≥0.2
Harbor Porpoise.	Morro Bay	Not listed	Not depleted, not strategic.	Resident	Small	Income	Fast	Fisheries interactions, ocean noise (including acoustic deterrent devices or "seal bombs").	No	No	Yes: S–BIA	Increasing	65	0
Harbor Porpoise.	Northern California/Southern Oregon.	Not listed	Not depleted, not strategic.	Resident	Small	Income	Fast	Fisheries interactions, ocean noise (including acoustic deterrent devices or "seal bombs").	No	No	No	Unk	195	0
Harbor Porpoise.	San Francisco/Russian River.	Not listed	Not depleted, not strategic.	Resident	Small	Income	Fast	Fisheries interactions, ocean noise (including acoustic deterrent devices or "seal bombs").	No	No	No	Stable	73	≥0.4

Note: N/A = Not Applicable, UND = Undetermined, Unk = Unknown.

As shown in table 97, the maximum annual allowable instances of take of Dall's porpoise under this proposed rule by Level A harassment and Level B harassment is 1,237 and 59,619, respectively, while the maximum allowable take of harbor porpoise by Level A harassment and Level B harassment is 88 (Morro Bay stock) and 9,960 (San Francisco/Russian River stock), respectively. No mortality is anticipated or proposed for authorization. The rule allows for a limited number of takes by non-auditory injury (two for Dall's porpoise, one for the Morro Bay stock of harbor porpoise). As described above, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these injuries are unlikely to impact reproduction or survival. The total take allowable across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as VHF cetaceans, Dall's and harbor porpoises are more susceptible to auditory impacts in mid- to high frequencies and from explosives than other species. As described in the Temporary Threshold Shift section above, any takes in the form of TTS are expected to be lower-level, of short duration (even the longest recovering in less than a day), and mostly not in a frequency band that would be expected to interfere with porpoise communication or other important auditory cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness. The rule also allows for a limited number of takes by non-auditory injury for Dall's porpoise and the Morro Bay stock of harbor porpoise (two and one, respectively). As described above in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these non-auditory injuries are unlikely to be of a nature or level that would impact reproduction or survival for these stocks.

Harbor porpoises are more susceptible to behavioral disturbance than other species. They are highly sensitive to many sound sources and generally demonstrate strong avoidance of most types of acoustic stressors. The information currently available regarding harbor porpoises suggests a very low threshold level of response for both captive (Kastelein *et al.,* 2000; Kastelein *et al.,* 2005) and wild (Johnston, 2002) animals. Southall *et al.* (2007) concluded that harbor porpoises are likely sensitive to a wide range of anthropogenic sounds at low received levels (approximately 90 to 120 dB). Research and observations of harbor porpoises for other locations show that this species is wary of human activity and will display profound avoidance behavior for anthropogenic sound sources in many situations at levels down to 120 dB re: 1 µPa (Southall *et al.,* 2007). Harbor porpoises routinely avoid and swim away from large, motorized vessels (Barlow 1988; Evans *et al.,* 1994; Palka and Hammond, 2001; Polacheck and Thorpe, 1990). Accordingly, and as described in the Estimated Take of Marine Mammals section, the threshold for behavioral disturbance is lower for harbor porpoises, and the number of estimated takes is higher, with many occurring at lower received levels than other taxa. Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 154 dB SPL and last from a few minutes to a few hours, at most. Associated responses would likely include avoidance, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours and not likely to exceed 24 hours.

As small odontocetes and income breeders with a fast pace of life, Dall's and harbor porpoises are less resilient to missed foraging opportunities than larger odontocetes. Although reproduction in populations with a fast pace of life are more sensitive to foraging disruption, these populations are quick to recover. Further, as described in the *Group and Species-Specific Analyses* section and the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, for the Monterey Bay and Morro Bay stocks of harbor porpoise, given the number of takes by harassment as compared to the stock/species abundance (see table 97) and the small resident populations, it is likely that some portion of the individuals taken are taken repeatedly over a limited number of days. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Given the magnitude and severity of the impacts discussed above to Dall's porpoises and harbor porpoises (considering annual take maxima and the total across 7 years) and their habitat, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are unlikely to result in impacts on the reproduction or survival of any individuals and, thereby, unlikely to affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed for authorization would have a negligible impact on Dall's porpoise and all four stocks of harbor porpoises.

Pinnipeds

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different pinniped stocks will incur, the applicable mitigation for each stock, and the status and life history of the stocks to support the negligible impact determinations for each. We have already described above why we believe the incremental addition of the moderate number of low-level auditory injury takes will not have any meaningful effect towards inhibiting reproduction or survival. We have also described above in this section the unlikelihood of any masking or habitat impacts having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Action Proponents' activities. Regarding the severity of individual takes by Level B harassment by behavioral disturbance for pinnipeds, the majority of these

responses are anticipated to occur at received levels below 172 dB, and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours.

In table 99 below for pinnipeds, we indicate the total annual mortality, Level A harassment, and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. In table 100 below, we indicate the status, life history traits, important habitats, and threats that inform our analysis of the potential impacts of the estimated take on the affected pinniped stocks.

TABLE 99—ANNUAL ESTIMATED TAKE BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY AND RELATED INFORMATION FOR PINNIPEDS IN THE HCTT STUDY AREA

Marine mammal species	Stock	NMFS stock abundance	NMSDD abundance	Maximum annual Level B harassment	Maximum annual Level A harassment	Maximum annual mortality	Maximum annual take	Maximum annual harassment as percentage of stock abundance	Season(s) with 50 percent of take or greater	Region(s) with 40 percent of take or greater
California Sea Lion.	U.S	257,606	199,121	1,899,749	723	3.86	1,900,476	738	Cold (53 percent).	SOCAL (74 percent).
Guadalupe Fur Seal.	Mexico	63,850	48,780	347,553	54	0.14	347,607	544	N/A	SOCAL (82 percent).
Northern Fur Seal.	Eastern Pacific	612,765	89,110	33,195	12	0	33,207	5	Cold (86 percent).	NOCAL (47 percent), PMSR (53 percent).
Northern Fur Seal.	California	19,634	14,115	22,098	10	0	22,108	113	Cold (58 percent).	PMSR (71 percent).
Steller Sea Lion	Eastern	36,308	3,181	999	3	0	1,002	3	Cold (56 percent).	NOCAL (48 percent), SOCAL (49 percent).
Harbor Seal	California	30,968	13,343	71,463	261	1.00	71,725	232	N/A	SOCAL (92 percent).
Hawaiian Monk Seal.	Hawaii	1,605	967	1,104	6	0	1,110	69	Cold (54 percent).	HRC (99 percent).
Northern Elephant Seal.	California Breeding.	194,907	49,526	118,514	111	0	118,625	61	Cold (62 percent).	SOCAL (57 percent).

Note: N/A = Not Applicable, UNK = Unknown. NMSDD abundances are averages only within the U.S. EEZ.

* Indicates which abundance estimate was used to calculate the maximum annual take as a percentage of abundance, either the NMFS SARs (Carretta *et al.,* 2024; Young, 2024) or the NMSDD (table 2.4–1 in appendix A of the application). Please refer to the Pinnipeds section for details on which abundance estimate was selected.

TABLE 100—LIFE HISTORY TRAITS, IMPORTANT HABITAT, AND THREATS TO PINNIPEDS IN THE HCTT STUDY AREA

Marine mammal species	Stock	ESA status	MMPA status	Movement ecology	Body size	Reproductive strategy	Pace of life	Chronic risk factors	UME, oil spill, other	ESA-designated critical habitat	BIAs II for Hawaii (Kratofil *et al.*, 2023) and West Coast (Calambokidis *et al.*, 2024)	Population trend	PBR	Annual mortality/serious injury (from other human activities)
California Sea Lion.	U.S	Not listed	Not depleted, not strategic.	Resident-migratory.	Small	Income	Fast	Fisheries interactions, power plant entrainment, illegal harassment, habitat degradation, vessel strike, chemical contaminants.	No	No	No	Stable	14,011	>321
Guadalupe Fur Seal.	Mexico ...	Threatened ...	Depleted, Strategic.	Migratory ...	Small	Income	Fast	Fisheries interactions, intentional illegal killing/harassment.	No	No	No	Increasing	1,959	≥10.0
Northern Fur Seal.	Eastern Pacific.	Not listed	Depleted, Strategic.	Migratory ...	Small	Income	Fast	Fisheries interactions, intentional killing/harassment, chemical contaminants.	No	No	No	Decreasing	11,151	296
Northern Fur Seal.	California	Not listed	Not depleted, not strategic.	Resident	Small	Income	Fast	Fisheries interactions.	No	No	No	Variable	527	≥1.2
Steller Sea Lion.	Eastern ..	Not listed	Not depleted, not strategic.	Resident	Small	Income	Fast	Fisheries interactions, harassment/.	No	No	No	Increasing	2,178	93.2
Harbor Seal.	California	Not listed	Not depleted, not strategic.	Resident	Small	Capital	Fast	Disturbance at rookeries, commercial aquaculture, illegal intentional killing, chemical contaminants.	No	No	No	Decreasing	1,641	43
Hawaiian Monk Seal.	Hawaii	Endangered ..	Depleted, Strategic.	Resident	Small	Capital	Fast	Fisheries interactions, illegal harassment, habitat degradation.	No	Yes	No	Increasing	5.3	≥4.8
Northern Elephant Seal.	California Breeding.	Not listed	Not depleted, not strategic.	Migratory ...	Small-Med.	Capital	Fast	Fisheries interactions, illegal harassment, chemical contaminants.	No	No	No	Increasing	5,328	11.2

Note: N/A = Not Applicable, UND = Undetermined, Unk = Unknown.

The Hawaiian monk seal (a NMFS Species in the Spotlight) and Guadalupe fur seal are listed as endangered and threatened, respectively, under the ESA and are considered depleted and strategic under the MMPA. Northern fur seals are not listed as endangered or threatened under the ESA, but the Eastern Pacific stock is considered depleted and strategic under the MMPA. The remaining pinniped stocks for which incidental take is proposed for authorization (see table 99) are neither ESA-listed nor considered depleted or strategic under the MMPA.

As shown in table 99 and table 100, these pinnipeds vary in stock abundance and movement ecology from, for example, the resident Hawaii stock of Hawaiian monk seal with an estimated abundance of 1,605 animals to the migratory Eastern Pacific stock of Northern fur seal with an estimated abundance of 612,765 animals. The HCTT Study Area overlaps the Hawaiian monk seal ESA-designated critical habitat (51 FR 16047, April 30, 1986; 53 FR 18988, May 26, 1988; 80 FR 50925, August 21, 2015), as described in the Description of Marine Mammals in the Area of Specified Activities section, and there are no known BIAs for pinnipeds that overlap the HCTT Study Area. There are no UMEs or other factors that cause additional concern for these stocks. Pinnipeds face a number of chronic anthropogenic and non-anthropogenic risk factors including fisheries interactions, illegal harassment, habitat degradation, disease, intentional killing/harassment, chemical contaminants, power plant entrainment, vessel strike, harmful algal blooms, commercial aquaculture, and harassment/disturbance at rookeries.

As shown in table 99, the maximum annual allowable instances of take by Level B harassment for pinnipeds ranges from 999 (Eastern stock of Steller sea lion) to 1,899,749 (U.S. stock of California sea lion), with 3 stocks below 23,000, 5 stocks above 23,000, and California sea lion being the only stock over 348,000. Take by Level A harassment is at or below 12 for four stocks, and above 12 for four stocks. As described above, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these injuries are unlikely to impact reproduction or survival. No mortality is anticipated or proposed for authorization for any pinniped stocks except the U.S. stock of California sea lion, Mexico stock of Guadalupe fur seal, and California stock of harbor seal. For those three stocks, the rule also allows for up to 27, 1, and 7 takes by serious injury or mortality, respectively, over the course of the 7-year rule, the impacts of which are discussed above in the Serious Injury and Mortality section. The total take proposed for authorization across all 7 years of the rule is indicated in table 54.

Regarding the potential takes associated with auditory impairment, as described in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section above, any takes in the form of TTS are expected to be lower-level, of short duration (from minutes to, at most, several hours or less than a day), and mostly not in a frequency band that would be expected to interfere with pinniped communication or other important auditory cues. Any associated lost opportunities or capabilities individuals might experience as a result of TTS would not be at a level or duration that would be expected to impact reproductive success or survival. For similar reasons, while auditory injury impacts last longer, the low anticipated levels of AUD INJ that could be reasonably expected to result from these activities are unlikely to have any effect on fitness.

The rule also allows for a limited number of takes by non-auditory injury (1 to 57) for 7 of the 8 stocks (less than five takes for all stocks except for the U.S. stock of California sea lion and California stock of harbor seal). As described above in the Auditory Injury from Sonar Acoustic Sources and Explosives and Non-Auditory Injury from Explosives section, given the limited number of potential exposures and the anticipated effectiveness of the mitigation measures in minimizing the pressure levels to which any individuals are exposed, these non-auditory injuries are unlikely to be of a nature or level that would impact reproduction or survival of these stocks, with the exception of the U.S. stock of California sea lion and California stock of harbor seal.

Due to the larger number of California sea lion and California stock of harbor seal individuals predicted to be exposed annually to levels associated with non-auditory injury (57 and 7, respectively), it is more likely that some subset of these individuals could potentially be injured in a manner that would result in them foregoing reproduction for a year (up to 10 California sea lions and 1 harbor seal). A year of foregone reproduction for a male is generally meaningless to population rates unless the animal ultimately dies. M/SI have been modeled for this activity separately, and NMFS does not anticipate that these non-auditory injuries would result in mortality, for young or adults. The U.S. stock of California sea lion is considered stable. While the population trend of the California stock of harbor seal is decreasing, neither of these stocks are considered depleted or strategic, and total annual mortality is well below PBR for both stocks. Importantly, the increase in a pupping interval by a year would have far less of an impact on a population rate than a mortality would and, accordingly, the number of instances of foregone reproduction predicted here would not be expected to adversely affect this stock through effects on annual rates of recruitment or survival.

Regarding the likely severity of any single instance of take by behavioral disturbance, as described above, the majority of the predicted exposures are expected to be below 172 dB SPL and last from a few minutes to a few hours, at most, with associated responses most likely in the form of moving away from the source, foraging interruptions, vocalization changes, or disruption of other social behaviors, lasting from a few minutes to several hours. Pinnipeds are small-bodied (or small to medium-bodied) income breeders with a fast pace of life but have a relatively lower energy requirement for their body size, which may moderate any impact due to foraging disruption. Further, as described in the *Group and Species-Specific Analyses* section above and in the Proposed Mitigation Measures section, mitigation measures are expected to further reduce the potential severity of impacts through real-time operational measures that minimize higher level/longer duration exposures and time/area measures that reduce impacts in high value habitat. In particular, this proposed rulemaking includes a Hawaii Island Marine Mammal Mitigation Area and a Hawaii 4-Islands Marine Mammal Mitigation Area which would reduce exposure of Hawaiian monk seals to levels of sound that have the potential to cause injury or behavioral impacts, including within a portion of Hawaiian monk seal critical habitat.

As described above, in addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. Given the number of takes by harassment as compared to the stock/species abundance alone (see table 99), and also in consideration of their movement pattern and whether

take is concentrated in areas in which animals are known to congregate, it is unlikely that these individual pinnipeds would be taken on more than a limited number of days within a year (with the exception of California sea lion for which some individuals may be taken on a limited to moderate number of days within a year) and, therefore, the anticipated behavioral disturbance is not expected to affect reproduction or survival. However, given the variety of activity types that contribute to take across separate exercises conducted at different times and in different areas, and the fact that many result from transient activities conducted at sea, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted. Further, many of these stocks are migratory and apart from the small resident populations, there are no known foraging areas or other areas within which animals are known to congregate for important behaviors, and for most stocks, the predicted takes are not concentrated within a specific region and season.

Given the magnitude and severity of the take by harassment discussed above and any anticipated habitat impacts, and in consideration of the required mitigation measures and other information presented, the Action Proponents' activities are unlikely to result in impacts on the reproduction or survival of any individuals of pinniped stocks, with the exception of the three stocks for which takes by M/SI are predicted and the two stocks for which an increased pupping interval could potentially occur. Regarding the U.S. stock of California sea lion and California stock of harbor seal, as described above, we do not anticipate the relatively limited number of individuals that might be taken by non-auditory injury in a manner that results in a year of foregone reproduction to adversely affect the stock through effects on rates of recruitment or survival, given the status of the stocks. Regarding the U.S. stock of California sea lion, Mexico stock of Guadalupe fur seal, and California stock of harbor seal, as described in the Serious Injury and Mortality section, given the status of the stocks and in consideration of other ongoing anthropogenic mortality, the amount of allowed M/SI take proposed here would not alone, nor in combination with the impacts of the take by harassment discussed above (which are not expected to impact the reproduction or survival of any individuals for those stocks), be expected to adversely affect rates of recruitment and survival. For these reasons, we have determined that the total take (considering annual maxima and across 7 years) anticipated and proposed for authorization would have a negligible impact on all pinniped species and stocks.

Preliminary Determination

Based on the analysis contained herein of the likely effects of the specified activities on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the specified activity will have a negligible impact on all affected marine mammal species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Classification

Endangered Species Act

There are 10 marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA with confirmed or possible occurrence in the HCTT Study Area: blue whale, fin whale, gray whale, humpback whale, sei whale, sperm whale, killer whale, false killer whale, Guadalupe fur seal, and Hawaiian monk seal. The humpback whale (86 FR 21082, April 21, 2021), killer whale (71 FR 69054, November 29, 2006; revised August 2, 2021 (86 FR 41668)), false killer whale (83 FR 35062, July 24, 2018), and Hawaiian monk seal (51 FR 16047, April 30, 1986; revised in 1988 (53 FR 18988, May 26, 1988) and in 2015 (80 FR 50925, August 21, 2015)) have critical habitat designated under the ESA in the HCTT Study Area.

The Action Proponents will consult with NMFS pursuant to section 7 of the ESA for the HCTT Study Area activities. NMFS will also consult internally on the issuance of the regulations and three LOAs under section 101(a)(5)(A) of the MMPA.

National Marine Sanctuaries Act

The Action Proponents and NMFS will work with NOAA's Office of National Marine Sanctuaries to fulfill our responsibilities under the National Marine Sanctuaries Act as warranted and will complete any NMSA requirements prior to a determination on the issuance of the final rule and LOAs.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review its proposed actions with respect to potential impacts on the human environment. Accordingly, NMFS plans to adopt the 2024 HCTT Draft EIS/OEIS for the HCTT Study Area, provided our independent evaluation of the document finds that it includes adequate information analyzing the effects on the human environment of issuing regulations and LOAs under the MMPA. NMFS is a cooperating agency on the 2024 HCTT Draft EIS/OEIS and has worked extensively with the Navy in developing the document. The 2024 HCTT Draft EIS/OEIS was made available for public comment at: *https://www.nepa.navy.mil/hctteis/,* which also provides additional information about the NEPA process, from December 13, 2024, to February 11, 2025. We will review all comments prior to concluding our NEPA process and making a final decision on the MMPA rulemaking and request for LOAs.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the MMPA rule and request for LOAs.

Executive Order 12866

The Office of Management and Budget has determined that this proposed rule is not significant for purposes of Executive Order 12866.

Executive Order 14192

This proposed rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

The Regulatory Flexibility Act (RFA) requires Federal agencies to prepare an analysis of a rule's impact on small entities whenever the agency is required to publish a notice of proposed rulemaking. However, a Federal agency may certify, pursuant to 5 U.S.C. 605(b), that the action will not have a significant economic impact on a substantial number of small entities. The Action Proponents are the only entities that would be affected by this proposed rulemaking, and the Action Proponents are not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Any requirements imposed by an LOA issued pursuant to these regulations, and any monitoring or reporting requirements imposed by these regulations, would be applicable only to the Action Proponents. NMFS does not expect the issuance of these regulations or the associated LOAs to result in any impacts to small entities pursuant to the RFA. Because this action, if adopted, would directly affect only the Action Proponents and not any small entities, NMFS concludes that the action would not result in a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 218

Administrative practice and procedure, Endangered and threatened species, Fish, Fisheries, Marine mammals, Penalties, Reporting and recordkeeping requirements, Transportation, Wildlife.

Dated: July 10, 2025.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, NMFS proposes to amend 50 CFR part 218 as follows:

PART 218—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 218 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Revise subpart H of part 218 to read as follows:

Subpart H—Taking and Importing Marine Mammals; Military Readiness Activities in the Hawaii-California Training and Testing Study Area

Sec.

218.70 Specified activity and geographical region.
218.71 Effective dates.
218.72 Permissible methods of taking.
218.73 Prohibitions.
218.74 Mitigation requirements.
218.75 Requirements for monitoring and reporting.
218.76 Letters of Authorization.
218.77 Modifications of Letters of Authorization.
218.78–218.79 [Reserved]

Subpart H—Taking and Importing Marine Mammals; Military Readiness Activities in the Hawaii-California Training and Testing Study Area

§ 218.70 Specified activity and geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy (including the U.S. Marine Corps; Navy), U.S. Coast Guard (Coast Guard), and U.S. Army (collectively referred to as the ''Action Proponents'') for the taking of marine mammals that occurs in the area described in paragraph (b) of this section and that occurs incidental to the activities listed in paragraph (c) of this section. Requirements imposed on the Action Proponents must be implemented by those persons they authorize or funds to conduct activities on their behalf.

(b) The taking of marine mammals by the Action Proponents under this subpart may be authorized in Letters of Authorization (LOAs) only if it occurs within the Hawaii-California Training and Testing (HCTT) Study Area. The HCTT Study Area includes areas in the north-central Pacific Ocean, from California west to Hawaii and the International Date Line, and including the Hawaii Range Complex (HRC), Southern California (SOCAL) Range Complex, Point Mugu Sea Range (PMSR), Silver Strand Training Complex, and the Northern California (NOCAL) Range Complex. Figure 1 to this paragraph (b) shows the location of the HCTT Study Area.

(c) The taking of marine mammals by the Action Proponents is only authorized if it occurs incidental to the Action Proponents conducting military readiness activities, including the following:

(1) Amphibious warfare;

(2) Anti-submarine warfare;

(3) Expeditionary warfare;

(4) Mine warfare;

(5) Surface warfare;

(6) Vessel evaluation;

(7) Unmanned systems;

(8) Acoustic and oceanographic science and technology;

(9) Vessel movement;

(10) Land-based launches; and

(11) Other training and testing activities.

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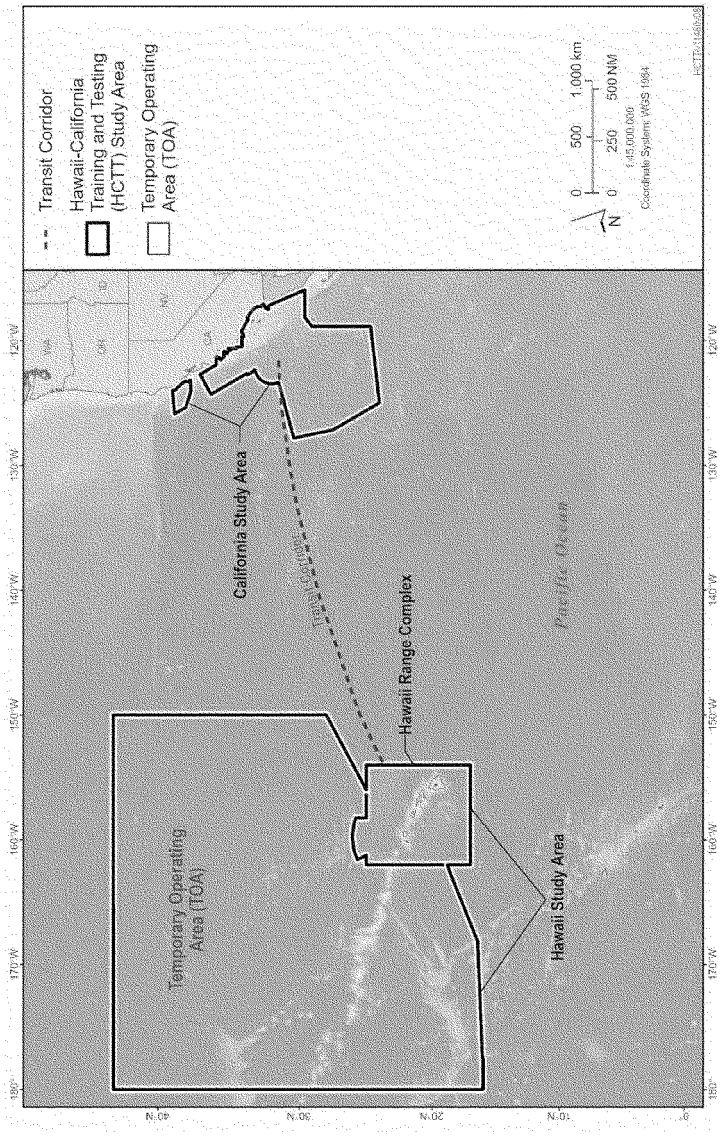
Figure 1 to Paragraph (b)—HCTT Study Area



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§ 218.71 Effective dates.

Regulations in this subpart are effective from December 21, 2025, through December 20, 2032.

§ 218.72 Permissible methods of taking.

(a) Under LOAs issued pursuant to §§ 216.106 of this chapter and this subpart, the Holder of the LOA (hereinafter ''Action Proponent'') may incidentally, but not intentionally, take marine mammals within the area described in § 218.70(b) by Level A harassment and Level B harassment associated with the use of active sonar and other acoustic sources and explosives, as well as serious injury or mortality associated with vessel strikes and explosives, provided the activity is in compliance with all terms, conditions, and requirements of this subpart and the applicable LOAs.

(b) The incidental take of marine mammals by the activities listed in § 218.70(c) is limited to the following species:

TABLE 1 TO PARAGRAPH (b)

Species	Stock
Gray whale	Eastern North Pacific.
Gray whale	Western North Pacific.
Blue whale	Central North Pacific.
Blue whale	Eastern North Pacific.
Bryde's whale	Eastern Tropical Pacific.
Bryde's whale	Hawaii.
Fin whale	Hawaii.
Fin whale	California/Oregon/Washington.
Humpback whale	Central America/Southern Mexico-California-Oregon-Washington.
Humpback whale	Mainland Mexico-California-Oregon-Washington.

TABLE 1 TO PARAGRAPH (b)—Continued

Species	Stock
Humpback whale	Hawaii.
Minke whale	Hawaii.
Minke whale	California/Oregon/Washington.
Sei whale	Hawaii.
Sei whale	Eastern North Pacific.
Sperm whale	Hawaii.
Sperm whale	California/Oregon/Washington.
Dwarf sperm whale	Hawaii.
Dwarf sperm whale	California/Oregon/Washington.
Pygmy sperm whale	Hawaii.
Pygmy sperm whale	California/Oregon/Washington.
Baird's beaked whale	California/Oregon/Washington.
Blainville's beaked whale	Hawaii.
Goose-beaked whale	Hawaii.
Goose-beaked whale	California/Oregon/Washington.
Longman's beaked whale	Hawaii.
Mesoplodont beaked whale	California/Oregon/Washington.
False killer whale	Main Hawaiian Islands Insular.
False killer whale	Northwest Hawaiian Islands.
False killer whale	Hawaii Pelagic.
False killer whale	Baja California Peninsula Mexico population.
Killer whale	Hawaii.
Killer whale	Eastern North Pacific Offshore.
Killer whale	West Coast Transient.
Melon-headed whale	Hawaiian Islands.
Melon-headed whale	Kohala Resident (Hawaii).
Pygmy killer whale	Hawaii.
Pygmy killer whale	California-Baja California Peninsula Mexico population.
Short-finned pilot whale	Hawaii.
Short-finned pilot whale	California/Oregon/Washington.
Bottlenose dolphin	Maui Nui.
Bottlenose dolphin	Hawaii Island.
Bottlenose dolphin	Hawaii Pelagic.
Bottlenose dolphin	Kaua'i/Ni'ihau.
Bottlenose dolphin	O'ahu.
Bottlenose dolphin	California Coastal.
Bottlenose dolphin	California/Oregon/Washington Offshore.
Fraser's dolphin	Hawaii.
Long-beaked common dolphin	California.
Northern right whale dolphin	California/Oregon/Washington.
Pacific white-sided dolphin	California/Oregon/Washington.
Pantropical spotted dolphin	Maui Nui.
Pantropical spotted dolphin	Hawaii Island.
Pantropical spotted dolphin	Hawaii Pelagic.
Pantropical spotted dolphin	O'ahu.
Pantropical spotted dolphin	Baja California Peninsula Mexico population.
Risso's dolphin	Hawaii.
Risso's dolphin	California/Oregon/Washington.
Rough-toothed dolphin	Hawaii.
Short-beaked common dolphin	California/Oregon/Washington.
Spinner dolphin	Hawaii Pelagic.
Spinner dolphin	Hawaii Island.
Spinner dolphin	Kaua'i/Ni'ihau.
Spinner dolphin	O'ahu/4 Islands Region.
Striped dolphin	Hawaii Pelagic.
Striped dolphin	California/Oregon/Washington.
Dall's porpoise	California/Oregon/Washington.
Harbor porpoise	Monterey Bay.
Harbor porpoise	Morro Bay.
Harbor porpoise	Northern California/Southern Oregon.
Harbor porpoise	San Francisco/Russian River.
California sea lion	U.S.
Guadalupe fur seal	Mexico.
Northern fur seal	Eastern Pacific.
Northern fur seal	California.
Steller sea lion	Eastern.
Harbor seal	California.
Hawaiian monk seal	Hawaii.
Northern elephant seal	California Breeding.

§ 218.73 Prohibitions.

(a) Except incidental take described in § 218.72 and authorized by a LOA issued under this subpart, it shall be unlawful for any person to do the following in connection with the activities described in this subpart:

(1) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under §§ 216.106 and this subpart;

(2) Take any marine mammal not specified in § 218.72(b);

(3) Take any marine mammal specified in § 218.72(b) in any manner other than as specified in the LOAs; or

(4) Take a marine mammal specified in § 218.72(b) after NMFS determines such taking results in more than a negligible impact on the species or stock of such marine mammal.

(b) [Reserved]

§ 218.74 Mitigation requirements.

(a) When conducting the activities identified in § 218.70(c), the mitigation measures contained in this section and any LOA issued under this subpart must be implemented by Action Proponent personnel or contractors who are trained according to the requirements in the LOA. If Action Proponent contractors are serving in a role similar to Action Proponent personnel, Action Proponent contractors must follow the mitigation applicable to Action Proponent personnel. These mitigation measures include, but are not limited to:

(1) *Activity-based mitigation.* Activity-based mitigation is mitigation that the Action Proponents must implement whenever and wherever an applicable military readiness activity takes place within the HCTT Study Area. The Action Proponents must implement the mitigation described in paragraphs (a)(1)(i) through (a)(1)(xxii) of this section, except as provided in paragraph (a)(1)(xxiii).

(i) *Active acoustic sources with power down and shut down capabilities.* For active acoustic sources with power down and shutdown capabilities (low-frequency active sonar ≥200 dB, mid-frequency active sonar sources that are hull mounted on a surface ship (including surfaced submarines), and broadband and other active acoustic sources >200 dB):

(A) *Mitigation zones and requirements.* During use of active acoustic sources with power down and shutdown capabilities, the following mitigation zone requirements apply:

(*1*) At 1,000 yd (914.4 m) from a marine mammal, Action Proponent personnel must power down active acoustic sources by 6 decibels (dB) total.

(*2*) At 500 yd (457.2 m) from a marine mammal, Action Proponent personnel must power down active acoustic sources by an additional 4 dB (10 dB total).

(*3*) At 200 yd (182.9 m) from a marine mammal, Action Proponent personnel must shut down active acoustic sources.

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in or on one of the following: aircraft; pierside, moored, or anchored vessel; underway vessel with space/crew restrictions (including small boats); or underway vessel already participating in the event that is escorting (and has positive control over sources used, deployed, or towed by) an unmanned platform.

(*2*) Two Lookouts on an underway vessel without space or crew restrictions.

(*3*) Lookouts must use information from passive acoustic detections to inform visual observations when passive acoustic devices are already being used in the event.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of using active acoustic sources (*e.g.,* while maneuvering on station).

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals during use of active acoustic sources.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(ii) *Active acoustic sources with shut down capabilities only (no power down capability).* For active acoustic sources with shut down capabilities only (no power down capability) (low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull mounted on a surface ship (*e.g.,* dipping sonar, towed arrays), high-frequency active sonar, air guns, and broadband and other active acoustic sources <200 dB):

(A) *Mitigation zones and requirements.* During use of active acoustic sources with shut down capabilities only, the following mitigation zone requirements apply:

(*1*) At 200 yd (182.9 m) from a marine mammal, Action Proponent personnel must shut down active acoustic sources.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in or on one of the following: aircraft; pierside, moored, or anchored vessel; underway vessel with space/crew restrictions (including small boats); or underway vessel already participating in the event that is escorting (and has positive control over sources used, deployed, or towed by) an unmanned platform.

(*2*) Two Lookouts on an underway vessel without space or crew restrictions.

(*3*) Lookouts must use information from passive acoustic detections to inform visual observations when passive acoustic devices are already being used in the event.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of using active acoustic sources (*e.g.,* while maneuvering on station).

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals during use of active acoustic sources.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(iii) *Pile driving and extraction.* For pile driving and extraction:

(A) *Mitigation zones and requirements.* During vibratory and impact pile driving and extraction, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease pile driving or extraction if a marine mammal is sighted within 5 yd (4.6 m) of a pile being driven or extracted.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in or on one of the following: shore, pier, or small boat.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation for 15 minutes prior to the initial start of pile driving or pile extraction.

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals during pile driving or extraction.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing vibratory or impact pile driving or extraction). The wait period for this activity is 15 minutes.

(iv) *Weapons firing noise.* For weapons firing noise:

(A) *Mitigation zones and requirements.* During explosive and non-explosive large-caliber (57 mm and larger) gunnery firing noise (surface-to-surface and surface-to-air), the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease weapons firing if a marine mammal is sighted within 30 degrees on either side of the firing line out to 70 yd (64 m) from the gun muzzle (cease fire).

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on a vessel.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of large-caliber gun firing (*e.g.,* during target deployment).

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals during large-caliber gun firing.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing explosive and non-explosive large-caliber gunnery firing noise (surface-to-surface and surface-to-air)). The wait period for this activity is 30 minutes.

(v) *Explosive bombs.* For explosive bombs:

(A) *Mitigation zones and requirements.* During the use of explosive bombs of any net explosive weight (NEW), the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease explosive bomb use if a marine mammal is sighted within 2,500 yd (2,286 m) from the intended target.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in an aircraft.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of bomb delivery (*e.g.,* when arriving on station).

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals during bomb delivery. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of explosive bombs of any NEW). The wait period for this activity is 10 minutes.

(vi) *Explosive gunnery.* For explosive gunnery:

(A) *Mitigation zones and requirements.* During air-to-surface medium-caliber (larger than 50 caliber and less than 57 mm), surface-to-surface medium-caliber, and surface-to-surface large-caliber explosive gunnery, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease air-to-surface medium-caliber use if a marine mammal is sighted within 200 yd (182.9 m) of the intended impact location.

(*2*) Action Proponent personnel must cease surface-to-surface medium-caliber use if a marine mammal is sighted within 600 yd (548.6 m) of the intended impact location.

(*3*) Action Proponent personnel must cease surface-to-surface large-caliber use if a marine mammal is sighted within 1,000 yd (914.4 m) of the intended impact location.

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on a vessel or in an aircraft.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of gun firing (*e.g.,* while maneuvering on station).

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals during gunnery fire. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing air-to-surface medium-caliber, surface-to-surface medium-caliber, surface-to-surface large-caliber explosive gunnery). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(vii) *Explosive underwater demolition multiple charge—mat weave and obstacle loading.* For explosive underwater demolition multiple

charge—mat weave and obstacle loading:

(A) *Mitigation zones and requirements.* During the use of explosive underwater demolition multiple charge—mat weave and obstacle loading of any NEW, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease explosive underwater demolition multiple charge—mat weave and obstacle loading if a marine mammal is sighted within 700 yd (640 m) of the detonation site.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) Two Lookouts, one on a small boat and one on shore from an elevated platform.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) The Lookout positioned on a small boat must observe the mitigation zone for marine mammals and floating vegetation for 30 minutes prior to the first detonation.

(*2*) The Lookout positioned on shore must use binoculars to observe for marine mammals for 10 minutes prior to the first detonation.

(*3*) Action Proponent personnel must observe the mitigation zone for marine mammals during detonations. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*4*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of explosive underwater demolition multiple charge—mat weave and obstacle loading of any NEW). The wait period for this activity is 10 minutes (determined by the Lookout on shore).

(viii) *Explosive mine countermeasure and neutralization (no divers).* For explosive mine countermeasure and neutralization (no divers):

(A) *Mitigation zones and requirements.* During explosive mine countermeasure and neutralization using 0.1–5 pound (lb) (0.05–2.3 kilogram (kg)) NEW and >5 lb (2.3 kg) NEW, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease 0.1–5 lb (0.05–2.3 kg) NEW use if a marine mammal is sighted within 600 yd (548.6 m) from the detonation site.

(*2*) Action Proponent personnel must cease >5 lb (2.3 kg) NEW use if a marine mammal is sighted within 2,100 yd (1,920.2 m) from the detonation site.

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on a vessel or in an aircraft during 0.1–5 lb (0.05–2.3 kg) NEW use.

(*2*) Two Lookouts, one on a small boat and one in an aircraft during >5 lb (2.3 kg) NEW use.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of detonations (*e.g.,* while maneuvering on station; typically, 10 or 30 minutes depending on fuel constraints).

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals, concentrations of seabirds, and individual foraging seabirds (in the water and not on shore) during detonations or fuse initiation. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for 10 or 30 minutes (depending on fuel constraints) for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing explosive mine countermeasure and neutralization using 0.1–5 pound (lb) (0.05–2.3 kilogram (kg)) NEW and >5 lb (2.3 kg) NEW). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(ix) *Explosive mine neutralization (with divers).* For explosive mine neutralization (with divers):

(A) *Mitigation zones and requirements.* During explosive mine neutralization (with divers) using 0.1–20 lb (0.05–9.1 kg) NEW (positive control), 0.1–29 lb (0.05–13.2 kg) NEW (time-delay), and >20–60 lb (9.1–27.2 kg) NEW (positive control), the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease 0.1–20 lb (0.05–9.1 kg) NEW (positive control) use if a marine mammal is sighted within 500 yd (457.2 m) of the detonation site (cease fire).

(*2*) Action Proponent personnel must cease 0.1–29 lb (0.05–13.2 kg) NEW (time-delay) and >20–60 lb (9.1–27.2 kg) NEW (positive control) use if a marine mammal is sighted within 1,000 yd (914.4 m) of the detonation site (cease fire).

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) Lookouts in two small boats (one Lookout per boat), or one small boat and one rotary-wing aircraft (with one Lookout each), and one Lookout on shore for shallow-water events during 0.1–20 lb (0.05–9.1 kg) NEW (positive control) use.

(*2*) Four Lookouts in two small boats (two Lookouts per boat) and one additional Lookout in an aircraft if used in the event during 0.1–29 lb (0.05–13.2 kg) NEW (time-delay) and >20–60 lb (9.1–27.2 kg) NEW (positive control) use.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Time-delay devices must be set not to exceed 10 minutes.

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of detonations or fuse initiation for positive control events (*e.g.,* while maneuvering on station) or for 30 minutes prior for time-delay events.

(*3*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals, concentrations of seabirds, and individual foraging seabirds (in the water and not on shore) during detonations or fuse initiation. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*4*) When practical based on mission, safety, and environmental conditions:

(*i*) Boats must observe from the mitigation zone radius mid-point.

(*ii*) When two boats are used, boats must observe from opposite sides of the mine location.

(*iii*) Platforms must travel a circular pattern around the mine location.

(*iv*) Boats must have one Lookout observe inward toward the mine location and one Lookout observe outward toward the mitigation zone perimeter.

(*v*) Divers must be part of the Lookout Team.

(*5*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for 30 minutes for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing explosive mine neutralization (with divers) using 0.1–20 lb (0.05–9.1 kg) NEW (positive control), 0.1–29 lb (0.05–13.2 kg) NEW (time-delay), and >20–60 lb (9.1–27.2 kg) NEW (positive control)). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(x) *Explosive missiles and rockets.* For explosive missiles and rockets:

(A) *Mitigation zones and requirements.* During the use of explosive missiles and rockets using 0.6–20 lb (0.3–9.1 kg) NEW (air-to-surface) and >20–500 lb (9.1–226.8 kg) NEW (air-to-surface), the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease 0.6–20 lb (0.3–9.1 kg) NEW (air-to-surface) use if a marine mammal is sighted within 900 yd (823 m) of the intended impact location (cease fire).

(*2*) Action Proponent personnel must cease >20–500 lb (9.1–226.8 kg) NEW (air-to-surface) use if a marine mammal is sighted within 2,000 yd (1,828.8 m) of the intended impact location (cease fire).

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in an aircraft.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of missile or rocket delivery (*e.g.,* during a fly-over of the mitigation zone).

(*2*) Action Proponent personnel must observe the applicable mitigation zone for marine mammals during missile or rocket delivery. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of explosive missiles and rockets using 0.6–20 lb (0.3–9.1 kg) NEW (air-to-surface) and >20–500 lb (9.1–226.8 kg) NEW (air-to-surface)). The wait period for this activity is 30 minutes for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(xi) *Explosive sonobuoys and research-based sub-surface explosives.* For explosive sonobuoys and research-based sub-surface explosives:

(A) *Mitigation zones and requirements.* During the use of explosive sonobuoys and research-based sub-surface explosives using any NEW of sonobuoys and 0.1–5 lb (0.05–2.3 kg) NEW for other types of sub-surface explosives used in research applications, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease use of explosive sonobuoys and research-based sub-surface explosives using any NEW of sonobuoys and 0.1–5 lb (0.05–2.3 kg) NEW for other types of sub-surface explosives used in research applications if a marine mammal is sighted within 600 yd (548.6 m) of the device or detonation sites (cease fire).

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on a small boat or in an aircraft.

(*2*) Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of detonations (*e.g.,* during sonobuoy deployment, which typically lasts 20–30 minutes).

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals during detonations. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of explosive sonobuoys and research-based sub-surface explosives using any NEW of sonobuoys and 0.1–5 lb (0.05–2.3 kg) NEW for other types of sub-surface explosives used in research applications). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(xii) *Explosive torpedoes.* For explosive torpedoes:

(A) *Mitigation zones and requirements.* During the use of explosive torpedoes of any NEW, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease use of explosive torpedoes of any NEW if a marine mammal is sighted within 2,100 yd (1,920.2 m) of the intended impact location.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in an aircraft.

(*2*) Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals, floating vegetation, and jellyfish aggregations immediately prior to the initial start of detonations (*e.g.,* during target deployment).

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals and jellyfish aggregations during torpedo launches. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) After the event, when practical, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of explosive torpedoes of any NEW). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(xiii) *Ship shock trials.* For ship shock trials:

(A) *Mitigation zones and requirements.* During ship shock trials using any NEW, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease ship shock trials of any NEW if a marine mammal is sighted within 3.5 nmi (6.5 km) of the target ship hull (cease fire).

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) On the day of the event, 10 observers (Lookouts and third-party observers combined), spread between aircraft or multiple vessels as specified in the event-specific mitigation plan.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must develop a detailed, event-specific monitoring and mitigation plan in the year prior to the event and provide it to NMFS for review.

(*2*) Beginning at first light on days of detonation, until the moment of detonation (as allowed by safety measures) Action Proponent personnel must observe the mitigation zone for marine mammals, floating vegetation, jellyfish aggregations, large schools of fish, and flocks of seabirds. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) If any injured or dead marine mammals are observed after an individual detonation, Action Proponent personnel must follow established incident reporting procedures and halt any remaining detonations until Action Proponent personnel can consult with NMFS and review or adapt the event-specific mitigation plan, if necessary.

(*4*) During the 2 days following the event (minimum) and up to 7 days following the event (maximum), and as specified in the event-specific mitigation plan, Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing ship shock trials). The wait period for this activity is 30 minutes.

(xiv) *Sinking Exercises.* For Sinking Exercises (SINKEX):

(A) *Mitigation zones and requirements.* During SINKEX using any NEW, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease SINKEX of any NEW if a marine mammal is sighted within 2.5 nmi (4.6 km) of the target ship hull (cease fire).

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) Two Lookouts, one on a vessel and one in an aircraft.

(*2*) Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations.

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) During aerial observations for 90 minutes prior to the initial start of weapon firing, Action Proponent personnel must observe the mitigation zone for marine mammals, floating vegetation, and jellyfish aggregations.

(*2*) From the vessel during weapon firing, and from the aircraft and vessel immediately after planned or unplanned breaks in weapon firing of more than 2 hours, Action Proponent personnel must observe the mitigation zone for marine mammals. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(*3*) Action Proponent personnel must observe the detonation vicinity for injured or dead marine mammals for 2 hours after sinking the vessel or until sunset, whichever comes first. If any injured or dead marine mammals are observed, Action Proponent personnel must follow established incident reporting procedures.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing SINKEX). The wait period for this activity is 30 minutes.

(xv) *Non-explosive aerial-deployed mines and bombs.* For non-explosive aerial-deployed mines and bombs:

(A) *Mitigation zones and requirements.* During the use of non-explosive aerial-deployed mines and non-explosive bombs, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease using non-explosive aerial-deployed mines and non-explosive bombs if a marine mammal is sighted within 1,000 yd (914.4 m) of the intended target (cease fire).

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in an aircraft.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the initial start of mine or bomb delivery (*e.g.,* when arriving on station).

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals during mine or bomb delivery. If a marine mammal is visibly injured or killed as a result of detonation, explosives use in the event must be suspended immediately.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of non-explosive aerial-deployed mines and non-explosive bombs). The wait period for this activity is 10 minutes.

(xvi) *Non-explosive gunnery.* For non-explosive gunnery:

(A) *Mitigation zones and requirements.* During the use of non-explosive surface-to-surface large-caliber ordnance, non-explosive surface-to-surface and air-to-surface medium-caliber ordnance, and non-explosive surface-to-surface and air-to-surface small-caliber ordnance, the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease non-explosive surface-to-surface large-caliber ordnance, non-explosive surface-to-surface and air-to-surface medium-caliber ordnance, and non-explosive surface-to-surface and air-to-surface small-caliber ordnance use if a marine mammal is sighted within 200 yd (182.9 m) of the intended impact location (cease fire).

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on a vessel or in an aircraft.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the start of gun firing (*e.g.,* while maneuvering on station).

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals during gunnery firing.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of non-explosive surface-to-surface large-caliber ordnance, non-explosive surface-to-surface and air-to-surface medium-caliber ordnance, and non-explosive surface-to-surface and air-to-surface small-caliber ordnance). The wait period for this activity is 30 minutes for activities conducted from vessels and for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(xvii) *Non-explosive missiles and rockets.* For non-explosive missiles and rockets:

(A) *Mitigation zones and requirements.* During the use of non-explosive missiles and rockets (air-to-surface), the following mitigation zone requirements apply:

(*1*) Action Proponent personnel must cease non-explosive missile and rocket (air-to-surface) use if a marine mammal is sighted within 900 yd (823 m) of the intended impact location.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout in an aircraft.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals and floating vegetation immediately prior to the start of missile or rocket delivery (*e.g.,* during a fly-over of the mitigation zone).

(*2*) Action Proponent personnel must observe the mitigation zone for marine mammals during missile or rocket delivery.

(D) *Commencement or recommencement conditions.* Action Proponent personnel must ensure one of the commencement or recommencement conditions in § 218.74(a)(1)(xxii) is met prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing use of non-explosive missiles and rockets (air-to-surface)). The wait period for this activity is 30 minutes for activities conducted by aircraft that are not fuel constrained and 10 minutes for activities involving aircraft that are fuel constrained (*e.g.,* rotary-wing aircraft, fighter aircraft).

(xviii) *Manned surface vessels.* For manned surface vessels:

(A) *Mitigation zones and requirements.* During the use of manned surface vessels, including surfaced submarines, the following mitigation zone requirements apply:

(*1*) Underway manned surface vessels must maneuver themselves (which may include reducing speed) to maintain the following distances as mission and circumstances allow:

(*i*) 500 yd (457.2 m) from whales.

(*ii*) 200 yd (182.9 m) from other marine mammals.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One or more Lookouts on manned underway surface vessels in accordance with the most recent navigation safety instruction.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals immediately prior to manned surface vessels getting underway and while underway.

(*2*) [Reserved]

(xix) *Unmanned vehicles.* For unmanned vehicles:

(A) *Mitigation zones and requirements.* During the use of unmanned surface vehicles and unmanned underwater vehicles already being escorted (and operated under positive control) by a manned surface support vessel, the following mitigation zone requirements apply:

(*1*) A surface support vessel that is already participating in the event, and has positive control over the unmanned vehicle, must maneuver the unmanned vehicle (which may include reducing its speed) to ensure it maintains the following distances as mission and circumstances allow:

(*i*) 500 yd (457.2 m) from whales.

(*ii*) 200 yd (182.9 m) from other marine mammals.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on a surface support vessel that is already participating in the event, and has positive control over the unmanned vehicle.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals immediately prior to unmanned vehicles getting underway and while underway.

(*2*) [Reserved]

(xx) *Towed in-water devices.* For towed in-water devices:

(A) *Mitigation zones and requirements.* During the use of in-water devices towed by an aircraft, a manned surface vessel, or an Unmanned Surface Vehicle or Unmanned Underwater

Vehicle already being escorted (and operated under positive control) by a manned surface vessel, the following mitigation zone requirements apply:

(*1*) Manned towing platforms, or surface support vessels already participating in the event that have positive control over an unmanned vehicle that is towing an in-water device, must maneuver itself or the unmanned vehicle (which may include reducing speed) to ensure towed in-water devices maintain the following distances as mission and circumstances allow:

(*i*) 250 yd (228.6 m) from marine mammals.

(*ii*) [Reserved]

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on the manned towing vessel or aircraft, or on a surface support vessel that is already participating in the event and has positive control over an unmanned vehicle that is towing an in-water device.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals immediately prior to and while in-water devices are being towed.

(*2*) [Reserved]

(xxi) *Net deployment.* For net deployment:

(A) *Mitigation zones and requirements.* During net deployment for testing of an Unmanned Underwater Vehicle, the following mitigation zone requirements apply:

(*1*) If a marine mammal is sighted within 500 yd (457.2 m) of the deployment location, the support vessel will:

(*i*) Delay deployment of nets until the mitigation zone has been clear for 15 minutes.

(*ii*) Recover nets if they are deployed.

(*2*) [Reserved]

(B) *Lookout requirements.* The following Lookout requirements apply:

(*1*) One Lookout on the support vessel.

(*2*) [Reserved]

(C) *Mitigation zone observation.* Action Proponent personnel must observe the mitigation zones in accordance with the following:

(*1*) Action Proponent personnel must observe the mitigation zone for marine mammals for 15 minutes prior to the deployment of nets and while nets are deployed.

(*2*) Nets must be deployed during daylight hours only.

(xxii) *Commencement or recommencement conditions.* Action Proponents must not commence or recommence an activity after a marine mammal is observed within a relevant mitigation zone until one of the following conditions has been met:

(A) *Observed exiting.* A Lookout observes the animal exiting the mitigation zone;

(B) *Concluded to have exited.* A Lookout concludes that the animal has exited the mitigation zone based on its observed course, speed, and movement relative to the mitigation zone;

(C) *Clear from additional sightings.* A Lookout affirms the mitigation zone has been clear from additional sightings for the activity-specific wait period; or

(D) *Platform or target transit.* For mobile events, the platform or target has transited a distance equal to double the mitigation zone size beyond the location of the last sighting.

(xxiii) *Exceptions to activity-based mitigation for acoustic and explosive stressors and non-explosive ordnance.* Activity-based mitigation for acoustic and explosive stressors and non-explosive ordnance will not apply to:

(A) Acoustic sources not operated under positive control (*e.g.,* moored oceanographic sources);

(B) Acoustic sources used for safety of navigation (*e.g.,* fathometers);

(C) Acoustic sources used or deployed by aircraft operating at high altitudes (*e.g.,* bombs deployed from high altitude (since personnel cannot effectively observe the surface of the water));

(D) Acoustic sources used, deployed, or towed by unmanned platforms except when escort vessels are already participating in the event and have positive control over the source;

(E) Acoustic sources used by submerged submarines (*e.g.,* sonar (since they cannot conduct visual observation));

(F) De minimis acoustic sources (*e.g.,* those >200 kHz);

(G) Vessel-based, unmanned vehicle-based, or towed in-water acoustic sources when marine mammals (*e.g.,* dolphins) are determined to be intentionally swimming at the bow or alongside or directly behind the vessel, vehicle, or device (*e.g.,* to bow-ride or wake-ride);

(H) Explosives deployed by aircraft operating at high altitudes;

(I) Explosives deployed by submerged submarines, except for explosive torpedoes;

(J) Explosives deployed against aerial targets;

(K) Explosives during vessel-launched or shore-launched missile or rocket events;

(L) Explosives used at or below the de minimis threshold;

(M) Explosives deployed by unmanned platforms except when escort vessels are already participating in the event and have positive control over the explosive;

(N) Non-explosive ordnance deployed by aircraft operating at high altitudes;

(O) Non-explosive ordnance deployed against aerial targets and land-based targets;

(P) Non-explosive ordnance deployed during vessel- or shore-launched missile or rocket events; and

(Q) Non-explosive ordnance deployed by unmanned platforms except when escort vessels are already participating in the event and have positive control over ordnance deployment.

(xxiv) *Exceptions to activity-based mitigation for physical disturbance and strike stressors.* Activity-based mitigation for physical disturbance and strike stressors will not be implemented:

(A) By submerged submarines;

(B) By unmanned vehicles except when escort vessels are already participating in the event and have positive control over the unmanned vehicle movements;

(C) When marine mammals (*e.g.,* dolphins) are determined to be intentionally swimming at the bow, alongside the vessel or vehicle, or directly behind the vessel or vehicle (*e.g.,* to bow-ride or wake-ride);

(D) When pinnipeds are hauled out on man-made navigational structures, port structures, and vessels;

(E) By manned surface vessels and towed in-water devices actively participating in cable laying during Modernization & Sustainment of Ranges activities; and

(F) When impractical based on mission requirements (*e.g.,* during certain aspects of amphibious exercises).

(2) *Geographic mitigation areas.* The Action Proponents must implement the geographic mitigation requirements described in paragraphs (a)(2)(i) through (a)(2)(xi) of this section.

(i) *Hawaii Island marine mammal mitigation area.* Figure 1 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Hawaii Island marine mammal mitigation area, the following requirements apply (year-round):

(A) *Surface ship hull-mounted mid-frequency active sonar.* The Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of helicopter dipping sonar (a mid-frequency active sonar source) annually within the mitigation area.

(B) *In-water explosives.* The Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) within the mitigation area.

(ii) *Hawaii 4-Islands marine mammal mitigation area.* Figure 1 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Hawaii 4-Islands marine mammal mitigation area, the following requirements apply:

(A) *Surface ship hull-mounted mid-frequency active sonar.* From November 15–April 15, the Action Proponents must not use MF1 surface ship hull-mounted mid-frequency active sonar within the mitigation area.

(B) *In-water explosives.* The Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) within the mitigation area (year-round).

(iii) *Hawaii humpback whale special reporting mitigation area.* Figure 1 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Hawaii humpback whale special reporting mitigation area, the following requirements apply:

(A) *Surface ship hull-mounted mid-frequency active sonar.* The Action Proponents must report the total hours of MF1 surface ship hull-mounted mid-frequency active sonar used from November through May in the mitigation area in their training and testing activity reports submitted to NMFS.

(B) [Reserved]

(iv) *Hawaii humpback whale awareness notification mitigation area.* Figure 1 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Hawaii humpback whale awareness notification mitigation area, the following requirements apply:

(A) *Hawaii humpback whale awareness notification mitigation area notifications.* The Action Proponents must broadcast awareness notification messages to alert applicable assets (and their Lookouts) transiting and training or testing in the Hawaii Range Complex to the possible presence of concentrations of humpback whales from November through May.

(B) *Visual observations.* Lookouts must use that knowledge to help inform their visual observations during military readiness activities that involve vessel movements, active sonar, in-water explosives (including underwater explosives and explosives deployed against surface targets), or the deployment of non-explosive ordnance against surface targets in the mitigation area.

(v) *Northern California large whale mitigation area.* Figure 2 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Northern California large whale mitigation area, the following requirements apply:

(A) *Surface ship hull-mounted mid-frequency active sonar.* From June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Central California Large Whale Mitigation Area, and the Southern California Blue Whale Mitigation Area.

(B) [Reserved]

(vi) *Central California large whale mitigation area.* Figure 2 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Central California large whale mitigation area, the following requirements apply:

(A) *Surface ship hull-mounted mid-frequency active sonar.* From June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Northern California Large Whale Mitigation Area, and the Southern California Blue Whale Mitigation Area.

(B) [Reserved]

(vii) *Southern California blue whale mitigation area.* Figure 2 to this paragraph (a)(2) shows the location of the mitigation areas. Within the Southern California blue whale mitigation area, the following requirements apply:

(A) *Surface ship hull-mounted mid-frequency active sonar.* From June 1–October 31, the Action Proponents must not use more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar (excluding normal maintenance and systems checks) total during training and testing within the combination of this mitigation area, the Northern California Large Whale Mitigation Area, and the Central California Large Whale Mitigation Area.

(B) *In-water explosives.* From June 1–October 31, the Action Proponents must not detonate in-water explosives (including underwater explosives and explosives deployed against surface targets) during large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) training and testing.

(viii) *California large whale awareness messages.* Figure 2 to this paragraph (a)(2) shows the location of the mitigation areas. For California large whale awareness messages, the following requirements apply:

(A) *California large whale awareness messages.* The Action Proponents must broadcast awareness messages to alert applicable assets (and their Lookouts) transiting and training or testing off the U.S. West Coast to the possible presence of concentrations of large whales, including gray whales (November–March), fin whales (November–May), and mixed concentrations of blue, humpback, and fin whales that may occur based on predicted oceanographic conditions for a given year (*e.g.,* May–November, April–November).

(B) [Reserved]

(ix) *California large whale real-time notification mitigation area.* Figure 2 to this paragraph (a)(2) shows the location of the mitigation areas. Within the California large whale real-time notification mitigation area, the following requirements apply:

(A) *California large whale real-time notification mitigation area notifications.* The Action Proponents will issue real-time notifications to alert Action Proponent vessels operating in the vicinity of large whale aggregations (four or more whales) sighted within 1 nmi (1.9 km) of an Action Proponent vessel within an area of the Southern California Range Complex (between 32–33 degrees North and 117.2–119.5 degrees West).

(B) [Reserved]

(x) *San Nicolas Island pinniped haulout mitigation area.* Figure 2 to this paragraph (a)(2) shows the location of the mitigation areas. Within the San Nicolas Island pinniped haulout mitigation area, the following requirements apply:

(A) *Haulouts.* Navy personnel must not enter pinniped haulout or rookery areas. Personnel may be adjacent to pinniped haulouts and rookery prior to and following a launch for monitoring purposes.

(B) *Missile and target use.* Missiles and targets must not cross over pinniped haulout areas at altitudes less than 305 m (1,000 ft), except in emergencies or for real-time security incidents. For unmanned aircraft systems (UAS), the following minimum altitudes will be maintained over pinniped haulout areas and rookeries: Class 0–2 UAS will maintain a minimum altitude of 300 ft; Class 3 UAS will maintain a minimum altitude of

500 ft; Class 4 or 5 UAS will not be flown below 1,000 ft.

(C) *Number of events.* The Navy may not conduct more than 40 launch events annually and 10 launch events at night annually.

(D) *Scheduling.* Launch events must be scheduled to avoid the peak pinniped pupping seasons (from January through July) to the maximum extent practicable.

(E) *Monitoring plan.* The Navy must implement a monitoring plan using video and acoustic monitoring of up to three pinniped haulout areas and rookeries during launch events that include missiles or targets that have not been previously monitored for at least three launch events.

(F) *Review of launch procedure.* The Navy must review the launch procedure and monitoring methods, in cooperation with NMFS, if any incidents of injury or mortality of a pinniped are discovered during post-launch surveys, or if surveys indicate possible effects to the distribution, size, or productivity of the affected pinniped populations as a result of the specified activities. If necessary, appropriate changes will be made through modification to the LOA prior to conducting the next launch of the same vehicle.

(xi) *National security requirement.* Should national security require the Action Proponents to exceed a requirement(s) in paragraphs (a)(2)(i) through (a)(2)(x) of this section, Action Proponent personnel must provide NMFS with advance notification and include the information (*e.g.,* sonar hours, explosives usage) in its annual activity reports submitted to NMFS.

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Figure 1 to Paragraph (a)(2)—Geographic Mitigation Areas for Marine Mammals in the Hawaii Study Area

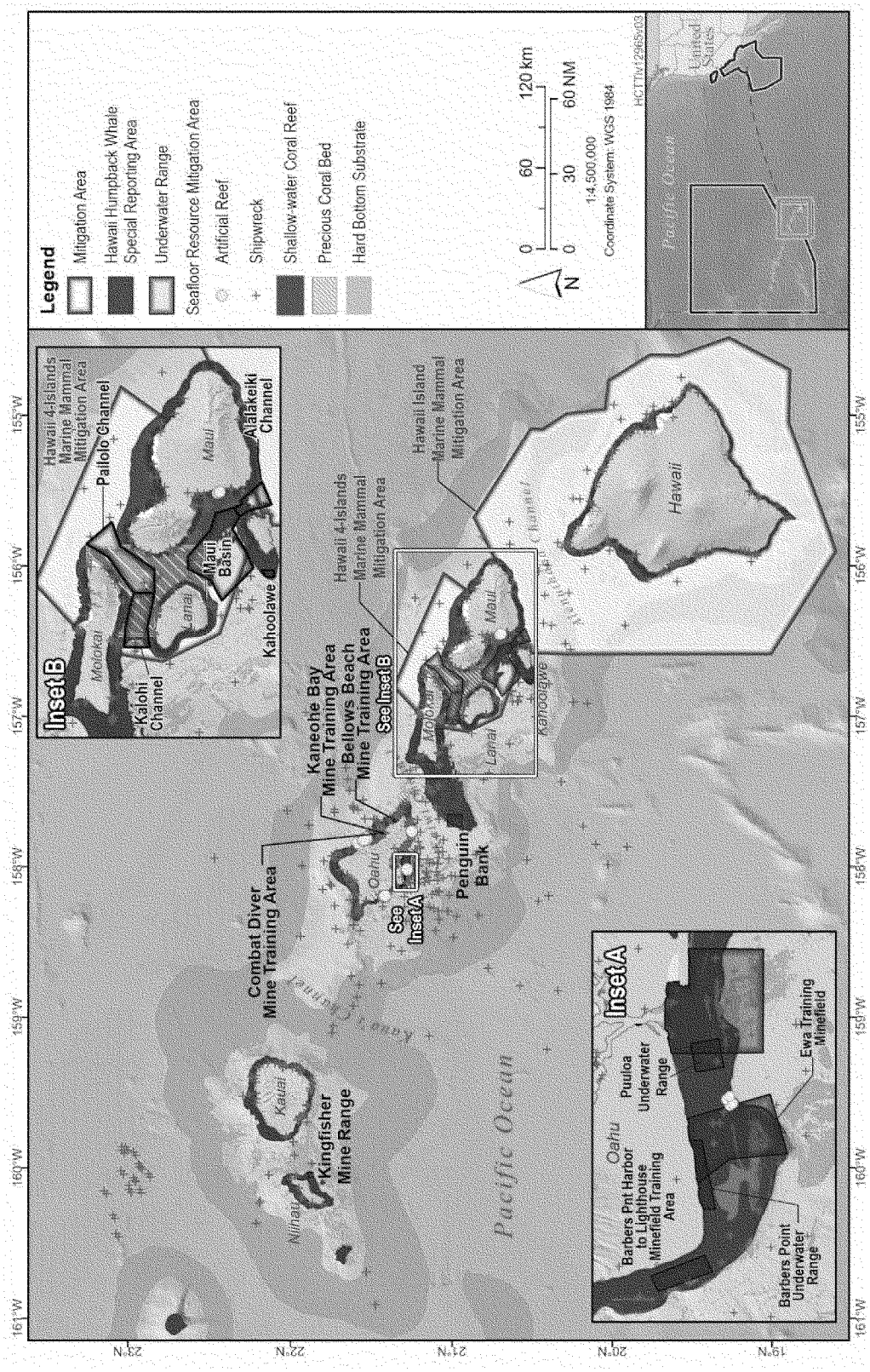
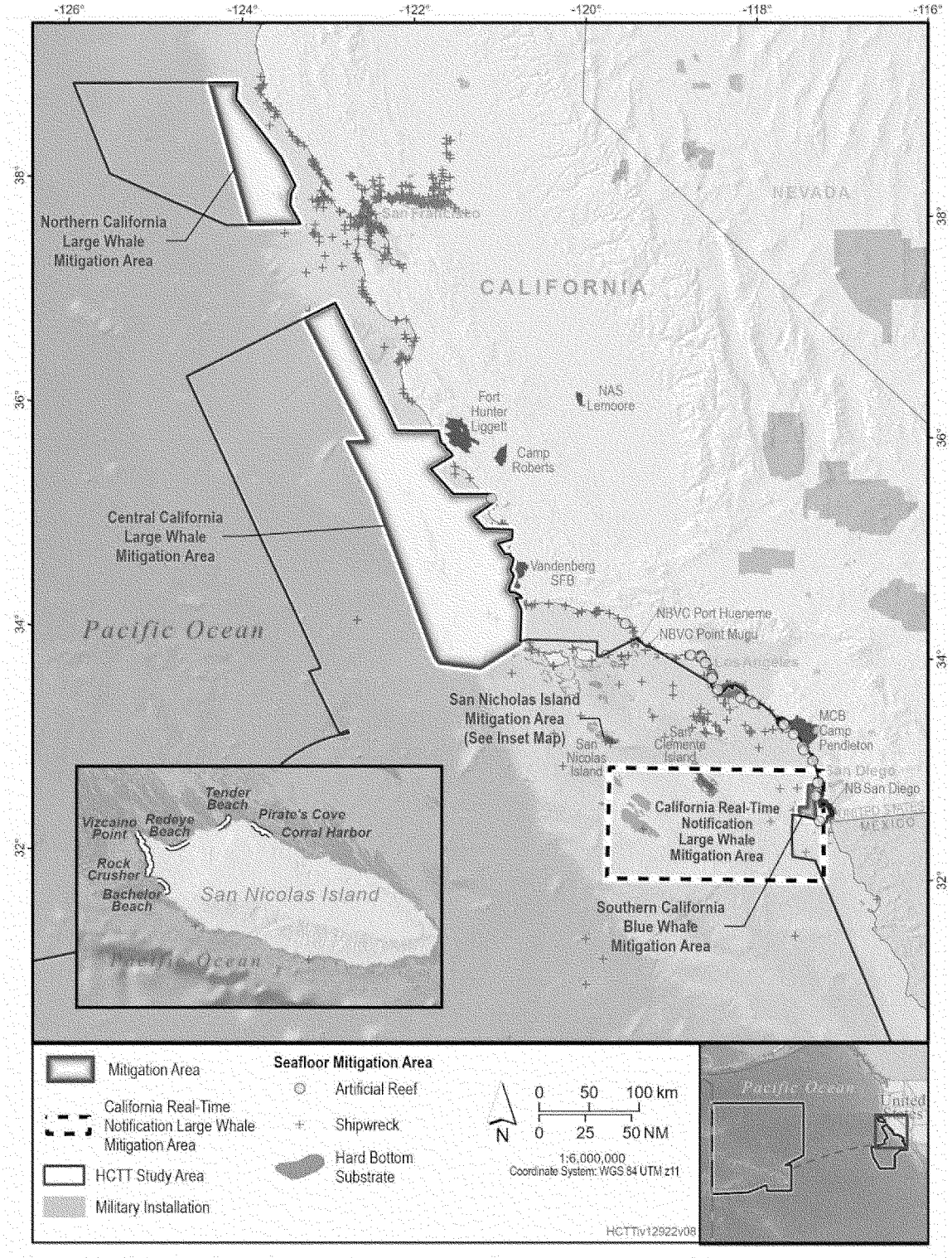


Figure 2 to Paragraph (a)(2)—Geographic Mitigation Areas for Marine Mammals in the California Study Area



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(b) [Reserved]

§ 218.75 Requirements for monitoring and reporting.

The Action Proponents must implement the following monitoring and reporting requirements when conducting the specified activities:

(a) *Notification of take.* If the Action Proponent reasonably believes that the specified activity identified in § 218.70 resulted in the mortality or serious injury of any marine mammals, or in any Level A harassment or Level B harassment of marine mammals not identified in this subpart, then the Action Proponent shall notify NMFS immediately or as soon as operational security considerations allow.

(b) *Monitoring and reporting under the LOAs.* The Action Proponents must conduct all monitoring and reporting required under the LOAs.

(c) *Notification of injured, live stranded, or dead marine mammals.* Action Proponent personnel must abide by the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or live stranded marine mammals are detected. The Notification and Reporting Plan is available at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

(d) *Annual HCTT Study Area marine species monitoring report.* The Action Proponents must submit an annual HCTT Study Area marine species monitoring report describing the implementation and results from the previous calendar year. Data collection methods will be standardized across range complexes and the HCTT Study Area to allow for comparison in different geographic locations. The draft report must be submitted to the Director, Office of Protected Resources, NMFS, annually. NMFS will submit comments or questions on the report, if any, within 3 months of receipt. The report will be considered final after the Action Proponents have addressed NMFS' comments, or 3 months after submittal of the draft if NMFS does not provide comments on the draft report. The report must describe progress of knowledge made with respect to intermediate scientific objectives within the HCTT Study Area associated with the Integrated Comprehensive Monitoring Program (ICMP). Similar study questions must be treated together so that progress on each topic can be summarized across all Navy ranges. The report need not include analyses and content that do not provide direct assessment of cumulative progress on the monitoring plan study questions.

(e) *Quick look reports.* In the event that the sound levels analyzed in promulgation of these regulations were exceeded within a given reporting year, the Action Proponents must submit a preliminary report(s) detailing the exceedance within 21 days after the anniversary date of issuance of the LOAs.

(f) *Annual HCTT Training and Testing Reports.* Regardless of whether analyzed sound levels were exceeded, the Navy must submit a detailed report (HCTT Annual Training Exercise Report and Testing Activity Report) and the Coast Guard and Army must each submit a detailed report (HCTT Annual Training Exercise Report) to the Director, Office of Protected Resources, NMFS annually. NMFS will submit comments or questions on the reports, if any, within 1 month of receipt. The reports will be considered final after the Action Proponents have addressed NMFS' comments, or 1 month after submittal of the drafts if NMFS does not provide comments on the draft reports. The annual reports must contain a summary of all sound sources used (total hours or quantity (per the LOAs) of each bin of sonar or other non-impulsive source; total annual number of each type of explosive exercises; and total annual expended/detonated rounds (missiles, bombs, sonobuoys, *etc.*) for each explosive bin). The annual reports must also contain cumulative sonar and explosive use quantity from previous years' reports through the current year. Additionally, if there were any changes to the sound source allowance in the reporting year, or cumulatively, the reports would include a discussion of why the change was made and include analysis to support how the change did or did not affect the analysis in the 2024 HCTT Draft EIS/OEIS and MMPA final rule. The annual reports must also include the details regarding specific requirements associated with the mitigation areas listed in paragraph (f)(4) of this section. The analysis in the detailed report must be based on the accumulation of data from the current year's report and data collected from previous annual reports. The detailed reports shall also contain special reporting for the Hawaii Humpback Whale Special Reporting Mitigation Area, as described in the LOAs. The final annual/close-out reports at the conclusion of the authorization period (year 7) will also serve as the comprehensive close-out reports and include both the final year annual incidental take compared to annual authorized incidental take as well as a cumulative 7-year incidental take compared to 7-year authorized incidental take. The HCTT Annual Training and Testing Reports must include the specific information described in the LOAs.

(1) *MTEs.* This section of the report must contain the following information for MTEs completed that year in the HCTT Study Area.

(i) *Exercise information (for each MTE).* For exercise information (for each MTE):

(A) Exercise designator.

(B) Date that exercise began and ended.

(C) Location.

(D) Number and types of active sonar sources used in the exercise.

(E) Number and types of passive acoustic sources used in exercise.

(F) Number and types of vessels, aircraft, and other platforms participating in each exercise.

(G) Total hours of all active sonar source operation.

(H) Total hours of each active sonar source bin.

(I) Wave height (high, low, and average) during exercise.

(ii) *Individual marine mammal sighting information for each sighting in each exercise where mitigation was implemented.* For individual marine mammal sighting information for each sighting in each exercise where mitigation was implemented:

(A) Date, time, and location of sighting.

(B) Species (if not possible, indication of whale/dolphin/pinniped).

(C) Number of individuals.

(D) Initial Detection Sensor (*e.g.,* passive sonar, Lookout).

(E) Indication of specific type of platform observation was made from (including, for example, what type of surface vessel or testing platform).

(F) Length of time observers maintained visual contact with marine mammal.

(G) Sea state.

(H) Visibility.

(I) Sound source in use at the time of sighting.

(J) Indication of whether animal was less than 200 yd (182.9 m), 200 to 500 yd (182.9 to 457.2 m), 500 to 1,000 yd (457.2 m to 914.4 m), 1,000 to 2,000 yd (914.4 m to 1,828.8 m), or greater than 2,000 yd (1,828.8 m) from sonar source.

(K) Whether operation of sonar sensor was delayed, or sonar was powered or shut down, and the length of the delay.

(L) If source in use was hull-mounted, true bearing of animal from the vessel, true direction of vessel's travel, and estimation of animal's motion relative to vessel (opening, closing, parallel).

(M) Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming, *etc.*) and if any calves were present.

(iii) *An evaluation (based on data gathered during all of the MTEs) of the effectiveness of mitigation measures designed to minimize the received level to which marine mammals may be exposed.* For an evaluation (based on data gathered during all of the MTEs) of the effectiveness of mitigation measures designed to minimize the received level to which marine mammals may be exposed:

(A) This evaluation must identify the specific observations that support any conclusions the Navy reaches about the effectiveness of the mitigation.

(B) [Reserved]

(2) *Sinking Exercises.* This section of the report must include the following information for each SINKEX completed that year in the HCTT Study Area:

(i) *Exercise information.* For exercise information:

(A) Location.

(B) Date and time exercise began and ended.

(C) Total hours of observation by Lookouts before, during, and after exercise.

(D) Total number and types of explosive source bins detonated.

(E) Number and types of passive acoustic sources used in exercise.

(F) Total hours of passive acoustic search time.

(G) Number and types of vessels, aircraft, and other platforms participating in exercise.

(H) Wave height in feet (high, low, and average) during exercise.

(I) Narrative description of sensors and platforms utilized for marine mammal detection and timeline illustrating how marine mammal detection was conducted.

(ii) *Individual marine mammal observation (by Action Proponent Lookouts) information for each sighting where mitigation was implemented.* For individual marine mammal observation (by Action Proponent Lookouts) information for each sighting where mitigation was implemented:

(A) Date/Time/Location of sighting.

(B) Species (if not possible, indicate whale, dolphin, or pinniped).

(C) Number of individuals.

(D) Initial detection sensor (*e.g.,* sonar or Lookout).

(E) Length of time observers maintained visual contact with marine mammal.

(F) Sea state.

(G) Visibility.

(H) Whether sighting was before, during, or after detonations/exercise, and how many minutes before or after.

(I) Distance of marine mammal from actual detonations (or target spot if not yet detonated): Less than 200 yd (182.9 m), 200 to 500 yd (182.9 to 457.2 m), 500 to 1,000 yd (457.2 m to 914.4 m), 1,000 to 2,000 yd (914.4 m to 1,828.8 m), or greater than 2,000 yd (1,828.8 m).

(J) Lookouts must report the observed behavior of the animal(s) in plain language and without trying to categorize in any way (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming *etc.*), including speed and direction and if any calves were present.

(K) The report must indicate whether explosive detonations were delayed, ceased, modified, or not modified due to marine mammal presence and for how long.

(L) If observation occurred while explosives were detonating in the water, indicate munition type in use at time of marine mammal detection.

(3) *Summary of sources used.* This section of the report must include the following information summarized from the authorized sound sources used in all training and testing events:

(i) *Totals for sonar or other acoustic source bins.* Total annual hours or quantity (per the LOA) of each bin of sonar or other acoustic sources (*e.g.,* pile driving and air gun activities); and

(ii) *Total for explosive bins.* Total annual expended/detonated ordnance (missiles, bombs, sonobuoys, *etc.*) for each explosive bin.

(4) *Special Reporting for Geographic Mitigation Areas.* This section of the report must contain the following information for activities conducted in geographic mitigation areas in the HCTT Study Area:

(i) *Hawaii Humpback Whale Special Reporting Mitigation Area.* The Action Proponents must report the total hours of MF1 surface ship hull-mounted mid-frequency active sonar used from November through May in the mitigation area.

(ii) *National security requirement.* If an Action Proponent(s) invokes the national security requirement described in § 218.74 (a)(2)(xi), the Action Proponent personnel must include information about the event in its Annual HCTT Training and Testing Report.

(g) *MTE sonar exercise notification.* The Action Proponents must submit to NMFS (contact as specified in the LOAs) an electronic report within 15 calendar days after the completion of any MTE indicating:

(1) *Location.* Location of the exercise;

(2) *Dates.* Beginning and end dates of the exercise; and

(3) *Type.* Type of exercise.

§ 218.76 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to this subpart, the Action Proponents must apply for and obtain LOAs.

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of this subpart.

(c) In the event of projected changes to the activity or to mitigation, monitoring, or reporting measures (excluding changes made pursuant to the adaptive management provision of § 218.77(c)(1)) required by an LOA, the Action Proponent must apply for and obtain a modification of the LOA as described in § 218.77.

(d) Each LOA will set forth:

(1) Permissible methods of incidental taking;

(2) Geographic areas for incidental taking;

(3) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species and stocks of marine mammals and their habitat; and

(4) Requirements for monitoring and reporting.

(e) Issuance of the LOA(s) must be based on a determination that the level of taking is consistent with the findings made for the total taking allowable under the regulations of this subpart.

(f) Notice of issuance or denial of the LOA(s) will be published in the **Federal Register** within 30 days of a determination.

§ 218.77 Modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 218.76 for the activity identified in § 218.70(c) shall be modified, upon request by the LOA Holder, provided that:

(1) The specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for the regulations in this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOAs under this subpart were implemented.

(b) For LOA modification requests by the applicants that include changes to the activity or to the mitigation, monitoring, or reporting measures (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), the LOA should be modified provided that:

(1) NMFS determines that the change(s) to the activity or the mitigation, monitoring or reporting do not change the findings made for the regulations and do not result in more than a minor change in the total estimated number of takes (or distribution by species or stock or years), and

(2) NMFS may publish a notice of proposed modified LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 and 218.76 of this chapter for the activities identified in § 218.70(c) may be modified by NMFS Office of Protected Resources under the following circumstances:

(1) After consulting with the Action Proponents regarding the practicability of the modifications, through adaptive management, NMFS may modify (including remove, revise or add to) the existing mitigation, monitoring, or reporting measures if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring measures set forth in this subpart.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA include, but are not limited to:

(A) Results from the Action Proponents' monitoring report and annual exercise reports from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent, or number not authorized by this subpart or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS shall publish a notice of proposed LOA(s) in the **Federal Register** and solicit public comment.

(2) If the NMFS Office of Protected Resources determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to §§ 216.106 of this chapter and 218.76, a LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within 30 days of the action.

§§ 218.78–218.79 [Reserved]

[FR Doc. 2025–13258 Filed 7–15–25; 8:45 am]

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FEDERAL REGISTER

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Book 2 of 2 Books

Pages 32351–33262

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, et al.

Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 424, 425, 427, 428, 495, and 512

[CMS–1832–P]

RIN 0938–AV50

Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for: the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; the Ambulatory Specialty Model; updates to the Medicare Diabetes Prevention Program expanded model; updates to drugs and biological products paid under Part B; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to the Medicare Promoting Interoperability Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 12, 2025.

ADDRESSES: In commenting, please refer to file code CMS–1832–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1832–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1832–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email. For all questions related to reporting a service on a claim, please contact your Medicare Administrative Contractor.

Michael Soracoe, Morgan Kitzmiller, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Hannah Ahn, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to potentially misvalued services under the PFS.

Julie Rauch, or *MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to Malpractice RVUs.*

Morgan Kitzmiller, Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov* for issues related to Geographic Practice Cost Indices.

Mikayla Murphy, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Erick Carrera, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to office/outpatient evaluation and management visit inherent complexity add-on and Digital Mental Health Treatment services.

Maya Peterson, Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment for advanced primary care management services.

Sarah Leipnik, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to global surgery payment accuracy.

Pamela West, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to outpatient therapy services and KX modifier thresholds.

Michelle Cruse, Erick Carrera, Zehra Hussain, or Hannah Ahn *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to dental services inextricably linked to other covered medical services.

Zehra Hussain, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786–3377, Rebecca Ray, (667) 414–0879, and Jae Ryu, (667) 414–0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B. *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to complex drug administration.

Allison Cipro, (667) 414–0758, for issues related to Medicare Diabetes Prevention Program.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and other quality reporting requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology and shared losses mitigation.

Kari Vandegrift, (410) 786–4008, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program participation options, and ACO participant and SNF affiliate change of ownership requirements.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Benjamin Picillo or Genevieve Kehoe, *AmbulatorySpecialtyModel@cms.hhs.gov,* or 1–844–711–2664 (Option 4) for issues related to the Ambulatory Specialty Model.

Amy Gruber, (410) 786–1542, for issues related to Ambulance Extender provisions.

Kati Moore, (410) 786–5471, for inquiries related to the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program (QPP).

Trevey Davis, (667) 290–8527, for inquiries related to the Advanced Alternative Payment Models (APMs) track of QPP.

Jessica Warren, (410) 786–7519, and Lisa Marie Gomez, (410) 786–1175, for inquiries related to the Medicare Promoting Interoperability Program.

Lisa Parker, (410) 786–4949, or *FQHC–PPS@cms.hhs.gov*, for issues related to FQHC payments.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, for issues related to RHC payments.

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2026 PFS proposed rule, refer to item CMS–1832–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov.*

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

CPT (Current Procedural Terminology) Copyright Notice: Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Deregulation Request for Information (RFI):

On January 31, 2025, President Trump issued Executive Order (EO) 14192 ''Unleashing Prosperity Through Deregulation,'' which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other stakeholders participating in the Medicare program. CMS has made available a Request for Information (RFI) at: *https://www.federalregister.gov/documents/2025/04/11/2025-06316/request-for-information-deregulation.* Please submit all comments in response to this request for information through the provided weblink.

I. Executive Summary

A. Purpose

This major annual rule proposes to revise payment policies under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4, March 15, 2025), Further Continuing Appropriations and Other Extensions Act of 2024 (Pub. L. 118–22, November 16, 2023), Consolidated Appropriations Act, 2023 (Pub. L. 117–328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this proposed rule includes proposals regarding other Medicare payment policies described in sections III. and IV.

This rulemaking proposes to update policies for the Medicare Prescription Drug Inflation Rebate Program codified or finalized at parts 427 and 428 consistent with sections 1847A(i) and 1860D–14B of the Social Security Act (the Act). With respect to the Medicare Part B Drug Inflation Rebate Program, this rulemaking proposes to describe the identification of payment amount benchmark quarter in certain instances and the calculation for the Part B rebate amount in such instances. With respect to the Medicare Part D Drug Inflation Rebate Program, this rulemaking proposes to clarify the calculation of a Part D rebate amount, and proposes a methodology for removal of units for a Part D rebatable drug for which a manufacturer provides a discount under the 340B Program, as well as the establishment of a 340B data repository for Part D claims.

This rulemaking proposes to modify policies for the Shared Savings Program, which is a voluntary program that started in 2012. The program allows healthcare providers to form or participate in Accountable Care Organizations (ACOs), to be held accountable for the quality and total cost of care for an assigned population of Medicare fee-for-service (FFS) beneficiaries.

B. Summary of the Key Provisions

Section 1848 of the Act requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing to establish RVUs for CY 2026 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies, and other policies regarding programs administered by CMS.

Specifically, this proposed rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Enhanced Care Management (section II.G.)
- Outpatient Therapy Services and KX Modifier Thresholds (section II.H.)
- Advancing Access to Behavioral Health Services (section II.I.)
- Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services (section II.J.)
- Payment for Skin Substitutes (section II.K.)
- Strategies for Improving Global Surgery Payment Accuracy (section II.L.)
- Determination of Malpractice Relative Value Units (RVUs) (section II.M.)
- Geographic Practice Cost Indices (GPCIs) (section II.N.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)

- Ambulatory Specialty Model (ASM) (section III.C.)
- Medicare Diabetes Prevention Program (MDPP) (section III.D.)
- Medicare Prescription Drug Inflation Rebate Program (section III.E.)
- Medicare Shared Savings Program (section III.F.)
- Changes to the Regulations Associated with the Ambulance Fee Schedule (section III.G.)
- Updates to the Quality Payment Program and Medicare Promoting Interoperability Program (section IV.)
- Collection of Information Requirements (section V.)
- Responses to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

C. Summary of Costs and Benefits

Based on our estimates, the Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this proposed rule is economically significant under section 3(f)(1) of Executive Order 12866. As required by section 1848(d)(1)(A) of the Act, beginning in 2026, there will be two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant as defined in section 1833(z)(2) of the Act (referred to as the qualifying APM conversion factor) and another for other items and services (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year (or, for CY 2026, equal to the single conversion factor for CY 2025) multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. Under these proposals, the 2026 qualifying APM conversion factor represents a projected increase of $0.39 (1.2 percent) from the current conversion factor of $32.3465. Similarly, the 2026 nonqualifying APM conversion factor represents a projected increase of $0.23 (0.7 percent) from the current conversion factor of $32.3465.

For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

In accordance with section 1848 of the Social Security Act (the Act), CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the American Medical Association (AMA))/ Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we referred readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked to develop the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We have stated that we believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology or how the PE/HR data are used. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward is developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2026 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2026, we have incorporated the available utilization data for one new specialty, Epileptologists, which we recognized effective July 1, 2024 through our established process. We are proposing to use proxy PE/HR values from Neurology for this new specialty, as there are no PPIS data for this specialty.

These updates are reflected in the ''CY 2026 PFS proposed rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is generally the same for both the facility and nonfacility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs. We note, too, that in this proposed rule we are proposing a modification in the allocation of indirect PE, described in detail below.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a

professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different healthcare providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the three most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning a specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list annually. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

The full list of expected specialty assignments is included in the CY 2026 public use files, which are available on the CMS website under downloads for the CY 2026 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

We note that for CY 2026, we are proposing a change to the methodology so that when work RVUs are used to

allocate indirect PE to the facility RVUs, they are assigned at one-half the amount allocated to the nonfacility PE RVUs for that same service. This proposed change is detailed later in this section.

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 as the denominator and Step 13 as the numerator, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: To calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included to calculate the BN adjustment. They are displayed in Table 1.

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TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in creating the file consistent with the current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time

adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 provides details in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80 * 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.
usage = variable, see discussion below in this proposed rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than two years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 3.

TABLE 3: SBA MAXIMUM INTEREST RATES

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2026.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to ensure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the 2017-based MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services (referred to as the ''2017-based MEI''). We also finalized a delay of the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the

public had an opportunity to comment on the rebased and revised 2017-based MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time had elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the implementation of the finalized 2017-based MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87 FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. We also solicited comments in the CY 2023 PFS proposed rule on when and how to best incorporate the 2017-based MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the 2017-based MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comments on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation, and many commenters expressed concerns with the redistributive impacts of the implementation of the 2017-based MEI in PFS ratesetting. Many commenters also noted the AMA's intent to collect practice cost data from physician practices, which could be used to derive cost share weights for the MEI and RVU shares.

In CY 2025 PFS rulemaking (89 FR 97722), we stated that in light of the AMA's current data collection efforts and because the methodological and data source changes to the 2017-based MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, similar to our discussion of this topic in the CY 2024 PFS rulemaking cycle (88 FR 78829 through 78831), we continued to believe that delaying the implementation of the finalized 2017-based MEI cost share weights for the RVUs was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. For these reasons, we did not propose to incorporate the 2017-based MEI in PFS ratesetting for CY 2024 and CY 2025. As we noted in the CY 2024 PFS final rule, many commenters on the CY 2024 PFS proposed rule supported our continued delayed implementation of the 2017-based MEI in PFS ratesetting (88 FR 78830). Most of these commenters recommended to us to pause consideration of other sources for the MEI until the AMA's efforts to collect practice cost data from physician practices concluded, although a few commenters recommended that we implement the MEI for PFS ratesetting as soon as possible. We stated that we agree with the commenters that it would be prudent, and avoid potential duplication of effort, to wait to consider other data sources for the MEI while the AMA's data collection activities were ongoing. We stated that as we discussed in the CY 2024 PFS final rule, we continue to monitor the data available related to physician services' input expenses, but we were not proposing to update the data underlying the MEI cost weights at that time.

At the time of publication of this proposed rule, the AMA has concluded their data collection efforts and, in early 2025, submitted data from its Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys to CMS for us to consider implementing the PE/HR data and cost shares in PFS ratesetting for CY 2026. We appreciate the AMA's data collection efforts, and recognize the significant efforts required to develop the survey and collect the data. We have prioritized review of the submitted information during the first part of this year based on our longstanding interest in the value of updated practice expense information. At this time, however, we have substantive concerns about the accuracy and suitability of the PPI and CPI Survey data as an immediate replacement for the current PE/HR data and cost shares for use in CY 2026 PFS ratesetting. Due to overarching concerns with the data as described below and our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through routine updates to the MEI, we are not proposing to implement the PE/HR or cost shares from the AMA's survey data at this time. Instead, we propose to maintain the current PE/HR and 2006-based MEI cost shares for CY 2026 PFS ratesetting.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2026 direct PE input public use files, which are available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-fafor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve the relativity of values among codes. For example, as medical practice and technologies change over time, standards could be updated simultaneously for all codes with the applicable clinical labor tasks instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist,

order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we believe that the three total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. We direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464) for additional details.

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. We direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584) for additional details.

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time, and among the medical specialties developing the recommendations. These variations have made it difficult for the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC mandated the use of a new PE worksheet for its recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations helps us simplify and standardize the hundreds of clinical labor tasks currently listed in our direct PE database. As in previous calendar years, to facilitate rulemaking for CY 2026, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule, we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy while maintaining stability and allowing interested parties to address potential

concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2026, we are proposing to update the price of 35 supplies and seven equipment items in response to the public submission of invoices following the publication of the CY 2025 PFS final rule. The 42 supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 6, CY 2026 Invoices Received for Existing Direct PE Inputs.

We received a series of invoices associated with the SD339 supply prior to our February 10th submission deadline and are proposing to update its pricing accordingly for CY 2026, as detailed in Table 6, CY 2026 Invoices Received for Existing Direct PE Inputs. We later received additional invoices associated with this supply several months following our February 10th deadline which arrived too late to be included in the proposed updated pricing for this supply as shown in Table 6. Consistent with our previously finalized policy associated with the February 10th deadline (79 FR 67608), we will review these invoices during the comment period following the publication of this CY 2026 PFS proposed rule for potential inclusion in the final rule.

We are not proposing to update the price of another eight supplies and one equipment item, which were the subject of public submission of invoices. Our reasons for not proposing updates to these prices are detailed below, and we are soliciting additional information from interested parties for assistance in pricing these supplies:

- *Radiation treatment vault (ER056):* We received pricing information associated with the radiation treatment vault from an interested party. However, this pricing information contained numerous costs associated with building construction which would not be included on a traditional invoice, such as surveying, plumbing and HVAC expenses, drywall packaging, and the installation of electrical equipment. As we previously stated in the CY 2021 PFS final rule about similar costs associated with proton beam treatment delivery services, the expenses associated with constructing new office facilities fall outside of our direct PE methodology and would be more accurately classified as a form of building maintenance or office rent under indirect PE (85 FR 84626). We do not agree that construction costs should be included as a form of direct PE because they are not individually allocable to a particular patient for a particular service. Therefore, we do not believe that it would serve the interests of relativity to include these building construction costs for the radiation treatment vault as a type of direct PE expense. In the absence of other pricing information associated with the radiation treatment vault, or pricing of the vault absent these building construction costs, we are proposing to maintain its current price of $773,104.
- *Congo red kits (SA110) and UltraView Universal DAB Detection Kit (SL488):* We received three invoices from interested parties requesting an increase in the price of the SA110 supply from $6.80 to $20.12 and another three invoices from interested parties requesting an increase in the price of the SL488 equipment from $12.28 to $41.26. In both cases, we do not understand how the typical price of these supplies could be increasing by such a large amount, tripling the current price in both cases, given that the price of both supplies was recently updated. Both the SA110 supply and the SL488 supply had their prices updated in the CY 2024 PFS final rule, with the SA110 supply increasing from $6.16 to $6.80 and the SL488 supply increasing from $9.70 to $12.28 (88 FR 78966 through 78967). We do not believe that the typical price for these supplies would increase to such a great degree given that their pricing was already recently updated for CY 2024; therefore, we are not proposing to update.
- *Catheter, balloon, rectal pressure (SD017); catheter, pressure, urodynamic (SD027); and transducer dome (pressure) (SD125):* We received one invoice from interested parties for each of these three supplies. Interested parties requested an increase in the price of the SD017 supply from $35.89 to $74.00, an increase in the price of the SD027 supply from $19.35 to $86.80, and an increase in the price of the SD125 supply from $3.58 to 17.32. However, in each of these three cases, it was unclear if the item on the invoice matched the supply item in question. The invoice for the SD017 supply listed a ''Abdominal Sensor Catheter'', the invoice for the SD027 supply listed a ''Single Sensor Catheter'', and the invoice for the SD125 supply listed a ''transducer cartridge with luer lock''. Given the differences between the names of the items in question, and the significant increases in requested pricing, we are not proposing to update the pricing of these three supplies as we cannot verify that the invoices refer to the same supply items.
- *Electrode, surface (SD062):* We received one invoice from interested parties requesting a decrease in the price of the SD062 supply from $1.58 to $0.34. The invoice appeared to state that there are 10 copies of 10 packs of 3 electrodes which, when dividing the total price of $103 by 300 electrodes, results in a price of $0.34 per electrode. We do not believe that the interested parties intended to submit an invoice resulting in a 78 percent decrease in pricing for the SD062 supply, and we are not convinced that we have correctly understood the unit quantity for this item. As a result, we are not proposing to change the pricing of the SD062 supply at this time.
- *Biohazard specimen transport bag (SM008):* We received one invoice from interested parties requesting an increase in the price of the SM008 supply from $0.087 to $0.750, an increase of more than 750 percent. However, when we reviewed the invoice, we determined that it referred to a different type of disposal bag than the biohazard specimen transport bag described by the SM008 supply, which explained the disparity in the pricing. We are therefore not proposing to update the pricing of the SM008 supply.
- *Wipes, lens cleaning (per wipe) (Kimwipe) (SM027):* We received one invoice from interested parties requesting an increase in the price of the SM027 supply from $0.04 to $0.33, an increase of approximately 700 percent. However, when we reviewed the supply in question, we found that lens cleaning wipes were readily available for purchase at the current price of $0.04 per wipe. We are therefore not proposing to update the pricing of the SM027 supply.

(1) Invoice Submission

We remind readers that we routinely accept public submissions of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often, these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule and will consider any invoices received after February 10th or outside of the public comment

process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

(2) Supply Pack Pricing Update

Interested parties previously notified CMS that they identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The interested parties indicated that CMS should rectify these mathematical errors as soon as possible to ensure that the sum correctly matches the totals from the individual items, and they recommended that we resolve these pricing discrepancies in the supply packs during CY 2024 rulemaking. The AMA RUC convened a workgroup on this subject and submitted recommendations to update pricing for a series of supply packs along with the RUC's comment letter for the CY 2024 rule cycle.

We appreciated the additional information and RUC workgroup recommendations regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost revisions in the pricing of supply packs and because we did not propose to address supply pack pricing in the CY 2024 proposed rule, we stated in the CY 2024 final rule that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes, which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We stated that interested parties would be better served if we comprehensively addressed this topic during future rulemaking in which commenters could provide feedback in response to proposed pricing updates (88 FR 78833 through 78834).

For CY 2025, we proposed to implement the supply pack pricing update and associated revisions as recommended by the RUC's workgroup (89 FR 97726 through 97727). We proposed to update the pricing of the ''pack, cleaning and disinfecting, endoscope'' (SA042) supply from $19.43 to $31.29, to update the pricing of the ''pack, drapes, cystoscopy'' (SA045) supply from $17.33 to $14.99, to update the pricing of the ''pack, ocular photodynamic therapy'' (SA049) supply from $16.35 to $26.35, to update the pricing of the ''pack, urology cystoscopy visit'' (SA058) supply from $113.70 to $37.63, and to update the pricing of the ''pack, ophthalmology visit (w-dilation)'' (SA082) supply from $3.91 to $2.33. As recommended by the RUC workgroup, we also proposed to delete the ''pack, drapes, laparotomy (chest-abdomen)'' (SA046) supply entirely. The updated prices for these supply packs were listed in the valuation of specific codes section of the preamble under Table 6, CY 2025 Invoices Received for Existing Direct PE Inputs (89 FR 97852).

In accordance with the RUC workgroup's recommendations, we also proposed to create 8 new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes, as they are, again, components contained within previously existing supply packs. We proposed to add:

- The kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- The Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;
- The drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- The drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- The post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- The y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- The ortho-phthalaldehyde 0.55 percent (for example, Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- The ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The new supply pack component items were listed in the valuation of specific codes section of the preamble under Table 8, CY 2025 New Invoices (89 FR 97853).

We also proposed the following additional supply substitutions based on the recommendations of the RUC workgroup. We proposed to remove the deleted SA046 supply pack and replace it with the drape, sterile, fenestrated 16in x 29in (SB011) supply for CPT codes 19020, 19101, 19110, 19112, 20101, and 20102. We proposed to remove the deleted SA046 supply pack and replace it with two supplies—the drape, sterile, three-quarter sheet (SB014) and the drape, towel, sterile 18in x 26in (SB019)—for CPT codes 19000 and 60300. We proposed to remove the deleted SA046 supply pack and replace it with 2 supplies—the drape, towel, sterile 18in x 26in (SB019) and the newly created Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply—for CPT codes 22510, 22511, 22513, and 22514. We proposed to remove the deleted SA046 supply pack without replacing it with anything for CPT code 22526; the RUC workgroup did not make a recommendation on what to do with CPT code 27278, which also previously contained the SA046 supply pack. Therefore, we also proposed not to replace the SA046 supply pack with any supplies for this code. The RUC workgroup also recommended removing the SA046 supply pack from CPT code 64595 with no replacement; however, this code was recently reviewed at the April 2022 RUC meeting and it no longer includes the SA046 supply.

In the comments on the CY 2025 PFS proposed rule (89 FR 97727 through 97729), several commenters supported the proposed supply pack pricing update as recommended by the RUC workgroup, however they indicated concern over the proposed decrease in the price of the urology cystoscopy visit pack (SA058) from $113.70 to $37.63. Commenters stated that the proposed pricing reduction in the SA058 supply could result in drastic payment rate cuts for physicians performing cystoscopy services in the office setting. Commenters requested that CMS either delay the pricing update or phase-in the supply pack changes over a four-year period like it has done for other PE changes with significant redistributive effects, allowing independent urology practices to better prepare for the negative financial impact this change will have.

After considering these comments, we agreed that the use of a phased-in transition period would be appropriate to allow practitioners to adjust to the updated pricing of these supplies. During our previous supply and equipment pricing update in the CY 2019 PFS final rule, we finalized a policy to phase in any updated pricing that we established during the 4-year transition period for very commonly used supplies and equipment, such as sterile gloves (SB024) or exam tables (EF023), even if invoices were provided as part of the formal review of a code family (83 FR 59475). Based on this previously established policy, we finalized the use of a pricing transition for three supply packs in Table 4:

TABLE 4: CY 2025 SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33

Following the same pattern as our previous supply/equipment and clinical labor pricing updates, we finalized the implementation of this pricing transition over 4 years such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2025, one-third of the difference between the CY 2025 price and the final price is implemented for CY 2026, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028. For the other proposed supply packs, the cystoscopy drapes pack (SA045) is only included in 7 HCPCS codes and the ocular photodynamic therapy pack (SA049) is only included in a single HCPCS code which do not meet these criteria established in previous rulemaking and described above. We therefore finalized each of them at their updated pricing for CY 2025 as proposed in the proposed rule. We believe that the use of this pricing transition will minimize any potential disruptive effects during the 4-year transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply packs.

Several commenters also stated that although five incomplete packs would have their pricing updated in the proposed rule, mathematical errors still remained for a number of additional supply packs. Commenters stated that only 3 of the 18 affirmed packs were priced correctly to match their components and provided tables showing the pricing of an additional 15 packs that needed mathematical correction by deconstructing the packs to determine the correct price through summing their individual components. Commenters requested that CMS initiate a correction of the packs pricing such that the sum of the individual components match the price of the corresponding pack as detailed in Table 5:

TABLE 5: SUPPLY PACK PRICING REQUESTED BY CY 2025 COMMENTERS

HCPCS Codes	Item Name	CMS Code	Current Price	New Price	% Change
111 codes	pack, basic injection	SA041	$10.45	$17.28	65%
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$1.98	-61%
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$1.35	-50%
239 codes	pack, pelvic exam	SA051	$20.16	$2.81	-86%
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$9.90	106%
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$11.54	111%
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$10.34	124%
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$18.18	149%
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$16.05	159%
120 codes	pack, drapes, ortho, large	SA080	$37.30	$25.38	-32%
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%
119 codes	pack, protective, ortho, large	SA083	$10.86	$14.75	36%
27 codes	pack, protective, ortho, small	SA084	$5.99	$8.15	36%

While we shared the concerns of the commenters regarding the need for accuracy in the pricing of these supply packs, we had reservations about their potential for pricing disruptions. Ten of these supply packs are included in the direct PE inputs for at least 100 HCPCS codes, and three of the packs are included in more than 1000 HCPCS codes. Many of these pricing updates would lead to drastic changes in pricing for these supply packs which are

included in hundreds of HCPCS codes, such as the SA051 pelvic exam pack decreasing in price from $20.16 to $2.81 (−86 percent) and the SA048 minimum multi-specialty visit pack decreasing in price from $5.02 to $1.98 (−61 percent). We were particularly concerned that these changes in supply pack pricing could lead to significant shifts in the overall PE RVU for affected HCPCS codes, without these proposed rates appearing in the proposed rule or allowing any opportunity for public comment.

Therefore, we did not finalize pricing updates for these additional 15 supply packs as requested by commenters. We anticipated returning to this subject in future rulemaking to allow any changes in associated pricing for HCPCS codes to appear in the proposed rule and provide an opportunity for the public to comment. Should these supply pack pricing updates be proposed in future rulemaking, we anticipated that we might propose the same pricing transition described above due to the number of potentially affected HCPCS codes. We finalized all of the other supply pack pricing changes as proposed, with the exception of the 4-year pricing transition for three supply packs as described above.

For CY 2026, we are proposing to continue implementing the supply pack pricing update and associated revisions as previously recommended by the RUC's workgroup. We are proposing to update the price of the 15 supply packs detailed in Table 5 which were received too late in CY 2025 to allow for proposed pricing or public comment. In the case of the surgical instruments cleaning pack (SA043), the moderate sedation pack (SA044) and the small ortho drapes pack (SA081), the proposed pricing update is modest enough that we are proposing these supplies move immediately to their final prices for CY 2026.

For the 12 other supply packs, we are proposing that they be incorporated into the muti-year supply pack pricing transition finalized in CY 2025 rulemaking. Rather than having two separate 4-year pricing transitions associated with supply packs, we are proposing that these 12 additional supply packs fold into the previous pricing transition using the same methodology, such that one-third of the difference between the CY 2025 price and the final price is implemented for CY 2026, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028 (89 FR 97728). With the inclusion of the SA042, SA058, and SA082 supply packs which began their pricing transition last year for CY 2025, we are proposing the total supply pack pricing update detailed in Table 6:

TABLE 6: CY 2026 SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33
SA041	111	$10.45	$17.28	-	$12.73	$15.00	$17.28
SA048	4568	$5.02	$1.98	-	$4.01	$2.99	$1.98
SA050	168	$2.72	$1.35	-	$2.26	$1.81	$1.35
SA051	239	$20.16	$2.81	-	$14.38	$8.59	$2.81
SA052	1079	$4.80	$9.90	-	$6.50	$8.20	$9.90
SA053	469	$5.47	$11.54	-	$7.49	$9.52	$11.54
SA054	1708	$4.62	$10.34	-	$6.53	$8.43	$10.34
SA055	12	$7.30	$18.18	-	$10.93	$14.55	$18.18
SA056	24	$6.20	$16.05	-	$9.48	$12.77	$16.05
SA080	120	$37.30	$25.38	-	$33.33	$29.35	$25.38
SA083	119	$10.86	$14.75	-	$12.16	$13.45	$14.75
SA084	27	$5.99	$8.15	-	$6.71	$7.43	$8.15
SD089	100	$20.56	$41.15	-	$27.42	$34.29	$41.15

This table also includes the hydrophilic guidewire (SD089) supply which we are proposing to transition in pricing over three years given its inclusion in approximately 100 HCPCS codes. We continue to believe that the use of this pricing transition will minimize any potential disruptive effects during the transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply items.

c. Technical Corrections To Direct PE Input Database and Supporting Files

Following the publication of the CY 2025 PFS final rule, we received a request from the RUC to remove all equipment items priced below $500 from the CMS ratesetting database. The RUC stated that since CMS has defined that medical equipment must be at least $500 and all equipment inputs under $500 are considered indirect expense, the 11 current equipment items under this threshold should no longer be listed as equipment. The RUC requested that CMS remove these items from its equipment list and from the specific HCPCS codes to conform to the definition of direct medical equipment and to ensure that the rule remains consistently applied.

We appreciate the RUC bringing this topic to our attention. However, we are not proposing to remove these 11 equipment items that fall under the $500 threshold from the CMS ratesetting database. These equipment items have historically been included as direct PE inputs in their respective HCPCS codes for the last two decades and, given the very small valuation associated with their use (such as the ED004 digital

camera priced at approximately 0.06 cents per minute of use), we do not believe that it is necessary to remove them from the database. We believe that it better serves relativity by continuing to maintain these equipment items due to their historical inclusion in their associated HCPCS codes, as opposed to the removal of long-standing direct PE inputs which may cause unnecessary confusion and lead to concern that the valuation of these services would be negatively impacted. We are soliciting comments on whether to maintain or remove these equipment items.

We also received a request from the RUC to update the names of several supplies and equipment items in the CMS ratesetting database. The RUC stated that these naming changes would remove specific product or brand names and more accurately describe the items in question. We agree with the RUC and we are proposing naming changes for the following supplies and equipment items:

- EQ392: We are proposing to rename the ''heart failure patient physiologic monitoring equipment package'' to ''patient physiologic monitoring equipment package''.
- ER089: We are proposing to rename the ''IMRT Accelerator'' to ''Radiation Treatment Delivery Linear Accelerator''.
- SD253: We are proposing to rename the ''atherectomy device (Spectronetics laser or Fox Hollow)'' supply to ''atherectomy device''.
- SD254: We are proposing to rename the ''covered stent (VIABAHN, Gore)'' to ''covered stent (VIABAHN)''.

We received a separate request from the RUC for a technical correction involving CPT code 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*). The RUC stated that there was a potential issue with the intraservice work time for CPT code 65780, which was recommended by the RUC with 35 minutes of work time and finalized by CMS with no work time refinements. However, CPT code 65780 was listed with 25 minutes of intraservice work time in the work time public use file issued with the CY 2025 PFS final rule; the RUC questioned whether this was a potential technical error. We have reviewed CPT code 65780 and concluded that the intraservice work time was unintentionally listed with the incorrect work time of 25 minutes; we are proposing to correct this to the intended work time of 35 minutes. We note that the total work time of 192 minutes was listed correctly for CPT code 65780 and does not require a technical correction.

We also received a request from the RUC for a technical correction involving CPT code 15851 (*Removal of sutures or staples requiring anesthesia (that is, general anesthesia, moderate sedation*)). The RUC stated that CPT code 15851 continued to receive PE RVUs in the nonfacility setting despite no longer having any direct PE inputs following its review at the January 2022 RUC meeting. Since CMS finalized the RUC's recommended lack of direct PE inputs for CPT code 15851 in the CY 2023 PFS final rule, the RUC questioned whether this was a potential technical error. We have reviewed CPT code 15851 and concluded that the continued assignment of PE RVUs in the nonfacility setting is an unintended technical error; we are proposing to correct this code by removing the nonfacility PE RVUs for CY 2026.

5. Development of Strategies for Updates to Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rulemaking, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, November 29, 1999) (BBRA) directed the Secretary to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. BBRA required us to establish criteria for accepting supplemental survey data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met in order to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we refer readers to discussions in the CY 2011 through 2014 final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and

potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA PPIS data for certain specialties (76 FR 73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule, we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we refer readers to our discussions in final rules for CY 2016 through 2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment on strategies to update PE data collection and methodology (87 FR 69429 through 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that may affect or factor into PE calculations. As described in previous rulemaking, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology currently relies on AMA PPIS data, which we have maintained represented the best aggregated available source of information at the time of its implementation. We noted in our CY 2023 and CY 2024 rules that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

b. Refreshed Data and Request for Information on Timing To Effectuate Routine Updates

In the CY 2024 PFS proposed rule, we continued to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Considering our ratesetting methodology and prior experiences implementing new data, we issued a follow-up from the CY 2023 comment solicitation for general information. We solicited comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and practitioner types. We also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In response to the CY 2024 RFI, most commenters stated that CMS should defer significant changes until the AMA PPIS results become available. For further background, refer to 88 FR 78841 through 78843. In responding to our RFI, the AMA RUC provided a set of responses, which many other commenters echoed in separate comments. In summary, the AMA RUC letter submission from CY 2024 suggested that CMS should not consider further changes until PPIS data collection and analysis is complete. Overall, the AMA comments generally do not support any change to the methodology and stated that CMS should wait to consider any further changes until PPIS updates become available. Further, we noted that through its contractor, Mathematica, the AMA secured an endorsement for the PPIS updates from each State society, national medical specialty society, and others prior to fielding the survey (88 FR 78843). Refer to the AMA's summary of the PPIS, available at *https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf.* The AMA stated that it expects analysis, reporting, and documentation to be completed by the end of CY 2024 and would share data with CMS when results become available.

Some commenters did not recommend that CMS defer significant changes until the AMA PPIS results become available. These commenters stated that reliance on the PPIS updates may not improve the accuracy and stability of the PE methodology because of the survey design, possible implementation challenges, and a possible lack of transparency or granularity in resulting datasets. Other commenters stated that dependence on the PPIS or survey data in general, due to timing and frequency constraints, may continue to jeopardize independent practice and discourage fair competition among suppliers and providers of services paid under the PFS. These commenters assert that if current trends continue, it will result in far fewer independent practices and more consolidation before the availability of updated survey data, undermining the sampling methodology of any survey and the general goals of our PE methodology updates.

As we stated in the CY 2025 proposed rule (89 FR 61614), we believe the AMA's approach may possibly mitigate nonresponse bias, which created challenges using previous PPIS data. However, we remain uncertain about whether endorsements prior to fielding the survey may inject other types of bias in the validity and reliability of the information collected. We believe it remains important to reflect on the challenges with our current methodology, and to continue to consider alternatives that improve the stability and accuracy of our overall PE methodology. We reiterate our discussion summarizing the responses to previous years' RFIs in each of the CY 2023 and CY 2024 final rules (refer to 87 FR 69429 through 69432 and 88 FR 78841 to 78843). We also requested general information from the public on ways that CMS may continue work to improve the stability and predictability of any future updates. Specifically, we

requested feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs. We stated that we believe that establishing a cycle of timing to update supply and equipment cost inputs every 4 years may be one means of advancing shared goals of stability and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and propose a phase-in period over the following 4 years. The phase-in approach maps to our experience with previous updates. Additionally, we stated that more frequent updates may have the unintended consequence of disproportionate effects of various supplies and equipment that have newly updated costs.

Further, we solicited feedback in the CY 2025 proposed rule RFI (89 FR 61614) on possible mechanisms to establish a balance whereby our methodology would account for inflation and deflation in supply and equipment costs. We stated that we remain uncertain how economies of scale (meaning a general principle that cost per unit of production decreases as the scale of production increases) should or should not factor into future adjustments to our methodology. We stated that there remains a diversity of perspectives among interested parties about such effects. We sought information about specific mechanisms that may be appropriate, and in particular, approaches that would leverage verifiable and independent third-party data that is not managed or controlled by active market participants.

In response to our CY 2025 proposed rule RFI (89 FR 97737), numerous commenters expressed concerns regarding CMS's current PE methodology, particularly highlighting its perceived inadequacies in accommodating modern medical technologies and services, such as Software as a Service (SaaS) and artificial intelligence (AI). These commenters stated that there is a need for CMS to revise its PE methodology to better reflect the actual costs of running medical practices today, which includes more frequent updates and the incorporation of direct costs for software and innovative technologies. Many also supported the AMA's PPIS efforts to ensure updated and accurate data informs PE calculations. Commenters urged CMS to collaborate closely with medical associations and incorporate broad stakeholder feedback without increasing reporting burdens, particularly for smaller practices.

We note that we have an ongoing contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. We will continue to study possible alternatives and have included analysis of the updated PPI and CPI Survey data in this proposed rule, as part of our ongoing work.

As previously stated above and discussed in sections II.N. and VI. of this proposed rule, we acknowledge that, at the time of publication of this proposed rule, the AMA concluded their data collection efforts and has submitted the data to CMS for us to consider implementing the PE/HR data and cost shares in PFS ratesetting for CY 2026. In the current system, accurate measurement of the indirect to direct PE ratio and the PE/HR for each specialty is critical to ensure that allocated indirect PE RVUs (and therefore total PE RVUs) accurately estimate service-level PE as defined by PFS ratesetting steps described above. Because the PE methodology is budget neutral, inaccuracies in the PE/HR data for some specialties can significantly impact the overall pool of PE available to distribute across all services, and therefore overall valuation and payment.

We appreciate the AMA's PPI and CPI Survey data collection efforts, and recognize the significant costs incurred to collect the data. However, our initial review of the new data raises substantive concerns about their accuracy, utility, and suitability as an immediate replacement for the current PE/HR data and cost shares for use in allocating nearly $91 billion in payments across PFS services. These concerns relate to issues including:

- *Low Response Rates and Representativeness:* A primary concern is the low response rate of the surveys. The 2024 PPI Survey had a response rate of 3 to 7 percent, depending on whether practices that did not click through the invitation email link were counted as non-respondents. The CPI Survey had a slightly higher response rate between 7 to 9 percent. In comparison, the 2008 PPIS had a response rate of 12 percent. Low response rates raise concerns as to whether responding practices are systematically different from sampled practices that did not or could not respond. Additionally, in response to lower-than-expected response rates, the AMA allowed 102 practices to volunteer to participate in the survey. Although most of these volunteer practices did not complete the survey, allowing practices to volunteer data adds to concerns about the representativeness of the data.

Additionally, the 2008 PE/HR estimates were based on the observations (about half of responses) that had no missing expense data, whereas the 2024 PE/HR estimates and the shares are based on observations that had at least some non-missing data where the missing data was imputed as described in the Survey Methods Report (Step 6).[1] It should be noted that some expense categories were reported more consistently by survey respondents. For example, 97 percent of the respondents reported compensation (physician work) compared to only 69 percent that were able to report non-billable drugs (direct expense under supplies) and information technology (indirect expense). Similarly, many survey respondents were not able to separately report expenses for qualified health providers (QHPs). Nearly 40 percent of the responses used in the calculation of the PE/HR estimates reported that they had nurse practitioners or physician assistants in their practice, but only 27 percent were able to separately report non-physician compensation expenses.

- *Small Sample Sizes and Sampling Variation:* Due in part to the low response rates, the number of respondents was small for many specialties included in the 2024 PPI and CPI data. For example, the PE/HR measures for Vascular Surgery are based upon responses from only 20 practices. Moreover, the PPI and CPI survey estimates give more weight to responses from practice types that would otherwise be under-represented in the sample, relative to the population of all eligible practices in a given specialty. For example, such an adjustment would be applied if the sample contained a higher proportion of facility-based practices than there are in the full population of practices in a given specialty. Applying such weights generally results in estimates that are less precise than an unweighted sample of a given size. One way to quantify this is via the effective sample size, which estimates the sample size from an unweighted sample that would be required to produce survey estimates that are as precise as those from the weighted sample. The effective sample size can be estimated as the ratio of the sample size to the design effect, which is reported in the PPI/CPI Methods Reports.[2] [3] For Vascular Surgery, the

[1] *https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf.*

[2] *https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf.*

Continued

reported design effect is 1.82, meaning that the 20 observations correspond to an effective sample size of only 11 (calculated as 11.0=20/1.82). For 12 of 18 broad specialty groupings reported in the 2024 PPI Survey, the effective sample size is less than 18.0 and for four of these specialties the effective sample size is less than 10.0. Similarly, in the CPI Survey data, the effective sample sizes are also small, with all but one below 20.0, and as low as 6.2 for Oral Surgery. Not including practices that volunteered, only 327 sampled practices completed the 2024 PPI Survey compared to 3,088 anticipated completions.

The low sample sizes contribute to substantial statistical uncertainty regarding the true specialty-level PE/HR measures. Figure A–B1 illustrates the 95 percent confidence intervals for direct and indirect PE/HR as reported in the 2024 PPI/CPI Surveys. The large points represent the new PE/HR estimates, the bars indicate the confidence intervals, and the smaller points show the current PE/HR estimates used in PFS ratesetting from the 2008 PPIS. The 2024 CPI and PPI Survey confidence intervals are so broad that they cover most of the original 2008 PPI PE/HR values in nominal dollars (that is, not adjusted for inflation). Therefore, in most cases, the new data are unable to establish statistically significant changes from the status quo, especially since the old PE/HR measures were themselves estimated with substantial levels of statistical uncertainty. Even so, the new PE/HR estimates differ enough from the old ones that many specialty-level impacts of adopting the new data are quite large. When translated into RVUs, the PE/HR standard errors for specialties such as Cardiology, Pathology, Ophthalmology, and Vascular Surgery correspond to a wide range of payments for services provided by those specialties meaning that the new data are compatible with a wide range of specialty impacts for many specialties.

- *Lack of Comparability to Previous Survey Data:* The 2024 PPI and CPI Survey data groups specialties in a considerably different way from the current structure, with 29 specialty groupings compared to 51 in the 2008 data. We found that using the 2008 PE/HR data averaged within the 2024 PPI Survey specialty groupings would lead to large specialty-level impacts in some cases, further complicating comparisons between the old and new data and indicating that the new 2024 specialty groupings is impactful on redistribution among the PFS alone. We refer readers to section VI. of this proposed rule for discussion of the impacts of the 2024 PPI Survey specialty groupings on PFS ratesetting. It is also unclear why some specialties were collapsed into relatively broad groups for the purposes of data collection and reporting while others were not.
- *Potential Measurement Error:* We are concerned that sampled practices were not able to accurately report the data necessary to respond to the PPI and CPI Surveys. For example, the survey contractor found that practices frequently had challenges reporting the number of physicians working in the practice. One may expect that the number of physicians in a practice is relatively easier for practices to measure than some of the specific costs integral to reporting PE/HR. However, the contractor noted that—prior to an adjustment—their estimate of the total number of physicians was nearly three times as large as the number of physicians in their sampling frame which ''indicated a large potential for measurement error in this estimate.'' [4] Also, because information on the number of physicians in each practice was available from external data which were obtained before survey data were collected, to inform the survey design, we believe it is likely that the number of physicians was highlighted as having high potential measurement error because it was possible to compare this measure against external data. Moreover, some responding practices reported that it took more than 40 hours to complete the survey, which suggests that the required data are not readily captured by their accounting systems and therefore may not be fully reliable.

Thus, we are left with doubts about not just the amount of data collected, but its quality as well.

- *Missing and Incomplete Data Submission:* The PPI Survey summary data was submitted to CMS in January 2025 and the CPI Survey summary data in February 2025. These initial submissions were missing from many of the elements required to analyze the data and determine their usability in our PE methodology. We inquired about these elements and have since received some additional information, but some of the information was not available due to the survey contract concluding, such as estimates based solely on the survey responses that had no missing expense data or the impact of the trims and edits of the data described in the PPI Survey Methods Report. Additionally, some data is completely missing from the submission, therefore we had to utilize old PE/HR data in analyses for specialties such as Independent Diagnostic Testing Facilities (IDTFs) when developing models to incorporate the data. Additionally, the American Occupational Therapists Association (AOTA) requested the continued crosswalk of PE/HR data from Physical Therapy to Occupational Therapy because the CPI respondents may have indirectly reported the salaries of occupational therapy assistants with provider compensation rather than including their salaries in clinical staff compensation.

Additionally, there is summary data provided from the PPI Survey [5] that are not provided for the CPI Survey.[6] For example, the PPI Survey summary data include two lines—''MEI shares'' and ''All [specialties]''—that could presumably be used to establish the share of total RVUs that should be attributed to work, practice expense, and malpractice, but we do not believe that they reflect the specialties' data from the CPI Survey, even though those specialties are included in PFS ratesetting, account for a significant portion of the PFS PE RVU pool, and draw from the same pool of RVUs as the PPI Survey specialties. Similarly, we do not have the corresponding CPI Survey specialty weighting information provided to CMS for the PPI Survey specialties, therefore, we have limited information to develop an approach for calculating shares for all CMS specialties accounted for in both the PPI and CPI Surveys.

In an effort to incorporate PPI and CPI Survey specialties' data despite the lack of analogous summary data, we developed possible methods to weight the data for all CMS specialties in a cohesive manner for use in the PFS PE methodology such as estimates of total RVUs and total service time by specialty used for CY 2026 PFS ratesetting. We refer readers to section VI. of this proposed rule for discussion of the different weighting methodologies and their resulting shares of work, PE, and MP.

Overall, the small sample sizes and the apparent presence of high levels of measurement error in data elements that could be compared to external estimates suggest that specialty-level PE/HR measures may be challenging to measure reliably through voluntary surveys alone. We note that the

[3] *https://www.ama-assn.org/system/files/cpi-survey-methods-report-main-report.pdf.*

[4] *https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf.*

[5] *https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.*

[6] *https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.*

interested parties may concur with this assertion based on the Methods Report, which states considerations for future data collection efforts that may forego the survey structure and rely on other practice expense sources such as tax returns. We believe that a more efficient and transparent system that could be updated on a regular basis may be possible using available administrative data (such as Medicare claims; hospital cost reports; publicly-reported tax information such as from IRS Form 990; and data collected by other agencies, such as the Census Bureau's Service Annual Survey (SAS)) to the fullest extent possible and relying on survey data only to fill gaps only where available data do not exist. An alternative to collecting any survey data would be to modify the PE allocation system so that it only relies only on data that can be measured accurately and on an on-going basis. For example, if there are components of indirect PE that are not captured in administrative data, those expense categories could potentially be re-classified as direct costs and accounted for in a manner similar to how direct costs are currently considered.

Beyond the use of the data in our PE methodology, we need information on the total share of PFS payments that should be allocated for work, PE, and MP. Data collected in the 2024 PPI and CPI Surveys could be used for this purpose, as well as potentially be considered in a construction of the MEI in the future; however, there still remain underlying concerns with the sample representativeness for these purposes. The AMA has asserted that shares derived from data collected from the Service Annual Survey (SAS) for the 2017-based MEI miss many physicians who work in facility settings and thereby understate the percent of total PFS payments that should be allocated to physician work. The data needed to derive the three component shares (work, PE, and MP) are more aggregated than the specialty-level PE/HR data required for the PE methodology, so we have fewer concerns with the small sample sizes for this application. However, we continue to have similar concerns with the data related to measurement error and sample representativeness for purposes of the shares.

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Figure 1: Comparison of PE/HR Data from 2008 PPIS and 2024 PPI and CPI Survey with 95% Confidence Intervals for the 2024 Data

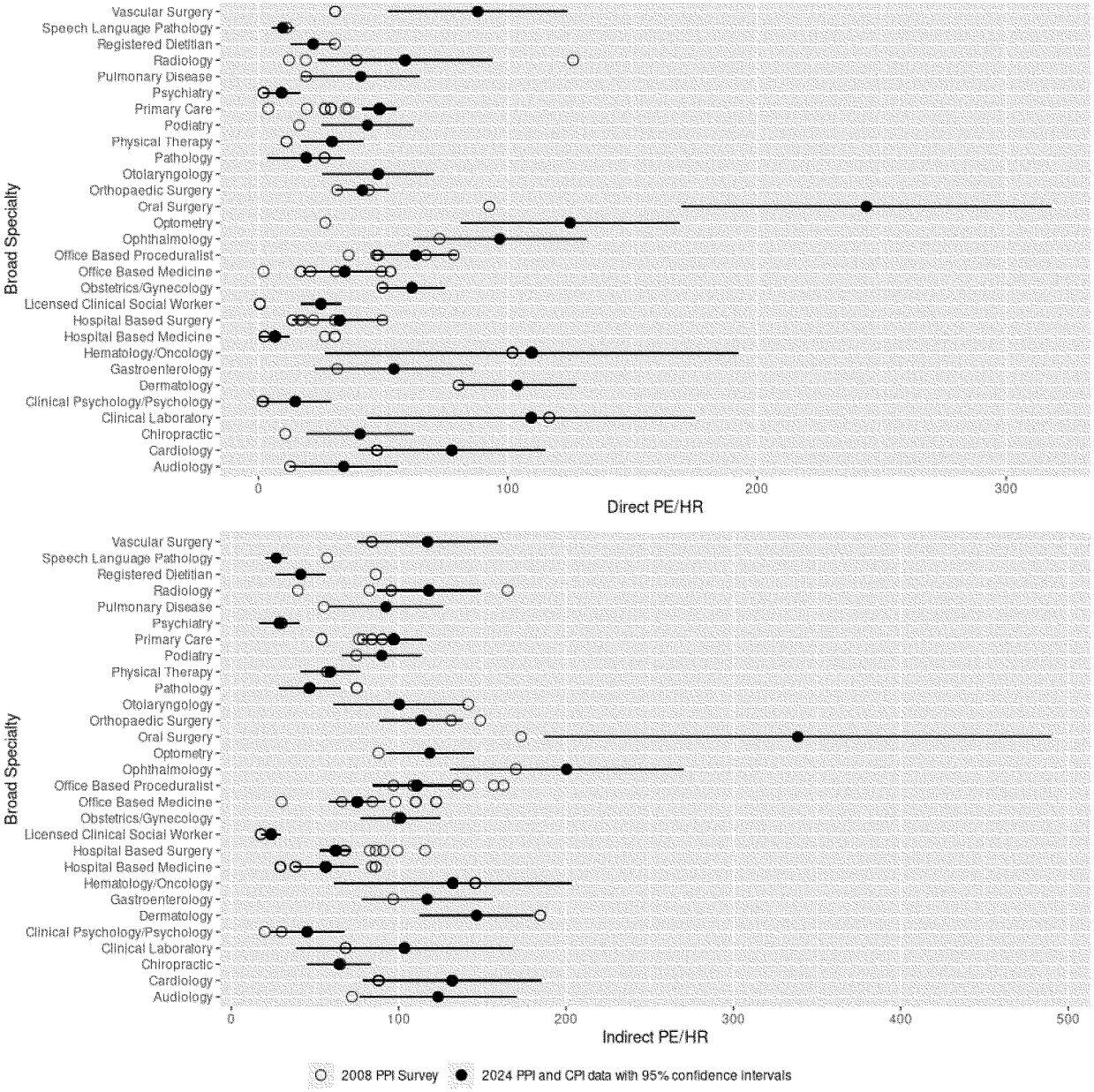

Figure 1: Comparison of PE/HR data from 2008 PPI Survey (small, hollow dots) and data from the 2024 PPI and CPI Survey (large, filled dots) with 95 percent confidence intervals for the 2024 data. Data are grouped by the 2024 specialty groupings.

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At the time of the publication of this proposed rule, we continue to conduct ongoing analyses on the potential impact of the AMA's PPI and CPI Survey data on PFS ratesetting. Due to overarching concerns with the data described above and our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through routine updates to the MEI, we reiterate that we are not proposing to implement the PE/HR data or cost shares from the AMA's survey data at this time, and are proposing instead to maintain the current PE/HR data and cost shares for CY 2026 PFS ratesetting. At the same time, we remain focused on proposals that reflect evolutions in practice, including the site of service payment differential discussed below, while we continue to hold strong interest in specialty-level practice expense updates. Consequently, we intend to work with interested parties, including the AMA, to understand whether and how such data should be used in PFS ratesetting in future rulemaking.

c. Updates to Practice Expense (PE) Methodology—Site of Service Payment Differential

While we are not proposing to incorporate the PPI and CPI Survey data into PFS ratesetting for CY 2026, we are proposing a significant refinement to our PE methodology to better reflect trends in physician practice settings. As detailed in the description of the

practice expense methodology above, many services have a site of service payment differential between the facility (F) and nonfacility (NF) settings under the PFS. Services furnished in the nonfacility setting, such as a physician's office, include the physician work RVUs, direct costs for supplies, clinical staff, and equipment, and indirect costs allocated based on the direct costs and the greater of either the clinical labor costs or the physician work RVUs. In the facility setting, the payment rate includes physician work RVUs and the indirect practice expense allocated based on the physician work RV*U*. The direct costs in the facility setting are paid under a different payment system than the PFS, such as the OPPS. Indirect costs allocated to services furnished in the facility setting are meant to reflect the typical costs associated with practice expenses in that setting of care.

In the decades since implementing the PE methodology, there have been significant transformations to the landscape of the healthcare delivery system in the United States, particularly regarding physician practice patterns. Historically, private practice was the dominant model for physicians, offering them autonomy, flexibility, and the opportunity to build independent practices. Specifically, in 1988, approximately 72 percent of physicians were full or part owners in their practice.[7] This percentage had dropped to 35.4 percent by 2024, representing a 52 percent decrease, with a corresponding rise in physicians in hospital-owned practices and physicians employed directly by a hospital. The percentage of physicians in hospital-owned practices has increased by over 47 percent, from 23.4 percent in 2012 to 34.5 percent in 2024. Similarly, 12.2 percent of physicians were employed directly by a hospital (or contracted directly with a hospital) in 2024, up from 5.6 percent in 2012.[8] In their June 2025 Report to Congress,[9] MedPAC notes that there are 9 specialties where 60 percent of the clinicians who billed Medicare furnished 90 percent or more of their services in the facility setting. These trends indicate a steady decline in the percentage of physicians working in private practice, with a corresponding rise in physician employment by hospitals; and growth in the percentage of physicians who practice exclusively, or almost exclusively, in the facility setting. When the PFS was established, the methodology for allocating indirect practice expense was based in part on an assumption that the physician maintained an office-based practice even when also practicing in a facility setting. In that context, the PE methodology has allocated the same amount of indirect costs per work RVU, without regard to setting of care.

We note that, in the AMA's comment letter on the CY 2023 PFS proposed rule,[10] they stated that physician practices maintain some indirect practice expense costs for physicians who are solely facility-based such as coding, billing, and scheduling. We acknowledge that these indirect costs should be accounted for in PFS payment through PE RVUs, but we believe that allocating the same amount of indirect practice expense based on work RVUs in both settings may overstate the range of indirect costs incurred by facility-based physicians if it is now less likely that they would maintain an office-based practice separate from their facility practice. In a 2018 report developed under contract with CMS, RAND noted that ''operating from the perspective of paying for the 'typical' instance of a procedure, these analyses suggest that the current system could be improved by shifting more of the allocation of PE RVUs to the physician office setting''.[11] As MedPAC notes in their June 2025 report, ''In cases when clinicians practice exclusively or almost exclusively in a facility, or where a facility is financing indirect PE for clinicians, payment to both entities for indirect PE costs may be duplicative and unnecessary''. While the relative relationship between the PE allocated to services furnished in a facility and nonfacility setting may have been more reflective of the actual expenses incurred by physicians when the PE methodology was originally established, maintenance of that element of the methodology in the face of changing practice patterns likely represents an imbalance of the practice expense allocated to the facility relative to the nonfacility. Within the PFS relative value system, any overstatement of practice expenses in the facility setting would affect the allocation of indirect costs in the nonfacility setting. This dynamic, in which relative resources involved in furnishing PFS services may not be adequately reflected in facility and nonfacility settings, has the potential to contribute to broader undesirable financial incentives toward higher-priced settings of care, like hospitals, and away from more efficient settings, like physician offices.[12] [13] [14] This could result in unnecessary costs for payers and beneficiaries, and obstacles to physicians and other professionals operating independent practices.

We share MedPAC's concerns regarding the potential for duplicative payment under the current PE methodology for allocating indirect costs for physicians practicing in the facility setting. Allocating the same amount of indirect PE per work RVU for services furnished in the facility setting as the nonfacility setting may no longer reflect contemporary physician practice trends. As we noted above, data suggests that fewer than half of physicians currently own their practices, but the underlying assumption embedded in the PFS payment methodology presumed that physicians generally maintained office practices (and incurred associated indirect costs) even when they furnished care in facility settings. For these reasons, for each service valued in the facility setting under the PFS, we are proposing to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to nonfacility PE RVUs beginning in CY 2026. This proposed change would occur in step 8 of the PE RVU Methodology described earlier in this section, in which indirect allocators (direct costs, clinical labor, and work RVUs) are assigned. For example, the work RVU for CPT code 33533 (*Coronary artery bypass, using arterial graft(s); single arterial graft*) is 33.75. For CY 2025, using the full work RVU as an indirect allocator, CPT code 33533 had approximately 12 indirect PE RVUs. Under this proposed change to the

[7] Kane CK. Emmons, DW. New data on physician practice arrangements: private practice remains strong despite shifts toward hospital employment. Chicago (IL): American Medical Association; 2013. Policy Research Perspective 2013–2.

[8] Kane CK. Physician Practice Characteristics in 2024: Private Practices Account for Less Than Half of Physicians in Most Specialties. American Medical Association.

[9] MedPAC. (2025). June 2025 Report to the Congress: Medicare Payment Policy. Chapter 1 Reforming physician fee schedule updates and improving the accuracy of relative payment rates. *https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_MedPAC_Report_To_Congress_SEC.pdf.*

[10] *https://downloads.regulations.gov/CMS-2023-0121-2694/attachment_1.pdf.*

[11] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

[12] *https://pmc.ncbi.nlm.nih.gov/articles/PMC4191490/#:~:text=Using%20generally%20accepted%20accounting%20practices,to%20more%20intense%20resource%20use.*

[13] *https://healthcostinstitute.org/hcci-originals-dropdown/all-hcci-reports/shifting-care-office-to-outpatient.*

[14] *https://www.bcbs.com/dA/392da3b5a7/fileAsset/BHI%20Issue%20Brief%20December_121323_SiteNeutral.pdf.*

methodology, where we would reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to nonfacility PE RVUs, CPT code 33533 would have approximately 7.2 indirect PE RVUs.

We note that this proposed change to the indirect cost allocation methodology is intended to better recognize the relative resources involved in furnishing services paid under the PFS in facility and nonfacility settings. We compare this proposed change to our current methodology, which functionally presumes approximately equal indirect costs incurred by physicians across sites of service. This presumption was initially made in the context of most practitioners maintaining office practices independent of the facilities in which they provided care, and as we discussed above, appears to be inconsistent with contemporary trends in physician practice. We understand from the AMA's comment letter on the CY 2023 PFS proposed rule noted above that physician practices may incur some indirect PE costs (such as coding, billing, and scheduling) for physicians who are facility-based. To better inform our consideration of how to account for any such costs in the PE RVU methodology, we are seeking comment on the specific types and magnitude of indirect PE costs incurred that are attributable to physicians who practice in part or exclusively in a facility setting, and any variables that affect whether and to what extent a practice would incur them. We are also seeking comments on whether our proposal to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to nonfacility PE RVUs is an appropriate reduction or whether we should consider a different percentage reduction for CY 2026 or in future years. While our proposed change to the methodology represents a starting point to correcting potential historic distortions in the allocation of indirect PE costs across settings of care, we intend to further examine our methodology and consider additional refinements based upon public comments received and any studies or data sources identified. We are seeking comments on whether there are additional data sources that might help identify a more precise site of service difference in the allocation of indirect PE RVUs. We believe the implementation of this proposal would more accurately account for the resource costs involved in physicians furnishing care across all settings and correct potential distortions in the allocation of indirect PE under our current methodology. We refer readers to section VI. of this proposed rule for discussion of the impacts of this proposal on CY 2026 PFS ratesetting.

We are specifically soliciting comments on whether and how this proposed policy should apply to codes with MMM global periods (maternity services) and how it could specifically impact access to maternity services, given our understanding that many of the patient encounters across those services occur in the office setting. As we noted in the CY 2024 PFS final rule (88 FR 78949), maternity services are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, which include a relatively large number of E/M visits performed along with delivery services and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method. Given that the work RVUs for maternity services encompass significant care during this lengthy period that may be furnished in the nonfacility setting, we are soliciting comment on whether we should include these services in our proposed policy to reduce the allocation of PE based on work in the facility setting.

We welcome comments on all aspects of this proposal, including ways to improve the allocation of facility and nonfacility PE RVUs in the future. We also seek comments on alternative approaches to improving the allocation of indirect PE as outlined in Chapter 1 of MedPAC's June 2025 Report to the Congress (pages 27 through 33).

d. Use of OPPS Data for PFS Ratesetting

For several kinds of PFS services, we are proposing to deviate from the use of the AMA survey data, and instead utilize data from auditable, routinely updated hospital data to either set relative or absolute rates, especially for technical services paid under the PFS. This approach promotes price transparency across settings, offers more predictable ratesetting outcomes, and limits the influence of anecdotal/survey data. We refer readers to sections II.E.24 and II.E.30 of this proposed rule for specific proposals related to radiation treatment delivery and superficial radiation therapy services and remote patient monitoring and remote therapeutic monitoring services respectively and section II.K of this proposed rule for specific proposals related to skin substitutes. Although we are proposing different methodologies for use of OPPS data based on service type, we are seeking comment on whether it would be preferable to adopt a single methodology, such as a scaler and how such a methodology would account for differences in practice expenses between services, such as services with extensive clinical staff time versus services where the valuation is primarily driven by the equipment costs.

6. Payment for Services in Urgent Care Centers

In the CY 2025 PFS proposed rule (89 FR 61746 through 61747), we sought comment on urgent care centers, noting that interested parties describe that hospital emergency departments are often used by beneficiaries to address non-emergent urgent care needs that could be appropriately served in less acute settings, but where other settings, such as physician offices, urgent care centers or other clinics, are not available or readily accessible. Patients enter EDs to treat common conditions like allergic reactions, lacerations, sprains and fractures, common respiratory illnesses (for example, flu or RSV), and bacterial infections (for example, strep throat, urinary tract infections or foodborne illness). Conditions like these often can be treated in less acute settings. We stated that we were interested in system capacity and workforce issues broadly and are interested in hearing more on those issues, including how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments.

In response to our CY 2025 PFS proposed rule (89 FR 61746 through 61747) question about whether the current ''Urgent Care Facility'' Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings other than the existing place of service codes,, commenters stated that the current place of service (POS) definitions are inadequately differentiated, especially if CMS wishes to encourage proliferation of the type of urgent care centers that can provide suitable alternatives to EDs, noting that POS 11 generally refers to physician offices that provide diagnostic and therapeutic care in an office setting, by appointment, typically during regular business hours; POS 17 generally refers to clinics that are attached to retail operations, such as pharmacies, grocery stores or big box stores, and provide low-acuity primary and preventive health care, such as vaccinations; and POS 20 refers to Urgent Care Facilities but does not adequately differentiate between those that offer services more akin to the typical general practitioner's office and those that offer enhanced diagnostic and therapeutic services and extended

hours. They recommended that the creation of a new POS code describing ''enhanced''' urgent care centers that offer specific diagnostic and therapeutic services and that operate outside typical business hours could fill this need. In response to our CY 2025 PFS proposed rule (89 FR 61746 through 61747) question about whether the current ''Urgent Care Facility'' Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings other than the existing code set and valuation, they stated that Medicare's fee-for-service payment systems do not recognize and adequately value services furnished in Urgent Care Clinics (UCCs) and stated that while there is some overlap in the types of professional services furnished in UCCs and physician offices, UCCs that operate for extended hours and that have enhanced diagnostic and therapeutic capabilities incur additional costs to provide these services.

In recent months, an interested party has requested that for CY 2026, we consider adopting a new Place of Service code for ''enhanced'' urgent care centers as well as create a new add-on G-code to describe the resource costs involved when practitioners furnish certain services in enhanced urgent care centers that offer extended hours and certain diagnostic and therapeutic services. The interested party suggested the following descriptor: ''*Visit complexity inherent to evaluation and management associated with medical care services that serve as the immediate focal point for all needed urgent, non-emergent health care services and/or with urgent, non-emergent medical care services that are related to diagnosis and treatment of an unscheduled, ambulatory patient's urgent, non-emergent conditions. (Add-on code, list separately in addition to office/outpatient evaluation and management visits, new or established)*'' and recommended that it be valued based on a crosswalk to HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)* and made billable with all levels of office/outpatient E/M visits for both new and established patients when services are furnished in an enhanced urgent care center.

We are seeking comments from the public regarding whether separate coding and payment is needed for evaluation and management visits furnished at urgent care centers, including whether or not an add-on code would be appropriate or if a new set of visit codes would be more practical We note that the process for requesting new place of service codes or modification of existing place of service codes is described on the CMS website at *https://www.cms.gov/medicare/coding-billing/place-of-service-codes/process-requesting-new-codes-modification-existing-codes.* Additionally, as discussed in Section II.B of this proposed rule, many PFS services have a site of service payment differential between the facility and nonfacility settings under the PFS. Services furnished in the nonfacility setting, such as a physician's office, include direct costs for supplies, clinical staff, and equipment, the physician work RVU and indirect practice expense allocated based on the direct costs and the physician work RVU. In the facility setting, the payment rate includes physician work and the indirect practice expense allocated based on physician work. The direct costs in the facility setting are paid under a different payment system other than the PFS, such as the OPPS. PE allocated to services furnished in the facility setting is meant to reflect typical costs associated with practice expenses in that setting of care. We note that we are proposing a change in our PE RVU methodology to better recognize variations in indirect costs between facility and nonfacility settings of care in section II.B of this rule. We note here that we are likewise interested in understanding how practice costs, including but not limited to indirect costs, may vary among different nonfacility settings of care. We are also interested in receiving feedback regarding how either the code set, or the PE methodology might be improved to better recognize the relative resources involved in furnishing services across these kinds of settings.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes (PMVC) under the PFS, using the same criteria used to identify PMVC, and to make appropriate adjustments.

As outlined in section II.E. of this proposed rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct practice expense (PE) inputs using other data sources, such as the Veterans Health Administration (VHA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties such as from the general medical-related community and the public. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*https://www.medpac.gov/document/report-to-the-congress-2006-medicare-payment-policy/*), MedPAC discussed the importance of appropriately valuing physicians'

services, stating that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases, or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*https://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using current processes for consideration of coding changes), which may involve consolidating individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous PMVC as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining PMVC in these areas over the upcoming years. As part of our current process, we identify PMVC for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies PMVC for review. Through our public nomination process for PMVC established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of PMVC as well. Individuals and groups may submit codes for review under the PMVC initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS e-mailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov,* with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd, Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual PMVC review and Five-Year Review process, we have reviewed over 1,700 PMVC to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of PMVC is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), we built upon the work we began in CY 2009 to review PMVC that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes'' [15]). In the CY 2009 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume,

[15] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

low intensity codes. In the fourth Five-Year Review of Work RVUs published in a separate notice (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of PMVC that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of PMVC that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2026 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058 through 73059), we finalized a process for the public to nominate PMVC. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate PMVC for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of PMVC may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be PMVC appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a PMVC. The public has the opportunity to comment on these and all other proposed PMVC. In each year's final rule, we finalize our list of PMVC.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for PMVC by February 10th and we display these nominations on our public website (*https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending*), where we include the submitter's name, their associated organization and the submitted studies for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the PMVC initiative. For CY 2026, we received 11 requests concerning various codes as PMVC. The nominations are as follows:

(1) Maxillofacial Prosthetic Services (CPT codes 21076, 21077, 21079, 21080, 21081, 21082, 21083, 21084, 21085, 21086, 21087)

An interested party nominated CPT codes 21076 (*Impression and custom preparation; surgical obturator prosthesis*), 21077 (*Impression and custom preparation; orbital prosthesis*), 21079 (*Impression and custom preparation; interim obturator prosthesis*), 21080 (*Impression and custom preparation; definitive obturator prosthesis*), 21081 (*Impression and custom preparation; mandibular resection prosthesis*), 21082 (*Impression and custom preparation; palatal augmentation prosthesis*), 21083 (*Impression and custom preparation; palatal lift prosthesis*), 21084 (*Impression and custom preparation; speech aid prosthesis*), 21085 (*Impression and custom preparation; oral surgical splint*), 21086 (*Impression and custom preparation; auricular prosthesis*), and 21087 (Impression and custom preparation; nasal prosthesis) as potentially misvalued based on what they believe to be missing, outdated, and undervalued practice expense inputs. The nominator stated that these misvalued PE inputs (equipment, supplies, and clinical staff time) result in inadequate payment rates to clinicians who furnish these services, which limits patient access to necessary care. The nominator indicated that the physician work values remain accurate for all of the nominated codes.

According to the nominator, maxillofacial prosthodontists provide specialized rehabilitation care for patients with compromised oral and facial anatomy due to conditions such as cancer, trauma, or congenital defects, addressing both physical and psychological challenges experienced by such patients. Custom prosthetic obturators are medical devices that restore vital oral functions in cancer patients with palatal defects. These implant-retained devices are prescribed based on the location of the defect: maxillary obturators for hard palate issues, pharyngeal obturators for soft palate problems, or a combination for both. The primary purpose of the intraoral prostheses is to enable patients to speak, eat, and swallow more naturally. The nominator stated that these implants can improve patients' quality of life and may eliminate the need for feeding tubes.

The nominator is concerned that CMS payment rates for maxillofacial prosthetic services, which were last reviewed in 1995, are outdated. In particular, the nominator stated that CPT codes 21080 and 21081 have undergone significant changes since the development of their PE values in the mid-1990s. At that time, mandibular reconstruction was rare, and removable prostheses were used to align the jaw. Microvascular reconstruction and virtual surgical planning have since transformed the procedures described by CPT codes 21080 and 21081, allowing precise prosthetic rehabilitation during surgery and improving oral function, speech, and quality of life. The nominator asserted that the PE inputs for CPT codes 21080 and 21081 did not account for these advancements, which did not exist in 1995 when the codes were valued. Furthermore, they stated that when these maxillofacial prosthetic services

were valued in 1995, CMS used inaccurate inputs, which they believe did not account for the appropriate clinical staff time and materials required for prostheses. They stated that changes in clinical staff time, supplies, and equipment require the direct PE inputs to be updated.

The nominator stated that significant technological advancements have also occurred for extraoral prostheses, such as orbital (CPT code 21077), auricular (CPT code 21086), and nasal prostheses (CPT code 21087). For orbital prostheses, hand sculpting and painting remain time-intensive tasks, with limited use of 3D technology. In auricular prostheses, 3D technology has significantly improved the waxing process. For nasal prostheses, preoperative scanning now helps to shape the prosthesis, leading to better cosmetic outcomes. All extraoral prostheses (for example, orbital, auricular, and nasal) now commonly use 3D technology, craniofacial implants, and color-matching devices, which were not standard in the 1990s. The nominator asserted that the practice expense inputs for these codes fail to account for these advancements.

Additionally, the nominator asserts that there are other instances where the nominated codes fail to reflect the significant technological advancements in treatment delivery since 1995. The nominator requested an update to the PE inputs for all of the nominated codes, stating that the dental x-ray (ER071), valued at $128,020.91, has been replaced by various pieces of capital equipment. For example, they listed a ''CMS Planmeca CBCT Imaging'' system, which costs $163,767.66, and stated that this takes the place of the x-ray unit, highlighting a notable price difference between the x-ray machine and the CT. Furthermore, they provided a lengthy list of additional equipment (*e.g.,* 3D printer) that is not accounted for in the PE inputs for all of the nominated codes, underscoring the extensive modernization in service delivery since 1995.

To support their nomination, the nominator included information on what they believe to be more accurate PE inputs, including invoices for supplies and equipment. For items where invoices paid were unavailable, price quotes from a supplier were included. In addition, their appendices included recommendations for deleting and adding supplies, equipment, and clinical staff time. For more information, we refer readers to the submitted nomination, which is posted in the public use files for this proposed rule available on our public website under PFS Federal Regulation Notices at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

Although the nomination stated that the work RVUs are accurate as currently valued, because these codes have not been reviewed in the last 30 years, we believe it is appropriate to examine both PE and work inputs. Given the technological advancements the nominator described, there may also be resulting changes in the physician work involved in performing these services, and therefore, a comprehensive review of both practice expense and work values would be appropriate. While we are not proposing to nominate these codes as potentially misvalued, we welcome public comments and recommendations, including those from the RUC, to better understand these codes, particularly regarding typical direct PE inputs and work values.

(2) Supervision of Preparation and Provision of Antigens for Allergen Immunotherapy (CPT codes 95145, 95146, 95147, 95148, 95149).

An interested party nominated the professional supervision of preparation and provision of stinging insect venom for allergen immunotherapy described by CPT codes 95145 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom*), 95146 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms*), 95147 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms*), 95148 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms*), and 95149 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms*) as potentially misvalued, stating that the current payment rates for these CPT codes do not accurately reflect the practice expenses required for these procedures. The nominator indicated that the cost to manufacture venom therapy has drastically increased since the last time these codes were reviewed by the RUC in 2001, citing higher labor and raw material costs.

Venom immunotherapy, used for treating insect stings, involves extracting venom from various stinging insects like honeybees and wasps. According to the nominator, the manufacturing process is labor-intensive, requiring 520 staff hours to manually extract venom from 130,000 insects per batch, along with substantial equipment investment. The final product is packaged in single, five, or twelve-dose vials for medical use. For more information, we refer readers to the submitted nomination, which is posted in the public use files for this proposed rule available on our public website under PFS Federal Regulation Notices at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

The nominator stated that before 1995, venom products were paid under product-specific HCPCS J-codes, but due to infrequent use and limited budget impact on the Medicare trust funds, CMS retired the J-codes and instead bundled venom products within CPT codes 95145, 95146, 95147, 95148, and 95149. According to the nominator, current payment rates for these codes are based on the Harvard valuation and have not been surveyed by the RUC since February 2001. The nominator stated that when surveyed in 2001, the PE inputs for these codes only accounted for swab-pad, antigen, syringe, and gloves. In contrast, the nominator indicated that CPT code 95165 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses),* which was more recently reviewed in 2016 and shares similar PE inputs as the nominated codes, includes additional items such as a surgical cap, gown, mask, alcohol, paper towel, and vial transport envelope. The nominator stated that, according to the 2019 standards for allergen extract compounding under USP Chapter 797,[16] the procedures described by CPT codes 95145, 95146, 95147, 95148, and 95149 require additional supplies and practice expenses, such as sterile powder-free gloves, face mask, hair net/beard net, gown/sterile garb, isopropyl alcohol, paper towel, sterile empty vials, and albumin saline, in addition to the allergenic extract. The nominator stated that these standards also mandate significantly more annual training for providers, including competency observation, media fill test, gloved fingertip test, and corrective actions. Furthermore, the nominator asserted

[16] *https://college.acaai.org/wp-content/uploads/2021/01/Section-21-USP-Compounding-Allergenic-Extracts.pdf.*

that the overall cost of venom therapy has increased substantially and submitted invoices to support this statement.

At this time, we are not proposing the CPT codes submitted by the nominator as potentially misvalued. CPT codes 95145–95149 are typically billed in conjunction with CPT codes 95115 and 95117. We note that the nominator has listed PE inputs that are also included in the inputs for CPT codes 95115 and 95117 and these same inputs may overlap with inputs included in CPT codes 95145–95149. While the PE inputs that overlap between CPT codes 95145–95149 and 95115 and 95117 may contain the necessary elements, we are seeking feedback regarding these overlapping PE inputs in relation to billing frequencies and the possibility of duplicative payment. Specifically, we request comments on whether these inputs overlap and what potential adjustments should be made to avoid duplicative payment. We request comments regarding the standard minutes for clinical activity code CA008 (Perform regulatory mandated quality assurance activity (pre-service)) and the standard unit measurement for supply code SH004 (albumin saline). Additionally, we seek input regarding the establishment of clinical activity codes for two specific procedures requested by the nominator: cleaning and disinfecting the compounding area, and sterile preparation of compounds.

Furthermore, anomalies were identified related to the clinical activities described by CA021 (Perform procedure/service—NOT directly related to physician work time). Specifically, the typical times associated with these activities in the RUC database are as follows: 2.3 minutes for CPT code 95145, 3.3 minutes for CPT code 95146, 2.3 minutes for CPT code 95147, 3.3 minutes for CPT code 95148, and 4.3 minutes for CPT code 95149. The nominator has requested 10 minutes for all of the nominated CPT codes without providing any justification for this time. Regarding the clinical labor direct inputs (L037D), we seek comments on several aspects of dosage preparation, including but not limited to: the typical number of dosages, the time required for preparation, the number of vials or dosages that can be prepared from each vial, and the total time needed for preparation of these vials and dosages. Additionally, we seek information about the derivation of the 2.3-minute time. This information would help inform the appropriate time for both clinical labor activities.

We received several invoices for mixed and single venom prices from the nominator; however, we are unable to determine the number of individual venoms in the mixed venom preparations. Specifically, supply codes SH009 (antigen, venom) and SH010 (antigen, venom, tri-vespid) are currently priced at $35.58 and $69.21 respectively, with prices last updated in the CY 2024 PFS final rule (88 FR 78967). The nominator stated that the venom cost has increased to $481.50 for a 5-dose wasp venom as of April 1, 2024, and submitted invoices to support this claim to update the current price. Since we are unsure whether these invoices are for mixed or single venom prices, we welcome additional invoices and comments regarding the methodology for calculating venom prices using mixture invoices. We welcome feedback to gain a broader understanding of these codes, including how standards of practice have evolved over time, as this information can help identify related coding issues.

(3) Electronic analysis of implanted neurostimulator pulse generator/transmitter (CPT codes 95970, 95976, 95977).

CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*), 95976 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional)* were nominated as potentially misvalued for two reasons identified by the nominator: there has been a significant shift in the clinical specialties utilizing these codes, and the PE inputs currently assigned to these codes may not accurately reflect the costs associated with analyzing and programming the hypoglossal nerve stimulation (HGNS) system.

The nominator stated that, from 2017 to 2023, there has been a significant change in the clinical specialties that utilize these codes in the non-facility setting. According to the nominator, while CPT codes 95970, 95976, and 95977 were primarily billed by neurologists when last surveyed by the RUC in 2017, the usage of these codes has shifted away from neurologists toward sleep specialists. The nominator asserted that this shift necessitates changes to the work RVUs and PE inputs for these codes. In addition, the nominator stated that many sleep specialists believe CPT codes 95970, 95976, and 95977 do not appropriately reflect the practice expenses involved in furnishing these services. According to the nominator, a survey conducted among several high-volume sleep specialists (the details of which the nominator did not share with CMS) showed unanimous agreement that these codes do not accurately reflect the practice expense inputs. These three codes currently have 0 minutes of clinical staff time included in the direct PE inputs. However, the nominator stated that based on the survey results the typical clinical staff time spent for patient care was 35 minutes for CPT code 95970, 37 minutes for CPT code 95976, and 46 minutes for CPT code 95977. The nominator stated that CPT codes 95970, 95976, and 95977 should reflect the same clinical staff time as similar analysis and programming procedures, such as CPT codes 93150 (*Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming*), 93151 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*), and 93153 (*Interrogation without programming of implanted phrenic nerve stimulator system*). The nominator stated that these codes more accurately account for the clinical staff time.

We appreciate the nominator sharing their survey results from high-volume

sleep specialists, which may indicate potential inaccuracies in the direct PE inputs for CPT codes 95970, 95976, and 95977. Our review of the submitted information, however, reveals a lack of survey details (for example, sampling methods, data collection procedures), so it is difficult to understand the context of the information provided by the nominator and identify potential biases of this survey. While we acknowledge potential changes in the specialties utilizing these codes, and sleep medicine's Medicare specialty percentage has grown over time, neurology remains the dominant billing practitioner type. For these reasons, we are not proposing to consider these codes as potentially misvalued. We are, however, seeking comments and additional information on the information provided by the nominator. This includes any analysis or studies demonstrating that one or more of these codes meet the criteria listed in section II.C.3 of this proposed rule, under ''Identification and Review of Potential Misvalued Services,'' particularly regarding changes in practice expense inputs for service delivery.

(4) Excimer laser treatment for psoriasis (CPT codes 96920, 96921, 96922).

An interested party nominated CPT codes 96920 (*Excimer laser treatment for psoriasis; total area less than 250 sq cm*), 96921 (*Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm*), and 96922 (*Excimer laser treatment for psoriasis; over 500 sq cm*) as potentially misvalued, due to the CPT Editorial Panel's recent modifications to the code descriptor and allegedly inaccurate data used by CMS in valuing these services.

According to the nominator, the misvaluation of these codes creates a significant healthcare access barrier by reducing payment for excimer laser therapy, which disproportionately impacts vulnerable populations while potentially increasing overall healthcare costs. The nominator stated that the low payment rates for these codes make it financially unfeasible for dermatologists to offer this FDA-approved treatment, effectively making it unavailable to Medicare beneficiaries despite its proven effectiveness and potential cost savings.

We discussed our review of these codes and our rationale for finalizing the current work RVUs and direct PE extensively in the CY 2025 PFS final rule (89 FR 97797 through 97801). We stated that we disagreed with the RUC recommended work RVUs for CPT codes 96920, 96921, and 96922 of 1.00, 1.07, and 1.32. The RUC noted that there have been multiple reviews of these CPT codes, and the valuation of the codes is currently based on the original valuation over two decades ago in 2002 where the physician time values were lower than the current times. A subsequent review in 2012 adopted new survey times while maintaining the work RVUs from 2002 for CPT codes 96920 and 96922. The RUC noted that for both CPT code 96921 and 96922, with the largest treatment area, the total times had not changed since first implemented more than 20 years ago. At the time we also believed that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure had increased, significant decreases in time should be reflected in decreases to work RVUs. We noted that our proposed work RVU of 0.83 maintained the intensity associated with the 2002 review of CPT code 96920, which we believed to be more appropriate than the significant increase in intensity that results from the RUC-recommended work RVU of 1.00 which nearly doubled the current intensity of the code (89 FR 97797). We had no evidence to indicate that the intensity of CPT code 96920 had increased to this degree given how the surveyed work time had substantially decreased.

For CY 2026, the nominator raised two issues related to these codes. First, according to the nominator, a coding change by the CPT Editorial Panel that was released in 2024 and effective January 1, 2025, modified the code descriptor from ''Laser treatment for inflammatory skin disease(psoriasis)'' to ''Excimer laser treatment for psoriasis.'' We remind readers that, in April 2022, the RUC referred CPT codes 96920, 96921, and 96922 to the CPT Editorial Panel to capture expanded indications beyond what was currently noted in the codes' descriptions to include laser treatment for other inflammatory skin disorders such as vitiligo, atopic dermatitis, and alopecia areata, and those expanded indications could reflect changes in physician work as compared to the codes' current descriptors. The coding change application was subsequently withdrawn from the September 2022 CPT Editorial Panel meeting when it was determined that existing literature was insufficient and did not support expanded indications at that time. Therefore, these CPT codes were re-surveyed and reviewed at the April 2023 RUC meeting without any revisions to their code descriptors. We note that, according to the CPT Editorial Panel and the RUC's publicly available meeting notes, since the descriptors for CPT codes 96920, 96921, and 96922 were established in 2002, psoriasis is the only approved indication and use for this treatment modality.[17]

While the nominator is working with the CPT Editorial Panel again to expand the indications for excimer laser treatment beyond psoriasis to include other inflammatory skin conditions, they stated that they believe establishing a temporary G-code for interim coverage is necessary and therefore requested that CMS create coding to more accurately reflect the clinically appropriate use of the excimer laser. The nominator states that this would ensure patients with skin conditions other than psoriasis can access excimer laser treatments without delay.

To provide more evidence as to the accuracy of including non-psoriasis inflammatory skin diseases in the code definition, the nominator provided a data compendium supporting the excimer laser's versatility and key studies demonstrating positive outcomes for conditions like vitiligo, atopic dermatitis, leukoderma, and alopecia areata. Reviewing these submitted studies, the nominator stated that sufficient clinical evidence exists to support expanding coverage for excimer laser treatment beyond just psoriasis. The nominator requested that CMS create additional coding to describe the expanded indications for the excimer laser treatment, because the nominator believes that the standard CPT process is time-consuming and could leave many patients without adequate care in the interim; thus, implementing a temporary G-code would ensure continued access to this essential therapy for these patients.

Second, the nominator provided additional invoices and data detailing PE costs related to the excimer laser devices. The nominator claimed that their own analysis relies on real-world data (which was not shared with CMS) and shows that CMS has overestimated the utilization rate of excimer lasers. Using their own survey, they found that on average, dermatologists perform 244 excimer laser treatments per device annually, with each treatment requiring approximately 38 to 46 minutes of excimer laser use. This amounts to nearly 15,000 minutes of total utilization per year, resulting in an effective utilization rate of 10 percent, rather than the 50 percent rate currently used by CMS. As stated in section II.B. of this proposed rule, we currently use an equipment utilization rate

[17] *https://www.ama-assn.org/system/files/ap-2023-ruc-meeting-minutes.pdf.*

assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Based on their real-world device utilization data, the nominator calculated the direct PE cost using CMS' standard equipment formula. The calculated equipment costs are $99.88 for CPT code 96920, $105.14 for CPT code 96921, and $120.91 for CPT code 96922. The nominator also stated that CMS currently assumes a maintenance cost of $7,560 for excimer lasers, based on a 5% maintenance rate applied to a purchase price of $151,200. However, the nominator stated that excimer lasers are technical devices with substantially higher maintenance costs. According to the nominator, the annual service cost for the excimer laser is $30,000, and they claimed that a laser chamber replacement service costs $44,000; however, as discussed in section II.B. of this proposed rule, we finalized a 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we stated that this estimate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. Therefore, we remind readers that we do not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs.

Moreover, the nominator asserted that CMS currently does not include the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the direct practice expense cost for these services. Based on our review of the January 2012 RUC recommendations submitted to CMS, it appears that these equipment items were removed by RUC PE Subcommittee for CY 2013. The requestor stated that the gas cylinder (EQ154) costs $6,300 (excluding labor and shipping costs), and the optical delivery system (EQ155) costs $7,429; however, no supporting invoices or evidence of the typicality of the equipment items' usage for these services were provided to support the equipment items' reintegration into the codes' direct practice expense.

Based on this information, the nominator recommended creating a G-code for excimer laser treatment of inflammatory skin diseases. Furthermore, they requested to include their own real-world data on excimer laser utilization rates in the practice expense calculation, adjust the maintenance cost in the practice expense calculation to reflect the actual cost of maintaining excimer laser devices, and reinstate the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the practice expense calculation.

We appreciate the detailed information submitted by the nominator. However, we continue to disagree that CPT codes 96920, 96921, and 96922 are potentially misvalued. We note that the CPT code change request was withdrawn from the AMA in September 2022 due to insufficient supporting literature for expanded indications. Additionally, according to RUC's publicly available meeting notes, psoriasis is the only approved indication and use for this treatment modality since the descriptors for CPT codes 96920, 96921, and 96922 were established in 2002. When the codes were resurveyed in April 2023, no descriptor revisions were made, as the available 2021 Medicare claims data indicated that the typical patient was being treated for psoriasis (96920, psoriasis = 79.3 percent).[18] Additionally, there have been numerous CPT Editorial Panel applications and actions since the withdrawn application at the September 2022 meeting,[19] including a February 2025 action.[20] However, at the time of drafting this proposed rule, the request for expanded indications does not appear to have been re-submitted or revisited by the specialty societies. We are seeking comments on whether creating a new HCPCS G-code that is not condition-specific would improve payment accuracy for this technology when used to treat conditions other than psoriasis. We are also seeking information regarding possible barriers to coding changes undertaken through the CPT Editorial Panel process. We are seeking information regarding the nominator's assertion that equipment items EQ154 and EQ155 are necessary and typical for these services, and invoices to support the nominator's asserted purchase prices, so as to provide a comprehensive understanding of the overall costs associated with these services. We note that, effective for January 1, 2027, based on the publicly available Summary of CPT Editorial Panel Actions from the February 2025 meeting,[21] the codes' descriptors will change from ''Excimer laser treatment for psoriasis'' to ''Laser treatment for psoriasis,'' absent subsequent CPT Editorial Panel actions. Therefore, we believe it is important for comments to support the typicality of these equipment items regardless of the type of laser used for these services.

(5) Optical coherence tomography (OCT) of retina (CPT code 0605T).

CPT code 0605T (*Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days*) was submitted as potentially misvalued. This code is a temporary CPT category III code and is assigned procedure status ''C'' (contractor priced) under the PFS. The nominator generally expressed concern that the initial pricing by the contractor was inaccurate and did not appropriately consider the cost of the OCT device when provided by the independent diagnostic testing facility (IDTF). The nominator requested that CMS revise the valuation of this code to properly account for the cost of the OCT imaging device used to provide this remote diagnostic retinal monitoring service.

The nominator stated that remote OCT allows for better management of patients with neovascular age-related macular degeneration (NV–AMD) and improved management has been shown to result in reduction in treatments.[22] [23] According to the nominator, one of the Medicare Administrative Contractors who priced the service did not

[18] *https://www.ama-assn.org/system/files/ap-2023-ruc-meeting-minutes.pdf.*

[19] *https://www.ama-assn.org/system/files/september-2022-cpt-summary-panel-actions.pdf.*

[20] *https://www.ama-assn.org/system/files/feb-2025-summary-of-panel-actions.pdf.*

[21] *https://www.ama-assn.org/system/files/feb-2025-summary-of-panel-actions.pdf.*

[22] Holekamp, Nancy M., et al. ''Prospective trial of Home OCT guided management of treatment experienced nAMD patients.'' *RETINA* (2022): 10–1097.

[23] Heier, Jeffrey S., et al. ''Clinical Use of Home OCT Data to Manage Neovascular Age-Related Macular Degeneration.'' *Journal of VitreoRetinal Diseases* (2024): 24741264241302858.

appropriately consider the cost of the OCT device provided by the IDTF, resulting in an inadequate payment rate that did not cover the direct operating costs. The nominator asserted that this code is misvalued because the contractor established its value by crosswalking to the valuation for remote physiological monitoring (RPM) CPT code 99454 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*). The nominator stated that CPT code 99454 represents a distinct type of service and falls under a different benefit category than remote OCT. The nominator asserted that while remote OCT is a diagnostic service that is provided by an IDTF, CPT code 99454 is an E/M service that is not permitted to be furnished by IDTFs. In addition, the device used to furnish remote OCT performs retinal imaging comparable to that performed in the physician office, has a useful life of 5 years, and costs $40,000. The nominator provided an invoice to support this claim. In contrast, the nominator indicated that the device used in the service described by CPT code 99454 captures simple physiologic data and costs $1,000. The nominator provided a device equipment cost per month of $666.67 for the device used to furnish remote OCT. Using the device cost calculation, the nominator estimated an unadjusted rate of $632.22 by following CMS' valuation methodology.

Overall, the nominator stated that CPT code 99454 is not an accurate crosswalk for remote OCT and recommended that CMS revise the valuation of CPT code 0605T to properly account for the higher cost of the OCT imaging device used to provide this remote diagnostic retinal monitoring service. The nominator stated that due to the current undervaluation, the prescribing physicians and their patients in need of remote monitoring of a treatable sight-threatening retinal disease do not have access to this service.

We are not proposing CPT code 0605T as potentially misvalued at this time. We note that the nominator submitted a single invoice in support of its assertions, which may not be reflective of typical costs, and we encourage interested parties to provide additional information. including invoices for the OCT devices. Also, we welcome comments on whether this code should be nationally priced and what inputs should be used if we were to set a national rate for this service.

(6) Mechanical separation of plasma from blood (CPT code 36514).

An interested party nominated CPT code 36514 (*Therapeutic apheresis; for plasma pheresis*) as potentially misvalued for two PE-related reasons. The first concern involves the assigned clinical labor code, L056A (RN/OCN), which the nominator states undervalues the therapeutic apheresis nurse's operating wage cost. The second concern relates to the equipment code, EQ084 (cell separator system), specifically its price and equipment utilization rate.

The nominator presented differences in therapeutic plasmapheresis or plasma exchange (TPE) procedure payments between settings, with 50 percent to 75 percent of the 100,000 annual TPE procedures occurring in hospital outpatient settings. The nominator stated that the payment differential is substantial: under the Hospital OPPS, the average CY 2025 Medicare payment rate for TPE performed in a hospital outpatient department is $1,639.28, excluding compensation for the supervising physician. In contrast, under the PFS, the average CY 2025 Medicare payment rate for the same procedure performed in a non-facility setting is $663.43. According to the nominator, the differences in payment rates have forced patients to receive treatment in more expensive hospital outpatient settings, as physicians cannot financially sustain the costs of performing TPE services in non-facility settings under the current payment rates. The nominator asserted that this payment structure not only limits patient access to care but also results in higher overall costs to the Medicare program, as procedures are channeled to the more expensive hospital outpatient setting where payment rates are nearly 2.5 times higher than non-facility rates.

The nominator stated that TPE is a complex extracorporeal blood therapy procedure used to treat patients with serious hematological, oncologic, neurological, rheumatologic, cardiac and autoimmune disorders. Therapeutic apheresis nurses performing this procedure require extensive specialized training to independently handle patients with a wide spectrum of serious illnesses and comorbidities. They must be trained and highly skilled in evaluating patients and managing clinical issues and adverse events that commonly arise during the procedure, particularly in patients with comorbid anemia, renal failure, cardiovascular disease, serum protein abnormalities or other risk factors.[24] Their key responsibilities include advanced vascular access, continuous management of the extracorporeal circuit, troubleshooting, patient assessment to manage adverse events, and medication administration. The nominator emphasized that therapeutic apheresis nurses' training and skill level are distinct from nurses collecting blood products from healthy donors.

The nominator summarized the wide range of median annual and hourly base salaries ($92,525 to nearly $125,000) for ''Apheresis Nurse'' or ''Apheresis RN'' positions identified across four leading online employment recruiting firms. According to the nominator, this variability likely stems from the differing mixes of higher-paid therapeutic apheresis nurse job postings versus lower-paid postings for nurses collecting blood products from healthy donors at community blood centers across these firms. Based on the listed position openings, the nominator found that the rate per minute for a therapeutic apheresis nurse, inclusive of benefits, likely ranges between $1.30 and $1.50 per minute, well over 60 percent higher than the $0.81 per minute valuation currently assigned to CPT code 36514 with the L056A labor code. Also, the nominator claimed that in order to accurately assess therapeutic apheresis nurse wages, other surveys could be employed focusing on nurses performing therapeutic procedures while excluding those working in blood/plasma collection centers from healthy volunteer donors, as the latter typically receive lower compensation despite using similar equipment.

The nominator proposes that CMS collaborate with the Department of Labor (DOL) to accurately assess therapeutic apheresis nurse salaries and establish a new clinical labor code with appropriate per-minute rates. This would replace the current L056A labor code used for CPT code 36514, which the nominator asserts undervalues these specialized nurses' wages and benefits. The new code would specifically exclude non-patient-facing nurses who perform blood product collection, ensuring more accurate compensation for this specialized role.

According to the nominator, the current Medicare payment rate for CPT code 36514 in the non-facility setting fails to adequately account for direct PE costs. First, based on fourth quarter 2024 U.S. sales data, the nominator

[24] Chhibber V and King KE. Management of the therapeutic apheresis patient (Chapter 12). In: *Apheresis: Principles and Practice, 3rd Edition.* Bethesda, MD: AABB Press, 2010.

requested updating the CMS Equipment File price for the cell separator system equipment code (EQ084) from $81,656.40 to $93,321.35, reflecting current market conditions. According to the nominator, the current rate of 0.5 for equipment code EQ084 implies that facilities perform 426 procedures per year per device; however, data from major hospitals, including the three largest-volume hospitals in the U.S., demonstrates that facilities average only 181 procedures per year per device, suggesting a more accurate utilization rate of 0.21. This discrepancy can significantly impact on the calculated costs and subsequent payment rates for equipment code EQ084.

After reviewing the nominator's submission, we do not believe that we have enough information to evaluate whether CPT code 36514 is potentially misvalued, and thus we are not proposing the code as potentially misvalued at this time. To assist us in further considering whether CPT code 36514 is potentially misvalued, we are seeking information on the direct practice expense inputs, particularly regarding the clinical labor code L056A and equipment code EQ084. Specifically, we seek comments on whether to establish a new therapeutic apheresis nurse clinical labor code in the non-facility setting. Also, we seek invoices and other associated information that could be used to update to the cell separator system equipment code EQ084 to reflect current market costs. We do not believe an update to the equipment utilization rate is necessary. We disagree with the nominator that an equipment utilization rate of 21 percent would be typical for the cell separator system. As we stated previously, we currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act. As we discussed in the CY 2021 PFS final rule, it would distort relativity to assign a utilization rate of 21 percent for the cell separator system equipment, as this would have the same effect as doubling the overall price of the equipment (85 FR 84629).

(7) Remote interrogation device evaluation (CPT code 93296).

An interested party nominated CPT code 93296 (*Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*) as potentially misvalued, because the service has experienced substantial changes in PE. The nominator emphasized that the current direct practice expense inputs do not accurately represent either the current standard of care or the actual resources required to provide the service, necessitating an urgent review of the code's resource input valuations.

CPT code 93296 is a technical component-only code describing remote monitoring of cardiac devices over 90 days. The nominator stated that this service enables healthcare providers to remotely evaluate implanted cardiac defibrillators and pacemakers, review device data, communicate with patients, and share findings with physicians. The monitoring helps prevent emergencies and reduces hospitalizations through early intervention and timely device adjustments. According to the nominator, the code's direct costs, last reviewed by RUC in 2016 and implemented in 2018, no longer reflect current service delivery requirements because technological advancements and expanded monitoring protocols have significantly increased service complexity and resource requirements.

According to the nominator, the service delivery for CPT code 93296 has evolved significantly, requiring enhanced organizational infrastructure and specialized clinical expertise. Modern service delivery involves complex data management, with each transmission requiring 32 distinct tasks [25] for complete patient care. The increased service complexity stems from advanced technology requirements, expanded patient monitoring needs, and more frequent device interrogation, shifting from quarterly to more regular intervals. These changes have created a notable disparity between current resource costs and existing valuations, necessitating updated mechanisms for data management and prioritization.

According to the nominator, the direct cost inputs for clinical labor and equipment do not reflect the current direct costs required to furnish the services. The nominator stated that the total direct cost of $25.84 (including clinical labor and equipment) exceeds the CY 2025 national non-facility PFS payment rate of $19.41. They stated that the current valuations do not reflect modern clinical staffing needs and equipment requirements for this pacemaker interrogation system service, despite similar updates being approved for comparable diagnostic services. To assess resource requirements, the nominator conducted an independent study among IDTFs, using standardized data collection and a volume-weighted analysis of 2023 service data. The nominator claimed that their findings demonstrate a significant disparity between current valuations and actual service delivery costs, supporting the need for comprehensive input review.

The study of IDTFs conducted by the nominator revealed that CPT code 93296 requires 83.66 minutes of non-physician clinical labor time, significantly more than CMS' current value of 28 minutes. This time encompasses eleven distinct tasks, from patient enrollment to quality assurance, with the most time-intensive activities being data review and analysis (25.25 minutes) and unscheduled alert management (21.84 minutes).

[25] Aileen M. Ferrick et al,. 2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Practical Management of the Remote Device Clinic (2023), *http://www.hrsonline.org/guideance/clinical-resources/2023-hrsehraaphrslahrs-expert-consensus-statement-practical-management-remote-device-clinic?gad_source=1&gclid=Cj0KCQiAkoe9BhDYARIsAH85cDOusU-vRRcEnwoXzUmN2COkX0_DiRVHuOM8cYMf8riBNXW-KrFagnAaAs5NEALw_wcB.*

TABLE 7: LIST OF NON-PHYSICIAN CLINICAL LABOR TIME FROM THE NOMINATOR'S SURVEY

Description	Time (minutes)
Patient enrollment and verification	0.08
Patient education and consent	0.90
Device preparation and setup	3.20
Data review and analysis	25.25
Unscheduled event and episode evaluation	8.70
Unscheduled alert management and reporting	21.84
Unscheduled transmission data archival and documentation	1.46
Scheduled summary report preparation and delivery	6.17
Patient support and inquiry response	2.96
Manual transmission and connectivity management	3.47
Quality assurance of alert and routine reports	9.63

Furthermore, the nominator stated that while the valuation for CPT code 93296 is currently based on electrodiagnostic technologists (L037A) at $0.44 per minute, the service is typically performed by cardiovascular technicians (L038B), who receive $0.60 per minute. Thus, the nominator believes that updating both the time and clinical staff classification is needed for accurate service valuation and consistency with other implantable device monitoring services.

Finally, the nominator requested two updates to the equipment costs for CPT code 93296. First, they recommended adjusting the equipment usage time to align with the updated clinical labor time for remote interrogation device evaluation. Second, they recommended changing the assigned equipment code from ''pacemaker interrogation, system'' (EQ320) priced at $123,250 to ''pacemaker follow-up system'' (EQ198) priced at $279,453. We note that no invoices were submitted to support these prices. The nominator believes that these changes would align the equipment valuation with actual costs and match similar CMS-approved device monitoring services.

Overall, the nominator stated that a review of CPT code 93296 current inputs reveals significant undervaluation in several key areas. According to the nominator, the existing resource costs for clinical labor times, labor types, and equipment costs do not adequately reflect the current service requirements. Based on the submitted information, however, we are not currently proposing to nominate this code as potentially misvalued. We request that the nominator submit a complete report detailing associated direct practice expense input assessment data to enable us to more fully consider whether the code is potentially misvalued. Additionally, we welcome comments, including any analysis or studies from the broader medical community, including the RUC, regarding whether this service has experienced substantial changes in practice expenses since its last review.

(8) Fine Needle Aspiration (FNA) (CPT codes 10021, 10004, 10005, 10006)

An interested party requested that CMS reconsider CPT codes 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), 10004 (*Fine needle aspiration biopsy, without imaging guidance; each additional lesion*), 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) for nomination as potentially misvalued, citing significant undervaluation since 2019. The nominator submitted a request to CMS for the reevaluation of these codes, stating that the payment changes have created a concerning cascade of negative consequences impacting the care of patients with thyroid nodules and cancer. Specifically, the nominator questions the fundamental basis of CMS' 2019 work RVU reductions for FNA procedures. While the RUC recommended work RVUs of 1.20 for CPT code 10021 and 1.63 for CPT code 10005, CMS instead implemented lower values of 1.03 and 1.46, respectively. The nominator strongly disagreed with CMS' methodology, particularly its comparison to CPT code 36440 (neonatal blood transfusion). The nominator argued that this crosswalk comparison is inappropriate because the neonatal procedure represents a fundamentally different type of service with distinct work intensity levels, requires different expertise, is rarely billed to Medicare, and serves an entirely different patient population than FNA procedures.

The nominator further emphasized that when the work RVU for CPT code 10005 was reduced by 10.5 percent

(from 1.94 to 1.46), it triggered a much larger 35.7 percent drop in payment. This substantial decrease has forced a significant shift in where these procedures are performed, moving from office-based settings to hospital facilities. Using claims data, the nominator stated that there has been a shift in the site of service for FNA procedures between 2018 and 2023; the percentage of procedures performed in facility settings increased from 52.06 percent in 2018 to 57.05 percent in 2023. Conversely, services performed in office settings declined from 47.05 percent in 2018 to 42.40 percent in 2023. The nominator claimed that this shift in performance of FNA from the office setting to hospital outpatient departments resulted in Medicare paying 524 percent more for the same procedure. With an additional cost of $584.92 per procedure at facility locations, the nominator claimed that this shift has resulted in increased Medicare expenses of $4.17 million.

Beyond the financial implications, the nominator stated that the low valuation of this code family has resulted in a shift to facility settings raising Medicare costs, reducing access, and reducing quality of care. According to the nominator, most concerning is the long-term impact on medical education, as new endocrinologists and surgeons are now avoiding learning FNA procedures altogether. Furthermore, the nominator referenced a study,[26] which discusses the potentially negative consequences of code devaluation on patient care and healthcare spending. Overall, to address these issues, the nominator specifically requested that CMS restore the work RVU values to those originally recommended by the RUC in 2019, stating that CMS' previous crosswalk to neonatal transfusion described by CPT code 36440 (*Push transfusion, blood, 2 years or younger*) was inappropriate given the significant differences in work intensity levels and required expertise between the procedures.

We appreciate the comprehensive information provided by the nominator, including their reference to recent research and detailed trend analysis. However, we note that these codes have undergone multiple recent reviews. Our review of these codes and our rationale for finalizing the current values are extensively discussed in the CY 2019 PFS final rule (83 FR 59517) and CY 2021 PFS final rule (85 FR 84599). Furthermore, this code family was previously nominated two times as potentially misvalued and discussed in the CY 2020 PFS final rule (84 FR 62625) and CY 2025 PFS final rule (89 FR 97743). For more information, we encourage the nominator to reference the discussions in previous rulemaking. We maintain our position and are not proposing this code family as potentially misvalued. We acknowledge the shift in site of service for FNA procedures between 2018 and 2023. While we do not currently consider these changes substantial enough to warrant immediate revaluation, we will continue to monitor the site-of-service trends closely. Should these patterns persist or accelerate, a new survey in the future may be necessary to accurately reflect these changes in practice patterns. We welcome public comments and recommendations, including those from the RUC, regarding whether these codes should be re-reviewed in light of the information submitted by the nominator.

(9) Nasal Sinus Irrigation (CPT Codes 31000 and 31002)

An interested party nominated CPT codes 31000 (*Lavage by cannulation; maxillary sinus (antrum puncture or natural ostium)*), and 31002 (*Lavage by cannulation; sphenoid sinus*) as potentially misvalued. The interested party expressed concern that these codes are undervalued due to missing pricing data for essential lavage supplies and stated that they are not currently priced in the non-facility setting.

Regarding both codes, the interested party identified two issues. They stated that this procedure uses the Cyclone® sinonasal suction and irrigation system, and requires additional tools, staff time and supplies. For CPT code 31000, the interested party stated that while the current PE supplies are valued at $33.68, this amount should be $333.68, reflecting a $300 increase to include the Cyclone device cost. Similarly, for CPT code 31002, the interested party proposed increasing the supply price from $26.74 to $326.74 to incorporate the Cyclone device cost. To support this claim, the interested party has provided seven paid invoices demonstrating the actual cost of the system.

The interested party also claimed that both codes do not have non-facility RVUs, but are primarily performed in non-facility settings. According to the AMA's RUC database's procedure volume data, CPT code 31002 is performed in the non-facility setting 81.4 percent of the time and CPT code 31000 is reported 77.2 percent of the time in the non-facility setting.[27]

The interested party emphasized that these misvaluations have real-world implications for patient care. The current valuations may limit physicians' ability to provide these services in both facility and non-facility settings, potentially affecting patient access to care, particularly for those who can only receive treatment in physician offices. Thus, the interested party requested a revaluation of the PE components for both codes and the establishment of non-facility PE inputs for these services.

Although we are not currently proposing to designate these codes as potentially misvalued, we acknowledge the interested party's concerns about their current valuation. Specifically, these concerns could stem from missing pricing data and observed changes in the typical site of service and dominant specialty since the last valuation. We note that CPT code 31000 is typically performed in the non-facility setting but question whether the Cyclone device is either typically used or necessary for the performance of this procedure. We note that CPT code 31002 does not have non-facility PE inputs, however it seems to typically be performed in the office setting with the dominant specialty listed as Allergy/Immunology and not Otolaryngology. We also question whether the Cyclone device is either typically used or necessary for the performance of this procedure. We believe that both codes would require a comprehensive review to address these potential changes in typical site of service and dominant specialty, as well as PE valuation. We welcome public comments regarding these issues concerning CPT codes 31000 and 31002. Interested parties are encouraged to submit relevant documentation, such as invoices or other evidence that demonstrates the typical resource costs for providing these services.

(10) Portable X-Ray Services (HCPCS Codes R0070, R0075)

In the CY 2025 PFS final rule, we acknowledged that several portable x-ray (PXR) suppliers and trade organizations continue to express longstanding concerns with how payment is established for transportation services related to PXR as described by HCPCS codes R0070 and R0075 (89 FR 97809). We also noted interested parties' request for greater consistency in the pricing of these services (89 FR 97809 through 97810).

[26] THYROID Volume 34 Number 11, 2024 *https://doi.org/10.1089/thy.2024.0442 Eldeiry, et al.* ''Impact of Changes in Fine Needle Aspiration Biopsy Reimbursement on Clinical Care of Patients with Thyroid Nodules in the United States''.

[27] *AMA RBRVS DataManager.* American Medical Association. (2025, January 15). *https://www.ama-assn.org/.*

We suggested that interested parties may best engage with the MACs on these issues by appropriately reporting cost data in the MAC requested format. We also recognized that we should maintain consistency in pricing these services that are more indicative of changes in costs that occur yearly. In this proposed rule, we are seeking comments on whether we should assign national pricing under the PFS for PXR transportation services; specifically, for HCPCS code R0070 (Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen) and HCPCS code R0075 (Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen). We believe that national pricing would be conducive to ensuring consistency in payment rates across localities and also create payment stability for these services.

To nationally price HCPCS codes R0070 and R0075, we could use reference codes that have only PE values and no work RVUs because these codes describe only the transportation services associated with PXR. Since these codes are currently paid using contractor pricing, we could also analyze the average MAC payment for them to inform national pricing. For example, we observed that HCPCS code R0070 was priced between $215 to 230 per service while HCPCS code R0075 was priced between $80 to 90 per service. Using these valuations could help to inform us of potential crosswalk codes in order to maintain consistency with the rates currently being paid. By converting the dollar payment for HCPCS codes R0070 and R0075 from Medicare Part B claims data into RVUs through the usage of our current conversion factor under the PFS, we identified potential crosswalk codes. For HCPCS code R0070, we could use a crosswalk to CPT code 93243 (External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report), which has a total national non-facility payment rate of $226.43 for CY 2025, and for HCPCS code R0075, we could use a crosswalk to CPT code 92582 (Conditioning play audiometry), which has a total national non-facility payment rate of $86.69 for CY 2025.

We welcome comments from the public on whether we should consider national pricing for HCPCS codes R0070 and R0075, as well as whether these potential crosswalk codes would appropriately value these services, and any other factors we should consider.

(11) Cryoablation Therapy To Treat Postoperative Pain

An interested party requested we establish a code to describe the additional intraoperative time required by the surgeon to perform adjunctive cryoablation therapy for postoperative pain management. According to the interested party, intraoperative cryoablation therapy is performed as a supplemental procedure alongside primary surgical procedures to provide postoperative pain relief for up to 60 days. The therapy works by freezing nerves near the surgical site without causing permanent damage, temporarily blocking pain signals during the patient's recovery period. The interested party stated that this procedure requires an additional 20–30 minutes of intraoperative time for the surgeon beyond the primary surgical procedure. The interested party referenced clinical evidence highlighting the use of intraoperative cryoablation to reduce the need for opioids in postsurgical patients, as well as recent guideline recommendations.[28] [29]

Currently, there is no specific code to account for the additional physician work associated with intraoperative cryoablation therapy. According to the nomination letter, we included the Cryo Nerve Block Therapy (CryoNB) on the list of devices eligible for temporary additional payments under the Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act [30] in the CY 2025 OPPS final rule (89 FR 94353 through 94354). However, the interested party stated barriers still exist for physician adoption mainly because there is currently no code to account for the 20–30 additional minutes of physician work associated with the intraoperative administration and delivery of cryoablation therapy.

Also, the interested party stated that many practitioners incorrectly interpret Medicare's anesthesia rules as prohibiting payment for extra professional services when the same surgeon provides ancillary cryoablation therapy.[31] According to the nominator, while CMS typically do not allow separate payments for anesthesia services when the same physician performs both the surgical procedure and anesthesia, this limitation does not apply to cryoablation therapy for postoperative pain management.[32] However, according to the interested party, ongoing confusion regarding this policy's application creates an unnecessary barrier to cryoablation procedures that could reduce or replace opioid use for Medicare beneficiaries.

The interested party stated that establishment of a G-code for physician work associated with intraoperative cryoablation therapy for postoperative pain would facilitate greater access for patients who require or prefer non-opioid alternatives for pain relief. The interested party further stated that such a G-code would help promote patient access to this alternative to opioids by clarifying that Medicare anesthesia rules do not apply to cryoablation for postoperative pain when furnished by the same surgeon. We are seeking public comments on whether a new G-code is needed to account for the additional intraoperative time required to perform cryoablation therapy, including service elements and valuation of work and practice expense, including potential crosswalk codes.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006), the CY 2021 PFS final rule (85 FR 84502), and the CY 2024 PFS final rule (88 FR 78861 through 78866) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services

[28] *Miller DL, Hutchins J, Ferguson MA, Barhoush Y, Achter E, Kuckelman JP. Intercostal Nerve Cryoablation During Lobectomy for Postsurgical Pain: A Safe and Cost-Effective Intervention. Pain Ther. 2025 Feb;14(1):317–328. doi: 10.1007/s40122–024–00694–3.*

[29] *Dunning J, Burdett C, Child A, Davies C, Eastwood D, Goodacre T, Haecker FM, Kendall S, Kolvekar S, MacMahon L, Marven S, Murray S, Naidu B, Pandya B, Redmond K, Coonar A. The pectus care guidelines: best practice consensus guidelines from the joint specialist societies SCTS/MF/CWIG/BOA/BAPS for the treatment of patients with pectus abnormalities. Eur J Cardiothorac Surg. 2024 66(1):ezae166.*

[30] *CY 2025 OPPS Final Rule, 89 Fed. Reg. 93912, 94354 (Nov. 27, 2024) (CMS specifically affirmed that ''the CryoNB System meets the statutory requirements and should be paid separately under this provision.'')*

[31] *See Medicare NCCI 2024 Coding Policy Manual, Chapter 13, pgs. 6–7 (revised Jan. 1, 2025), available at: https://www.cms.gov/files/document/13-chapter13-ncci-medicare-policy-manual-2025finalcleanpdf.pdf.*

[32] *AHA Coding Clinic®, Q3 2024 vol. 11, no. 3 (effective with discharges Aug. 1, 2024).*

from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed and assigned to categories established through notice and comment rulemaking. Under the process we established beginning in CY 2003, we evaluated whether a service should be assigned to the Medicare Telehealth Services List and designated as *Category 1:* Services similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List or *Category 2:* Services that were not similar to those on the current Medicare Telehealth Services List.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID–19 pandemic. This new category described services that were added to the Medicare Telehealth Services List during the PHE, for which there was likely to be clinical benefit when furnished via telehealth, but there was not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis ultimately needed to meet the criteria under Category 1 or 2 to be permanently added to the *Medicare Telehealth* Services List. To add specific services on a Category 3 basis, we would conduct a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth.

In the CY 2024 PFS final rule (88 FR 78861 through 78866), we consolidated these three categories and implemented a revised 5-step process for making additions, deletions, and changes to the Medicare Telehealth Services List (5-step process), beginning for the CY 2025 Medicare Telehealth Services List. The 5-step process review criteria are set forth in the CY 2024 PFS final rule (88 FR 78861 through 78866), includes the following steps: (1) Determine whether the service is separately payable under the PFS; (2) Determine whether the service is subject to the provisions of section 1834(m) of the Act; (3) Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3); (4) Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking; and (5) Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system. Rather than categorizing a service as ''Category 1'', ''Category 2,'' or ''Category 3,'' each service is now assigned a ''permanent'' or ''provisional'' status. A service is assigned a ''provisional'' status if it meets steps 1, 2, and 3 of our review process, and, if while there is not enough evidence to demonstrate that the service is of clinical benefit, there is enough evidence to suggest that further study may demonstrate such benefit.

b. Proposal To Modify the Medicare Telehealth Services List and Review Process

Section 1834(m)(4)(F)(ii) of the Act requires that the Secretary establish a process that provides, on an annual basis, for the addition or deletion of services to the definition of telehealth services for which payment can be made when furnished via telehealth under the conditions specified in section 1834(m) of the Act. As specified at § 410.78(f), except for a temporary policy that was limited to the PHE for COVID–19, we make changes to the list of Medicare telehealth services through the annual PFS rulemaking process. Our current 5-step review process reflects the stepwise method by which we consider requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning with the CY 2025 Medicare Telehealth Services List (88 FR 78861 through 78871).

We are proposing, beginning for the CY 2026 Medicare Telehealth Services List, to revise the 5-step review process for reviewing requests to the Medicare Telehealth Services List. Based on feedback from interested parties, we believe that we need to simplify our telehealth list review process by focusing our review on whether the service can be furnished using an interactive telecommunications system. The current 5-step review process has proven to be unclear for requestors. Interested parties, including requestors, have emphasized that it is difficult to ascertain the level of clinical evidence needed for a service with a provisional designation to be redesignated permanent. Additionally, for new services or services with low utilization, interested parties have had a difficult time providing peer-reviewed evidence applicable to the service and/or the Medicare beneficiary patient population. Lastly, based on feedback from interested parties and our own internal review, the 5-step process insufficiently accounts for the vital role of professional judgment exercised by physicians and other practitioners. We continue to believe that physicians and other practitioners, given their in-depth knowledge of their beneficiaries' clinical needs, are best positioned to exercise their professional judgment in determining whether a service can be safely furnished via telehealth and whether furnishing a service via telehealth will provide clinical benefit justifying its use.

We therefore are proposing to remove Step 4 (Consider whether the service elements of the requested service map to the service elements of services on the list that has a permanent status described in previous final rulemaking) and Step 5 (Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system) from our review criteria and retain Steps 1 through 3 (detailed below). Under this proposal, services on the Medicare Telehealth Services List would no longer be designated ''permanent'' or ''provisional''. All services listed or added on the Medicare Telehealth Services List would be considered included on a permanent basis. Note, CMS would still reserve the right to remove services included on the Medicare Telehealth Services List based on internal review or feedback received from interested parties in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). If finalized, all codes currently on the list (provisional or permanent) will remain on the Medicare Telehealth Services List. Because CMS has already determined that services with a ''provisional'' designation satisfy the standards represented in Steps 1 through 3 in prior rulemaking cycles, we do not believe further review would be required to justify their inclusion on the Medicare Telehealth Services List under the revised process. We continue to request information from interested parties about service(s) that may be appropriate for addition to or deletion from the list of Medicare telehealth services and their effects on beneficiary access, safety, and quality of care.

We are proposing to retain Steps 1 through 3 and eliminate Steps 4 through 5 because we believe that the standards represented in Steps 1 through 3 alone are sufficient guardrails to ensure that only services separately payable under the PFS, subject to the provisions of section 1834(m) of the Act, and capable of being furnished using an interactive telecommunications system are considered Medicare telehealth services. For additional information, these steps are further discussed in the CY 2024 PFS final rule (88 FR 78861 through 78866). We do not believe Steps 4 through 5 are necessary, because as discussed above, we believe the complex professional judgment of the physician or practitioner is sufficient to ensure a service can be safely furnished via telehealth and that the service will be clinically beneficial to the beneficiary. We believe that the determination to utilize the complex professional judgment of the physician or practitioner will better allow practitioners to determine if telehealth is appropriate for that specific Medicare beneficiary and that specific clinical scenario.

We expect that physicians and other practitioners would consider the entirety of the circumstances, including the clinical profile and needs of the beneficiary, to determine the appropriate modality for furnishing the service. This specification is similar to the requirements set forth for the process by which CMS updates the list of covered surgical procedures in Medicare when furnished within an ambulatory surgical center (ASC) (also called the ASC covered procedures list (CPL)), which were established in the 2021 OPPS Final Rule (85 FR 86148 through 86149). In addition, this specification is similar to our policy regarding the in-person visit requirements for telehealth behavioral health services (''. . . the practitioner is not precluded from scheduling in-person visits at a more frequent interval, should such visit be determined to be clinically appropriate or preferred by the patient'' (86 FR 65057)) and for audio-only telehealth services (''practitioners should always use their clinical judgment in deciding to furnish services via telehealth, including in the patient's home, to ensure that appropriate care is being delivered; including scheduling in-person care as needed'' (89 FR 97761)). We strive to balance the goals of increasing practitioner and patient choice of service modality with the consideration of patient safety for all Medicare beneficiaries. Notably, the addition of a service to the Medicare Telehealth Services List does not mean that it is appropriate to be furnished via telehealth to every Medicare beneficiary in every clinical scenario—as always, the physician or practitioner should use his or her complex professional judgment to determine the appropriate service modality on a case-by-case basis. As technology advances and more services may be safely furnished via telehealth and paid under the PFS, it is increasingly important for physicians or practitioners to exercise their professional judgment in determining the generally appropriate service modality for their patients to receive a service.

We believe our proposal to remove steps 4 through 5 of the 5-step review process would expand and build upon our intent to simplify and reduce the administrative burden of submission and review of services to the Medicare Telehealth Services List. We believe our proposed policy would allow patients and physicians or practitioners to determine the most appropriate service modality for an individual patient while continuing to ensure patient safety. As discussed above, physicians and other practitioners are best positioned to make patient-specific service modality determinations. Physicians and other practitioners have the greatest familiarity with and understanding of the needs of their individual patients and will use their complex professional judgment to determine whether a service can be safely furnished via telehealth, given their patients' clinical profiles and needs, among other essential considerations.

We believe physicians and other practitioners would consider important safety factors when determining the appropriate service modality for their specific beneficiaries. We continue to encourage the review and use of clinical practice guidelines, peer-reviewed literature, and similar materials that illustrate the typical setting of care, population of beneficiaries, and clinical scenarios that practitioners would encounter when furnishing the Medicare Telehealth service using only interactive, two-way audio-video communications technology or two-way, real-time audio-only communication technology for services furnished to a patient in their home, as permitted in accordance with 42 CFR 410.78(a)(3). We are proposing to refine the regulatory process for adding services to or deleting services from the Medicare Telehealth Services List by removing Steps 4 and 5 and maintaining the current Steps 1 through 3. The steps are listed in detail below:

Step 1. Determine whether the service is separately payable under the PFS.

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS because, as further discussed in CY 2024 PFS final rule (88 FR 78861 through 78866), Medicare telehealth services are limited to those services for which separate Medicare payments can be made under the PFS. Before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should therefore first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files).

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act. If we determine at Step 1 that a service is separately payable under the PFS, we apply Step 2 under which we determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. Section 1834(m) of the Act provides for payment to a physician or other practitioner for a service furnished via an interactive telecommunications system, notwithstanding that the furnishing physician or practitioner and patient are not in the same location, at the same amount that would have been paid if the service was furnished without the telecommunications system. We have historically interpreted this to mean that only services that are ordinarily furnished with the furnishing physician or practitioner and patient in the same location can be classified as a ''telehealth service'' for which payment can be made under section 1834(m) of the Act. Given that there may be a range of services delivered using certain telecommunications technology that, though they are separately payable under the PFS, do not fall within the definition of telehealth service set forth in section 1834(m) of the Act, the aim of Step 2 is therefore to determine whether the service at issue is, in whole or in part, inherently a face-to-face service. Services that fall outside the definition of telehealth services generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-

visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we therefore review during this Step 2 whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient and physician or practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

Step 3 is corollary to Step 2 and is used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In Step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from requesters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed.

Additionally, we are proposing to simplify our Medicare Telehealth Services List review process by removing the distinction between provisional and permanent services and focusing our review on whether the service can be furnished using an interactive, two-way audio-video telecommunications system. We are seeking comments on our proposal to refine the Medicare Telehealth Services List review process. We also invite comments regarding safety and/or quality concerns. We would like to re-emphasize that a service's presence on the Medicare telehealth list does not indicate that CMS believes that telehealth may be appropriate in all circumstances; instead, we rely on physicians and other practitioners to use their professional judgment to make appropriate determinations based on the needs of the individual patient.

c. Requests To Add Services to the Medicare Telehealth Services List for CY 2026

We received several requests to add various services to the Medicare Telehealth Services List, effective for CY 2026, some of which we believe would meet the proposed revised criteria for being added to the Medicare Telehealth Services List. That is, we reviewed these services and found that they would meet the criteria of the 3-step process proposed in section D(1)(b). The requested services are listed in Table 8.

Consistent with the deadline for our receipt of code valuation recommendations from the American Medical Association's Relative Value Scale Update Committee (AMA RUC) and other interested parties (83 FR 59491) and with the process set forth in prior calendar years, for CY 2026, requests to add services to the Medicare Telehealth Services List must have been submitted to and received by CMS by February 10, 2025. Consistent with the deadline for our receipt of code valuation recommendations from the AMA RUC and other interested parties (83 FR 59491) and with the process set forth in prior calendar years, for CY 2027, requests to add services to the Medicare Telehealth Services List must be submitted to and received by CMS by February 10, 2026. The deadline for each request to add a service to the Medicare Telehealth Services List must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the Medicare Telehealth Services List, including where to send these requests, and to view the current Medicare Telehealth Service List, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

TABLE 8: CY 2026 REQUESTS FOR ADDITION TO THE MEDICARE TELEHEALTH SERVICES LIST

Category	HCPCS	Short Descriptor
Multiple-Family Group Psychotherapy	90849	Multiple family group psytx
Group Behavioral Counseling for Obesity	G0473	Group behave couns 2-10
Infectious Disease Add-On	G0545	Inherent visit to inpt
Auditory Osseointegrated Sound Processor	92622	Dx aly aud oi snd prcsr 1st
	92623	Dx aly aud oi snd prcsr each
Dialysis	90935	Hemodialysis one evaluation
	90937	Hemodialysis repeated eval
	90945	Dialysis one evaluation
	90947	Dialysis repeated eval
Telemedicine E/M	98000	Synch audio-video new sf 15
	98001	Synch audio-video new low 30
	98002	Synch audio-video new mod 45
	98003	Synch audio-video new hi 60
	98004	Synch audio-video est sf 10
	98005	Synch audio-video est low 20
	98006	Synch audio-video est mod 30
	98007	Synch audio-video est hi 40
	98008	Synch audio-only new sf 15
	98009	Synch audio-only new low 30
	98010	Synch audio-only new mod 45
	98011	Synch audio-only new high 60
	98012	Synch audio-only est sf 10
	98013	Synch audio-only est low 20
	98014	Synch audio-only est mod 30
	98015	Synch audio-only est high 40
Home INR Monitoring	G0248	Demonstrate use home INR mon

The following is a discussion of the requests received for the addition of services to the Medicare Telehealth Services List:

(1) Multiple-Family Group Psychotherapy

We received a request to add CPT code 90849 (*Multiple-Family Group Psychotherapy*) to the Medicare Telehealth Services List. This code describes the provision of psychotherapy to multiple adult or adolescent patients and their family members simultaneously. This code was requested to be added in the CY 2022 PFS Final Rule, but we did not add it to the Medicare Telehealth Services List at the time because these services were not separately payable and had a restricted payment status, indicating that claims must be adjudicated on a case-by-case basis when furnished in-person 86 FR 65052. In the CY 2023 PFS Final Rule, we finalized a change in the procedure status indicator for CPT code 90849, which is now assigned an A for active status meaning that the service is now separately payable under the PFS. Based on our review, we believe this service now meets step 1 of our review process because it is currently assigned status indicator A, meets step 2 of our review process because it is a service ordinarily furnished with the furnishing practitioner and patient in the same location and therefore is subject to the provisions of section 1834(m) of the Act, and meets step 3 because that all elements of this service may be furnished using an interactive telecommunications system as defined in § 410.78(a)(3). Therefore, we are proposing to add this service to the Medicare Telehealth Services List. We welcome public comments on this proposal.

(2) Group Behavioral Counseling for Obesity

We received a request to add CPT code G0473 (*Face-to-face behavioral counseling for obesity, group (2–10), 30 minutes*) to the Medicare Telehealth Services List. This code includes a 30-minute group session that consists of a dietary assessment, counseling, and behavioral therapy, as well as one face-to-face visit per week for each week for the first month, one face-to-face visit every other week for months two through six, and one face-to-face visit per month for months seven through twelve (if an individual loses 3kg in the first six months). Based on our review, we believe this service meets step 1 of our review process because it is currently assigned status indicator A, meets step 2 of our review process because it is a service ordinarily furnished with the furnishing practitioner and patient in the same location and therefore is subject to the provisions of section 1834(m) of the Act, and meets step 3 because that all elements of this service may be furnished using an interactive telecommunications system as defined in 410.78(a)(3). Therefore, we propose to add this service to the Medicare Telehealth Services List. We welcome public comments on this proposal.

(3) Infectious Disease Add-On

We received a request to add CPT code G0545 (*Visit complexity inherent to hospital inpatient or observation care*

associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent) to the Medicare Telehealth Services List. This code can include service elements such as disease transmission risk assessment and mitigation, public health investigation and analysis, and complex antimicrobial therapy counseling. Based on our review, we believe this service meets step 1 of our review process because it is currently assigned status indicator A (meaning that the service is separately payable under the PFS), meets step 2 of our review process because it is a service ordinarily furnished with the furnishing practitioner and patient in the same location and therefore is subject to the provisions of section 1834(m) of the Act, and meets step 3 because that all elements of this service may be furnished using an interactive telecommunications system as defined in 410.78(a)(3). Therefore, we propose to add this service to the Medicare Telehealth Services List. We welcome public comments on this proposal.

(4) Auditory Osseointegrated Sound Processor

We received a request to add CPT codes 92622 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes*) and 92623 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure*)) to the Medicare Telehealth Services List. Based on our review, we believe these services meet step 1 of our review process because they are currently assigned status indicator A (meaning that the service is separately payable under the PFS), meet step 2 of our review process because they are services ordinarily furnished with the furnishing practitioner and patient in the same location and therefore subject to the provisions of section 1834(m) of the Act, and meet step 3 because that all elements of these services may be furnished using an interactive telecommunications system as defined in 410.78(a)(3). Therefore, we propose to add these services to the Medicare Telehealth Services List. We welcome public comments on this proposal.

(5) Dialysis

We received a request to add dialysis procedures described by CPT codes 90935 (*Hemodialysis procedure with single evaluation by a physician or other qualified health care professional*), 90937 (*Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription*), 90945 (*Dialysis procedure other than hemodialysis (for example, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional*), and 90947 (*Dialysis procedure other than hemodialysis (for example, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription*) to the Medicare Telehealth Services List. These codes describe reviewing medical records, obtaining an interval history, performing an expanded problem focused or detailed physical examination, formulating and/or revising diagnosis and treatment plan(s) (moderate or high complexity medical decision-making), and discussing diagnosis and treatment. On either a single or two or more visits, the practitioner assesses the patient and response so far to dialysis, writes and/or reviews orders, and supervises dialysis.

We are not proposing to add these services to the Medicare Telehealth Services List at this time, as we do not believe that we have enough information to determine if these services meet step 3 of the Medicare Telehealth review process. It is not clear under what clinical circumstances this service could be furnished via telehealth and how all service elements would be performed when furnished via telehealth. We seek comments on whether the elements of the service are capable of being delivered via an interactive telecommunication system as required for Medicare telehealth services under § 410.78(a)(3). We also seek comments regarding the service elements clinical staff at the originating site are performing and how these patient interactions compare to service elements that the professional may be furnishing via telehealth. When adding ESRD-related services (CPT codes 90963–90966, 90967–90970) to the Medicare Telehealth Service list in the CY 2015 (80 FR 41783) and CY 2017 (81 FR 80194) final rules with comment period, we noted the clinical examination of the access site must still be furnished face-to-face ''hands-on'' (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA. We seek comment to see if this requirement would also be appropriate for CPT codes 90935, 90937, 90945, and 90947 or if any other service elements need to be furnished ''hands-on.'' At this time, we require more information to determine whether this requirement of a ''hands-on'' clinical examination by a physician, CNS, NP, or PA would inhibit furnishing these services via telehealth, or if a practitioner at the originating site could perform this requirement.

(6) Home INR Monitoring

We received a request to add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List for CY 2026. This service, as described by HCPCS code G0248, encompasses a face-to-face demonstration of the use and care of the INR monitor, obtaining at least one blood sample, providing instructions for reporting home INR test results, and documenting the patient's ability to perform testing and report results. In response to this request for the CY 2025 PFS proposed rule, commenters explained in detail that the interaction with the patient described by this service is generally delivered by individuals considered to be clinical staff and not a physician or practitioner as defined under section 1834(m)(4) of the Act. ''Clinical staff'' means someone who is supervised by a physician or other qualified health care professional and is allowed by law, regulation, and facility policy to perform or assist in a specialized professional service but does not individually report that professional service. After reviewing these comments and receiving additional information from interested parties, especially those that reminded us that the patient interactions for this service typically occur with clinical staff, it is clear that this is not a service that is generally furnished via a telecommunications system by a physician or a practitioner, as defined under section 1834(m)(4) of the Act, but rather is a technical part of a service delivered by clinical staff employed or otherwise providing services for a supplier. Indeed, the patient interaction portion of the service is valued under the PFS as typically involving the clinical staff of a supplier rather than the professional work of a physician or practitioner. Furthermore, there is no restriction on billing for this service and a physician/practitioner visit code on

the same day, which suggests that the interaction between the clinical staff and the patient described by this service is severable from the kind of professional service that falls under the scope of section 1834(m) of the Act. We understand that before the broad adoption of telecommunications technology for patient interactions nearly 6 years ago, these interactions may have typically taken place in person, and we considered the request to add this service to the telehealth list in that context. However, the interaction described explicitly by the code does not indicate an interaction between the patient and a physician or other practitioner. Because such an interaction falls outside the scope of the definition of Medicare telehealth service, it does not meet step 2 of our review process. Therefore, we are not proposing adding HCPCS code G0248 to the Medicare list of telehealth services. We welcome public comments on this proposal.

(7) Telemedicine E/M Services

We received a request to add the telemedicine E/M services (CPT codes 98000–98015) to the Medicare Telehealth Services List. These services do not satisfy the criteria under Step 1 of our process. Specifically, they are not separately payable under the Medicare PFS, as they are currently assigned status indicator I (Not valid for Medicare purposes). Given that these services are not separately payable when furnished in person, they likewise will not be separately payable when furnished via telehealth. Therefore, this service does not meet Step 1 of our review process. We are not proposing to add them to the Medicare list of telehealth services. We welcome public comments on this proposal.

(8) Clarification on DMHT/RPM/RTM

We have received a number of questions regarding Digital Mental Health Treatment (DMHT), Remote Physiologic Monitoring (RPM), and Remote Therapeutic Monitoring (RTM) services and the applicability of the telehealth rules. We would like to clarify that these services, which are inherently non-face-to-face, do not meet the definitions of 1834(m) of the Act, fall outside the scope of the definition of Medicare telehealth service, and do not meet step 2 of our review process. These services are not subject to section 1834(m) of the Act.

(9) Services Requested To Be Transitioned From Provisional to Permanent

We received a number of submissions requesting for services on the Medicare Telehealth Services List designated as ''provisional'' to be designated as ''permanent.'' If our proposal to eliminate these designations is finalized, these codes will remain on the Medicare Telehealth Services List. If not, rather than selectively adjudicating only those services for which we received requests for potential permanent status, we believe it would be appropriate to complete a comprehensive analysis of all provisional codes currently on the Medicare Telehealth Services List before determining which codes should be made permanent. We are therefore proposing to not making determinations to recategorize provisional codes as permanent at this time. For CY 2026, we propose to revise the Medicare Telehealth Services criteria. We propose to remove steps 4 and 5 from the review process. Using these revised criteria, we propose to add 5 new codes to the Medicare Telehealth Services list that are not on the CY 2025 Medicare Telehealth Services list. After consideration of the priorities discussed above, we believe that these proposed policies will increase the flexibility for physicians or other practitioners to exercise their complex professional judgment, factoring in patient safety considerations, and for flexibility for patients to choose the modality of care in which to receive services. The services we propose adding to the Medicare Telehealth Services List are listed in Table A–D2.

(10) Deleted Services

In section II.I. of this proposed rule, we proposed to delete HCPCS code G0136. This code is currently on the Medicare Telehealth Services List, so it will also be deleted from the list if finalized.

TABLE 9: SERVICES PROPOSED FOR ADDITION TO THE MEDICARE TELEHEALTH SERVICES LIST FOR CY 2026

Category	HCPCS	Short Descriptor
Multiple-Family Group Psychotherapy	90849	Multiple family group psytx
Group Behavioral Counseling for Obesity		G0473 Group behave couns 2-10
Infectious Disease Add-On	G0545	Inherent visit to inpt
Auditory Osseointegrated Sound Processor	92622	Dx aly aud oi snd prcsr 1st
	92623	Dx aly aud oi snd prcsr each

d. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain frequency restrictions on how often physicians and other practitioners may furnish the service via telehealth. These include a limitation of one subsequent hospital care service furnished through telehealth every three days, added in the CY 2011 PFS final rule (75 FR 73317 through 73318), one subsequent nursing facility visit furnished through telehealth every 14 days, added in the CY 2011 PFS final rule (75 FR 73318), and one critical care consultation service furnished through telehealth per day, added in the CY 2017 final rule (81 FR 80198). In establishing these limits, we cited concerns regarding these patients' potential acuity and complexity.

We temporarily removed these frequency restrictions during the PHE for COVID–19. In the March 31, 2020 COVID–19 interim final rule with comment period (IFC) (85 FR 19241), we stated that we did not believe the frequency limitations for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations furnished via Medicare telehealth were appropriate or necessary for the duration of the PHE because this would have been a patient population who would have otherwise not had access to clinically appropriate in-person treatment. Although the frequency limitations resumed effect on May 12,

2023 (upon expiration of the PHE), through enforcement discretion during the remainder of CY 2023 and notice-and-comment rulemaking for CY 2024 and CY 2025, Medicare telehealth frequency limitations were suspended for CY 2025 (89 FR 97758 through 97760) for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations.

In the CY 2024 (88 FR 78877) and CY 2025 PFS final rules (89 FR 97758 through 97760), we solicited comments from interested parties on how physicians and other practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE. As discussed in those final rules, many commenters supported permanently removing these frequency limitations, stating that they are arbitrary and re-imposing the limitations would result in decreased access to care; that physicians and other practitioners should be allowed to use their professional judgment to determine the type of visit, how many visits, and the type of treatment that is the best fit for the patient so long as the standard of care is met; and that lifting these limitations during the PHE has been instructive and demonstrates the value of continuing such flexibilities. Some commenters did not support removing these frequency limitations, citing patient acuity and safety. However, our analysis of claims data from 2020 to 2023 indicates that the volume of services that would be affected by implementing these limitations is relatively low; in other words, these services are not being furnished via telehealth with such frequency that, if the frequency limits were in place, they would be met or exceeded very often or for many beneficiaries. Claims data from 2020 to 2023 suggest that less than five percent of beneficiaries who received one or more of these services (subsequent care services in inpatient and nursing facility settings, and critical care consultations) received them as telehealth services. In addition, we have solicited comments on this policy for two years and have received overwhelming support for continuing this flexibility, with minimal commenters not supporting the removal of frequency limitations.

We believe that physicians and other practitioners, who have the greatest familiarity and insight into the needs of individual beneficiaries, can use their complex professional judgment to determine whether they can safely furnish a service via telehealth, given the entirety of the circumstances, including the clinical profile and needs of the beneficiary, to determine the appropriate service modality. We strive to balance the goals of increasing physician or practitioner and patient choice of service modality with consideration of patient safety for all Medicare beneficiaries. As technology advances and more services may be safely furnished via telehealth and paid under the PFS, it is increasingly important for physicians and other practitioners to exercise their professional judgment in determining the generally appropriate service modality for their patients to receive a service. Notably, the removal of these frequency limitations does not mean that these services are appropriate to be furnished via telehealth to every Medicare beneficiary in every clinical scenario—as always, the physician or practitioner should use his or her complex professional judgment to determine the appropriate service modality on a case-by-case basis.

We are proposing to permanently remove frequency limitations on furnishing these services via telehealth for the following codes relating to Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services:

1. Subsequent Inpatient Visit CPT Codes:

- 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);
- 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*
- 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes:

- 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. when using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*);
- 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);
- 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); and
- 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS Codes

- G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.*); and
- G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.*)

We are seeking comments on these proposals, specifically additional information regarding potential concerns about patient safety and quality of care.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests described under § 410.32 and services incident to a physician's (or other practitioner's) professional service described under § 410.26 (incident-to services), are required to be furnished under specific minimum levels of supervision by a physician or other practitioner. We define three levels of supervision in our regulation at

§ 410.32(b)(3): General Supervision, Direct Supervision, and Personal Supervision. Notwithstanding the temporary measures implemented in response to the PHE for COVID–19 and extended thereafter, direct supervision has historically required the physician (or other supervising practitioner) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It has not historically been interpreted as mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. Again, notwithstanding the temporary measures implemented in response to the PHE for COVID–19 and extended thereafter, we have historically established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Direct supervision is required for various types of services, including most incident-to-services under § 410.26, many diagnostic tests under § 410.32, pulmonary rehabilitation services under § 410.47, cardiac rehabilitation and intensive cardiac rehabilitation services under § 410.49, and certain hospital outpatient services as provided under § 410.27(a)(1)(iv). In the March 31, 2020 COVID–19 IFC, we amended the definition of ''direct supervision'' for the duration of the PHE for COVID–19 (85 FR 19245 through 19246) at § 410.32(b)(3)(ii) to state that the necessary presence of the physician (or other practitioner) for direct supervision includes virtual presence through audio/video real-time communications technology. Instead of requiring the supervising physician's (or other practitioner's) physical presence, the amendment permitted a supervising physician (or other practitioner) to be considered ''immediately available'' through virtual presence using two-way, real-time audio/visual technology for diagnostic tests, incident-to services, pulmonary rehabilitation services, and cardiac and intensive cardiac rehabilitation services. We made similar amendments at § 410.27(a)(1)(iv) to specify that direct supervision for certain hospital outpatient services may include virtual presence through audio/video real-time communications. The CY 2021 PFS final rule (85 FR 84538 through 84540), CY 2024 PFS final rule (88 FR 78878), and CY 2025 PFS Final rule (89 FR 97764) subsequently extended these policies through December 31, 2025.

In the CY 2024 PFS proposed rule, we solicited comments on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we stated we were interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. We stated we were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy (88 FR 52302). As discussed in the CY 2024 PFS final rule (88 FR 78878), in the absence of evidence that patient safety is compromised by virtual direct supervision, we were concerned about an abrupt transition to our pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner. We noted that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as incident-to-services, and that physicians and/or other supervising practitioners, in certain instances, would need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. We acknowledged the utilization of this flexibility and recognize that many practitioners have stressed the importance of maintaining it. This flexibility has been available and widely utilized since the beginning of the PHE, and we recognized that it may enhance patient access.

In the CY 2025 PFS final rule (89 FR 97763), we acknowledged the utilization of this flexibility and stated we recognized that many practitioners have stressed the importance of maintaining it but were seeking additional information regarding potential patient safety and quality of care concerns. Given the importance of certain services being furnished under direct supervision in ensuring quality of care and patient safety, and in particular the ability of the supervising practitioner to intervene if complications arise, we stated that we believed an incremental approach is warranted, particularly in instances where unexpected or adverse events may arise for procedures which may be riskier or more intense. In light of these potential safety and quality of care implications, and exercising an abundance of caution, we finalized the revision of the regulation at § 410.26(a)(2) to state that for the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall continue to include virtual presence through audio/video real-time communications technology (excluding audio-only): services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and services described by CPT code 99211 (office and other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

In response to overwhelming support and requests to extend this policy permanently for a wider set of services than the ones that were finalized in the CY 2025 PFS Final Rule, we are proposing to continue to build on this incremental approach to allow certain services to be furnished under direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only). We are proposing to permanently adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26, except for services that have a global surgery indicator of 010 or 090. This information can be found in the PFS PPRVU public use file (*https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files*). These global surgery indicators are defined in IOM Pub. 100–04, chapter 23, section 50.6 as 010 ''Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable'' and 090 ''Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount.'' The

purpose of excluding these services is to ensure the quality of care and patient safety, and in particular, the ability of the supervising practitioner to intervene if complications arise, particularly in complex, high-risk instances where unexpected or adverse events may occur or for procedures that may be riskier or more intense where a patient's clinical status can quickly change. For such services, in-person supervision would be necessary to allow for rapid on-site decision-making in the event of an adverse clinical situation.

We would like to note that, similar to our guidance above regarding Medicare Telehealth services, our proposed definition of direct supervision (allowing ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only) for all services described under § 410.26, except for services that have a global surgery indicator of 010 or 090), does not mean that it is appropriate to allow virtual presence for every service for every Medicare beneficiary in every clinical scenario. As always, the physician or practitioner should use his or her complex professional judgment to determine the appropriate supervision modality on a case-by-case basis.

We are proposing to revise the regulation at § 410.26(a)(2) to state that the presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

We are proposing to revise the regulations at § 410.32(b)(3)(ii) to state that the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

We note that because to the definition of direct supervision applicable to cardiac, pulmonary, and intensive cardiac rehabilitation services relies on the definition of direct supervision set forth at § 410.32(b)(3)(ii), the definition of direct supervision for these services would similarly be modified to include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator. We are seeking comment on applying this definition to the applicable services under § 410.32 and the applicable cardiac, pulmonary, and intensive cardiac rehabilitation services.

We are seeking comment on whether to adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26, except for services that have a 000, 010, or 090 global surgery indicator. For each of these proposals, we are also seeking additional information regarding potential concerns about patient safety and quality of care for services that have a 000 global surgery indicator and if it is necessary to exclude these services from allowing the presence of the physician (or other practitioner) to include virtual presence through audio/video real-time communications technology (excluding audio-only). Global surgery indicator 000 is defined in IOM Pub. 100–04, chapter 23, section 50.6 as ''Endoscopic or minor procedure with related preoperative and postoperative relative values on the day of the procedure only included in the fee schedule payment amount; evaluation and management services on the day of the procedure generally not payable''. We believe that these services, which have no minimum postoperative period, do not have the same potential patient safety risk that services with a 010 or 090 global surgery indicator may have. We are seeking comments on these proposals.

b. Proposed Changes to Teaching Physicians' Billing for Services Involving Residents With Virtual Presence

As discussed in the CY 2025 PFS final rule (89 FR 97764 through 97765), in the CY 2021 PFS final rule (85 FR 84577 through 84585), we established a policy that after the end of the PHE for COVID–19, teaching physicians may meet the requirements set forth at § 1842(b)(7)(A)(i)(I) to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites located outside of OMB-defined metropolitan statistical areas (MSAs). We made this location distinction consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas. We noted that this policy provides the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought, under section 1842(b)(7)(A)(i)(I) of the Act. In addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. We refer readers to the CY 2021 PFS final rule (85 FR 84577 through 84584) for a more detailed description of our specific concerns. At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service personally provided by residents to be paid for the service under the PFS, in locations that were within an MSA. This policy applied to all services, regardless of whether the patient was co-located with the resident or for services provided virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties expressed concerns regarding the requirement that the teaching physician be physically present with the resident when a service is furnished virtually (as a Medicare telehealth service) within an MSA. Some interested parties stated that during the PHE for COVID–19, when residents provided telehealth services, and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service, available immediately in real-time, and had access to the electronic health record. After reviewing the public comments, we finalized a temporary policy that allowed the teaching physician to have a virtual presence in all teaching settings, but only in clinical instances when the service was furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment was sought, through audio/video real-time communications technology, in all residency training locations through December 31, 2024.

As stated in the CY 2025 PFS final rule (89 FR 97765), we were concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services. We also understood that teaching physicians gained clinical experience providing services involving residents with virtual presence during the PHE for COVID–19 and could help us to identify circumstances where the teaching physician can routinely provide sufficient personal and identifiable services to the patient through their virtual presence during the key portion of the Medicare telehealth service. We sought comments and information to help us consider other clinical treatment situations where it may be appropriate to continue to permit the virtual presence of the teaching physician, while continuing to support patient safety, meeting the clinical needs for all patients and ensuring burden reduction without creating risks to patient care or increasing opportunities for fraud.

As summarized in the CY 2025 PFS final rule (89 FR 97764 through 97765), commenters encouraged us to establish this policy permanently and include in -person services to promote access to care, stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident. While we continue to consider clinical scenarios where it may be appropriate to permit the virtual presence of the teaching physician, we are proposing to transition back to our pre-PHE policy, which would maintain the rural exception established in the CY 2021 PFS final rule recognizing the unique challenges and importance of expanding medical education opportunities in rural settings. We are not proposing to extend our current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings through December 31, 2025, but only when the service is furnished virtually (for example, a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). As always, documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology.

As discussed in earlier in this proposed rule, we are concerned that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act. Therefore, we now believe that permitting Medicare payment to continue for this PHE flexibility is no longer necessary. This proposal to not extend our current policy to allow teaching physicians to have a virtual presence for services furnished virtually aligns with our statutory obligations under section 1842(b)(7)(A)(i)(I) of the Act, which requires teaching physicians to provide appropriate oversight and personal involvement in resident-furnished services for which Medicare payment is sought.

Under this proposal, for services provided within MSAs, physicians must maintain physical presence during critical portions of all resident-furnished services to qualify for Medicare payment, not just in-person services, ensuring consistent oversight standards. Documentation requirements remain rigorous, with medical records needing to clearly demonstrate the teaching physician's physical presence during key service portions. However, as we discussed earlier in this proposed rule, recognizing the unique challenges faced by rural healthcare providers, we maintain flexibility for services provided outside MSAs. In these rural settings, teaching physicians may continue utilizing audio/video real-time communications technology to fulfill the presence requirement, provided they maintain active, real-time observation and participation in the service. This geographical distinction aligns with our longstanding commitment to enhancing Medicare beneficiary access to covered services in rural areas.

The proposed to not extend flexibilities for virtual services would not impact teaching physicians' ability to provide virtual supervision of residents for educational purposes. Teaching physicians retain the discretion to provide greater involvement in resident-furnished services and may determine when virtual presence is appropriate based on the specific services and the experience level of the residents involved.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed percentage increase in the MEI for CY 2026 is 2.7 percent and is based on the expected historical percentage increase of the 2017-based MEI. For the final rule, we propose to update the MEI increase for CY 2026 based on historical data through the second quarter of 2025. Therefore, for CY 2026, the proposed payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $31.85. Table 10 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

TABLE 10: THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$20.00
2003	3.0	$20.60
2004	2.9	$21.20
2005	3.1	$21.86
2006	2.8	$22.47
2007	2.1	$22.94
2008	1.8	$23.35
2009	1.6	$23.72
2010	1.2	$24.00
2011	0.4	$24.10
2012	0.6	$24.24
2013	0.8	$24.43
2014	0.8	$24.63
2015	0.8	$24.83
2016	1.1	$25.10
2017	1.2	$25.40
2018	1.4	$25.76
2019	1.5	$26.15
2020	1.9	$26.65
2021	1.4	$27.02
2022	2.1	$27.59
2023	3.8	$28.64
2024	4.6	$29.96
2025	3.56	$31.01
2026*	2.7	$31.85

*Reflects the most recent estimate of the CY 2026 MEI percentage increase and will be updated in the final rule based on historical data through the second quarter of 2025.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comments about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule. We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new

services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, regarding our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

a. Background

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We note that we are obligated under the statute to

consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we adjusted work RVUs to account for significant changes in time, we started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old-time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and suggested that our actions in adjusting the recommended work RVUs are inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we employed to identify potential values that reconcile the RUC-recommended work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. (83 FR 59515) We note that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 19 contains a list of codes and descriptors for which we are proposing work RVUs for CY 2026; this includes all codes for which we received RUC recommendations by February 10, 2025. The proposed work RVUs, work time and other payment information for all CY 2026 payable codes are available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/index.html*).

b. Proposed Efficiency Adjustment

(1) Background

CMS has historically relied on survey data provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) to estimate practitioner time, work intensity, and practice expense for the purpose of establishing RVUs for the codes used for payment under the PFS. As described in section II.C. of this proposed rule, CMS regularly revalues codes as part of its potentially misvalued codes initiative, as required by section 1848(c)(2)(K) of the Act, using RUC survey data that shows clinicians' estimates of how long a particular service takes to complete. In the CY 2025 PFS final rule, we summarized public comments that we had received expressing concerns with using RUC data as a source of valuation and identifying a need for empirical data in the context of valuing advanced primary care management services (89 FR 97898). In response to these comments, we indicated that we were open to alternative recommendations for how to price these and other services, and that we would consider all options presented to us with a preference for information with empirical evidence behind it. We also reminded commenters that we do not exclusively rely on RUC recommendations and can

receive data and recommendations from other outside sources as well.

The limits of survey data are in part based on the nature of the surveys. There have been longstanding concerns about the use of surveys that have low response rates, low total number of responses, and a large range in responses, all of which may undermine the accuracy of recommendations relying on survey data.[33] For example, a Government Accountability Office (GAO) Report found that the median number of responses to surveys administered by the RUC for payment year 2015 was 52, the median response rate was only 2.2 percent, and 23 of the 231 surveys had under 30 respondents. Another study conducted compared operative times in the National Surgical Quality Improvement Project to RUC survey times, adjusted for patient variables, and found a wide variation in the median RVU per hour ratio for 11 surgical specialties, with the highest specialties overreporting (via RUC values) by 27 and 23 minutes per case. All surgical specialties showed overreporting in RUC survey times compared to operative times. This resulted in high RVU per hour payments for surgeons in those specialties.[34]

With such low response rates, we are concerned that those practitioners who respond to the RUC surveys may be fundamentally different than those clinicians who do not respond to the surveys. Widely read journals, such as the Journal for the American Medical Association, specify that for submitting authors, ''survey studies should have sufficient response rates (generally greater than or equal to 60%), and appropriate characterization of nonresponders to ensure that nonresponse bias does not threaten the validity of the findings.'' [35] The GAO report noted that the RUC has undertaken steps to mitigate the effects of possible biases; however, the report goes on to describe the potential conflicts of interest survey respondents may have, as those that serve Medicare beneficiaries would benefit from an increase in the relative values for the services they perform.[36] Another component of these surveys is the selection of another service code that is similar to the service in question. Since there are so many procedure, radiology, and diagnostic test codes, the selection of a high-valued service for potential comparisons, either by the specialty society administering the survey, or by respondents, could further bias results. Additionally, RUC surveys contain clinical vignettes, and expert reviewers have raised concerns that these clinical vignettes are not typical and thus may lead to biased recommendations that usually overinflate time spent on the service.[37] And as detailed in section II.B. of this proposed rule, we further articulate the particular challenges of using the recently completed PPI survey data, including the quality of the data, sampling variation, and lack of comparability to previous survey data—similar challenges that we have experienced over time with surveys estimating the time and work intensity of individual services, used to establish the work RVUs. CMS has historically had to rely on survey data due to a lack of other more reliable sources of information, but in recent years many new methods to identify empiric inputs used in valuation have been developed.[38]

In the CY 2024 PFS proposed rule (88 FR 78975 through 78982), we requested comments on how we may evaluate E/M services more regularly and comprehensively. We raised specific questions for commenters to consider, including whether the methods used by the RUC and CMS were appropriate to accurately value E/M and other HCPCS codes, and we requested that commenters provide specific recommendations on improving data collection and making better evidence-based and more accurate payments for E/M and other services. In response, as we summarized in the CY 2024 PFS final rule (88 FR 78977), commenters stated that the methods used do not lead to accurate valuation and that the problems lie with the nature of E/M services and the PFS's budget neutrality adjustment. They stated that the resources used in furnishing the work portion of E/M services are primarily a function of the time the clinician spends with the patient and, therefore, are not amenable to efficiency gains and that the valuation process is not responsive to efficiency gains, leading to passive devaluation of E/M services under the constraints of budget neutrality. At the time, we responded that we recognized that there are opportunities to improve how all services are valued and better account for resource variation for different types of care under the PFS.

For several years, we have been concerned about not accounting for the efficiencies gained in work RVUs for non-time-based services. As we discuss below, non-time-based codes, such as codes describing procedures, radiology services, and diagnostic tests, should become more efficient as they become more common, professionals gain more experience, technology is improved, and other operational improvements (including but not limited to enhancements in procedural workflows) are implemented. We would highlight, however, that there are often many years between a code's introduction and revaluation within the RUC process, with only a few hundred out of the more than 9,000 codes paid under the PFS considered for revaluation annually by the RUC. While there is significant variability in how often codes are reviewed by the RUC, on average, CMS estimates that there are 25.49 years since a code valuation has been reviewed by the RUC (this includes 5382 out of 9970 codes which were never reviewed). When we exclude from the average those codes that have never been reviewed, the average is 17.69 years since the last review of a code by the RUC. We note that these numbers weight each code equally and the PFS itself is heavily weighted by utilization towards a much smaller number of often utilized codes.

Furthermore, even when a code is reviewed by the RUC, 2 to 3 years usually pass between when the survey data was collected and its use by CMS in setting rates becomes effective. In the intervening years without revaluation, we are most likely overvaluing codes by not accounting for these efficiencies gained in the valuation of work RVUs for non-time-based services. And even when recommendations have been submitted by the RUC to CMS as potentially misvalued codes from 2009 to 2025, the RUC only recommended a decrease in the physician time and resources for the codes 39 percent of the time.[39]

[33] *https://www.gao.gov/products/gao-15-434.*

[34] Uppal, S., Barber, E.L., Reynolds, R.K., Rice, L.W., & Spencer, R J. 2019. Discrepancies created by surgeon self-reported operative time and its impact on procedure relative value units (RVUs) and reimbursement. *Gynecologic Oncology, 154,* 14. *https://doi.org/10.1016/j.ygyno.2019.04.039.*

[35] Journal of the American Medical Association, Instructions for Authors. Available from: *https://jamanetwork.com/journals/jama/pages/instructions-for-authors.*

[36] *https://www.gao.gov/products/gao-15-434.*

[37] Zuckerman, S., K. Merrell, R. Berenson, et al. 2016. Collecting empirical physician time data: Piloting an approach for validating work relative value units. Report prepared for the Centers for Medicare & Medicaid Services. Washington, DC: The Urban Institute. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Collecting-Empirical-Physician-Time-Data-Urban-Report.pdf.*

[38] National Academies for Sciences, Engineering, and Math. Improving Primary Care Valuation Processes to Inform the Physician Fee Schedule. Available from: *https://nap.nationalacademies.org/catalog/29069/improving-primary-care-valuation-processes-to-inform-the-physician-fee-schedule.*

[39] American Medical Association. ''AMA/Specialty Society RVS Update Committee: An Overview of the RUC Process.'' Available from:

Studies have demonstrated that CMS continues to overvalue non-time-based services. In a pilot project for CMS conducted by the Urban Institute in 2016,[40] which compared data obtained from electronic health records and direct observation, the ratios of fee schedule time to empirical time were often inflated, with the largest discrepancies in imaging and other test interpretations. In the study, the median ratio of PFS time to empiric intraservice physician time for CT and MRI scans was 2.13, for noninvasive cardiac testing was 4.00, and for mammography was 1.67. Another study compared estimated procedure time from anesthesia claims and the PFS time, and found that the mean estimated procedure time was 27 percent lower than the time used for PFS valuation.[41] Expert reviewers have attributed some of the discrepancies to automation and personnel substitution that has become prevalent in the time between when CMS adopted many codes and when those codes are revalued.[42] MedPAC, in their 2018 recommendations to Congress, recommended three options to offset these historic distortions, including passive devaluation: (1) an automatic reduction to the prices of new services and services with high growth rates; (2) an extension of the annual numeric target for CMS to reduce the prices of overpriced services; and (3) an across-the-board reduction to all fee schedule services other than ambulatory E&M services.[43] For reasons we will further describe below in this section, we are proposing a modified version of this third option for procedures, radiology, and diagnostic tests.

Section 1848(c)(2)(B)(ii)(I) of the Act provides that the Secretary shall, to the extent he determines to be necessary, adjust the number of RVUs to take into account changes in medical practice. We believe that many of the efficiency gains that historically may not have been fully reflected in the valuation of work RVUs for non-time-based services represent or have been caused by changes in medical practice, as described in further detail below. To take into account changes in medical practice and better reflect the resources involved in furnishing services paid under the PFS, we are proposing to establish an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services. Our initial proposed approach is designed to be conservative in nature, as we are concerned about making too many changes at once to the current methodology. In the future, we may consider making additional corresponding updates to the direct PE inputs for clinical labor and equipment costs. Our proposal is based on our assumption that both the intraservice portion of physician time and the work intensity (including mental effort, technical effort, physical effort, and risk of patient complications) would decrease as the practitioner develops expertise in performing the specific service. As expertise develops, learning leads to enhanced familiarity with the various aspects of a service, variations in the anatomy of each patient, and confidence in the practitioner's own ability to handle unexpected challenges that arise.

For example, one cross-specialty observational study found that increased surgical experience was associated with significant reductions in operative time for coronary artery bypass grafting, total knee replacement, and bilateral reduction mammoplasty.[44] While this expertise in part develops as a practitioner accumulates years of experience following the culmination of training, it also accumulates across the entire health system with the creation of a new procedure or service that practitioners must grow accustomed to. Furthermore, changes in medical practice such as enhancements in operational workflows and technology advancements after the introduction of a new procedure or service can further reduce the risk associated with the service and increase efficiencies. When a new surgical technique is introduced, operational workflows and procedures are based on previous experience with a similar service, which may not directly translate to the new procedure. These workflows generally evolve over time as experience grows, and tend to result in improvements, which make the service more efficient. This is consistent with systematic reviews demonstrating that with increased case volume and years of expertise, surgeons demonstrate decreased risk of poor outcomes.[45] Other studies have found that with increased experience performing new procedures, clinicians demonstrate increased operational efficiency and decreased time. For example, one systematic review found that for clinicians newly introduced to robotic thoracic surgery, a reduction in operating time based on the increasing number of cases performed.[46] Another study concluded that for robotic thoracic procedures, the hourly productivity increase for experienced and proficient surgeons ranged from 11.4 work relative value units/hour (+26%) for lobectomy to 17.0 work relative value units/hour (+50%) for segmentectomy.[47] These changes in practitioner experience, operational workflows, and new technologies in totality represent large-scale, system-wide changes in medical practice as described in section 1848(c)(2)(B)(ii)(I) of the Act that may not have been previously accounted for in the valuation of non-time based codes. Given the relative infrequency of service revaluation under the PFS and the limitations of reliance on survey data, we are concerned that the RVUs we have established for codes paid under the PFS may not reflect these efficiencies accrued as practitioners gain experience, operational workflows improve, and new technology is adopted.

(2) Proposed Methodology for the Efficiency Adjustment

To calculate the efficiency adjustment, we propose using the Medicare Economic Index (MEI) productivity adjustment. The MEI is a measure of inflation faced by physicians with respect to their practice costs and general wage levels, and includes inputs used in furnishing physicians' services such as physician's own time, non-physician employees' compensation, rents, medical equipment, and more. Every year, the CMS Office of the

https://www.ama-assn.org/system/files/ruc-update-booklet.pdf.

[40] Zuckerman, S., K. Merrell, R. Berenson, et al. 2016. Collecting empirical physician time data: Piloting an approach for validating work relative value units. Report prepared for the Centers for Medicare & Medicaid Services. Washington, DC: The Urban Institute.*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Collecting-Empirical-Physician-Time-Data-Urban-Report.pdf.*

[41] Crespin, Daniel, Teague Ruder, Andrew Mulcahy, Ateev Mehotra. ''Variation in Estimated Surgical Procedure Times Across Patient Characteristics and Surgeon Specialties.'' JAMA Surg. 2022 May 1;157(5):e220099. doi: 10.1001/jamasurg.2022.0099.

[42] Zuckerman et al, 2016.

[43] MedPAC Report to Congress, 2018. Chapter 3: Rebalancing Medicare's Physician Fee Schedule Toward Ambulatory Evaluation and Management Services.'' Available from: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch3_medpacreport_sec.pdf.*

[44] Maruthappu, Mahiben, Antoine Duclos, Stuart Lipsitz, Dennis Orgill, Matthew Carty. ''Surgical Learning Curves and Operational Efficiency: A Cross-Specialty Observational Study.'' BMJ Open. 2015 Mar 13;5(3):e006679.

[45] *https://pubmed.ncbi.nlm.nih.gov/25072442/.*

[46] Power, Alexandra, Desmond D'Souza, Susan Moffatt-Bruce, Robert Merritt, Peter Kneuertz. ''Defining the Learning Curve of Robotic Thoracic Surgery: What Does it Take? Surg Endosc. 2019 Dec;33(12):3880–3888. doi: 10.1007/s00464–019–07035–y. Epub 2019 Aug 2.

[47] *https://pubmed.ncbi.nlm.nih.gov/37562675/.*

Actuary (OACT) subtracts the MEI productivity adjustment from the MEI percent change moving average to calculate the final MEI update. The MEI productivity adjustment used for the final MEI update reflects the most recent historical estimate of the 10-year moving average growth of private nonfarm business total factor productivity, as calculated by the Bureau of Labor Statistics.[48] Every year, the productivity adjustment for the final MEI update is calculated by OACT based on historical data. For example, in 2026 the productivity adjustment for the final MEI update will reflect historical data through 2024. OACT incorporates a 10-year moving average to minimize yearly fluctuations in productivity associated with normal business cycles. The productivity adjustment to be applied to the proposed MEI percent change moving average for CY 2026 is listed in Table 11 (0.8 percent), and it will be updated for the final rule based on the most up to date data. The MEI productivity adjustment is substantively similar to the productivity adjustment required for the hospital inpatient prospective payment system (IPPS) and outpatient prospective payment system (OPPS) at sections 1886(b)(3)(B)(xi)(II) and 1833(t)(3)(F)(i) of the Act, respectively. The main difference is that the MEI productivity adjustment reflects historical data at the time of the CY update and the OPPS and IPPS productivity adjustments reflect a forecast to correspond to the FY update.

For CY 2026, we are proposing to apply the efficiency adjustment using a look-back period of 5 years. We considered a couple initial look-back periods. As previously described, despite the efforts to update valuation, many codes have never been revalued, and even for codes that have been revalued, there is, on average, more than 17 years since revaluation recommendations submitted by the RUC. Thus, using a look-back period of 17 years would help to account for the average amount of time that has elapsed since the last revaluation. However, using a look-back period of 17 years may be imprecise because, even when a code has been reviewed by the RUC, historic reliance on survey data may have skewed results and not properly accounted for efficiencies in the physician time and work RVU. We are also proposing to apply the efficiency adjustment to the codes that the RUC and CMS have reviewed within the look-back period of 5 years, including codes being proposed for revaluation this year, as many of the challenges discussed previously in this section, namely reliance on survey data, still apply. We realize that adjusting for the efficiencies gained would be a change in our payment methodology, and so as an initial conservative approach, we are proposing a look-back of 5 years. This represents our intended cadence for updating the efficiency adjustment (3 years), plus an additional 2 years, since it has historically taken about 2 years to make changes to PFS valuation after we receive new recommendations from the RUC.

We recognize that over time, there may be variation in the efficiencies accrued service-by-service (for example, the previously cited research has identified that efficiencies have been gained more in minor procedures and radiology services than in major inpatient procedures). But because PFS intraservice time is higher than empirical intraservice time on average for studied non-time based services,[49] [50] we believe that applying the efficiency adjustment to non-time-based services more broadly, instead of applying it only to certain services that may be more likely to accrue efficiency gains, may help to improve the overall accuracy of our valuation of these services under the PFS. Furthermore, a look-back period of 5 years is not intended to account for the full magnitude of previously unaccounted for efficiency gains in services paid under the PFS, and we may consider making refinements to the efficiency adjustment in future rulemaking to better account for these gains. To implement this efficiency adjustment, we propose to decrease the work RVUs and make corresponding changes to the intraservice physician time for codes describing non-time-based services by a factor equal to the MEI productivity adjustment, equivalent to if this factor had been applied every year over the past 5 years.

This methodology would yield a proposed efficiency adjustment of 2.5 percent, a downward (negative) adjustment for certain codes, for CY 2026. Given the 5-year look back period, the formula sums all productivity adjustments included in the final MEI updates from CY 2022–CY 2026. The CY 2026 productivity adjustment will be updated for the CY 2026 final rule to reflect more recent historical data from the Bureau of Labor Statistics.

TABLE 11 PROPOSED EFFICIENCY ADJUSTMENT FOR CY 2026

CY	MEI Productivity Adjustment (%)
2022	0.2
2023	0.5
2024	0.4
2025	0.6
2026*	0.8*
Efficiency Adjustment	**2.5%**

** Proposed, will be updated for CY 2026 final rule*

Using the methodology described above, we have included Table A–E2, which outlines examples of two different CPT codes that would be subject to the proposed efficiency adjustment. Table 12 is intended only as an illustrative example. For more information on the impacts of this proposed policy, see the Regulatory Impact Analysis in section VII.C.2.c. of this proposed rule.

[48] 87 FR 69709.

[49] Zuckerman et al, 2016.

[50] Crespin, Daniel, Teague Ruder, Andrew Mulcahy, Ateev Mehotra. ''Variation in Estimated Surgical Procedure Times Across Patient Characteristics and Surgeon Specialties.'' JAMA Surg. 2022 May 1;157(5):e220099. doi: 10.1001/jamasurg.2022.0099.

TABLE 12: EXAMPLES OF PROPOSED EFFICIENCY ADJUSTMENT

CPT Code	Short Descriptor	Current Intraservice Time (min)	Current Work RVU	Intraservice Time after Efficiency Adjustment (min)	Work RVU after Efficiency Adjustment
11200	Rmvl skin tags up to&inc 15	7	0.82	6.83	0.8
63047	Lam facetectomy & foramotomy 1 vrt sgm lumbar	90	15.37	87.75	14.99

We solicit comments on the initial look-back period and the use of the MEI productivity adjustment percentage values for calculation of the efficiency adjustment for 2026. We seek comments on whether adjustments should be made in future rulemaking to also adjust the direct PE inputs for clinical labor and equipment time that correspond with the physician time inputs.

If finalized for CY 2026, we propose to apply the efficiency adjustment to the intraservice portion of physician time and work RVUs every 3 years. This timing would imply that the next efficiency adjustment after CY 2026 would be calculated and applied in CY 2029 PFS rulemaking, reflecting efficiency gains measured from 2027 through 2029. We are proposing to update and apply the proposed efficiency adjustment with a cadence of every 3 years to align with the other updates under the PFS, including updates to the Geographic Practice Cost Index (GPCI) and Malpractice (MP) RVUs, to allow for streamlining so that interested parties can expect updates on a similar timeframe. We also seek comments as to whether or not efficiencies stop accruing for services after a predefined number of years.

We are proposing to apply this efficiency adjustment to non-time-based services that we expect to accrue efficiencies over time. We are proposing to apply the adjustment to all codes except time-based codes, including but not limited to, E/M visits, care management services, behavioral health services, services on the CMS telehealth list, and maternity codes with a global period of MMM. This adjustment would apply to all codes that are assigned a procedure status of A (active), B (bundled), C (contractor/carrier priced code), I (not valid for Medicare purposes), N (noncovered service by Medicare), R (restricted coverage), and T (injections), and are not otherwise excluded. Included code families represent the procedures, diagnostic tests, and radiology services that CMS expects to accrue efficiencies over time as changes in medical practice occur, including changes in clinician expertise, workflows, and technology. We seek comments on the codes expected to accrue efficiencies over time. The full descriptions of these indicators can be found in the Medicare Claims Processing Manual, Chapter 23 at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c23.pdf.* Additionally, a list of the codes we are proposing to apply this adjustment to can be found under the Downloads section posted with this proposed rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

Finally, we understand that accruing efficiencies does not apply equally to all services, and that efficiencies gained over time may often apply more to services that take less time to perform. Efficiencies gained in services that could be performed many times per day such as cataract extractions, skin biopsies, and CT scans, allow the practitioner to perform more of those services in a given day. We seek comments on whether and how we should consider additional efficiencies for services that require less time to perform. Additionally, we seek comments on whether the introduction of new artificial intelligence has or will lead to otherwise unaccounted for efficiencies gained in specific services.

Going forward, we also propose that the public may submit nominations via the ''Potentially Misvalued Codes'' process, as described in section II.C. of this proposed rule, if they believe the efficiency adjustment will lead to inaccurate physician time and work RVUs for a particular code. Nominations submitted should include supporting information. For the reasons discussed previously in this section, we propose that CMS will place greater emphasis on ''empiric'' supporting information for the codes nominated, to avoid the limitations of using survey data. Proposed examples of empiric data may include electronic health record logs, operating room logs, and time-motion data and should be robust enough to achieve a high degree of assuredness as to accuracy and be inclusive of multiple types of practices (for example, inclusive of academic, health centers, and private practices wherever possible). We solicit comments on what kinds of data CMS should consider as valid, reliable, empiric information for this purpose.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 20 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the

portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this proposed rule, we also note that many of the refinements listed in Table 20 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2026 are displayed in the CY 2026 direct PE input files, available on the CMS website under the downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2026 PE RVUs as displayed in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, in that rule we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2026 we received invoices for several new supply and equipment items. Tables 20 and 21 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of

pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 20 and 21 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price may have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2026 are available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we referred readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on February 8, 2006) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under section 1833(t)(2)(D) of the Act, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor under the PFS, for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we referred readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2026, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined at section 1848(b)(4)(B) of the Act for purposes of this cap. Beginning for CY 2026, we are proposing to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0598T (*Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound pathogens and measure wound size, per session; first anatomic site (e.g., lower extremity, right leg*), 0599T (*Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound pathogens and measure wound size, per session; each additional anatomic site (e.g., upper extremity, left leg) (List separately in addition to code for primary procedure)*), 0944T (*3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation*), 0946T (*Orthopedic implant movement analysis using paired computed tomography (CT) examination of the target structure, including data acquisition, data preparation and transmission, interpretation and report (including CT scan of the joint or extremity performed with paired views)*), 0961T (*Shortwave infrared radiation imaging, surgical pathology specimen, to assist gross examination for lymph node localization in fibroadipose tissue, per specimen (List separately in addition to code for primary procedure)*), 0972T (*Assistive algorithmic classification of burn healing (i.e., healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report*), 0984T (*Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision,*

interpretation, and report; initial vessel (List separately in addition to code for primary procedure)), 0985T (*Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)*), 0986T (*Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)*), 0987T (*Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)*), 70XX1 (Computed tomographic *angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing*), 70XX2 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s),* including image postprocessing *performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)*), 70XX3 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy*), and 77X09 (*Surface radiation therapy; superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to the code for primary procedure)*). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

4. Valuation of Specific Codes for CY 2026

(1) Tympanostomy (CPT Code 0583T)

In the CY 2025 PFS final rule (89 FR 97745 through 97746), we reviewed Category III CPT code 0583T (*Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia)* as potentially misvalued. We considered whether to establish national payment for CPT code 0583T, which is used to report tympanostomy using the TULA system, or whether to create a device-agnostic G-code which could be used to report tympanostomies using the TULA or other devices. We stated that CPT code 69433 (*Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia*) might serve as a sufficient base code, adequately describing most of the surgeon's work and facility resources. In response to comments supporting the latter approach, we established separate payment for HCPCS code G0561 (*Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral (List separately in addition to 69433) (Do not use in conjunction with 0583T)*) to be billed with CPT code 69433 in order to describe the additional resource costs associated with using the innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories and finalized contractor pricing for CY 2025.

We have received input from interested parties expressing gratitude for the creation of HCPCS code G0561 but also continuing to request that CMS establish national pricing for CPT code 0583T. In response, we are seeking comments on whether to nationally price both codes, and what inputs for physician work, time, and direct practice expense would most accurately capture the resource costs associated with performing both procedures. For example, in response to a similar request for comment in CY 2025 PFS rulemaking, commenters recommended a direct crosswalk to the values associated with CPT code 31295 (*Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa*) which they stated was similar to CPT code 0583T with respect to the intensity and invasiveness of the procedure, preparation time for the procedure, and total time to complete the surgery. We are seeking comments on whether interested parties continue to believe CPT code 31295 would be an accurate comparison or whether there are other services that CMS should consider.

(2) Temporary Female Intraurethral Valve-Pump (CPT Codes 0596T and 0597T)

For the CY 2025 PFS final rule (89 FR 97710), we reviewed CPT codes 0596T (*Temporary female intraurethral valve-pump (i.e., voiding prosthesis); initial insertion, including urethral measurement*) and 0597T (*Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, replacement*) as potentially misvalued. We added pricing for 3 new supplies related to these services: (1) inFlow Measuring Device, (2) inflow Valve Pump Device, and (3) inFlow Activator Kit. The RUC reviewed and surveyed these codes as potentially misvalued for the January 2025 meeting and stated that they would flag for the RAW in 3 years.

We are proposing the RUC-recommended work RVU of 2.43 for CPT code 0596T and the RUC-recommended work RVU of 1.05 for CPT code 0597T.

We are proposing the RUC-recommended direct PE inputs for both CPT codes without refinement.

(3) Limb Lengthening-Shortening—Femur (CPT Codes 27465, 27466, 27468, and 27XX0)

The CPT Editorial Panel created a new Category I code, CPT code 27XX0 *(Osteotomy(ies), femur, unilateral, with insertion of an externally controlled intramedullary lengthening device, including iliotibial band release when performed, imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device)* in May 2024. This code describes femur lengthening using the insertion of an externally controlled intramedullary lengthening device, including imaging. CPT code 27XX0 and the other codes within this code family, including CPT codes 27465 *(Osteoplasty, femur; shortening (excluding 64876),* 27466 *(Osteoplasty, femur; lengthening),* and 27468 *(Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer),* were surveyed during the September 2024 RUC Meeting.

We are proposing the RUC-recommended work RVUs of 26.65, 21.13, and 22.65 for CPT codes 27XX0, 27465, and 27466, respectively. We are also proposing the direct PE inputs for CPT codes 27XX0, 27465, and 27466 without refinement.

However, for CPT code 27468, we disagree with the RUC's recommendation to contractor price this code. We believe CPT code 27468 is valued appropriately and should not be paid under contractor pricing based on the results of ten surveys. We are instead proposing to maintain the current work RVU and direct PE inputs for CPT code 27468 for CY 2026.

(4) Limb Lengthening-Shortening—Tibia (CPT Codes 27715 and 27XX1)

The CPT Editorial Panel created a new Category I code, CPT code 27XX1, *(Osteotomy(ies), tibia, including fibula when performed, unilateral, with insertion of an externally controlled intramedullary lengthening device, including imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device)* in May 2024. This code describes tibia lengthening using the insertion of an externally controlled intramedullary lengthening device, including imaging. CPT codes 27XX1 and 27715 (*Osteoplasty, tibia and fibula, lengthening or shortening)* were surveyed for the September 2024 RUC Meeting.

We are proposing the RUC-recommended work RVU of 28.00 for CPT code 27XX1 and the work RVU of 22.50 for CPT 27715. We are also proposing the direct PE inputs for CPT codes 27XX1 and 27715 without refinement.

(5) Arthrodesis Great Toe (CPT Codes 28750 and 28755)

At the April 2024 Relativity Assessment Workgroup (RAW), the RAW identified CPT code 28750 (*Arthrodesis, great toe; metatarsophalangeal joint*) on the ''different performing specialty from survey screen,'' where the top specialty performing over 50 percent of the Medicare claims did not survey the service or the top two specialties did not survey the service. The RAW noted that when this service was last valued in 1995, podiatry, which now performs over half of the volume for this service, was not involved in the survey. CPT code 28755 (*Arthrodesis, great toe; interphalangeal joint*) which was valued by the Harvard Studies and never surveyed by the RUC, was added as part of the code family. CPT codes 28750 and 28755, were surveyed at the January 2025 AMA RUC meeting.

We are proposing the RUC-recommended work RVU of 8.75 for CPT code 28750.

We disagree with the RUC-recommended work RVU of 7.50 for CPT code 28755 and we are instead proposing a work RVU of 6.76. The RUC-recommended valuation would place it above the median range when compared to other 90-day global codes with similar work times and the current time and work values. We are proposing a work RVU of 6.76 for CPT code 28755 based on a direct crosswalk to CPT code 28122 (*Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (for example, osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*). CPT code 28122 shares the same intraservice work time of 45 minutes as compared with CPT code 28755, it has a very similar total time (230 minutes as compared with 234 minutes), and both of these codes also contain four postoperative office visits in their global periods. We are supporting this proposed work RVU of 6.76 with the total time ratio for CPT code 28755, which calculates at a work RVU of 6.64 (the total time is increasing from 172 minutes to 234 minutes for an increase of 36 percent, which results in a work RVU of 6.64 when multiplied with the current work RVU of 4.88 for CPT code 28755). Our proposed work RVU of 6.76 is further supported by a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 26785 (*Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed, single*) at a work RVU of 6.60 and an upper bracket of CPT code 56620 (*Vulvectomy simple; partial*) at an RVU of 7.53.

We are proposing the RUC-recommended direct PE inputs for all of the codes in this family.

(6) Closure Left Atrial Appendage With Endocardial Implant (CPT Code 33340)

The Relativity Assessment Workgroup (RAW) reviewed CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*) in 2023 as part of the new technology/service screen. Around that same time, specialty societies asserted that this service was undergoing rapid change. Therefore, the RAW recommended specialty societies conduct a survey for the April 2024 RUC meeting.

We are proposing the RUC-recommended work RVU of 10.25 for CPT code 33340. We are also proposing the RUC-recommended direct PE inputs for CPT code 33340 without refinement.

(7) Thoracic Branch Endograft Services (CPT Codes 33880, 33881, 33883, 33886, 33XX2, and 35XX1)

At the September 2024 CPT Editorial Panel meeting, CPT approved endovascular repair of thoracic aortic aneurysms (TEVAR) coding changes. CPT deleted three codes describing the procedure and replaced them with two new codes and four revised codes in the TEVAR family. These revisions update the TEVAR code family to more accurately describe the current practice and current coding standards. The new codes are CPT code 33XX2 (*Endovascular repair of the thoracic aorta by deployment of a branched endograft multipiece system involving an aorto-aortic tube device with a fenestration for the left subclavian artery stentgraft(s) and all aortic tube endograft extension(s) placed from the level of the left common carotid artery to the celiac artery, including preprocedure sizing and device selection, all target zone angioplasty, all nonselective catheterization(s) and left subclavian artery selective catheterization(s), all associated radiological supervision and interpretation*), CPT code 35XX1 (*Bypass graft, with other than vein; carotid-contralateral carotid*), CPT code 33880 (*Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation*), CPT code 33881 (*by deployment of an aorto-aortic tube endograft not involving coverage of the left subclavian artery origin and all endograft extension(s) placed from the level of the left subclavian carotid artery to the celiac artery*), CPT code 33883 (*Proximal extension prosthesis(s) not involving coverage of the left subclavian artery origin, delayed placement after endovascular repair of the thoracic aorta, including preprocedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed*), and CPT code 33886 (*Distal extension prosthesis(s) from the level of the left subclavian artery to the celiac artery, delayed placement after endovascular repair of descending thoracic aorta, including preprocedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation*). The new codes in this code family were surveyed at the January 2025 AMA RUC meeting.

The RUC surveyed this code family and there were overall decreases in the work times. The RUC-recommended work RVUs do not appear to fully

account for these decreases. Although we do not believe that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, decreases in the surveyed work time should typically be reflected in decreases to the work RVU.

We reviewed the RUC recommendations and found them to be high, relative to other codes with the same or similar times. Based on a search of similarly timed codes in the RUC database, the RUC-recommended values exceed the work RVUs for five of the six codes.

We disagree with the RUC recommended work RVU of 30.00 for CPT code 33880 and we are instead proposing a work RVU of 27.00. This valuation was higher than nearly all of the other 90-day global codes with similar time values. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with an intraservice time of 120 minutes and similar total time around 546 minutes. We are instead proposing a direct crosswalk to CPT code 32672 (*Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed*) at the previously mentioned work RVU of 27.00. CPT code 32672 shares the same intraservice work time of 120 minutes as compared with CPT code 33880, it has a similar total time (567 minutes as compared with 546 minutes), and both of these codes each have two postoperative office visits in their global periods. We are supporting this proposed work RVU of 27.00 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 43820 (*Gastrojejunostomy; without vagotomy*) at a work RVU of 22.53 and an upper bracket of CPT code 34702 (*Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (for example, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)*) with a work RVU of 36.00.

We disagree with the RUC recommended work RVU of 26.75 for CPT code 33881 and we are instead proposing a work RVU of 22.53. The RUC's recommended work RVUs do not match the surveyed drops in work time (from 200 minutes to 110 minutes for CPT code 33881) and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 43820 has a slightly higher intraservice work time of 120 minutes as compared with CPT code 33881 which has 110 minutes, it has a very similar total time (545 minutes as compared with 506 minutes), and three postoperative office visits as compared to CPT code 33881 which has two postoperative office visits in the global period. We are supporting this proposed work RVU of 22.53 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 34707 at a work RVU of 22.28 and an upper bracket of CPT code 43880 at an RVU of 27.18.

We disagree with the RUC recommended work RVU of 39.00 for CPT code 33XX2 and we are instead proposing a work RVU of 35.00. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 180 minutes and similar total time around 621 minutes. We are proposing a work RVU of 35.00 for CPT code 33XX2 based on a direct crosswalk to CPT code 33390 (*Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; simple (i.e., valvotomy, debridement, debulking, and/or simple commissural resuspension)*). There were several recently reviewed codes in the RUC database search that have the exact same intraservice time with higher total times and a lower work RVU. CPT code 33390 shares the same intraservice work time of 180 minutes as compared with CPT code 33880, it has a very similar total time (621 minutes as compared with 622 minutes), and both of these codes also contain two postoperative office visits in their global periods. We are supporting this proposed work RVU with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 33647 (*Repair of atrial septal defect and ventricular septal defect, with direct or patch closure*) at a work RVU of 33.00 and an upper bracket of CPT code 35216 (*Repair blood vessel, direct; intrathoracic, without bypass*) at an RVU of 35.00.

We disagree with the RUC recommended work RVU of 24.25 for CPT code 33883 and we are instead proposing a work RVU of 19.91. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 90 minutes and similar total time around 486 minutes. We are proposing a work RVU of 19.91 for CPT code 33883 based on a direct crosswalk to CPT code 44320 (*Colostomy or skin level cecostomy*).

The RUC-recommended work RVUs do not match the surveyed drops in work time (from 120 minutes to 90 minutes) for CPT code 33883 and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 44320 shares the same intraservice work time of 90 minutes as compared with CPT code 33883, it has a slightly higher total time (507 minutes as compared with 486 minutes), and three postoperative office visits as compared to two post operative office visits for CPT code 33883 in the global period. We are supporting this proposed work RVU of 19.91 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 33267 (*Exclusion of left atrial appendage, open, any method (for example, excision, isolation via stapling, oversewing, ligation, plication, clip)*) at a work RVU of 18.50 and an upper bracket of CPT code 43611 (*Excision, local; malignant tumor of stomach*) at an RVU of 20.38.

We disagreed with the RUC recommended work RVU of 23.50 for CPT code 33886 and we are instead proposing a work RVU of 19.91. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 90 minutes and similar total time around 486 minutes. We are proposing a work RVU of 19.91 for CPT code 33886 based on a direct crosswalk to CPT code 44320. The RUC-recommended work RVUs do not match the surveyed drops in work time (from 100 minutes to 90 minutes) for CPT code 33886 and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 44320 shares the same intraservice work time of 90 minutes as compared with CPT codes 33886, it has a slightly higher total time (507 minutes as compared with 486 minutes), and three postoperative office visits as compared to two post operative office visits for CPT code 33886 in the global period. We are supporting this proposed work RVU of 19.91 with a pair of other 90-day global codes with

similar work time values, with a lower bracket of CPT code 33267 at a work RVU of 18.50 and an upper bracket of CPT code 43611 at an RVU of 20.38.

We disagree with the RUC recommended work RVU of 27.40 for CPT code 35XX1 and we are instead proposing a work RVU of 23.53. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 150 minutes and similar total time around 486 minutes. Furthermore, we note that there was a decrease in the intraservice time by 23 minutes and the intraservice time ratio for this code suggests that the RUC-recommendation is too high. We are proposing a work RVU of 23.53 for CPT code 35XX1 based on a direct crosswalk to CPT code 32669 (*Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)*). We note that CPT code 35XX1 was also valued by the RUC using a crosswalk code to maintain relativity within the family.

The RUC's recommended work RVUs do not reflect surveyed drops in work time (from 173 minutes to 150 minutes) for CPT code 35XX1and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 32669 shares the same intraservice work time of 150 minutes as compared with CPT code 35XX1, it has a slightly higher total time (502 minutes as compared with 486 minutes), and both of these codes also contain two postoperative office visits in their global periods. We are supporting this proposed work RVU of 23.53 with a pair of other 090-day global codes with similar work time values, with a lower bracket of CPT code 22612 (*Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)*) at a work RVU of 23.53 and an upper bracket of CPT code 35666 (*Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery*) at an RVU of 23.66.

We are proposing the RUC-recommended direct PE inputs for all the codes in this family.

(8) Lower Extremity Revascularization (CPT Codes 37XX1, 37X02, 37X03, 37X04, 37X05, 37X06, 37X07, 37X08, 37X09, 37X10, 37X11, 37X12, 37X13, 37X14, 37X15, 37X16, 37X17, 37X18, 37X19, 37X20, 37X21, 37X22, 37X23, 37X24, 37X25, 37X26, 37X27, 37X28, 37X29, 37X30, 37X31, 37X32, 37X33, 37X34, 37X35, 37X36, 37X37, 37X38, 37X39, 37X40, 37X41, 37X42, 37X43, 37X44, 37X45, and 37X46)

In October 2018, three CPT codes (37225, 37227, and 37229) were flagged by the Relativity Assessment Workgroup for high-cost supplies review, leading to a series of significant changes in the lower extremity revascularization (LER) code family. After multiple reviews and discussions between 2018 and 2024, the CPT Editorial Panel ultimately created four new subsections and 46 new codes to replace the existing 16 codes (CPT codes 37220–37235) for LER services. According to the RUC, this comprehensive update was driven by technological advances, changes in practice settings, and the need to better differentiate between a stenosis (i.e. a straightforward lesion) and an occlusion (that is, a complex lesion) procedures. These codes were surveyed for the September 2024 RUC meeting and recommendations submitted to CMS for consideration in the CY 2026 PFS proposed rule. See table 13 for a summary of the codes, and their long descriptors.

According to the RUC, not all codes received a full survey from participants. Eleven selected core codes had complete survey responses from all respondents, while the remaining 35 codes underwent an abbreviated survey process. The 35 abbreviated survey codes were split into two groups and survey respondents only received one of those two groups along with the 11 core codes. There were two notable changes made to the abbreviated survey. First, survey respondents were provided with one of the anchor codes as a comparator instead of using a reference service list; second, survey respondents were only asked one question per abbreviated code in the intensity/complexity section. Therefore, respondents did not complete all elements of the abbreviated survey, as some elements were pre-populated. We note that this method could potentially introduce inaccuracies and bias in the survey outcomes.

For CY 2026, we are proposing the RUC-recommended work RVUs for all 46 CPT codes. However, we have concerns about the survey data, specifically regarding the small sample size and large variations in responses. We encourage commenters to submit additional data for our consideration in determining the valuation of work and direct PE inputs for these CPT codes. Table 13 also shows the proposed work RVUs for the 46 CPT codes:

TABLE 13: CPT LONG DESCRIPTORS AND PROPOSED WORK RVUS FOR LOWER EXTREMITY REVASCULARIZATION PROCEDURES

CPT Code	Long Descriptors	Proposed Work RVUs
37XX1	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	7.30
+37X02	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.00
37X03	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	10.75
+37X04	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.89
37X05	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	8.75
+37X06	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.00
37X07	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all*	12.69

CPT Code	Long Descriptors	Proposed Work RVUs
	imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	
+37X08	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel*	4.25
+37X09	*Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)*	3.00
37X10	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	7.75
+37X11	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.00
37X12	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	10.50
+37X13	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.00
37X14	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	8.75
+37X15	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary*	3.73

CPT Code	Long Descriptors	Proposed Work RVUs
	to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	
37X16	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	14.75
+37X17	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	5.00
37X18	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	9.00
+37X19	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel*	4.00
37X20	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	12.63
+37X21	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	5.50
37X22	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological*	11.00

CPT Code	Long Descriptors	Proposed Work RVUs
	supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	
+37X23	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.25
37X24	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	15.00
+37X25	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	6.00
+37X26	*Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)*	4.00
37X27	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	9.80
+37X28	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.00
37X29	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	12.31

CPT Code	Long Descriptors	Proposed Work RVUs
+37X30	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.26
37X31	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	10.00
+37X32	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.34
37X33	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	13.46
+37X34	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	5.00
37X35	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	13.50
+37X36	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.75

CPT Code	Long Descriptors	Proposed Work RVUs
37X37	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	17.00
+37X38	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	6.50
37X39	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	15.00
+37X40	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	6.50
37X41	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	18.00
+37X42	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure*	8.16
37X43	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing*	11.00

CPT Code	Long Descriptors	Proposed Work RVUs
	the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	
+37X44	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.00
37X45	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	13.70
+37X46	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure*	5.00

We are proposing the RUC-recommended PE inputs for all 46 CPT codes, with several revisions to address discrepancies found in the documentation. Regarding the drug-coated balloon (SD382), which is priced at $2,343.33, the RUC recommendations show inconsistent quantity allocations across different code sets. The RUC documentation specifies two units for the initial vessel and one unit for additional vessels in CPT codes 37X10—37X13 and 37X18—37X21. However, for CPT codes 37X14—37X15 and 37X22—37X23, only one unit is listed for the initial vessel. Furthermore, CPT codes 37X16—37X17 and 37X24—37X26 have no quantity values specified at all. To address these inconsistencies, we propose updating the initial vessel quantities to one unit of the SD382 drug-coated balloon for CPT codes 37X10, 37X12, 37X18, and 37X20, while maintaining one unit for additional vessels.

The RUC recommends a quantity of two for supply code SD379 (drug eluting stent, tibial) for four CPT codes in the tibial and peroneal vascular territory, CPT codes 37X33, 37X34, 37X41, and 37X42. The RUC-recommended quantity exceeds the number of units of supply code SD266 (stent, self-expanding 2–5 mm XPERT (Abbott)) currently used in CPT code 37230, 37234, 37231, and 37235, respectively. We are proposing to reduce the quantity from two to one for supply code SD379 (drug eluting stent, tibial) in each of the four CPT codes 37X33, 37X34, 37X41, and 37X42.

For this code family, the RUC recommended 34 minutes of equipment time for the Professional PACS Workstation (ED053). We believe this recommendation contains an unintended technical error regarding the equipment time. Therefore, we propose using the standard equipment formula for the professional PACS workstation, which calculates equipment minutes as the sum of intraservice work time plus half of the preservice work time.

While we are proposing the listed refinements above, we are seeking comments on whether we should create G-codes to describe the use of high-cost supplies. Alternatively, we are seeking comments on whether we could use the Hospital Outpatient Prospective Payment System (OPPS) mean unit cost data (MUC) to accurately price these services and their supplies based on how these supplies are paid for in the hospital setting. We seek comments on whether there is additional information we should consider in establishing proposed payments for these services.

(9) Irreversible Electroporation of Tumors (CPT Codes 4001X and 5XX11)

At the September 2024 CPT Editorial Panel Meeting, two new CPT codes were created for reporting percutaneous irreversible electroporation ablation of one or more tumors: CPT codes 4001X (*Ablation, irreversible electroporation, liver, 1 or more tumors, including imaging guidance, percutaneous*) and 5XX11 (*Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous*). These new CPT codes were surveyed at the January 2025 AMA RUC meeting. For CY 2026, we are proposing the RUC-recommended work RVUs of 9.41 for CPT code 4001X and 13.50 for CPT code 5XX11.

We are proposing the following refinements to the direct PE inputs for CPT code 4001X. We disagree with the RUC recommendation to use the standard 90-day global pre-service clinical labor times in the Facility setting for CPT code 4001X since this is a 0-day global procedure. We do not agree that it would serve the interests of relativity to use the 90-day global clinical labor standard times for a 0-day global service. Therefore, we are proposing the standard 000/010 global day extensive pre-service clinical labor times in the Facility setting, resulting in

the following changes: the minutes associated with CA002 (*Coordinate pre-surgery services (including test results)*) are reduced from 20 minutes to 10 minutes; the minutes associated with CA003 (*Schedule space and equipment in facility*) are reduced from 8 minutes to 5 minutes; the minutes associated with CA004 (*Provide pre-service education/obtain consent*) are reduced from 20 minutes to 7 minutes; and the minutes associated with CA005 (*Complete pre-procedure phone calls and prescription*) are reduced from 7 minutes to 3 minutes.

We are proposing the RUC-recommended direct PE inputs for CPT code 5XX11 without refinement.

(10) Endoscopic Sleeve Gastroplasty (CPT Code 4XX04)

In September 2024, CPT approved the addition of a new code to report transoral gastric restrictive procedures using an endosurgical approach. CPT code 4XX04 (*Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed)* was surveyed for the January 2025 RUC meeting.

The RUC-recommended a direct crosswalk to CPT 36832 (*Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure))* with a work RVU of 13.50. During the RUC prefacilitation meeting, 1 unit of CPT code 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and a moderate level of medical decision making)* was removed from the postoperative period, and 20 minutes of work time was added into the immediate post-service time. The RUC also revised the global period of CPT code 4XX04 to reduce the work and time value of CPT code 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter)* to half of the original value. We believe the RUC partially applied the 23-hr policy when it applied the policy to the immediate postservice time but not to the work RVU. The 23-hour policy established in the CY 2011 PFS final rule (75 FR 73226) applies to services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours. We discussed in the CY 2011 PFS final rule that we believe the value of these codes should not reflect work that is typically associated with an inpatient service. We believe the 23-hour policy in its entirety should be applied to CPT code 4XX04, which includes the work RVUs along with the immediate post service time. Following the valuation methodology we established for the 23 hour policy in the CY 2011 PFS final rule (75 FR 73226), we are proposing a work RVU of 12.56 for CPT code 4XX04. The steps are as follows:

Step (1): The RUC appropriately reduced the hospital discharge day management service included in the global period from 1 to 0.5; therefore, we will skip this step.

Step (2): 13.50 − 1.39 ** = 12.11

Step (3): 12.11 + (20 minutes × 0.0224) *** = 12.56 RVUs

* Value associated with ½ hospital day discharge management service.

** Value associated with an inpatient hospital visit, CPT Code 99232.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

We are proposing the RUC-recommended direct PE inputs for CPT code 4XX04 without refinement.

(11) Transurethral Robotic-Assisted Resection of Prostate (CPT Codes 52500, 52601, 52630, 52648, 52649, and 52XX1)

In May 2024, the CPT Editorial Panel created a new CPT code to report transurethral robotic-assisted waterjet resection of the prostate, including ultrasound guidance: CPT code 52XX1 (*Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed*). CPT code 52XX1 was surveyed for the September 2024 RUC meeting along with the existing codes in this code family: CPT code 52500 (*Transurethral resection of bladder neck (separate procedure)*), CPT code 52601 (*Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*), CPT code 52630 (*Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*), CPT code 52648 (*Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)*), and CPT code 52649 (*Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)*). For CY 2026, the RUC-recommended a work RVU of 6.00 for CPT code 52500, a work RVU of 10.25 for CPT code 52XX1, a work RVU of 10.00 for CPT code 52601, a work RVU of 6.55 for CPT code 52630, a work RVU of 10.05 for CPT code 52648, and a work RVU of 14.56 for CPT code 52649.

We are proposing the RUC-recommended work RVU of 6.00 for CPT code 52500, the work RVU of 10.25 for CPT code 52XX1, the work RVU of 10.00 for CPT code 52601, the work RVU of 6.55 for CPT code 52630, and the work RVU of 10.05 for CPT code 52648.

We note that the RUC will be placing CPT code 52XX1 on the New Technology/New Services list and CPT code 52XX1 will be re-reviewed by the RUC in 3 years to ensure correct valuation, patient population, and utilization assumptions. Also, we received external input suggesting the RVU for CPT code 52XX1 should be higher than the RUC recommendation of 10.25 and that an RVU of 14.56 (same as the RUC recommendation for CPT code 52649) would be more appropriate. However, given the survey times and comparisons to similarly timed codes with similar intensity, an RVU of 14.56 for CPT code 52XX1 would not be accurate. The RUC's valuation for CPT code 52XX1 is typical for a procedure code with the same work time values (that is, 60 minutes intra-service time and 234 minutes of total time). With all of these considerations, we believe that proposing a work RVU of 10.25 for CPT code 52XX1 maintains relativity with the other CPT codes in this family.

For CPT code 52649, we disagree with the RUC-recommended work RVU of 14.56 and we are proposing an RVU of 13.00 instead, based on a crosswalk to CPT code 53500 (*Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (for example, postsurgical obstruction, scarring)*). We believe the RUC-recommended work RVU of 14.56 is too high and should be lowered due to the decrease in intraservice time of 30 minutes (from 120 minutes to 90 minutes), and the decrease in total time by 16 minutes (from 279 minutes to 263

minutes). An RVU of 13.00 for CPT code 52649 is supported by the range of CPT code 64912 (*Nerve repair; with nerve allograft, each nerve, first strand (cable)*) with an RVU of 12.00, the same intraservice time and 272 minutes of total time, and by CPT code 15730 (*Midface flap (that is, zygomaticofacial flap) with preservation of vascular pedicle(s)*) with an RVU of 13.50, the same intraservice time and 255.5 minutes of total time.

We are proposing the RUC-recommended direct PE inputs for CPT codes 52500, 52XX1, 52601, 52630, and 52649 without refinement. For CPT code 52648, we are proposing to remove the 6 minutes of clinical labor time for CA021 (Perform procedures/services—NOT directly related to physician work time). Therefore, the equipment time reported under EF031 (table, power) has also been reduced by 6 minutes (from 95 minutes to 89 minutes) to reflect the removal of clinical labor activity CA021 from CPT code 52648. We note that CPT code 52648 is performed in the facility setting only and the standard is 0 minutes for CA021 in the facility. Also, supply item SL036 (cup, biopsy-specimen sterile 4oz) was reported as a non-facility PE input for CPT code 52648. Since CPT code 52648 is only performed in the facility setting, we believe inclusion of supply item SD036 as a non-facility PE input was unintentional and therefore proposing to remove.

(12) Cystourethroscopy (CPT Code 52XX2)

At the September 2024 CPT Editorial Panel Meeting, CPT code 0619T (*Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed*) was deleted and replaced with CPT code 52XX2, which describes an endoscopic procedure for the management of benign prostatic enlargement that entails using both a non-medication-coated and a medication-coated balloon to open the prostatic urethra. CPT code 52XX2 (*Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a non-drug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed*) was surveyed at the January 2025 AMA RUC meeting.

We are proposing the RUC-recommended work RVU of 3.62 for CPT code 52XX2. For direct PE, we are proposing to refine the clinical labor associated with clinical activity CA023 (Monitor patient following procedure/service, no multitasking) to 0 minutes for CPT code 52XX2. We note that the RUC-recommended a direct crosswalk of most clinical labor times for CPT code 52XX2 based on reference CPT code 52441 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant*), however, the PE Summary of Recommendations for CPT code 52XX2 only describes patient monitoring activities done while multi-tasking and does not describe any no-multitasking (1:1) patient monitoring time (clinical activity code CA023) like it was described in the PE SOR for CPT code 52441, reviewed for CY 2020 PFS rulemaking. We are therefore proposing to remove this clinical labor time.

We also disagree with the RUC-recommended 40 minutes for the clinical labor associated with clinical activity CA025 (Clean scope) and are proposing to refine CA025 to the standard 30 minutes for a flexible scope. We would like to note that, while the PE SOR for CPT code 52XX2 did not justify non-standard times for clinical activities CA016 (Prepare, set-up and start IV, initial positioning and monitoring of patient) and CA017 (Sedate/apply anesthesia) of 2 minutes, we are not proposing to refine these clinical activity times because there was a robust explanation of these non-standard times in the PE SOR for CPT code 52441, which is a clinically similar endoscopy code requiring positioning and anesthetic activities that warrant the non-standard times for CPT codes 52441 and 52XX2.

For medical supplies, we are proposing to remove the SM022 (sanitizing cloth-wipe (patient)) supply because there are five of these cloth wipes included in the SA058 supply (pack, urology cystoscopy visit).

For equipment times, we are proposing to refine the time for the ES031 (scope video system (monitor, processor, digital capture, cart, printer, LED light)) and ES018 (fiberscope, flexible, cystoscopy) equipment items to account for the clinical labor times that should be included in the standard scope systems and scope equipment formulas. We disagree with the RUC-recommended 64 minutes for ES031 and ES018, and we are proposing to refine ES031 to 52 minutes and ES018 to 79 minutes in accordance with our standard equipment time formulas for scopes and scope video systems. We are proposing all other direct PE inputs for CPT code 52XX2.

(13) Prostate Biopsy Services (CPT Codes 55705, 55706, 5XX00, 5XX01, 5XX02, 5XX03, 5XX04, 5XX07, 5XX08, 5XX09, 5XX10, and 76872)

At the April 2022 Relativity Assessment Workgroup (RAW), prostate biopsy services were reviewed and identified as services performed by the same physician on the same date of service 75 percent of the time or more. As a result of that review, the RAW requested action plans for September 2022 to determine if specific code bundling solutions should occur for CPT codes 55700 (*Biopsy, prostate; needle or punch, single or multiple, any approach*) and CPT code 76872 (*Ultrasound, transrectal;*). The RAW referred that issue to the CPT Editorial Panel for revision of descriptors and for clarity in reporting CPT code 55700 with CPT code 76872. At the May 2024 CPT Editorial Panel meeting, CPT deleted existing CPT code 55700, revised CPT codes 55705 (*Biopsy, prostate; any approach, non-imaging-guided*) and 76872 and added 9 new codes that clarify reporting for prostate biopsies and the imaging procedures that accompany them.

CPT codes 55705, 55706 (*Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance*), 5XX00 (*Biopsy, prostate, transrectal, ultrasound-guided (i.e., sextant), ultrasound-localized*), 5XX01 (*Biopsy, prostate, transrectal, ultrasound-guided (i.e., sextant) with MRI-fusion guidance*), 5XX02 (*Biopsy, prostate, transperineal, ultrasound-guided (i.e., sextant), ultrasound-localized*), 5XX03 (*Biopsy, prostate, transperineal, ultrasound-guided (i.e., sextant) with MRI-fusion guidance*), 5XX04 (*Biopsy, prostate, transrectal, MRI-ultrasound-fusion guided, targeted lesion(s) only*), 5XX07 (*Biopsy, prostate, transperineal, MRI-ultrasound-fusion guided, targeted lesion(s) only, first targeted lesion*), 5XX08 (*Biopsy, prostate, in-bore CT- or MRI-guided (i.e., sextant), with biopsy of additional targeted lesion(s), first targeted lesion*), 5XX09 (*Biopsy, prostate, in-bore CT- or MRI-guided targeted lesion(s) only, first targeted lesion*), and 5XX10 (*Biopsy, prostate, each additional, MRI-ultrasound fusion or in-bore CT- or MRI-guided targeted lesion (List separately in addition to code for primary procedure)*), and 76872 were surveyed at the September 2024 RUC meeting.

We are proposing the RUC-recommended work RVUs for all twelve CPT codes in this family. We are proposing a work RVU of 1.93 for CPT code 55705, a work RVU of 4.27 for CPT

code 55706, a work RVU of 2.63 for CPT code 5XX00, a work RVU of 3.39 for CPT code 5XX01, a work RVU of 3.23 for CPT code 5XX02, a work RVU of 3.81 for CPT code 5XX03, a work RVU of 2.61 for CPT code 5XX04, a work RVU of 3.10 for CPT code 5XX07, a work RVU of 4.00 for CPT code 5XX08, a work RVU of 3.62 for CPT code 5XX09, a work RVU of 1.05 for CPT code 5XX10, and a work RVU of 0.67 for CPT code 76872.

We are proposing the RUC-recommended direct PE inputs for all of the codes in this family.

(14) Laparoscopic Prostatectomy (CPT Codes 55840, 55842, 55845, 55866, 55867, 558X1, and 558X2)

In April 2023, the RUC's Relativity Assessment Workgroup identified CPT codes 38571 (*Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy*) and 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*) as typically reported together 75 percent or more based on 2021 Medicare claims data and referred them to the CPT Editorial Panel to possibly develop a code bundling solution. In May 2024, the CPT Editorial Panel created two new codes to report laparoscopic prostatectomy with lymph node biopsy(ies) (limited pelvic lymphadenectomy) and with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes, respectively: CPT code 558X1 *(Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with lymph node biopsy(ies) (limited pelvic lymphadenectomy)* and 558X2 ((*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes*). These new codes were surveyed along with the rest of the family, CPT code 55840 (*Prostatectomy, retropubic radical, with or without nerve sparing*), 55842 (*Prostatectomy, retropubic radical, with or without nerve sparing; with lymph :node biopsy(s) (limited pelvic lymphadenectomy)*), 55845 (*Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes*), 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*), and 55867 (*Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed*) at the September 2024 RUC meeting.

We are proposing the RUC's recommended work RVU for five of the six codes in the Laparoscopic Prostatectomy family. We are proposing a work RVU of 21.36 for CPT code 55840, a work RVU of 21.36 for CPT code 55842, a work RVU of 25.18 for CPT code 55845, a work RVU of 22.46 for CPT code 55866, a work RVU of 22.46 for CPT code 558X1, and a work RVU of 19.53 for CPT code 55867.

We disagree with the RUC's recommended work RVU of 29.35 for CPT code 558X2 and we are instead proposing a work RVU of 27.41 based on a crosswalk to CPT code 50543 (*Laparoscopy, surgical; partial nephrectomy*). The RUC's recommended work RVU of 29.35 is based on a crosswalk to CPT code 27059 (*Radical resection of tumor (for example, sarcoma), soft tissue of pelvis and hip area; 5 cm or greater*). However, CPT code 27059 is a procedure typically performed on an inpatient basis, with nearly 200 minutes of additional total time higher than the surveyed work time for CPT code 558X2 (608 minutes as compared with 434 minutes), due to the inclusion of five inpatient office visits in its global period. CPT code 558X2 will typically be performed on an outpatient basis and does not contain any inpatient office visits in its global period, which leads us to believe that CPT code 27059 is not the most accurate choice of CPT code for a valuation crosswalk.

Instead, we believe that it is more accurate to propose a work RVU of 27.41 for CPT code 558X2 based on the crosswalk to CPT code 50543. This crosswalk code is another type of surgical laparoscopy which more closely matches the intraservice work time (240 minutes against 230 minutes) and total work time (557 minutes against 434 minutes) of CPT code 558X2. We also note that the intensity of CPT code 558X2 is anomalously high in relation to the rest of this code family at the RUC's recommended work RVU of 29.35, roughly 30–40 percent higher than any of its peer codes. While we agree that CPT code 558X2 should have the highest intensity amongst this group of codes, we believe that our proposed work RVU of 27.41 reflects a more accurate intensity relative to the rest of the family.

For the direct PE inputs, we are proposing to correct what appears to be an error in the recommendations for CPT code 55867. The RUC-recommended 106 minutes of clinical labor time for the CA039 (Post-operative visits (total time)) activity based on two Level 4 office visits included in the global period for CPT code 55867. However, this CPT code instead contains one Level 3 and one Level 4 office visit which sum to 89 minutes of clinical labor time, not 106 minutes. We are proposing to make this correction to the CA039 clinical labor time for CPT code 55867, which also carries over to the equipment time for the power table (EF031) and the surgical light (EF014). We are proposing the direct PE inputs as recommended by the RUC in all other cases for this code family.

(15) Endovascular Therapy With Imaging (CPT Codes 61624, 61626, 75894, and 75898)

In April 2022, the Relativity Assessment Workgroup (RAW) requested action plans to evaluate potential code bundling solutions for the following code pairs: CPT code 61624 (*Transcatheter permanent occlusion or embolization [for example, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation], percutaneous, any method; central nervous system [intracranial, spinal cord]*) and CPT code 75894 (*Transcatheter therapy, embolization, any method, radiological supervision and interpretation*), CPT code 61624 and CPT code 75898 (*Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis*), CPT code 61626 (*Transcatheter permanent occlusion or embolization [e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation], percutaneous, any method; non-central nervous system, head or neck [extracranial, brachiocephalic branch]*) and CPT code 75894, and CPT code 61626 and CPT code 75898. The RUC reviewed these codes during the April 2024 RUC meeting. For CY 2026, the RUC-recommended a work RVU of 20.00 for CPT code 61624, an RVU of 15.31 for CPT code 61626, an RVU of 2.25 for CPT code 75894, and an RVU of 1.85 for CPT code 75898.

We are proposing the RUC-recommended work RVU of 2.25 for CPT code 75894 and work RVU of 1.85 for CPT code 75898. However, we have concerns about the survey data due to the significant variations in both work values and intraservice times reported by respondents. These variations can suggest that the proposed RVU values at the 25th percentile may not accurately

reflect the actual work involved in performing these services. As a result, we are seeking public comments regarding the proposed work RVUs for CPT codes 75894 and 75898.

We disagree with the RUC-recommended work RVUs for CPT codes 61624 and 61626. For CPT code 61624, we are proposing a work RVU of 17.06 instead of the RUC-recommended 20.00. This proposal is based on a crosswalk to CPT code 49622 (*Repair of parastomal hernia, any approach (that is, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated*). This crosswalk is supported by a range of CPT code 33224 (*Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)*) with a work RVU of 9.04, 135 minutes intra-service time and 204 minutes total time, and CPT code 93590 (*Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve*.) with a work RVU of 21.70, 135 minutes intraservice time and 223 minutes total time. The intraservice time for CPT code 61624 decreased from 232 to 150 minutes, reducing by 82 minutes, and the total time decreased from 362 to 246 minutes, reducing by 116 minutes, which supports a lower RVU. The lower work RVU proposal of 17.06 reflects the significant decreases in both intraservice time and total time for CPT code 61624.

For CPT code 61626, we are proposing a work RVU of 13.46 instead of the RUC-recommended work RVU of 15.31. This proposal is based on a crosswalk to CPT code 49594 (*Repair of anterior abdominal hernia[s] [that is, epigastric, incisional, ventral, umbilical, spigelian], any approach [that is, open, laparoscopic, robotic], initial, including implantation of mesh or other prosthesis when performed, total length of defect[s]; 3 cm to 10 cm, incarcerated or strangulated*). This crosswalk is supported by a range of CPT code 55881 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation*) with a work RVU of 9.80, 120 minutes intra-service time and 202 minutes total time, and CPT code 93580 (*Percutaneous transcatheter closure of congenital interatrial communication (that is, Fontan fenestration, atrial septal defect) with implant*) with a work RVU of 17.97, 120 minutes intraservice time and 210 minutes total time. The intraservice time for CPT code 61626 decreased by 53 minutes, and the total time decreased by 90 minutes, which supports a lower RVU. The lower work RVU proposal of 13.46 reflects the significant decreases in both intraservice time and total time for CPT code 61626.

We are also proposing the RUC-recommended direct PE inputs for CPT codes 61624, 75894, and 75898 without refinement. However, we disagree with a few RUC-recommended direct PE inputs for CPT code 61626. We are proposing to refine the clinical staff time for the CA011 activity 'Provide education/obtain consent' to the standard of 2 minutes for CPT code 61626. Since no rationale was provided in the PE Summary of Recommendations for extending clinical staff time beyond the standard 2 minutes for the CA011 activity, we believe 2 minutes is more appropriate than the RUC-recommended 5 minutes. We are also proposing to change the medical supply quantity of the SD172 (guidewire, cerebral (Bentson)) supply from 1 to 0 because CPT code 61626 describes non-central nervous system procedures, while SD172 is a cerebral guidewire; thus, we believe this supply is not typically used in this service.

Additionally, regarding the clinical labor associated with CA024 (Clean room/equipment by clinical staff), we believe that the RUC's recommendation of 3 minutes for CA024 was not properly accounted for in one of the equipment time formula inputs. Therefore, we are proposing an increase of 3 minutes to the equipment time for the angiography room (EL011), which increases from 124 to 127 minutes for this code to incorporate this missing time associated with the CA024 activity. Lastly, for CPT code 61626, the equipment time for the professional PACS workstation (ED053) should be half of the physician preservice time plus the full physician intraservice time. We believe this was an unintended error, and we are proposing 152 minutes after rounding up from 151.5 minutes.

Although we are proposing the direct PE inputs for CPT codes 75894 and 75898 without refinement, we have concerns over one of the RUC-recommended direct PE inputs, CA021 (Perform procedure/service—NOT directly related to physician work time) as the involvement of additional vascular interventional technologists remains unclear. According to the RUC recommendation, CPT codes 61624 and 61626 should not be reported in conjunction with CPT codes 75894 and 75898. And the RUC's recommendation of 60 minutes of clinical labor time for CPT code 75894 and 45 minutes for CPT code 75898 associated with the CA021 activity did not include an adequate explanation for these activities when CPT codes 75894 and 75898 are performed in the absence of CPT codes 61624 and 61626. Thus, we are proposing the direct PE inputs as recommended by the RUC; however, due to the concerns mentioned above, we are seeking public comments regarding the recommended CA021 clinical labor time of 60 minutes for CPT code 75894 and 45 minutes for CPT code 75898, specifically what intraservice clinical labor time would be typical for these procedures.

(16) Guided High Intensity Focused Ultrasound (CPT Code 61715)

In September 2023, the CPT Editorial Panel created a new Category I code to describe magnetic resonance image guided high intensity focused ultrasound (MRgFUS) intracranial ablation for treatment of a severe central tremor that is recalcitrant to other medical treatments for CY 2025 to replace the existing Category III code.

For CY 2025, we finalized the implementation of CPT code 61715 (*Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed*) as a global-only code with direct PE inputs in the facility setting only, as recommended by the RUC. After implementation, an interested party raised concerns about the lack of non-facility pricing for the new CPT code 61715, which would result in an untenable non-facility payment equal to the established facility payment. The interested party expressed concerns about access to the service in the non-facility setting given the facility payment rate and provided information about the appropriateness of the service in the non-facility setting and the payments set by the MACs for the predecessor code. The interested party stated that the predecessor code, CPT code 0398T, was paid $9,750 in the non-facility setting by one MAC, and for CY 2025, CPT code 61715 is paid at $1,180 in the non-facility setting due to being set equal to the facility payment, absent established non-facility PE RVUs. In an effort to temporarily resolve this issue for CY 2025, we implemented PC/TC splits for CPT code 61715, with contractor-pricing for the global and technical components, which would restore MAC discretion in pricing this

service, including in the non-facility setting.

For CY 2026, we are seeking comments on non-facility pricing of this service to address the issue permanently. When considering potential crosswalk or reference codes for proposed direct PE inputs in the non-facility setting, we found all codes in the CPT code 615XX, 616XX, 617XX, and 618XX series are only valued in the facility setting and therefore were not tenable crosswalk codes for the non-facility direct PE. Additionally, there are MRI-guidance ultrasound ablation Category III codes that could be commensurate for non-facility direct PE, such as CPT code 0071T (*Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue*), and the previous predecessor code of CPT code 61715, CPT code 0398T, but they are/were contractor-priced under the PFS and do not have direct PE inputs for consideration.

We considered the prostate tissue MRI-guided ultrasound ablation codes, CPT codes 55881 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation*) and 55882 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed*) as possible references because they are valued in the non-facility setting, but they include very high-cost disposable supplies and equipment that are specific to the CPT codes including SA136 (TULSA–PRO Disposable Kit) and EQ410 (TULSA–PRO TDC Cart), as well as some other direct PE inputs that may not be typical for CPT code 61715.

We also considered partial crosswalks of CPT codes for portions of CPT code 61715, such as CPT codes 77372 (*Radiation* treatment *delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based*), 61800 (*Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)*), 61736 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*), and 61796 (*Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion*), but these codes have similar challenges related to the facility-only pricing and/or direct PE inputs that would not be applicable to or typical for CPT code 61715.

Given these challenges, we are seeking comments on appropriate non-facility direct PE inputs (clinical labor, disposable supplies, and medical equipment), and/or appropriate crosswalk codes for non-facility direct PE inputs for CPT code 61715. We would also consider a non-facility direct PE RVU crosswalk (in lieu of establishing specific non-facility direct PE inputs) for CPT code 61715 if that PE RVU could be substantiated by commenters. We note that we would not consider the MACs' established payment for the predecessor CPT code 0398T, particularly outlier payment rates, as substantiation for a PE RVU crosswalk for CPT code 61715 because there was significant variation among the MACs' payment for CPT code 0398T, some of which did not establish payment in the non-facility. Additionally, the established MAC payments do not differentiate between work, PE, and malpractice, making it difficult to establish a reasonable PE RVU for CPT code 61715 based on MAC payment alone. We received a second letter from an interested party stating that the previous non-facility payment rate for CPT code 0398T was $9,750, but we note that this payment rate is a significant outlier payment based on the reported range of payments from the MACs in April 2022. The range of reported payments in the facility setting reported by the MACs in April 2022 for CPT code 0398T was $440.50 to $20,842.19, and $1,554.58 to $2,036.75 when the highest and lowest outliers were removed. Of note, when the outliers were removed from the range, the established payment by the MACs for CPT code 0398T are commensurate with the established national facility pricing of $1,180 for CPT code 61715. In April 2022, only one MAC reported an established non-facility payment of $2,036.75, therefore, we are unable to substantiate the interested parties' statement about a non-facility payment of $9,750 and are seeking comments on any additional information about the established MAC payments for CPT code 0398T that we could use to consider non-facility pricing for CPT code 61715.The second interested party requested contractor-pricing for CPT code 61715 for CY 2026. We note that, in an effort to temporarily resolve this issue for CY 2025, we implemented the PC/TC splits for CPT code 61715, with contractor-pricing for the global and technical components, to restore MAC discretion when it came to pricing this service. Therefore, for CY 2026, we are seeking comments on national pricing options in the non-facility setting to address it permanently. We are also seeking comments in the form of clinical evidence to support the appropriateness of this service in the non-facility setting and the appropriateness of the established PC/TC split for CPT code 61715.

(17) Percutaneous Interlaminar Lumbar Decompression (CPT Codes 62XX0 and 62XX1)

In September 2024, CPT created two new Category I codes to replace existing Category III code 0275T. CPT codes 62XX0 (*Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; one insterspace, lumbar*) and 61XX1 (*Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (that is, CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure*) were surveyed for the January 2025 RUC meeting. CPT code 62287 (*Decompression percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar*) was not surveyed as part of the code family due to low utilization (approximately 100 claims in 2023 per the RUC). Specialty societies stated that a code change application requesting the deletion of CPT code 62287 will take place for the 2026 CPT cycle.

We are proposing the RUC-recommended work RVUs for both CPT code 62XX0 (8.00) and CPT code 62XX1 (4.25) without refinement. We are also proposing the RUC-recommended direct PE inputs without refinement for both CPT code 62XX0 and 62XX1.

(18) Percutaneous Decompression of Median Nerve (CPT Code 647XX)

In September 2024, the CPT Editorial Panel created a new CPT code to report percutaneous decompression of the median nerve at the carpal tunnel using ultrasound guidance and a balloon

dilation device while transecting the transcarpal ligament: CPT code 647XX (*Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance*). For CY 2026, the RUC-recommended a work RVU of 2.70 for CPT code 647XX.

We are proposing the RUC-recommended work RVU of 2.70 for CPT code 647XX. We would like to note that CPT code 647XX is a new technology procedure, previously reported with an unlisted code, and we received external input suggesting the RVU should be 6.00, which is much higher than the RUC recommendation. However, a review of similarly timed procedures does not support an RVU greater than the RUC recommendation of 2.70. The RUC's valuation for CPT code 647XX is very typical for a procedure code with the same work time values (that is, 20 minutes intra-service time and 57 minutes of total time) and has a typical intensity for this kind of procedure.

We are proposing the RUC-recommended direct PE inputs for CPT code 647XX without refinement.

(19) Baroreflex Activation Therapy (CPT Codes 64XX5, 64XX6, 64XX7, 64XX8, 64XX9, 64X10, 93XX4, and 93XX5)

Baroreflex activation therapy (BAT) treats heart failure symptoms and resistant hypertension by electrically stimulating carotid baroreceptors within the carotid artery. The BAT modulation system received FDA approval in August 2019, and the CPT Editorial Panel approved conversion from a Category III code set to a Category I code set at the September 2024 CPT Panel meeting through the creation of the following CPT codes: 64XX5 (*Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (that is, total system), and intraoperative interrogation and programming*), 64XX6 (*Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only*), 64XX7 (*Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only*), 64XX8 (*Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator*), 64XX9 (*Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator; lead only*), 64X10 (*Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator; pulse generator only*), 93XX5 (*Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (for example, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming, including optimization of tolerated therapeutic level setting*), and 93XX4 (*Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (for example, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming*). This code family describes the implantation, replacement, revision, removal and interrogation/programming of a BAT modulation system and was surveyed for the January 2025 RUC meeting.

We are proposing the RUC's recommended work RVU for seven of the eight codes in the Baroreflex Activation Therapy family. We are proposing a work RVU of 11.00 for CPT code 64XX5, a work RVU of 11.30 for CPT code 64XX6, a work RVU of 8.01 for CPT code 64XX7, a work RVU of 12.13 for CPT code 64XX8, a work RVU of 8.95 for CPT code 64XX9, a work RVU of 8.23 for CPT code 64X10, and a work RVU of 0.90 for CPT code 93XX5.

We disagree with the RUC's recommended work RVU of 0.79 for CPT code 93XX4 and we are instead proposing a work RVU of 0.65 based on a crosswalk to CPT code 93279 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber*), which was the top reference code from the survey. We believe that it is more accurate to base the work valuation for CPT code 93XX4 on this crosswalk to CPT code 93279 due to the close clinical similarity between the two procedures (both of them cardiac device evaluations) which share the same intraservice work time of 10 minutes and the same total work time of 22 minutes.

The RUC recommended the survey 25th percentile work RVU of 0.79 for CPT code 93XX4, stating that CPT code 93XX4 has a higher estimated intensity and complexity than the two key reference services (including CPT code 93279). However, we do not agree that CPT code 93XX4 should be valued at a higher work RVU based on the intensity for a clinically similar device evaluation code like CPT code 93279. The RUC's recommended work RVU of 0.79 results in an intensity for CPT code 93XX4 which is close to 40 percent higher than the intensity for peer CPT code 93XX5. We do not believe that this results in an accurate valuation for the two new codes given that CPT code 93XX4 describes cases where the BAT device is working properly and does not require adjustment, whereas CPT code 93XX5 describes cases where the BAT device is working properly but requires additional device programming. We believe that CPT code 93XX5 should have the higher intensity given the additional device programming required in this code to achieve optimal therapeutic levels for the BAT device. Therefore, we are proposing a work RVU of 0.65 for CPT code 93XX4, which we believe reflects more accurate relativity between CPT code 93XX4 and CPT code 93XX5.

We are proposing the direct PE inputs as recommended by the RUC for CPT codes 64XX5–64X10. For CPT codes 93XX4 and 93XX5, we disagree with the RUC- recommended use of the RN (L051A) clinical labor type. These kinds of device evaluation procedures typically do not make use of RN clinical labor; for example, reference codes 93279 and 93281, which were used as a model for the direct PE inputs of these two new codes, both use a combination of the RN/LPN/MTA blend (L037D) and Medical/Technical Assistant (L026A) clinical labor types. Therefore, we are proposing to refine the clinical labor for CPT codes 93XX4 and 93XX5 from RN (L051A) to the RN/LPN/MTA blend (L037D); we are proposing that the numerical values for each clinical labor input will remain the same, with only the staff type changing from L051A to L037D. We are proposing the rest of the RUC-recommended PE inputs without refinement.

(20) Percutaneous Electrical Nerve Field Stimulation (CPT Code 64X11)

In September 2024, the CPT Editorial Panel created a new CPT code to report percutaneous electrical nerve field stimulation of cranial nerves: CPT code 64X11 (*Percutaneous electrical nerve field stimulation, cranial nerves, without implantation*). For CY 2026, the RUC-recommended a work RVU of 1.50 for CPT code 64X11.

We are proposing the RUC-recommended work RVU of 1.50 for CPT code 64X11, and the RUC-recommended direct PE inputs without refinement.

(21) Laminotomy—Repair of Disc Defect (CPT Code 6XX13)

In September 2024, the CPT Editorial Panel created a new add-on code to report the repair of an annular defect by implantation of a bone anchored annular closure device after a laminotomy (hemilaminectomy): CPT code 6XX13 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)*). CPT codes 63030 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar*) and 63035 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)*) were identified as codes in the same family as CPT code 6XX13, but were recently surveyed in 2022 and discussed in the CY 2023 PFS final rule (87 FR 69495 through 64999). The specialty societies stated that the work for these procedures is unchanged and distinct from the work of the new code, and therefore only surveyed CPT code 6XX13.

For CY 2026, we are proposing the RUC-recommended work RVU of 2.50 for CPT code 6XX13. There are no direct PE inputs for CPT code 6XX13.

(22) Cerebral Perfusion & CT Angiography-Head & Neck (CPT Codes 70496, 70498, 70XX1, 70XX2, and 70XX3).

In May 2024, the CPT Editorial Panel created three new codes for cerebral perfusion and CT angiography of the head and neck: CPT code 70XX1 (*Computed tomographic angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing*), CPT code 70XX2 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)*), and 70XX3 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy*). Codes 70XX1, 70XX2, and 70XX3 were surveyed for the September 2024 RUC meeting, along with the existing standalone codes for CTA head and CTA neck in this code family: CPT code 70496 (*Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing*) and CPT code 70498 (*Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing*).

We are proposing the RUC-recommended work RVU of 2.50 for CPT code 70XX1, the work RVU of 0.77 for CPT code 70XX2, the work RVU of 1.00 for CPT code 70XX3, and the work RVU of 1.75 for both CPT codes 70496 and 70498.

We are proposing the RUC-recommended direct PE inputs for CPT codes 70XX1, 70XX2, 70XX3, 70496, and 70498 without refinement.

(23) Coronary Atherosclerotic Plaque Assessment (CPT Code 75XX6)

In September 2024, the CPT Editorial Panel created new Category I CPT code 75XX6 (*Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified health care professional*) and deleted the four existing Category III CPT codes associated with coronary atherosclerotic plaque assessment.

We are proposing the RUC-recommended work RVU of 0.85 for CPT code 75XX6. For the direct PE inputs, these recommendations also include a new supply item, Plaque Characterization Analysis Software, that lists a per-patient fee of $1500 for the plaque data analysis summary generated by the vendor. This RUC-recommended supply item accounts for the overwhelming majority of this CPT code's PE valuation. We continue to have concerns that software analysis fees are not well accounted for in our direct PE methodology, as discussed for CPT code 75580 (*Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*) in our CY 2024 final rule (88 FR 78901); however, we recognize that the analysis represents a significant part of the resource costs associated with this procedure.

Similar to our previously finalized policy for CPT code 75580, we are therefore proposing to identify a crosswalk code for CPT code 75XX6 based on the OPPS assignment for the current coding under which this service is paid, Category III CPT code 0625T (*Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography*). We are proposing to crosswalk the PE RVU for CPT code 75XX6 to the PE RVU for CPT code 77373 (*Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions*), which is a PE-only code with no work RVU and which closely approximates the OPPS assignment previously employed by Category III CPT code 0625T. As we have previously stated in rulemaking, we believe that crosswalking the PE RVU for CPT code 75XX6 to a code with similar resource costs (CPT code 77373) allows CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 75XX6, which would not typically be considered direct PE under our current methodology (86 FR 65038 and 65039).

(24) Use of the Relationship Between OPPS APC Relative Weights To Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT Codes 77387, 77402, 77407, 77412, and 77417), Superficial Radiation Treatment (CPT Codes 77X05, 77X07, 77X08, and 77X09), and Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

A. Background

We typically establish two separate PE RVUs for services that can be furnished in either a nonfacility setting, such as a physician's office, or a facility setting, such as a hospital. The nonfacility PE RVUs reflect all the direct and indirect practice expenses involved in furnishing a particular service when the entire service is furnished in a nonfacility setting. The facility PE RVUs reflects the direct and indirect practice expenses associated with furnishing a particular service in a setting such as a hospital, where those facilities incur a portion of the costs and receive a separate Medicare payment for the service. The types of costs covered by the facility fee are comparable to the PE costs incurred by physicians in non-facility settings, namely direct and indirect costs. For certain services, such as radiation treatment delivery services, the coding itself reflects differing types of resources associated with furnishing the service—from coding describing the technical aspects of the treatment delivery only, which do not include any physician work, to codes that describe both the physician work and the technical resources associated with that work. The former services are valued through information on the direct practice expenses, whereas the latter are valued through the resource costs associated with the physician work and any applicable direct practice expenses.

When services are furnished in the facility setting, such as a Hospital Outpatient Department (HOPD) or an Ambulatory Surgical Center (ASC), the total combined Medicare payment (made to the facility and the professional) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting. This payment difference is largely based on differences in statutory provisions that specify how payment amounts are determined under the PFS and under facility payment systems, like the Hospital Outpatient Prospective Payment System (OPPS). CMS has received feedback from interested parties that the difference reflects the greater costs that facilities incur than those incurred by practitioners furnishing services in offices and other nonfacility settings. For example, interested parties have indicated that hospitals incur higher overhead costs because they maintain the capability to furnish services 24 hours a day and 7 days per week, generally furnish services to higher acuity patients than those who receive services in physicians' offices, and have additional legal obligations such as complying with the Emergency Medical Treatment and Labor Act (EMTALA). Additionally, hospitals incur expenses to meet conditions of participation and ASCs incur expenses to meet conditions for coverage in order to participate in Medicare; many of these conditions are not applicable in nonfacility settings.

While we receive recommendations from the RUC that include information on resource costs, this information relies heavily on the voluntary submission of information by individuals furnishing the service. Furthermore, in the case of certain direct costs, such as the price of high-cost disposable supplies and expensive capital equipment, even voluntary information has been very difficult to obtain or validate. Such incomplete, small sample, potentially biased or inaccurate resource input costs may distort our valuation of the nonfacility PE RVUs used in calculating PFS payment rates for individual services. As MedPAC noted in their comment to the CY 2011 PFS proposed rule, ''using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers might not result in objective and accurate prices because each group has a financial stake in the process''. We have repeatedly stated, such as in the CY 2018 final rule, that ''we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs'' (82 FR 52998).In addition to the difficulty we face in obtaining accurate information about some of the direct PE inputs, the data used in the PFS PE methodology can often be outdated. Although we received updated PPI survey information from the AMA, we are not proposing to utilize this new data in our practice expense methodology due to concerns we identified in section II.B. of this proposed rule. We refer readers there for further discussion.

Under the PFS, we strive to maintain relativity in a variety of ways. For example, we typically review the work RVUs, physician time, and direct PE inputs for all codes within families of codes. We also routinely compare work RVUs across services with similar clinical characteristics, global periods, etc. For direct PE inputs, we routinely make standardized assumptions regarding the typical involvement of clinical staff or use of medical equipment based on the kind of service being furnished.

However, we also recognize that the utility of using the exact same methodologies to establish and maintain appropriate relativity under the PFS can be especially limited for services that are difficult to compare to other PFS services. Radiation treatment delivery services are a clear example of this dynamic. Generally, the PFS practice expense methodology serves the purpose of using direct cost and professional work data to assign relative value units to services. In establishing nonfacility PE RVUs, these settings include physician offices for a range of kinds of care and specialties as well as independent clinics/suppliers. However, the costs for furnishing radiation treatment delivery services in nonfacility settings (that is, freestanding radiation therapy centers) include capital-intensive and specialized resources that are difficult to compare to the kinds of resources involved in furnishing most other kinds of services in other nonfacility settings. For example, the sum of the current prices for the equipment inputs used in the PE calculations for radiation treatment delivery services (*i.e.,* $3,000,966 for ER089 (IMRT accelerator) and $773,104 for ER056 (radiation treatment vault)) is well over twice the price of the next most expensive piece of equipment ($1,559,013 for EL008 (room, MR) used in furnishing other types of services in other nonfacility settings. Furthermore, other inputs for capital equipment over $1 million are utilized in a wide array of services for multiple specialties, while the equipment inputs for radiation treatment delivery services are more specialized in that they are used in a small number of services and predominantly in radiation oncology. We have long had difficulty understanding how best to characterize the costs associated with architectural infrastructure needs prompted by use of linear accelerators. In the CY 2016 PFS final rule (80 FR 70953), we stated that we believe at least some portions of the costs associated with the radiation treatment vault construction are indirect PE under the established methodology. We most recently noted this difficulty in CY 2021 PFS rulemaking when addressing our inability to use the recommended direct PE inputs for proton beam therapy services (85 FR

84625). We described difficulty using invoices provided, given that they did not separately identify the direct PE inputs (that is, cost of the equipment) from that of the infrastructure needs surrounding the equipment. For the CY 2016 PFS final rule (80 FR 70954), technical PFS rate setting concerns related to how costs were allocated to different codes based on presumptions about costs of image guidance, prompted CMS to maintain the HCPCS G-codes under the PFS in use for reporting radiation treatment delivery services instead of newly introduced CPT codes. (These HCPCS G codes, which mirrored the coding structure prior to the newly introduced CPT codes, were developed for CY 2015 PFS rulemaking in order to allow CMS to include the changes to radiation treatment delivery services in the CY 2016 PFS proposed rule). At that time, CMS adopted the new CPT codes for use under the OPPS, where payment calculations did not suffer from the same problems. Since that time, outpatient radiation therapy services have been reported to Medicare using two different sets of HCPCS codes, depending on whether the services are provided in a HOPD or in a nonfacility setting paid under the PFS.

For CY 2026, the CPT Editorial Panel has again revised the codes describing radiation treatment delivery services. This presents an opportunity both to consider adopting CPT codes under the PFS and to re-examine how to best assign relative value units to radiation treatment delivery and superficial radiation treatment delivery services under the PFS. If we were to utilize the RUC-recommended direct PE inputs and new RUC PE survey data to value the new, newly payable, and revised codes in these code families, valuation, and ultimately payment, for these services would be subject to the additional volatility associated with small sample surveys, the unique dynamic of capital-intensive costs, and voluntarily submitted invoice data.

We considered the RUC recommended PE inputs for the new, and revised codes listed above in the context of the concerns we outlined above. Specifically, we considered how PE is allocated for under the standard methodologies and noted that radiation treatment delivery and superficial radiation treatment services require long-term capital and infrastructure investments more like facility costs than most other services paid under the PFS. Therefore, we have determined that identifying an alternative data source that is more routinely updated and standardized would improve the accuracy of valuation for these services.

One alternative data source that we have examined is the use of OPPS cost data to develop PE RVUs. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. Under contract with CMS, RAND Corporation (''RAND'') examined the feasibility of using OPPS cost data in developing PE RVUs.[51] [52] RAND noted that ''if OPPS-based costs were used to construct total PE RVUs, the valuation process would also be streamlined by using a single data source, thereby eliminating the valuation complexities posed by having separate direct and indirect cost RVU pools.'' RAND identified a number of methodological issues that would need to be resolved to utilize OPPS cost data for all PFS services but found that the potential benefits justified investments to further develop this option. RAND noted that using OPPS data ''might not be appropriate for the entirety of services in the MPFS and the advisability of using OPPS data should be evaluated by categories of costs and/or services.'' Considering that the resources involved in furnishing radiation treatment delivery and superficial radiation treatment delivery services seem to be primarily driven by capital costs that aren't as likely to vary greatly between facilities like hospitals and free standing centers, and because the billing codes for the services (both old and new) are already stratified into professional and technical services, these services have obvious characteristics that make use of OPPS data particularly appropriate. Additionally, use of routinely updated, auditable, and standardized cost data from hospital cost reports that is currently used in setting rates under the OPPS offers the possibility of long-term stable rates that many interested parties have long sought and that may be helpful in maintaining access to care for capital-intensive services. Consequently, we believe that using OPPS data in setting the relative rates for these kinds of services represents the best source for improved valuation of practice expense in free-standing radiation centers.

We have long noted that data obtained from hospital cost reports is regularly updated, auditable, and required to adhere to national standards for reporting. For example, in the CY 2015 PFS final rule (79 FR 67569), we noted that ''routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our usual methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year''.

Under OPPS, services are grouped based on clinical characteristics and resource costs into Ambulatory Payment Classifications (APCs). The OPPS methodology utilizes charges from claims data and cost-to-charge ratios developed from cost report data to establish the geometric mean costs for each APC. APC payments are in turn based on the geometric mean costs associated with the services within the APC.

While the costs involved in furnishing technical services in the facility setting could generally be expected to be greater than or equal to those of providing the same service in the nonfacility setting, we believe that the *relationship* of the costs of services within a code family under the PFS would likely mirror the relationship of those costs of services under the OPPS. (The Ambulatory Surgical Center (ASC) fee schedule, which relies on OPPS relative weights multiplied by an ASC conversion factor, is an example of using the same underlying data to establish relative values in two payment systems while continuing to recognize differences in cost structure between settings). For example, if ''service A'' is twice as costly under the OPPS as ''service B'', it is reasonable to assume that the resource costs of ''service A'' are twice as costly as ''service B'' under the PFS. We would expect that the relationship between the resources involved in furnishing services within the same code family under the OPPS would be similar under the PFS. Given that the APC is the payment unit under the OPPS, we believe that applying the relationship of the APC relative weights to the codes within the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families is the most accurate and transparent mechanism to translate the

[51] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

[52] Burgette, Lane F., Joachim O. Hero, Jodi L. Liu, Catherine C. Cohen, Barbara O. Wynn, Katie Merrell, et al. Practice Expense Data Collection and Methodology.'' RAND Corporation, November 1, 2021. *https://www.rand.org/pubs/research_reports/RRA1181-1.html.*

relationship of the cost data under the OPPS to the PFS. This approach would help to mitigate volatility in relativity among services that would be attributable to small sample surveys, voluntarily submitted invoice data, or PE allocation methodologies that are not designed primarily for capital-intensive costs in architecture and medical equipment as costly as linear accelerators. Therefore, we are proposing to use this relationship between the relative weights of the OPPS APCs to which the codes in these families are assigned to value the PE portion of the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families. We are proposing to use the CY 2026 proposed OPPS APC relative weights and to update these in the final rule based on the updated OPPS APC relative weights. The OPPS APC relative weights can be found in ''Addendum B'' under ''OPPS Addenda'' under the most recent proposed or final rule listed at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* We are also proposing to value the MP RVUs for the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families with our usual methodology for PE-only services.

While we believe that the relationship between services within the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families are well approximated by the relationship between those services under the OPPS, we recognize that the RVUs for these groups of services must reflect the resources involved in furnishing services relative to other services paid under the PFS. As such, the proposed PE RVUs for the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families, which are based on the relationship of the relative weights of the OPPS APCs to which these codes are assigned, were calculated using the portion of total PE and MP RVUs accounted for by the volume and PE RVUs of these families as they existed in CY 2025. In other words, we calculated the RVUs for these codes so that the overall PE and MP RVUs for these services represent the same share of total PE and MP RVUs in CY 2025 and CY 2026.

Under the PE methodology, the allocation of indirect PE for a given family of services impacts the allocation of indirect PE for other services furnished by the specialties that furnish that family of services (''relevant specialties''). This results from specialty-specific calculations that occur in steps 12 through 15, described in section II.B. of this proposed rule, that are impacted by the size of the pool of indirect allocators (that is, work RVUs and direct costs) for each specialty. Since the codes in these families have historically contained direct PE inputs, and have historically been allocated indirect PE RVUs using the usual methodology, the proposed PE RVUs for CY 2026 have been calculated in a manner that maintains the same effect on the indirect allocation for other services had the PE RVUs been calculated under the usual methodology. In other words, in calculating the proposed PE RVUs for CY 2026, we approximated the direct costs for these services and allocated indirect PE RVUs per the standard methodology in order to both arrive at PE RVUs based on the proposal described above and also maintain relativity with the PE RVUs across the fee schedule. We have included those approximated direct costs in the downloads section of our website to facilitate transparency. We note that the direct PE input public use file does not include these proxy inputs since they only serve the purpose of stabilizing the PE allocated to other services. We seek comments on this aspect of the methodology in particular, especially given our interest in transparency in rate setting.

We are seeking comments on our proposal to use the relative relationship between the proposed OPPS APC relative weights to establish the PE RVUs for these code families.

We believe that this proposal will improve the accuracy of the relative values established for these services and prevent reliance on irregularly updated information for establishing and maintaining payment for these services under the PFS. Additionally, we believe that the alignment of coding, underlying cost data and billing units between settings paid under the PFS and OPPS will have additional salutary effects, especially in price transparency for patients and payers.

B. Radiation Oncology Treatment Delivery (CPT Codes 77387, 77402, 77407, 77412, and 77417)

At the September 2024 CPT Editorial Panel meeting, the Panel approved the revision of CPT codes 77402, 77407 and 77412 to establish a technique-agnostic family of codes and bundle imaging into the three CPT codes, and the deletion of CPT codes 77385, 77386 and 77014. The related guidelines and tables were all updated to reflect the consolidated services for radiation oncology treatment delivery. These services were subsequently reviewed by the RUC and a valuation recommendation was submitted to CMS for inclusion in CY 2026 rulemaking. Please see Table 14 for the current and CY 2026 code descriptors (where applicable) for the CPT codes in this family.

TABLE 14: COMPARISON BETWEEN CURRENT AND CY 2026 LONG DESCRIPTORS

HCPCS	Current Long Descriptor	CY 2026 Long Descriptor
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day	Deleted
77402	Radiation treatment delivery, >=1 MeV; simple	Radiation treatment delivery; Level 1 (for example, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed
77407	Radiation treatment delivery, >=1 MeV; intermediate	Radiation treatment delivery; Level 2, single isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed
77412	Radiation treatment delivery, >=1 MeV; complex	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (for example, 2D, 3D, or IMRT) OR a single isocenter photon therapy (eg, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple	Deleted
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex	Deleted
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed	
77014	Computed tomography guidance for placement of radiation therapy fields	Deleted
77417	Therapeutic radiology port image(s)	

Although these CPT codes were established for CY 2015, CMS has not used them for payment under the PFS. In October 2013, the CPT Editorial Panel created CPT codes 77402, 77407, 77412, 77385, 77386 and 77387, which were reviewed at the January 2014 RUC meeting for CY 2015. Previously, radiation treatment delivery had been reported with 17 CPT codes. CMS identified concerns with the packaging of Image-guided Radiation Therapy (IGRT) into some of the delivery codes in the family and not others. As a result, CMS created 17 HCPCS G-codes, to mirror the existing codes (at the time), maintained CPT code 77014, and established values that linked directly to the existing values/inputs for the PFS. Table 15 includes the HCPCS G-codes and their long descriptors.

TABLE 15: HCPCS G-CODES FOR RADIATION TREATMENT DELIVERY

HCPCS	Long Descriptor
G6001	Ultrasonic guidance for placement of radiation therapy fields
G6002	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy
G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev
G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6-10 mev
G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11-19 mev
G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20 mev or greater
G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: up to 5 mev
G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 6-10 mev
G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 11-19 mev
G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 20 mev or greater
G6011	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 mev
G6012	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10 mev
G6013	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19 mev
G6014	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 mev or greater
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg,3d positional tracking, gating, 3d surface tracking), each fraction of treatment

Over the past several years, the Radiation Oncology community met with CMS and CMMI to address the concerns identified by CMS in the 2015 code set as well as the possibility of creating an episode-based alternative payment approach for radiation therapy services. The G-codes were identified in a Relativity Assessment Workgroup (RAW) screen (CMS/Other source with 2019 estimated Medicare utilization over 20,000). The RAW did not agree with the specialty societies' request to maintain the current valuation. As a result, the CPT Editorial Panel reviewed the radiation oncology delivery treatment family at the September 2024 CPT meeting and established a technique-agnostic family of codes and bundled imaging into all three services. The Panel approved the revision of CPT codes 77402, 77407 and 77412 and the deletion of 77385, 77386 and 77014. The specialty societies have also requested that CMS delete the related G-codes, G6001 through G6017. As stated previously, we have not recognized the radiation treatment delivery CPT codes for payment under PFS and have instead used the G-codes to describe these services, based primarily on concerns related to how the conventional practice expense methodology applies to these services. For CY 2026, we are proposing to delete the 17 G-codes and recognize the newly revised CPT codes for payment under the PFS, in conjunction with our proposal to utilize OPPS cost data to establish PE RVUs, as previously described.

We are proposing the RUC-recommended work RVU of 0.70 for the single code in the family that has a physician work component, CPT code 77387.

We are proposing to utilize the relationship between the proposed OPPS APC relative weights for APCs 5621, 5622, and 5623 to inform the valuation of PE-only CPT codes 77402, 77407, and 77412 when paid under the PFS. As described above, we believe that the relationship between the OPPS APC relative weights more accurately reflects the relative resource costs associated with furnishing these services.

To facilitate the use of the relationship of the OPPS APC relative weights to establish PE RVUs for radiation treatment delivery services, we believe it is important to standardize the billing units and bundling rules between the settings. That is, services in this code family that describe technical costs and are not separately payable under the OPPS will not be separately payable under the PFS, because the associated costs are incorporated into the costs for separately paid codes. As a result, the proposed PE RVUs for the

services in this code family, which are developed based on the relationship of the APC relative weights to which services in this family are assigned, include a redistribution of the PE RVUs from the newly bundled services to the other services in that family, as described below.

In an effort to align the relationship between the PFS payment for this code family with the OPPS payment, we are proposing to assign Procedure Status ''B'' to the technical component of CPT code 77387 to maintain consistency with OPPS payment for this code, which is packaged into payment for the treatment delivery codes, CPT codes 77402, 77407, and 77412, and therefore is not separately payable under the OPPS. As described in section II.B. of this proposed rule, typically, when services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. In the case of CPT code 77387, we are proposing that the PE and total RVU for the global service will equal the PE and total RVU for the professional component only because the technical component is not separately payable under the PFS since the relative resources are included in the valuation of another code (treatment delivery). We are proposing to display CPT code 77387 in Addendum B with the professional and technical components, where the technical component has non-payable Procedure Status ''B,'' as well as the global service equal to the payable professional component, We are also seeking comment on strategies to mitigate billing confusion that could result from this relatively novel circumstance where the technical component of a service is bundled but the professional component is separately reported. Specifically, we are seeking comments on whether displaying the global service equal to the professional component is problematic, and if it would be preferable to eliminate the global code and display only the professional and technical components in Addendum B.

Similarly, for PE-only CPT code 77417 (*Therapeutic radiology port image(s)*), we are proposing to assign Procedure Status ''B'' to align with OPPS payment for this code, which is packaged into payment for the treatment delivery codes, CPT codes 77402, 77407, and 77412 and therefore would not be separately reportable under the PFS. Similarly, of course, it is packaged under the OPPS.

C. Superficial Radiation Therapy (CPT Codes 77X05, 77X07, 77X08, and 77X09)

Superficial radiation therapy is currently provided using CPT code 77401 (*Radiation treatment delivery, superficial and/or ortho voltage, per day*) in conjunction with CPT code 77280 (*Therapeutic radiology simulation-aided field setting; simple*) and HCPCS code G6001 (*Ultrasonic guidance for placement of radiation therapy fields*).

In October 2020, HCPCS code G6001 was identified by the RAW via the CMS/Other Medicare utilization over 20,000 screen. In January 2021, the RUC recommended referring G6001 to CPT to develop new code(s) that reflect the different process of care between the two specialties (dermatology and radiation oncology). After a 2-year delay to allow time for re-review, the CPT Editorial Panel created four codes and a new subsection to report surface radiation therapy in September 2024. These codes will replace CPT code 77401 and HCPCS code G6001 which were scheduled for deletion by the CPT Editorial Panel and recommended for deletion by CMS, respectively. This code family was surveyed for the January 2025 RUC meeting.

The new codes are as follows:

- 77X05: *Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting.*
- 77X07: *Surface radiation therapy, superficial, delivery, <150 kV, per fraction (e.g., electronic brachytherapy).*
- 77X08: *Surface radiation therapy, orthovoltage, delivery, >150–500 kV, per fraction.*
- 77X09: *Surface radiation therapy, superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to the code for primary procedure).*

We are proposing the RUC-recommended work RVU for the two codes in the family that have a work RVU. We are proposing a work RVU of 0.77 for CPT code 77X05 and a work RVU of 0.30 for CPT code 77X09.

Similar to our approach for the radiation oncology treatment delivery codes discussed above, we believe that using the relationship between the relative weights of the OPPS APCs to which codes in this family are assigned likely more accurately reflect the actual costs of these services compared to use of direct PE input and PE allocation methodologies. Therefore, similar to our proposal for radiation treatment delivery services, we are proposing to use this relationship to establish the RVUs for the PE portion of these services.

We are proposing to utilize the relationship between the proposed OPPS APC assignments for APCs 5621 and 5732 to inform the valuation of PE-only CPT codes 77X07 ((*Surface radiation therapy, superficial, delivery, <150 kV, per fraction (eg, electronic brachytherapy)*)) and 77X08 (*Surface radiation therapy, orthovoltage, delivery, >150–500 kV, per fraction*), and for the technical component of CPT code 77X05 (*Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting*) when paid under the PFS.

In an effort to align the relationship between the PFS payment for this code family with the relationship of the OPPS information used to develop the RVUs, we are proposing to assign Procedure Status ''B'' to the technical component of CPT code 77X09 to align with OPPS of this code whose costs are packaged into payment for the treatment delivery CPT codes 77X07 and 77X08. We are proposing to display CPT code 77X09 in Addendum B with the professional and technical components, where the technical component is non-payable Procedure Status ''B,'' as well as the global service equal to the payable professional component, but are seeking comment on strategies to mitigate possible billing confusion that could result from this relatively novel circumstance where the technical component of a service is bundled but the professional component is separately reported. Specifically, we are seeking comments on whether displaying the global service equal to the professional component is problematic, and if it would be preferable to eliminate the global service and display the professional and technical components only in Addendum B.

TABLE 16: SUMMARY OF CODING PROPOSALS FOR RADIATION ONCOLOGY TREATMENT DELIVERY AND SUPERFICIAL RADIATION THERAPY CODES

CPT Code-Modifier	Long Descriptor	OPPS Payment Status	OPPS Proposed APC	PFS Procedure Code Status	PE Only Code?
77402	Radiation treatment delivery; Level 1 (eg, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed	S	5621	A	✓
77407	Radiation treatment delivery; Level 2, single isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed	S	5622	A	✓
77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (eg, 2D, 3D, or IMRT) OR a single isocenter photon therapy (eg, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed	S	5623	A	✓
77417	Therapeutic radiology port image(s)	N	N/A	B	
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed	N	N/A	A	
77387-26 Professional component				A	
77387-TC Technical component				B	
77X05	Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting	S?	5732	A	
77X05-26 Professional component				A	
77X05-TC Technical component				A	
77X07	Surface radiation therapy, superficial, delivery, <150 kV, per fraction (eg, electronic brachytherapy)	S?	5621	A	✓
77X08	Surface radiation therapy, orthovoltage, delivery, >150-500 kV, per fraction	S?	5621	A	✓
77X09	Surface radiation therapy, superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to the code for primary procedure)	N	N/A	A	
77X09-26 Professional component				A	
77X09-TC Technical component				B	

D. Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

PFS payment amounts for proton beam treatment delivery services are currently determined by local Medicare Administrative Contractors (MACs). As discussed in CY 2021 rulemaking (85 FR 84625 through 84626), we have not previously established RVUs for these services due to the unique nature of the equipment costs associated with these services compared to other capital costs addressed by our usual PE methodology. Given the proposals described above to establish RVUs for the new and revised CPT codes for Radiation Oncology and Superficial Radiation Treatment Delivery Services, we are seeking comments on whether we should adopt a similar approach to establish RVUs for

proton beam treatment delivery services. We note that these services are assigned to APCs 5623 and 5625 under the OPPS with established Medicare payment rates (unlike the contractor pricing in place for these services under the PFS). We are specifically seeking comments on how we might establish national pricing and total RVUs for these services to maintain relativity within the PFS. For example, would using the overall ratio between OPPS and PFS payment for radiation oncology treatment services to establish initial year RVUs for proton beam treatment delivery services accurately reflect the relative resources involved in furnishing the services? Alternatively, would it be more appropriate to consider the overall difference between the OPPS and Medicare payment as currently determined by the MACs for these services, or are there other alternative methods we should consider? We welcome comments on this topic.

(25) Combination COVID–19 Vaccine Administration (CPT Codes 90480 and 9X16X)

In September 2024, the CPT Editorial Panel created a new add-on code, 9X16X (*each additional component administered (List separately in addition to code for primary procedure)*), to report when each additional non-COVID vaccine component is administered with the COVID–19 vaccine. CPT code 90480 (*Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SAR CoV2) (coronavirus disease [COVID19]) vaccine; first or only component of each vaccine administered*) was revised as part of this family of services.

We received RUC recommendations for CPT code 90480 that affirmed the September 2023 work and PE RUC recommendations. We previously established CPT code 90480 with a procedure status of ''X'' on the PFS and the code is therefore not payable under the PFS. Payment for this CPT code is also addressed under previously finalized policies associated with the emergency use authorization declaration. We refer readers back to the CY 2025 PFS final rule (89 FR 97710) for more information on this previously finalized policy.

We also received RUC recommendations for add-on CPT code 9X16X. The RUC recommendations for this CPT code do not include work or PE inputs as the recommendations suggest that the work and PE is already included in the administration base code and this add-on code is intended for tracking purposes of the second vaccine.

We are proposing to maintain procedure status ''X'' for CPT code 90480 and assign procedure status ''X'' to CPT code 9X16X.

(26) Immunization Counseling (CPT Codes 90XX1, 90XX2, and 90XX3)

In May 2024, the CPT Editorial Panel created three new time-based CPT codes 90XX1, 90XX2, and 90XX3 to report vaccine counseling performed where a vaccine is not administered. CPT code 90XX1 (*Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; 3 minutes up to 10 minutes*), CPT code 90XX2 (*Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 10 minutes up to 20 minutes*) and CPT code 90XX3 (*Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 20 minutes*). These services were surveyed and reviewed at the September 2024 RUC meeting.

In 2022, CMS created six new HCPCS codes so that Medicaid providers could bill for stand-alone vaccine counseling, ''State Health Official Letter #22–002 ''Medicaid and CHIP Coverage of Standalone Vaccine Counseling''.[53] The six HCPCS codes are:

G0310 (*Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 5 to 15 mins time. (This code is used for Medicaid billing purposes.)*)

G0311 (*Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 16–30 mins time. (This code is used for Medicaid billing purposes.)*)

G0312 (*Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 5 to 15 mins time. (This code is used for Medicaid billing purposes.)*)

G0313 *Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 16–30 mins time. (This code is used for Medicaid billing purposes.)*

G0314 *Immunization counseling by a physician or other qualified health care professional for COVID–19, ages under 21, 16–30 mins time. (This code is used for the Medicaid Early and Periodic Screening, Diagnostic, and Treatment Benefit (EPSDT.)*

G0315 *Immunization counseling by a physician or other qualified health care professional for COVID–19, ages under 21, 5–15 mins time. (This code is used for the Medicaid Early and Periodic Screening, Diagnostic, and Treatment Benefit (EPSDT.)*

The RUC requested that CMS delete HCPCS codes G0310–G0313, and replace them with the new CPT codes 90XX1, 90XX2, and 90XX3. However, we are proposing to assign status indicator (''I'') to each of these three services, as not valid for Medicare purposes. Medicare uses other coding for reporting of, and payment for immunization counseling. We are not proposing any work RVUs or PE RVUs for any of the three new CPT codes.

(27) Colon Motility Services (CPT Codes 91XX1 and 91XX2)

In April 2023, the Relativity Assessment Workgroup (RAW) identified CPT codes 91120 and 91122 as reported together 75 percent of the time or more based on 2021 Medicare claims data. The RUC noted that these services are reported together 95 percent of the time and recommended that the specialty societies work with the CPT Editorial Panel to develop a code bunding solution. In May 2024, the CPT Editorial Panel created two new codes, CPT code 91XX1 (*Rectal sensation, tone, and compliance study (for example, barostat)*) and CPT code 91XX2 (*Anorectal manometry, with rectal sensation and rectal balloon expulsion test, when performed*) to describe these services to replace CPT codes 91120 and 91122. The two new codes were surveyed for the September 2024 RUC meeting.

For CY 2026, the RUC-recommended a work RVU of 3.05 for CPT code 91XX1 and 2.70 for CPT code 91XX2. We are proposing these RUC recommendations without refinement.

For the direct PE inputs, we disagree with the RUC-recommended 17 minutes of clinical labor associated with CA013 (Prepare room, equipment and supplies) for CPT code 91XX2.We are proposing a time of 2 minutes for CA013, which is the standard time for this PE input. We are proposing the RUC recommendation of 17 minutes of clinical labor time for CA013 for CPT code 91XX1 to account for a previous

[53] *https://www.medicaid.gov/state-resource-center/downloads/stnd-vacc-cou-spec-hcpcs-codes.pdf.*

input of 15 minutes to calibrate equipment in similar codes. We recognize it is not typical to have different values for the same clinical labor activity across a code family, and we welcome comments as to the appropriateness of these refinements.

We disagree with the RUC-recommended 30 minutes of clinical labor associated with CA024 (Clean room/equipment by clinical staff) for CPT 91XX1 as we believe this is unnecessarily long, and does not match similar services. We are proposing a CA024 time of 10 minutes for both codes (CPT 91XX1 and 91XX2) based off reference CPT code 45300 (*Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)*).

We are also proposing to refine the SM015 supply (Enzymatic detergent) to a quantity of 4 ounces for both codes, to match similar inputs for similar services. We seek comment on the appropriateness of this refinement, as we do not believe that 120 ounces of the SM015 supply would be typical or necessary given that no HCPCS code on the entire PFS uses more than 8 ounces of this supply.

We are proposing all of the other RUC recommendations for direct PE for CPT codes 91XX1 and 91XX2 without refinement.

(28) Dark Adaptation Diagnostic and Screening Services (CPT Codes 92284 and 922X1)

In 2023, the specialty societies prepared and submitted a Category I Code Change Application to create CPT code 922X1 *(Screening dark adaptation measurement (for example, rod recovery intercept time), with interpretation and report),* which describes the screening test for retinal and optic nerve disease. This code was created to differentiate between diagnostic dark adaptation testing and screening testing that has possibly been reported under CPT code 92284 *(Diagnostic dark adaptation examination (for example, rod and cone sensitivities, rod-cone breakpoint), with interpretation and report).* CPT also added a parenthetical to CPT code 92284, to describe how the diagnostic dark adaptation test is conducted in order to identify patients with macular degeneration or inherited retinal diseases when they have symptomatic visual loss without any identifiable cause or clinical examination.

CPT code 92XX1 describes a screening service that has not been determined to be a preventive service under Section 1861 of the Social Security Act and as such is not covered under Medicare. We are proposing to assign status indicator (''N'') to this service, as a non-covered service. We will list the RUC-recommended RVUs for display purposes only.

In the CY 2023 PFS final rule we finalized a work RVU of 0.00 for CPT code 92284 as proposed (87 FR 69513). The RUC had surveyed this procedure in 2021, reviewed the survey results for the procedure and recommended 1 minute of pre-service time, 3 minutes of intra-service time, 1 minute of immediate post-service time, totaling 5 minutes, all of which reduced the surveyed times. The RUC also recommended a work RVU of 0.14. We disagreed with the RUC-recommended work RVU of 0.14 for CPT code 92284. We found that the recommended work RVU did not adequately reflect reductions in physician time, since the diagnostic screening is usually completed during an E/M visit and largely consists of interpreting machine generated results.

For this latest review of CPT code 92284 in CY 2026, we disagree with the RUC-recommended work RVU of 0.32 and are proposing a work RVU of 0.29 for CPT code 92284 based on reference to code CPT 92132 (*Computerized ophthalmic diagnostic imaging (e.g., optical coherence tomography [OCT]), anterior segment, with interpretation and report, unilateral or bilateral*), for which we finalized 0.29 work RVU in the CY 2025 PFS. Our proposed work RVU is also supported by reference to CPT code 71110 (*Radiologic examination, ribs, bilateral; 3 views*), with a work RVU of 0.29. Both reference codes have intra-service work times of 6 minutes and total times of 8 minutes. While the intra-service work time of both reference codes is 1 minute less than the RUC-recommended median survey time for CPT code 92284, they each have 1 minute for pre-service and post-service times. We believe it is more appropriate to use these reference codes than the RUC-recommended cross walk to CPT 92282 *(Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral)* with a work value of 0.32 RVU because we believe the RUC-recommended intra-service work time and work RVU are overstated relative to the current instar-service work time and work RVU for CPT code 92284. Additionally, we also searched for crosswalks to CPT codes the same intra-service time and a range of similar pre-and post-service times and found that the recommended work RVU of 0.32 fell near the top of this range, which would not maintain relativity of the work values among the identified CPT codes.

We are proposing the RUC-recommended direct PE inputs for CPT code 92284 without refinement.

(29) Coronary Therapeutic Services and Procedures (CPT Codes 92920, 92924, 92928, 92933, 92937, 92941, 92943, 92973, 92X01, 92X02, 93571, and 93572)

In the CY 2013 PFS final rule (77 FR 69063 through 69064), we reviewed 13 new codes to describe percutaneous coronary intervention (PCI) services and assigned bundled status to all the add-on codes for the additional branches off the major coronary arteries because we believed that separately paying for branch-level stents may encourage increased placement of stents. To bundle the work of each new add-on code into its respective base code, we used the RUC-recommended utilization crosswalk to determine what percentage of the base code utilization would be billed with the add-on code, and added that percentage of the RUC-recommended work RVU and physician time for the add-on code to the RUC-recommended work RVU and physician time of the base code.

In September 2022, the CPT Editorial Panel created one new Category I CPT code for percutaneous coronary lithotripsy. The new add-on CPT code 92972 (*Percutaneous transluminal coronary lithotripsy*) was reviewed by the RUC on an interim basis for CY 2024 while the entire PCI code family was referred to the CPT Editorial Panel for restructuring. Subsequently, the code family was revised at the February 2024 CPT Editorial Panel meeting, including the deletion of the bundled add-on codes, and surveyed for the April 2024 RUC meeting.

The following is a list of the CPT codes and their long descriptors: CPT codes 92920 (*Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)*), 92924 (*Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)*), 92928 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); one lesion involving one or more coronary segments*), 92933 (*Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)*), 92937 (*Percutaneous transluminal*

revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed, single vessel major coronary artery and/its branches), 92941 (*Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single major coronary artery and/or its branches or single bypass graft and/or its subtended branches*), 92943 (*Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach*), 92973 (*Percutaneous transluminal coronary thrombectomy aspiration mechanical (List separately in addition to code for primary procedure)*), 92X01 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); two or more distinct coronary lesions with two or more coronary stents deployed in two or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch*), 92X02 (*Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches*), 93571 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; initial vessel (List separately in addition to code for primary procedure)*), and 93572 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; each additional vessel (List separately in addition to code for primary procedure)*).We are proposing the RUC-recommended work RVU for all twelve codes in the family. We are proposing a work RVU of 8.35 for CPT code 92920, a work RVU of 10.13 for CPT code 92924, a work RVU of 10.00 for CPT code 92928, a work RVU of 11.94 for CPT code 92933, a work RVU of 11.30 for CPT code 92937, a work RVU of 12.72 for CPT code 92941, a work RVU of 13.69 for CPT code 92943, a work RVU of 1.75 for CPT code 92973, a work RVU of 12.00 for CPT code 92X01, a work RVU of 15.00 for CPT code 92X02, a work RVU of 1.80 for CPT code 93571, and a work RVU of 1.44 for CPT code 93572.

However, we note these work RVUs as recommended by the RUC set new upper ranges for multiple codes in the RUC Database. For example, the proposed work RVU of 12.00 for CPT code 92X01 sets a new upper range on RUC Database searches for 000-day global codes with an intraservice time of 75 minutes, with a previous maximum value of 10.25 work RVUs for CPT code 49614 (*Repair of anterior abdominal hernia(s) (that is, epigastric, incisional, ventral, umbilical, spigelian), any approach (that is, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated*), with the same intraservice time and 165 minutes of total time. Similarly, we shared in the RUC's difficulties finding major surgical procedures with the 000-day global period with similar times to use as potential reference or bracket codes.

The RUC did not recommend, and we are not proposing any direct PE inputs for these facility-based services.

(30) RSV Monoclonal Antibody Administration (CPT Codes 96380 and 96381)

In September 2023, CPT created two Category I codes, 96380 (*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional*) and 96381 ((*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection*) to report administration of respiratory syncytial virus (RSV), monoclonal antibody and seasonal dose, with and without counseling. These codes were effective October 6, 2023 for immediate use. At the time, the RUC did an immediate review of these codes and issued interim recommendations to CMS. The RUC reviewed these codes again at the April 2024 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.28 for CPT code 96380 and 0.17 for CPT code 96381.

We are proposing the RUC-recommended direct PE inputs without refinement. (30) Remote Monitoring (CPT codes 98975, 98976, 98977, 98978, 98980, 98981, 98XX4, 98XX5, 98XX6, 98XX7, 99091, 99453, 99454, 99457, 99458, 99473, 99474, 99XX4, and 99XX5)

In September 2024, the Current Procedural Terminology (CPT) Editorial Panel added one code and made code revisions to report remote physiologic monitoring (RPM) device supply for 2 to 15 days and 16–30 days within a 30-day period to report RPM parameters; created one new code and code revisions to report RPM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; added three remote therapeutic monitoring (RTM) device supply codes to report respiratory, musculoskeletal and cognitive behavioral therapy for 2 to 15 days and 16 to 30 days within a 30-day period; created one new code and made code revisions to report RTM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; and revised remote monitoring guidelines.

Remote physiologic monitoring (RPM) represents the remote monitoring of parameters such as weight, blood pressure, and pulse oximetry to monitor a patient's condition and inform their management. The remote physiologic monitoring code set currently includes CPT codes 99453, 99454, 99091, 99457, 99458, 99473, and 99474 (code descriptors can be found in Table 17). For CY 2026, the CPT Editorial Panel created two new RPM codes to describe RPM services that describe less than 16 days of data transmission per 30-day period and less than 20 minutes of interactive communication per month: CPT codes 99XX4 and 99XX5. The CPT Editorial Panel also made edits to specify the minimum days of data transmission per 30-day period for CPT code 99454 (new code descriptors and revised code descriptors can be found in Table 18). None of the RPM codes (CPT codes 99091, 99474, 99XX5, 99457, and 99458) met the minimum survey requirements established by the RUC for the January 2025 RUC meeting. As a result, the RUC-recommended that CPT codes 99091, 99474, 99XX5, 99457, and 99458 be resurveyed after 1 year of utilization data is available for this CPT 2026 code structure. All RPM codes are expected to be reviewed at the January 2028 RUC meeting.

Remote therapeutic monitoring (RTM) represents the monitoring of adherence

to at-home therapeutic interventions. RTM can be provided for a variety of conditions, and there are distinct device supply codes that have been created for three types of therapeutic monitoring: respiratory system, cognitive behavioral therapy, and musculoskeletal system monitoring. The remote therapeutic monitoring code set currently includes CPT codes 98975, 98976, 98977, 98978, 98980, and 98981 (code descriptors can be found in Table 17). For CY 2026, the CPT Editorial Panel created four new RTM codes to describe RTM services that describe less than 16 days of data transmission per 30-day period and less than 20 minutes of interactive communication per month: CPT codes 98XX4, 98XX5, and 98XX7. The CPT Editorial Panel also made edits to specify the minimum days of data transmission per 30-day period for CPT codes 98976, 98977, and 98978 (new code descriptors and revised code descriptors can be found in Table 18). All of the codes in the RTM family are considered new technology (CPT codes 98975, 98XX4, 98976, 98XX5, 98977, 98XX7, 98XX7, 98980, and 98981) and will be placed on the New Technology list to be reviewed after 3 years of data are available (April 2030).

TABLE 17: CY 2025 REMOTE MONITORING CODES

Code	Long Descriptor
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment

Code	Long Descriptor
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, each 30 days
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, each 30 days
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, each 30 days
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)

TABLE 18: PROPOSED CY 2026 REMOTE MONITORING CODES

Code	Long Descriptor
99453	No changes for CY 2026
99XX4	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial: device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period
99091	No changes for CY 2026
99XX5	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes
99457	No changes for CY 2026
99473	No changes for CY 2026
99474	No changes for CY 2026
99458	No changes for CY 2026
98975	No changes for CY 2026
98XX4	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period
98XX5	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period

98XX6	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period
98XX7	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes
98980	No changes for CY 2026
98981	No changes for CY 2026

A. Valuation for Remote Physiologic Monitoring (RPM)

For CPT code 99091, we disagree with the RUC's recommendation of 0.70 work RVUs and are proposing to maintain the current work RVU of 1.10 and the corresponding physician time inputs. This code, as well as the other RPM codes, did not meet the minimum survey requirements established by the RUC for the January 2025 RUC meeting. The RPM coding will be resurveyed after 1 year of utilization data is available for this 2026 CPT code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately. The RUC did not recommend, and we are not proposing any direct PE inputs for CPT code 99091.

For CPT code 99XX5, we disagree with the RUC's recommendation of 0.39 work RVUs and are proposing a work RVU of 0.31, with 10 minutes or intra-service/total time. We disagree with the recommended value and propose a work RVU of 0.31 for CPT code 99XX5 based on the total time ratio between the 20 minutes of total time assigned to CPT code 99457 and the 10 minutes of total time assigned to CPT code 99XX5. This ratio equals 50 percent, and 50 percent of the current work RVU of 0.61 rounds to a work RVU of 0.31. Although we do not believe that the decrease in time described in the code descriptor must equate to a one-to-one or linear decrease in the valuation of work RVUs, since the two components of work are time and intensity, significant reductions in time for codes with equivalent intensity should generally be reflected in decreases to work RVUs. In the case of CPT code 99XX5, we believe it would be more accurate to propose the total time ratio at a work RVU of 0.31 to account for these decreases in work time compared to CPT code 99457. We also propose using this time ratio with the current PE inputs for CPT code 99457 for clinical staff time. We are proposing 5 minutes of CA021 intra-service clinical labor time and 15 minutes of CA037 post-service clinical labor time for CPT code 99XX5.

For CPT code 99457, we disagree with the RUC's recommendation of 0.45 work RVUs and are proposing to maintain the current work RVU of 0.61, the current work time of 20 minutes, and the current direct PE inputs. This code, as well as the other RPM codes, did not meet the minimum survey requirements established by the RUC for the January 2025 RUC meeting. RPM coding will be resurveyed after 1 year of utilization data is available for this 2026 CPT code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately. For CPT code 99458, we disagree with the RUC's recommended direct PE inputs and are proposing to maintain the current inputs. We are proposing the RUC-recommended work RVU of 0.61 for CPT code 99458, as this work RVU was reviewed by the RUC and resulted in no recommended changes for CY 2026. Our proposal to maintain current work RVUs and PE inputs is due to the lack of survey data supporting changes to these codes' valuation, as none of the RPM codes met the minimum survey requirements established by the RUC for the January 2025 RUC meeting. We also believe it is important to maintain relativity between RPM and RTM codes describing equivalent amounts of treatment management time and effort.

For CPT code 99474, we are proposing the RUC-recommended work RVU of 0.18 and direct PE inputs without refinement, as this code was reviewed by the RUC and resulted in no recommended changes for CY 2026.

For CPT code 99473, which is a PE-only code, we are proposing the RUC-recommended direct PE inputs without refinement, as this code was reviewed by the RUC and resulted in no recommended changes for CY 2026.

For CPT code 99453, which is a PE-only code, we are proposing the RUC-recommended PE inputs without refinement.

For the PE-only CPT codes 99XX4 and 99454, the RUC's recommendations include a ''digital remote physiologic monitoring device app,'' which is a per-click vendor fee that has not traditionally been included as a form of direct PE. We understand that as these technologies evolve, the issues involving the use of software and other forms of digital tools become more difficult to account for accurately in our standard PE methodology. We acknowledge that for CPT codes 99XX4 and 99454, the overall payment rate is driven by practice expense supply and equipment inputs rather than physician work or clinical staff time We have concerns with the RUC-recommended PE inputs for device supply and equipment, as these inputs are difficult to accurately account for due to lack of substantive invoices and other types of supportive data. As MedPAC noted in their comment to the CY 2011 PFS proposed rule, ''using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers might not result in objective and accurate prices because each group has a financial stake in the process''. We have repeatedly stated, such as in the CY 2018 final rule, that ''we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs'' (82 FR 52998). Given our concerns with the RUC-recommended PE inputs and our inability to verify the pricing for these inputs, we believe that using Hospital Outpatient Prospective Payment System (OPPS) cost data to value CPT codes 99XX4 and 99454 may more accurately reflect the actual costs of these technologies. We assume the costs incurred in furnishing these PE-only

codes would be the same across settings of care (physician office and hospital outpatient), since these codes do not have any physician work and only account for PE associated with device supply and data transmission. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. We propose to use OPPS cost data to establish the valuation for the practice expense portion of Remote Physiologic Monitoring CPT codes 99XX4 and 99454. We believe that the OPPS cost data is more accurate than the PE inputs recommended by the RUC. OPPS practice expense data obtained from cost reports is regularly updated, auditable, and required to adhere to national standards for reporting. For example, in the CY 2015 PFS final rule (79 FR 67569), we noted that ''routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year''. We are proposing to utilize the OPPS total geometric mean cost for CPT code 99454 to inform the valuation of CPT codes 99XX4 and 99454 when paid under the PFS. We are proposing to calculate this value by dividing the OPPS Geometric Mean Cost (GMC) for CPT code 99454, which is represented in a dollar amount, by the estimated CY 2026 PFS conversion factor (CF), which represents the dollar value of an RVU, in order to convert the GMC dollar amount into RVUs. The resulting value will be our proposed PE RVU for CPT codes 99XX4 and 99454. We are proposing the same valuation for both CPT codes 99XX4 and 99454 since the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted.

We are seeking comments on these proposals.

B. Valuation for Remote Therapeutic Monitoring (RTM)

For CPT code 98XX7, we disagree with the RUC's recommendation of 0.66 work RVUs and are proposing a work RVU of 0.31, with 10 minutes or intra-service/total time. We are proposing this work RVU for CPT code 98XX7 based on the total time ratio between CPT code 98980's time of 20 minutes and CPT code 98XX7's time of 10 minutes. This ratio equals 50 percent, and 50 percent of the current work RVU of 0.62 for CPT code 98980 equals a work RVU of 0.31 for CPT code 98XX7. Although we do not believe that the decrease in time described in the code descriptor must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant reductions in time for codes with equivalent intensity should generally be reflected in decreases to work RVUs. In the case of CPT code 98XX7, we believe it would be more accurate to propose the total time ratio at a work RVU of 0.31 to account for these decreases in work time compared to CPT code 98980. We are also proposing using this time ratio with the current direct PE inputs for CPT code 98980. We are proposing 5 minutes of CA021 intra-service clinical labor time and 15 minutes of CA037 post-service clinical labor time for CPT code 98XX7. We are proposing this clinical labor using the RN/LPN/MTA (L037D) blend as this has historically been the typical clinical labor type for remote therapeutic monitoring services.

For CPT code 98980, we disagree with the RUC's recommendation of 0.78 work RVUs and are proposing to maintain the current work RVU of 0.62, the current 20 minutes of intra-service/total work time, and the current direct PE inputs. For CPT code 98981, we disagree with the RUC's recommendation of 0.70 work RVUs and are proposing to maintain the current work RVU of 0.61 and the current direct PE inputs; the RUC recommended, and we are proposing to maintain the current 20 minutes of intra-service/total work time. These proposals are due to wanting to maintain relativity between RPM and RTM codes describing equivalent amounts of treatment management time and effort. RTM coding will be placed on the New Technology list to be reviewed after 3 years of data are available for this CPT 2026 code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately.

For the PE-only CPT code 98975, the RUC's recommendations include a ''Remote musculoskeletal therapy monitoring program enrollment fee.'' We are not proposing a price for this input at this time as we believe this type of fee has not traditionally been included as a form of direct PE and would constitute forms of indirect PE under our methodology. We understand that as the PE data age, these issues involving the use of software and other forms of digital tools become more complex. However, in general we believe that this type of cost is most similar to indirect PE costs rather than direct costs, which must be individually allocable to a particular patient for a particular service. Additionally, we believe that indirect technology costs associated with RTM are better accounted for in the data transmission RTM codes (CPT codes 98XX5 and 98977, discussed below) that will also be reported during the beneficiary's course of treatment. We look forward to continuing to seek out new data sources to help in updating the PE methodology. The RTM coding will be placed on the New Technology list to be reviewed after 3 years of data are available for this 2026 CPT code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately. We are proposing to maintain the current direct PE inputs for CPT code 98975.

For the PE-only CPT codes 98XX5 and 98977, the RUC's recommendations include a ''Remote musculoskeletal therapy monitoring monthly supply fee,'' which is a per-click vendor fee that has not traditionally been included as a form of direct PE. We understand that as these technologies evolve, the issues involving the use of software and other forms of digital tools become more difficult to account for accurately in our standard PE methodology. We acknowledge that for CPT codes 98XX5 and 98977, the overall payment rate is driven by practice expense supply and equipment inputs rather than physician work or clinical staff time. We have concerns with the RUC-recommended PE inputs for device supply and equipment, as these inputs are difficult to accurately account for due to lack of substantive invoices and other types of supportive data. As MedPAC noted in their comment to the CY 2011 PFS proposed rule, ''using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers might not result in objective and accurate prices because each group has a financial stake in the process''. We have repeatedly stated, such as in the CY 2018 final rule, that ''we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs'' (82 FR 52998). Given our concerns with the RUC-recommended PE inputs and our inability to verify the pricing for these inputs, we believe that using Hospital Outpatient Prospective Payment System

(OPPS) cost data to value CPT codes 98XX5 and 98977 may more accurately reflect the actual costs of these technologies as opposed to the PE inputs as recommended by the AMA RUC. We assume the costs incurred in furnishing these PE-only codes would be the same across settings of care (physician office and hospital outpatient), since these codes do not have any physician work and only account for PE associated with device supply and data transmission. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. We propose to use OPPS cost data to establish the valuation for the practice expense portion of Remote Therapeutic Monitoring CPT codes 98XX5 and 98977. We believe that the OPPS cost data is more accurate than the PE inputs recommended by the RUC. OPPS practice expense data obtained from cost reports is regularly updated, auditable, and required to adhere to national standards for reporting. For example, in the CY 2015 PFS final rule (79 FR 67569), we noted that ''routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year''. We are proposing to utilize the OPPS total geometric mean cost for CPT code 98977 to inform the valuation of CPT codes 98XX5 and 98977 when paid under the PFS. We are proposing to calculate this value by dividing the OPPS Geometric Mean Cost (GMC) for CPT code 98977, which is represented in a dollar amount, by the estimated CY 2025 PFS conversion factor (CF), which represents the dollar value of an RVU, in order to convert the GMC dollar amount into RVUs. The resulting value will be our proposed PE RVU for CPT codes 98XX5 and 98977. We are proposing the same valuation for both CPT codes 98XX5 and 98977 since the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted.

We are also proposing to maintain the current clinical staff type for the RTM codes (RN/LPN/MTA), as opposed to the RUC recommendation of physical therapy assistant, since the dominant specialty type that bills this code, family medicine, did not participate in the survey.

We are also soliciting comments specifically on data to support the recommended PE inputs for this code, including invoices, additional data, or evidence to support the position.

The RUC-recommended and we are proposing to contractor price the PE-only CPT codes 98XX4 and 98976.

CPT codes 98XX6 and 98978 are PE-only codes. We are proposing to contractor price CPT code 98XX6 and proposing to maintain contractor pricing for CPT code 98978.

We are seeking comments on these proposals.

C. Comment Solicitation

We are seeking comments on whether there are differences in the valuation of remote physiologic and remote therapeutic monitoring, specifically whether the services have similar costs and/or practice expense inputs. We are currently proposing similar valuations for what we have historically viewed as similar remote monitoring services (for example, RTM and RPM treatment management, RTM and RPM device supply, RTM and RPM data transmission), but are interested in gaining more information regarding any differences in work (in the case of timed codes, if there are varying levels of intensity between remote therapeutic vs. physiologic monitoring), clinical staff time, supplies, equipment, etc. We are particularly interested in comments that include data or evidence to support the position.

(31) Hearing Device Services (CPT Codes 9X01X, 9X02X, 9X03X, 9X04X, 9X07X, 9X08X, 9X09X, 9X10X, 9X11X, 9X12X, 9X13X, and 9X14X)

At the February 2024 CPT Editorial Panel meeting, 12 new Category I codes were created to report hearing devices services (for example, air-conduction hearing aids) including hearing aid candidacy determination, hearing aid selection, hearing aid fitting, follow-up after fitting, hearing aid verification, and assistive-device services. The current CPT codes, 92590–92595, were recommended for deletion. CPT codes 9X01X–9X14X were reviewed at the April 2024 RUC HCPAC meeting for CY 2026.

The following is a list of the new CPT codes and their long descriptors: CPT code 9X01X (*Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (for example, speech-in-noise, suprathreshold hearing measures) discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; first 30 minutes*), CPT code 9X02X (*Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (for example, speech-in-noise, suprathreshold hearing measures) discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; each additional 15 minutes*), CPT code 9X03X (*Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; first 30 minutes*), CPT code 9X04X (*Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; each additional 15 minutes*), CPT code 9X07X (*Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; first 60 minutes*), CPT code 9X08X (*Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes*), CPT code 9X09X (*Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (for example, verification, programming adjustment(s), device connection(s), and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; first 30 minutes*), CPT code 9X10X (*Hearing aid post-fitting follow-*

up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (for example, verification, programming adjustment(s), device connection(s), and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes), CPT code 9X11X (*Behavioral verification of amplification including aided thresholds, functional gain, speech in noise, when performed*), CPT code 9X12X (*Hearing-aid measurement, verification with probe-microphone*), CPT code 9X13X (*Hearing device verification, electroacoustic analysis*), and CPT code 9X14X (*Hearing assistive device, supplemental technology fitting services (for example, personal frequency modulation (FM)/digital modulation (DM) system, remote microphone, alerting devices)*).

The RUC is recommending contractor pricing for all twelve codes in the family. However, section 1862(a)(7) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for hearing aids or examinations therefore, it has been our established policy not to pay for these hearing device services on the PFS, as their predecessor CPT codes 92590–92595 all have non-payable status codes. Therefore, we are proposing to maintain the same policy of assigning non-payable status codes to each of the twelve new CPT codes in this family.

(32) Scalp Cooling Services (CPT Codes 9XX01, 9XX02, and 9XX03)

At the September 2024 CPT Editorial Panel meeting, CPT deleted two Category II CPT codes and created three new Category I CPT codes, CPT code 9XX01(*Mechanical Scalp cooling, including individual cap supply with head measurement, fitting, and patient education),* 9XX02(*mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and pre-cooling period*), and 9XX03(*mechanical scalp cooling; each 30 minutes*)) to report scalp cooling services to address chemotherapy induced alopecia. The new codes were surveyed for the January 2025 RUC meeting and the RUC determined that the code family requires no physician work and are practice expense (PE) only services. As such, the RUC did not recommend, and we are not proposing work RVUs for these codes.

We disagree with the RUC-recommended 5 minutes of service period clinical staff time in direct PE input CA021 (Perform procedure/service—not directly related to physician work time) for CPT code 9XX01. We are proposing 27 minutes of clinical labor time for CA021 based off reference CPT code 99453 (*Remote monitoring of physiologic parameter(s) (for example, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*). We have received feedback from interested parties that 5 minutes does not adequately account for the full duration of time required to educate, measure, fit, and calibrate the cap. We agree with interested parties and believe that the 27 minutes of clinical staff time in CA021 for CPT code 99453 better accounts for the full duration of time required for this service. We are proposing all other direct PE inputs, supplies, and equipment as recommended by the RUC for CPT code 9XX01. We are also proposing all direct PE inputs, supplies, and equipment as recommended by the RUC for CPT codes 9XX02 and 9XX03 without refinement.

TABLE 19: CY 2026 WORK RVUs FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	C	2.43	2.43	No
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	C	1.05	1.05	No
27465	Osteoplasty, femur; shortening	18.60	21.13	21.13	No
27466	Osteoplasty, femur; lengthening	17.28	22.65	22.65	No
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	19.97	C	19.97	Yes
27715	Osteoplasty, tibia and fibula, lengthening or shortening	15.50	22.50	22.50	No
27XX0	Osteotomy(ies), femur, unilateral, with insertion of an externally controlled intramedullary lengthening device, including iliotibial band release when performed, imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NEW	26.65	26.65	No
27XX1	Osteotomy(ies), tibia, including fibula when performed, unilateral, with insertion of an externally controlled intramedullary lengthening device, including imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NEW	28.00	28.00	No
28750	Arthrodesis, great toe; metatarsophalangeal joint	8.57	8.75	8.75	No
28755	Arthrodesis, great toe; interphalangeal joint	4.88	7.50	6.76	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	14.00	10.25	10.25	No
33880	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft covering the left subclavian artery and all aortic tube endograft extension(s) proximally in the aortic arch and ascending aorta and distally to the celiac artery, when performed	34.58	30.00	27.00	No
33881	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft not involving coverage of the left subclavian artery origin and all endograft extension(s) placed from the level of the left subclavian carotid artery to the celiac artery	29.58	26.75	22.53	No
33883	Delayed placement of proximal extension prosthesis(es) not involving coverage of the left subclavian artery origin, after endovascular repair of the thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed	21.09	24.25	19.91	No
33886	Delayed placement of distal extension prosthesis(es) from the level of the left subclavian artery to the celiac artery, after endovascular repair of descending thoracic aorta, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation	18.09	23.50	19.91	No
33XX2	Endovascular repair of the thoracic aorta by deployment of a branched endograft multipiece system involving an aorto-aortic tube device with a fenestration for the left subclavian artery stentgraft(s) and all aortic tube endograft extension(s) placed from the level of the left common carotid artery to the celiac artery, including pre-procedure sizing and device selection, all target zone angioplasty, all nonselective catheterization(s) and left subclavian artery selective catheterization(s), and all associated radiological supervision and interpretation	NEW	39.00	35.00	No
35XX1	Bypass graft, with other than vein; carotid-contralateral carotid	NEW	27.40	23.53	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37X02	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No
37X03	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	10.75	10.75	No
37X04	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.89	3.89	No
37X05	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	8.75	8.75	No
37X06	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37X07	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	12.69	12.69	No
37X08	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No
37X09	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No
37X10	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	7.75	7.75	No
37X11	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37X12	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	10.50	10.50	No
37X13	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37X14	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	8.75	8.75	No
37X15	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.73	3.73	No
37X16	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	14.75	14.75	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37X17	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.00	5.00	No
37X18	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	9.00	9.00	No
37X19	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37X20	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	12.63	12.63	No

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37X21	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.50	5.50	No
37X22	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	11.00	11.00	No
37X23	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No
37X24	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	15.00	15.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37X25	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	6.00	6.00	No
37X26	Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37X27	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	9.80	9.80	No
37X28	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No
37X29	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	12.31	12.31	No

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37X30	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.26	4.26	No
37X31	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	10.00	10.00	No
37X32	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.34	3.34	No
37X33	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	13.46	13.46	No

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37X34	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.00	5.00	No
37X35	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	13.50	13.50	No
37X36	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.75	4.75	No
37X37	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	17.00	17.00	No

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37X38	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	6.50	6.50	No
37X39	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	15.00	15.00	No
37X40	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	6.50	6.50	No
37X41	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	18.00	18.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37X42	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	8.16	8.16	No
37X43	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	11.00	11.00	No
37X44	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37X45	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	13.70	13.70	No
37X46	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.00	5.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
37XX1	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	7.30	7.30	No
4001X	Ablation, irreversible electroporation, liver, 1 or more tumors, including imaging guidance, percutaneous	NEW	9.41	9.41	No
4XX04	Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed	NEW	13.50	12.56	No
52500	Transurethral resection of bladder neck (separate procedure)	8.14	6.00	6.00	No
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	13.16	10.00	10.00	No
52630	Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	6.55	6.55	6.55	No
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	12.15	10.05	10.05	No
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	14.56	14.56	13.00	No
52XX1	Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed	NEW	10.25	10.25	No
52XX2	Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a nondrug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed	NEW	3.62	3.62	No
55705	Biopsy, prostate, any approach, nonimaging-guided	4.61	1.93	1.93	No
55706	Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance	6.28	4.27	4.27	No
55840	Prostatectomy, retropubic radical, with or without nerve sparing;	21.36	21.36	21.36	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	21.36	21.36	21.36	No
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	25.18	25.18	25.18	No
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed;	22.46	22.46	22.46	No
55867	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed	19.53	19.53	19.53	No
558X1	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with lymph node biopsy(ies) (limited pelvic lymphadenectomy)	NEW	22.46	22.46	No
558X2	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	NEW	29.35	27.41	No
5XX00	Biopsy, prostate, transrectal, ultrasound-guided (ie, sextant, ultrasound-localized discrete lesion[s])	NEW	2.63	2.63	No
5XX01	Biopsy, prostate, transrectal, ultrasound-guided (ie, sextant) with MRI-fusion-guidance, first targeted lesion	NEW	3.39	3.39	No
5XX02	Biopsy, prostate, transperineal, ultrasound-guided (ie, sextant, ultrasound-localized discrete lesion[s])	NEW	3.23	3.23	No
5XX03	Biopsy, prostate, transperineal, ultrasound-guided (ie, sextant) with MRI-fusion-guidance biopsy, first targeted lesion	NEW	3.81	3.81	No
5XX04	Biopsy, prostate, transrectal, MRI-ultrasound-fusion guided, targeted lesion(s) only, first targeted lesion	NEW	2.61	2.61	No
5XX07	Biopsy, prostate, transperineal, MRI-ultrasound-fusion guided, targeted lesion(s) only, first targeted lesion	NEW	3.10	3.10	No
5XX08	Biopsy, prostate, in-bore CT- or MRI-guided (ie, sextant), with biopsy of additional targeted lesion(s), first targeted lesion	NEW	4.00	4.00	No
5XX09	Biopsy, prostate, in-bore CT- or MRI-guided targeted lesion(s) only, first targeted lesion	NEW	3.62	3.62	No
5XX10	Biopsy, prostate, each additional, MRI-ultrasound fusion or in-bore CT- or MRI-guided targeted lesion (List separately in addition to code for primary procedure)	NEW	1.05	1.05	No
5XX11	Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous	NEW	13.50	13.50	No

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61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), including all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention, percutaneous, any method; central nervous system (intracranial, spinal cord)	20.12	20.00	17.06	No
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), including all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention, percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	16.60	15.31	13.46	No
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed	18.95	-	18.95	No
62XX0	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; one interspace, lumbar	NEW	8.00	8.00	No
62XX1	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No
647XX	Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance	NEW	2.70	2.70	No
64X10	Removal of baroreflex activation therapy (BAT) modulation system; pulse generator only	NEW	8.23	8.23	No
64X11	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation	NEW	1.50	1.50	No
64XX5	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	NEW	11.00	11.00	No
64XX6	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	NEW	11.30	11.30	No
64XX7	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	NEW	8.01	8.01	No
64XX8	Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator	NEW	12.13	12.13	No

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64XX9	Removal of baroreflex activation therapy (BAT) modulation system; lead only	NEW	8.95	8.95	No
6XX13	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)	NEW	2.50	2.50	No
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	1.75	No
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	1.75	No
70XX1	Computed tomographic angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing	NEW	2.50	2.50	No
70XX2	Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)	NEW	0.77	0.77	No
70XX3	Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy	NEW	1.00	1.00	No
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation	1.31	2.25	2.25	No
75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	1.65	1.85	1.85	No
75XX6	Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified health care professional	NEW	0.85	0.85	No
76872	Ultrasound, transrectal;	0.69	0.67	0.67	No
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed	I	0.70	0.70	No
77402	Radiation treatment delivery; Level 1 (that is, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed	I	0.00	0.00	No
77407	Radiation treatment delivery; Level 2, single isocenter (that is, 3D or IMRT), photons, including imaging guidance, when performed	I	0.00	0.00	No

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77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (that is, 2D, 3D, or IMRT) OR a single isocenter photon therapy (that is, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed	I	0.00	0.00	No
77417	Therapeutic radiology port image(s)	0.00	0.00	B	No
77X05	Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting	NEW	0.77	0.77	No
77X07	Surface radiation therapy; superficial, delivery, ≤150 kV, per fraction (that is, electronic brachytherapy)	NEW	0.00	0.00	No
77X08	Surface radiation therapy; orthovoltage, delivery, >150-500 kV, per fraction	NEW	0.00	0.00	No
77X09	Surface radiation therapy; superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to code for primary procedure)	NEW	0.30	0.30	No
90480	Immunization administration by intramuscular injection, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine; first or only component of each vaccine administered	X	0.25	X	Yes
90832	Psychotherapy, 30 minutes with patient	1.86	-	1.94	No
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service	1.64	-	1.71	No
90834	Psychotherapy, 45 minutes with patient	2.45	-	2.56	No
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service	2.08	-	2.17	No
90837	Psychotherapy, 60 minutes with patient	3.63	-	3.78	No
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service	2.74	-	2.86	No
90839	Psychotherapy for crisis; first 60 minutes	3.43	-	3.58	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.64	-	1.71	No
90845	Psychoanalysis	2.30	-	2.40	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.63	-	2.74	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.74	-	2.86	No
90849	Multiple-family group psychotherapy	0.65	-	0.67	No
90853	Group psychotherapy (other than of a multiple-family group)	0.65	-	0.67	No
90XX1	Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; 3 minutes up to 10 minutes	NEW	0.24	I	No
90XX2	Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 10 minutes up to 20 minutes	NEW	0.50	I	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
90XX3	Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 20 minutes	NEW	0.75	I	No
91XX1	Rectal sensation, tone, and compliance study (that is, barostat)	NEW	3.05	3.05	No
91XX2	Anorectal manometry, with rectal sensation and rectal balloon expulsion test, when performed	NEW	2.70	2.70	No
92284	Diagnostic dark adaptation examination (that is, rod and cone sensitivities, rod-cone breakpoint), with interpretation and report	0.00	0.32	0.29	No
922X1	Screening dark adaptation measurement (that is, rod recovery intercept time), with interpretation and report	NEW	0.17	N	No
92920	Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)	9.85	8.35	8.35	No
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)	11.74	10.13	10.13	No
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 1 lesion involving 1 or more coronary segments	10.96	10.00	10.00	No
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)	12.29	11.94	11.94	No
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed, single major coronary artery and/or its branches	10.95	11.30	11.30	No
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single major coronary artery and/or its branches or single bypass graft and/or its subtended branches	12.31	12.72	12.72	No
92943	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach	12.31	13.69	13.69	No
92973	Percutaneous transluminal coronary mechanical aspiration thrombectomy (List separately in addition to code for primary procedure)	3.28	1.75	1.75	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
92X01	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 2 or more distinct coronary lesions with 2 or more coronary stents deployed in 2 or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch	NEW	12.00	12.00	No
92X02	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches	NEW	15.00	15.00	No
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; initial vessel (List separately in addition to code for primary procedure)	1.38	1.80	1.80	No
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; each additional vessel (List separately in addition to code for primary procedure)	1.00	1.44	1.44	No
93XX4	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming	NEW	0.79	0.65	No
93XX5	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (that is, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming, including optimization of tolerated therapeutic level setting	NEW	0.90	0.90	No
96156	Health behavior assessment, or re-assessment (that is, health-focused clinical interview, behavioral observations, clinical decision making)	2.30	-	2.40	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	1.59	-	1.66	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes	0.55	-	0.57	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	0.23	-	0.24	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes	0.11	-	0.11	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	1.70	-	1.77	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes	0.60	-	0.63	No
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional	0.24	0.28	0.28	No
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection	0.17	0.17	0.17	No
98975	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
98976	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period	0.00	C	C	No
98977	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period	0.00	0.00	0.00	No
98978	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period	C	0.00	C	No
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 20 minutes	0.62	0.78	0.62	Yes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)	0.61	0.70	0.61	No
98XX4	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period	NEW	C	C	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
98XX5	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period	NEW	0.00	0.00	No
98XX6	Remote therapeutic monitoring (that is, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period	NEW	0.00	C	No
98XX7	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes	NEW	0.66	0.31	No
99091	Collection and interpretation of physiologic data (that is, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	1.10	0.70	1.10	Yes
99453	Remote monitoring of physiologic parameter(s) (that is, weight, blood pressure, pulse oximetry, respiratory flow rate); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
99454	Remote monitoring of physiologic parameter(s) (that is, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period	0.00	0.00	0.00	No
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 20 minutes	0.61	0.45	0.61	Yes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)	0.61	0.61	0.61	No
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	0.00	0.00	0.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	0.18	0.18	0.18	No
99XX4	Remote monitoring of physiologic parameter(s) (that is, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period	NEW	0.00	0.00	No
99XX5	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes	NEW	0.39	0.31	No
9X01X	Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (that is, speech-in-noise, suprathreshold hearing measures), discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; first 30 minutes	NEW	C	N	No
9X02X	Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (that is, speech-in-noise, suprathreshold hearing measures), discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	C	N	No
9X03X	Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; first 30 minutes	NEW	C	N	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
9X04X	Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	C	N	No
9X07X	Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; first 60 minutes	NEW	C	N	No
9X08X	Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	C	N	No
9X09X	Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (that is, verification, programming adjustment[s], device connection[s], and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; first 30 minutes	NEW	C	N	No
9X10X	Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (that is, verification, programming adjustment[s], device connection[s], and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	C	N	No
9X11X	Behavioral verification of amplification including aided thresholds, functional gain, speech in noise, when performed (List separately in addition to code for primary procedure)	NEW	C	N	No
9X12X	Hearing-aid measurement, verification with probe-microphone (List separately in addition to code for primary procedure)	NEW	C	N	No
9X13X	Hearing device verification, electroacoustic analysis	NEW	C	N	No
9X14X	Hearing assistive device, supplemental technology fitting services (that is, personal frequency modulation [FM]/digital modulation [DM] system, remote microphone, alerting devices)	NEW	C	N	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
9X16X	Immunization administration by intramuscular injection, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine; each additional component administered (List separately in addition to code for primary procedure)	NEW	0.00	X	No
9XX01	Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education	NEW	0.00	0.00	No
9XX02	Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period	NEW	0.00	0.00	No
9XX03	Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure)	NEW	0.00	0.00	No
GPCM1	Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately in addition to the Advanced Primary Care Management code).	NEW	-	1.88	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS Work Time Refinement
GPCM2	Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment (list separately in addition to Advanced Primary Care Management code).	NEW	-	2.05	No
GPCM3	Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team (list separately in addition to Advanced Primary Care Management code).	NEW	-	0.93	No

TABLE 20: CY 2026 DIRECT PE REFINEMENTS

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
37X03	Revsc evasc ivt angio cplx 1	ED053	Professional PACS Workstation	NF		34	99	E18: Refined equipment time to conform to established policies for PACS Workstations	3.98
37X05	Revsc evasc ivt stent sf 1st	ED053	Professional PACS Workstation	NF		34	94	E18: Refined equipment time to conform to established policies for PACS Workstations	3.68
37X07	Revsc evasc ivt st cplx 1st	ED053	Professional PACS Workstation	NF		34	136	E18: Refined equipment time to conform to established policies for PACS Workstations	6.25
37X10	Revsc evasc fpvt angio sf 1	ED053	Professional PACS Workstation	NF		34	79	E18: Refined equipment time to conform to established policies for PACS Workstations	2.76
37X10	Revsc evasc fpvt angio sf 1	SD382	Drug coated balloon	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2343.33
37X12	Revsc evsc fpvt angio cplx 1	ED053	Professional PACS Workstation	NF		34	109	E18: Refined equipment time to conform to	4.60

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
								established policies for PACS Workstations	
37X12	Revsc evsc fpvt angio cplx 1	SD382	Drug coated balloon	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2343.33
37X14	Revsc evsc fpvt stent sf 1st	ED053	Professional PACS Workstation	NF		34	94	E18: Refined equipment time to conform to established policies for PACS Workstations	3.68
37X16	Revsc evasc fpvt st cplx 1st	ED053	Professional PACS Workstation	NF		34	129	E18: Refined equipment time to conform to established policies for PACS Workstations	5.82
37X18	Revsc evsc fpvt athrc sf 1st	ED053	Professional PACS Workstation	NF		34	109	E18: Refined equipment time to conform to established policies for PACS Workstations	4.60
37X18	Revsc evsc fpvt athrc sf 1st	SD382	Drug coated balloon	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2343.33
37X20	Revsc evsc fpvt athrc cplx 1	ED053	Professional PACS Workstation	NF		34	137	E18: Refined equipment time to conform to	6.31

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
								established policies for PACS Workstations	
37X20	Revsc evsc fpvt athrc cplx 1	SD382	Drug coated balloon	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2343.33
37X22	Rvsc evsc fpvt st athrc sf 1	ED053	Professional PACS Workstation	NF		34	134	E18: Refined equipment time to conform to established policies for PACS Workstations	6.13
37X24	Rvsc evsc fpvt st athr cpx 1	ED053	Professional PACS Workstation	NF		34	142	E18: Refined equipment time to conform to established policies for PACS Workstations	6.62
37X27	Revsc evsc tpvt angio sf 1st	ED053	Professional PACS Workstation	NF		34	109	E18: Refined equipment time to conform to established policies for PACS Workstations	4.60
37X29	Rvsc evsc tpvt angio cplx 1	ED053	Professional PACS Workstation	NF		34	119	E18: Refined equipment time to conform to established policies for PACS Workstations	5.21

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
37X31	Revsc evasc tpvt st sf 1st	ED053	Professional PACS Workstation	NF		34	119	E18: Refined equipment time to conform to established policies for PACS Workstations	5.21
37X33	Revsc evasc tpvt st cplx 1st	ED053	Professional PACS Workstation	NF		34	139	E18: Refined equipment time to conform to established policies for PACS Workstations	6.44
37X33	Revsc evasc tpvt st cplx 1st	SD379	drug eluting stent, tibial	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2750.00
37X34	Revsc evasc tpvt st cplx ea	SD379	drug eluting stent, tibial	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2750.00
37X35	Revsc evsc tpvt athrc sf 1st	ED053	Professional PACS Workstation	NF		34	139	E18: Refined equipment time to conform to established policies for PACS Workstations	6.44
37X37	Revsc evsc tpvt athrc cplx 1	ED053	Professional PACS Workstation	NF		34	169	E18: Refined equipment time to conform to established policies for PACS Workstations	8.27

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
37X39	Rvsc evsc tpvt st athrc sf 1	ED053	Professional PACS Workstation	NF		34	161	E18: Refined equipment time to conform to established policies for PACS Workstations	7.78
37X41	Rvsc evsc tpvt st athr cpx 1	ED053	Professional PACS Workstation	NF		34	189	E18: Refined equipment time to conform to established policies for PACS Workstations	9.50
37X41	Rvsc evsc tpvt st athr cpx 1	SD379	drug eluting stent, tibial	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2750.00
37X42	Rvsc evsc tpvt st ath cpx ea	SD379	drug eluting stent, tibial	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-2750.00
37X43	Revsc evasc imvt angio sf 1	ED053	Professional PACS Workstation	NF		34	119	E18: Refined equipment time to conform to established policies for PACS Workstations	5.21
37X45	Revsc evsc imvt angio cplx 1	ED053	Professional PACS Workstation	NF		34	139	E18: Refined equipment time to conform to established policies for PACS Workstations	6.44

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
37XX1	Revsc evasc ivt angio sf 1st	ED053	Professional PACS Workstation	NF		34	79	E18: Refined equipment time to conform to established policies for PACS Workstations	2.76
4001X	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.16
4001X	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.62
4001X	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.02
4001X	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-5.40
52648	Laser surgery of prostate	L037D	RN/LPN/MTA	F	Perform procedure/service---NOT directly related to physician work time	6	0	L1: Refined time to standard for	-3.24

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
								this clinical labor task	
52648	Laser surgery of prostate	SL036	cup, biopsy-specimen sterile 4oz	NF		1	0	S5: Refined supply quantity to conform with other codes in the family	-0.80
52XX2	Cysto 1st trurl prst8 comis	ES018	fiberscope, flexible, cystoscopy	NF		64	79	E4: Refined equipment time to conform to established policies for scopes	0.61
52XX2	Cysto 1st trurl prst8 comis	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		64	52	E4: Refined equipment time to conform to established policies for scopes	-3.21
52XX2	Cysto 1st trurl prst8 comis	L037D	RN/LPN/MTA	NF	Clean scope	40	30	L1: Refined time to standard for this clinical labor task	-5.40
52XX2	Cysto 1st trurl prst8 comis	L037D	RN/LPN/MTA	NF	Monitor patient following procedure/service, no multitasking	5	0	G1: See preamble text	-2.70
52XX2	Cysto 1st trurl prst8 comis	SM021	sanitizing cloth-wipe (patient)	NF		1	0	S1: Duplicative; supply is included in SA058	-0.07
55867	Laps surg prst8ect smpl stot	EF014	light, surgical	F		106	89	E7: Refined equipment time to conform to office visit duration	-0.05

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
55867	Laps surg prst8ect smpl stot	EF031	table, power	F		106	89	E7: Refined equipment time to conform to office visit duration	-0.27
55867	Laps surg prst8ect smpl stot	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	106	89	L9: Refined clinical labor to align with number of post-operative visits	-9.18
61626	Tcat perm occls/embol noncns	ED053	Professional PACS Workstation	NF		165	152	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.80
61626	Tcat perm occls/embol noncns	EL011	room, angiography	NF		124	127	E2: Refined equipment time to conform to established policies for highly technical equipment	13.57
61626	Tcat perm occls/embol noncns	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	3	G1: See preamble text	1.62
61626	Tcat perm occls/embol noncns	L037D	RN/LPN/MTA	NF	Coordinate post-procedure services	3	0	G1: See preamble text	-1.62
61626	Tcat perm occls/embol noncns	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.62
61626	Tcat perm occls/embol noncns	SD172	guidewire, cerebral (Bentson)	NF		1	0	S3: Supply not typically	-48.27

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
								used in this service	
77402	Radiation tx delivery lvl 1	ED035	video camera	NF		17	0	G1: See preamble text	-0.06
77402	Radiation tx delivery lvl 1	EQ139	intercom (incl. master, pt substation, power, wiring)	NF		17	0	G1: See preamble text	-0.06
77402	Radiation tx delivery lvl 1	ER039	laser targeting system (4 diodes)	NF		17	0	G1: See preamble text	-0.26
77402	Radiation tx delivery lvl 1	ER056	radiation treatment vault	NF		17	0	G1: See preamble text	-22.34
77402	Radiation tx delivery lvl 1	ER065	water chiller (radiation treatment)	NF		17	0	G1: See preamble text	-0.70
77402	Radiation tx delivery lvl 1	ER089	IMRT accelerator	NF		17	0	G1: See preamble text	-173.10
77402	Radiation tx delivery lvl 1	ER090	Computer system, record and verify, IMRT	NF		17	0	G1: See preamble text	-8.53
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0	G1: See preamble text	-0.89
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-8.90
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-8.90
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	3	0	G1: See preamble text	-2.67

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77402	Radiation tx delivery lvl 1	SB006	drape, non-sterile, sheet 40in x 60in	NF		1	0	G1: See preamble text	-0.13
77402	Radiation tx delivery lvl 1	SB022	gloves, non-sterile	NF		2	0	G1: See preamble text	-0.60
77402	Radiation tx delivery lvl 1	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77402	Radiation tx delivery lvl 1	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77402	Radiation tx delivery lvl 1	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.07
77407	Radiation tx delivery lvl 2	ED035	video camera	NF		22	0	G1: See preamble text	-0.07
77407	Radiation tx delivery lvl 2	EQ139	intercom (incl. master, pt substation, power, wiring)	NF		22	0	G1: See preamble text	-0.08
77407	Radiation tx delivery lvl 2	ER039	laser targeting system (4 diodes)	NF		22	0	G1: See preamble text	-0.33
77407	Radiation tx delivery lvl 2	ER056	radiation treatment vault	NF		22	0	G1: See preamble text	-28.91
77407	Radiation tx delivery lvl 2	ER065	water chiller (radiation treatment)	NF		22	0	G1: See preamble text	-0.91
77407	Radiation tx delivery lvl 2	ER089	IMRT accelerator	NF		22	0	G1: See preamble text	-224.01
77407	Radiation tx delivery lvl 2	ER090	Computer system, record and verify, IMRT	NF		22	0	G1: See preamble text	-11.04
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	15	0	G1: See preamble text	-13.35
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Review examination with interpreting MD/DO	2	0	G1: See preamble text	-1.78
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure	3	0	G1: See preamble text	-2.67

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
					appropriate medical records are available				
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	3	0	G1: See preamble text	-2.67
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	15	0	G1: See preamble text	-13.35
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	2	0	G1: See preamble text	-1.78
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.	1	0	G1: See preamble text	-0.89
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0	G1: See preamble text	-0.89
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77407	Radiation tx delivery lvl 2	SB006	drape, non-sterile, sheet 40in x 60in	NF		2	0	G1: See preamble text	-0.26
77407	Radiation tx delivery lvl 2	SB022	gloves, non-sterile	NF		2	0	G1: See preamble text	-0.60
77407	Radiation tx delivery lvl 2	SB026	gown, patient	NF		1	0	G1: See preamble text	-0.59
77407	Radiation tx delivery lvl 2	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77407	Radiation tx delivery lvl 2	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77407	Radiation tx delivery lvl 2	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.07
77412	Radiation tx delivery lvl 3	ED035	video camera	NF		31	0	G1: See preamble text	-0.10

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77412	Radiation tx delivery lvl 3	EQ139	intercom (incl. master, pt substation, power, wiring)	NF		31	0	G1: See preamble text	-0.11
77412	Radiation tx delivery lvl 3	ER039	laser targeting system (4 diodes)	NF		31	0	G1: See preamble text	-0.47
77412	Radiation tx delivery lvl 3	ER056	radiation treatment vault	NF		31	0	G1: See preamble text	-40.73
77412	Radiation tx delivery lvl 3	ER065	water chiller (radiation treatment)	NF		31	0	G1: See preamble text	-1.28
77412	Radiation tx delivery lvl 3	ER089	IMRT accelerator	NF		31	0	G1: See preamble text	-315.66
77412	Radiation tx delivery lvl 3	ER090	Computer system, record and verify, IMRT	NF		31	0	G1: See preamble text	-15.56
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	24	0	G1: See preamble text	-21.36
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	24	0	G1: See preamble text	-21.36
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	3	0	G1: See preamble text	-2.67
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0	G1: See preamble text	-0.89
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.	1	0	G1: See preamble text	-0.89
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Review examination with interpreting MD/DO	2	0	G1: See preamble text	-1.78

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77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	2	0	G1: See preamble text	-1.78
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77412	Radiation tx delivery lvl 3	L152A	Medical Physicist	NF	Perform procedure/service--- NOT directly related to physician work time	5	0	G1: See preamble text	-10.70
77412	Radiation tx delivery lvl 3	SB006	drape, non-sterile, sheet 40in x 60in	NF		2	0	G1: See preamble text	-0.26
77412	Radiation tx delivery lvl 3	SB022	gloves, non-sterile	NF		2	0	G1: See preamble text	-0.60
77412	Radiation tx delivery lvl 3	SB026	gown, patient	NF		1	0	G1: See preamble text	-0.59
77412	Radiation tx delivery lvl 3	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77412	Radiation tx delivery lvl 3	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77412	Radiation tx delivery lvl 3	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.07
77X05	Surf radj ther tx planning	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (100% of physician intra-service time)	2	0	G1: See preamble text	-1.08
77X05	Surf radj ther tx planning	SB026	gown, patient	NF		1	0	G1: See preamble text	-0.59
77X07	Surf radj ther supfc<=150kv	EF031	table, power	NF		17	0	G1: See preamble text	-0.27
77X07	Surf radj ther supfc<=150kv	EQ168	light, exam	NF		17	0	G1: See preamble text	-0.06

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77X07	Surf radj ther supfc<=150kv	ER045	Superficial radiation therapy system	NF		17	0	G1: See preamble text	-25.44
77X07	Surf radj ther supfc<=150kv	ER120	Lead Blocking Shield Kit	NF		17	0	G1: See preamble text	-0.15
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	2	0	G1: See preamble text	-1.08
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	2	0	G1: See preamble text	-1.08
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	0	G1: See preamble text	-1.62
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-1.62
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)	2	0	G1: See preamble text	-1.08
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G1: See preamble text	-1.08
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-1.62
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	2	0	G1: See preamble text	-1.08
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.54
77X07	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	1	0	G1: See preamble text	-0.54
77X07	Surf radj ther supfc<=150kv	SB023	gloves, non-sterile, nitrile	NF		2	0	G1: See preamble text	-2.12
77X07	Surf radj ther supfc<=150kv	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77X07	Surf radj ther supfc<=150kv	SG035	dressing, 3in x 4in (Telfa, Release)	NF		1	0	G1: See preamble text	-0.05

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77X07	Surf radj ther supfc<=150kv	SG079	tape, surgical paper 1in (Micropore)	NF		8	0	G1: See preamble text	-0.08
77X07	Surf radj ther supfc<=150kv	SJ038	petroleum jelly	NF		1	0	G1: See preamble text	-0.37
77X07	Surf radj ther supfc<=150kv	SJ053	swab-pad, alcohol	NF		1	0	G1: See preamble text	-0.04
77X07	Surf radj ther supfc<=150kv	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77X07	Surf radj ther supfc<=150kv	SM013	disinfectant, surface (Envirocide, Sanizide)	NF		1	0	G1: See preamble text	-0.18
77X08	Surf rad thr orthvlt>150-500	EF023	table, exam	NF		15	0	G1: See preamble text	-0.16
77X08	Surf rad thr orthvlt>150-500	ER128	Orthovoltage Treatment Delivery System	NF		15	0	G1: See preamble text	-22.87
77X08	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	2	0	G1: See preamble text	-1.78
77X08	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77X08	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77X08	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-4.45
77X08	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	2	0	G1: See preamble text	-1.78
77X08	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-4.45
77X08	Surf rad thr orthvlt>150-500	SB006	drape, non-sterile, sheet 40in x 60in	NF		2	0	G1: See preamble text	-0.26

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77X08	Surf rad thr orthvlt>150-500	SB023	gloves, non-sterile, nitrile	NF		2	0	G1: See preamble text	-2.12
77X08	Surf rad thr orthvlt>150-500	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77X08	Surf rad thr orthvlt>150-500	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77X08	Surf rad thr orthvlt>150-500	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.07
91XX1	Rct snsatn tone&cmplianc std	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	30	10	G1: See preamble text	-10.80
91XX1	Rct snsatn tone&cmplianc std	SM015	enzymatic detergent	NF		120	4	S6: Refined supply quantity to what is typical for the procedure	-25.52
91XX2	Anrct mano rct snsatn&balo	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	30	10	G1: See preamble text	-10.80
91XX2	Anrct mano rct snsatn&balo	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	17	2	L1: Refined time to standard for this clinical labor task	-8.10
91XX2	Anrct mano rct snsatn&balo	SM015	enzymatic detergent	NF		120	4	S6: Refined supply quantity to what is typical for the procedure	-25.52
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Obtain vital signs	0	5	L5: Clinical labor type replaces another clinical labor type; see preamble text	2.70
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Complete post-procedure diagnostic forms, lab and x-ray requisitions	0	3	L5: Clinical labor type replaces another	1.62

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
								clinical labor type; see preamble text	
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	0	2	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.08
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	L5: Clinical labor type replaces another clinical labor type; see preamble text	5.40
93XX4	Interrog crtd sins bat ip wo	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28

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93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Obtain vital signs	5	0	L4: Clinical labor type replaced by another labor type; see preamble text	-3.80
93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Prepare room, equipment and supplies	2	0	L4: Clinical labor type replaced by another labor type; see preamble text	-1.52
93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Provide education/obtain consent	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28
93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Clean room/equipment by clinical staff	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28
93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Perform procedure/service---NOT directly related to physician work time	10	0	L4: Clinical labor type replaced by another labor type; see preamble text	-7.60
93XX4	Interrog crtd sins bat ip wo	L051A	RN	NF	Complete post-procedure diagnostic forms, lab and x-ray requisitions	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28
93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	30	L5: Clinical labor type replaces another clinical labor type; see preamble text	16.20

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93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	0	2	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.08
93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Obtain vital signs	0	5	L5: Clinical labor type replaces another clinical labor type; see preamble text	2.70
93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Complete post-procedure diagnostic forms, lab and x-ray requisitions	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX5	Interrog crtd sins bat ip w/	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	0	3	L5: Clinical labor type replaces another clinical labor type; see preamble text	1.62
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Complete post-procedure diagnostic	3	0	L4: Clinical labor type	-2.28

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
					forms, lab and x-ray requisitions			replaced by another labor type; see preamble text	
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Obtain vital signs	5	0	L4: Clinical labor type replaced by another labor type; see preamble text	-3.80
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Perform procedure/service---NOT directly related to physician work time	30	0	L4: Clinical labor type replaced by another labor type; see preamble text	-22.80
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Clean room/equipment by clinical staff	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Provide education/obtain consent	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	L4: Clinical labor type replaced by another labor type; see preamble text	-2.28
93XX5	Interrog crtd sins bat ip w/	L051A	RN	NF	Prepare room, equipment and supplies	2	0	L4: Clinical labor type replaced by another labor type; see preamble text	-1.52
98975	Rem ther mntr 1st setup&edu	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	35	G1: See preamble text	18.90

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
98975	Rem ther mntr 1st setup&edu	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	10	G1: See preamble text	5.40
98975	Rem ther mntr 1st setup&edu	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	0	3	G1: See preamble text	1.62
98975	Rem ther mntr 1st setup&edu	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	35	0	G1: See preamble text	-21.35
98975	Rem ther mntr 1st setup&edu	L039B	Physical Therapy Assistant	NF	Prepare room, equipment and supplies	2	0	G1: See preamble text	-1.22
98975	Rem ther mntr 1st setup&edu	L039B	Physical Therapy Assistant	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-1.83
98975	Rem ther mntr 1st setup&edu	SK057	paper, laser printing (each sheet)	NF		1	0	G1: See preamble text	-0.02
98980	Rtm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	30	G1: See preamble text	16.20
98980	Rtm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	G1: See preamble text	5.40
98980	Rtm tx mgmt 1st 20 min	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-6.10
98980	Rtm tx mgmt 1st 20 min	L039B	Physical Therapy Assistant	NF	Conduct patient communications	15	0	G1: See preamble text	-9.15
98981	Rtm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	G1: See preamble text	5.40
98981	Rtm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	10	G1: See preamble text	5.40
98981	Rtm tx mgmt ea addl 20 min	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-6.10

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
98981	Rtm tx mgmt ea addl 20 min	L039B	Physical Therapy Assistant	NF	Conduct patient communications	5	0	G1: See preamble text	-3.05
98XX7	Rtm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	5	G1: See preamble text	2.70
98XX7	Rtm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	15	G1: See preamble text	8.10
98XX7	Rtm tx mgmt 1st 10 min	L039B	Physical Therapy Assistant	NF	Conduct patient communications	10	0	G1: See preamble text	-6.10
98XX7	Rtm tx mgmt 1st 10 min	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-3.05
99454	Rem mntr physiol param 16-30	EQ392	heart failure patient physiologic monitoring equipment package	NF		43200	0	G1: See preamble text	-48.85
99454	Rem mntr physiol param 16-30	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	11	0	G1: See preamble text	-5.94
99454	Rem mntr physiol param 16-30	SD385	digital remote physicologic monitoring device app	NF		1	0	G1: See preamble text	-6.62
99457	Rpm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	8	10	G1: See preamble text	1.08
99457	Rpm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	12	30	G1: See preamble text	9.72
99458	Rpm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	12	10	G1: See preamble text	-1.08
99458	Rpm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	7	10	G1: See preamble text	1.62

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
99XX4	Rem mntr physiol param 2-15	EQ392	heart failure patient physiologic monitoring equipment package	NF		20160	0	G1: See preamble text	-22.80
99XX4	Rem mntr physiol param 2-15	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	11	0	G1: See preamble text	-5.94
99XX4	Rem mntr physiol param 2-15	SD385	digital remote physicologic monitoring device app	NF		1	0	G1: See preamble text	-6.62
99XX5	Rpm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	6	15	G1: See preamble text	4.86
99XX5	Rpm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	3	5	G1: See preamble text	1.08
9XX01	Mchnl sclp cool meas ftg	L056A	RN/OCN	NF	Perform procedure/service---NOT directly related to physician work time	5	27	G1: See preamble text	17.82

TABLE 21: CY 2026 DIRECT PE REFINEMENTS – EQUIPMENT REFINEMENTS CONFORMING TO CHANGES IN CLINICAL LABOR TIME

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	Nonfacility (NF)/Facility (F)	Labor Activity (where applicable)	RUC Recommendation or Current Value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change (in dollars)
52648	Laser surgery of prostate	EF031	table, power	F		95	89	E15: Refined equipment time to conform to changes in clinical labor time	-0.09

TABLE 22: CY 2026 INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
0446T, 0448T	implantable interstitial glucose sensor	SD334	$3,000.00	$6,000.00	100%	-	620
36514	cell separator system	EQ084	$81,656.40	$93,705.58	15%	46	218
37XX1, 37X03, 37X05, 37X07, 37X10, 37X12, 37X14, 37X16, 37X18, 37X20, 37X22, 37X24, 37X27, 37X29, 37X31, 37X33, 37X35, 37X37, 37X39, 37X41, 37X43, 37X45 + 74 other codes	guidewire, hydrophilic	SD089	$20.56	$27.42	33%	3	-
37XX1, 37X03, 37X05, 37X07, 37X10, 37X12, 37X14, 37X16, 37X18, 37X20, 37X22, 37X24, 37X27, 37X29, 37X31, 37X33, 37X35, 37X37, 37X39, 37X41, 37X43,	catheter, (Glide)	SD147	$48.95	$50.65	3%	3	-

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
37X45 + 40 other codes							
37X18, 37X20, 37X22, 37X24, 37X35, 37X37, 37X39, 37X41	atherectomy device	SD253	$3,048.33	$3,447.50	13%	2	63,494
37X07, 37X08, 37X15, 37X16, 37X17, 37X23, 37X24, 37X25 + 2 other codes	covered stent (VIABAHN)	SD254	$3,129.00	$3,931.17	26%	5	5,772
37X07, 37X16, 37X20, 37X24, 37X29, 37X33, 37X37, 37X41	Reentry device (Frontier, Outback, Pioneer)	SD255	$2,343.12	$3,100.00	32%	2	28,041
53854	kit, Rezum delivery device	SA128	$1,220.00	$3,090.00	153%	6	2,648
55874	Biodegradable Material Kit - PeriProstatic	SA126	$2,965.00	$4,036.22	36%	9	7,466
77402, 77407, 77412	Radiation Treatment Delivery Linear Accelerator	ER089	$3,000,966.47	$3,999,493.00	33%	1	1,502,416
77402, 77407, 77412	water chiller (radiation treatment)	ER065	$9,847.33	$15,309.00	55%	1	1,502,416
77X07	Superficial radiation therapy system	ER045	$204,999.67	$395,000.00	93%	1	452,289
88182, 88184, 88185	flow cytometer	EP014	$205,774.80	$211,250.00	3%	1	2,133,243

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
88182, 88184, 88185	Isoton II diluent	SL084	$0.0020	$0.0035	75%	3	2,133,243
88184	calibration beads (each test)	SL021	$11.46	$13.09	14%	3	92,800
88184, 88185	lysing reagent (FACS)	SL089	$5.532	$6.009	9%	3	2,132,513
88344	34 Beta E12	SL496	$5.38	$8.34	55%	3	107,784
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	$18.01	$20.91	16%	6	371,033
91040, 91XX1	barostat system, with hardware & software	EQ070	$23,625.00	$39,275.00	66%	1	315
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$292.50	$285.00	-3%	8	672,717
95144, 95165	antigen, multi (pollen, mite, mold, cat)	SH007	$8.96	$13.00	45%	69	5,917,413
99XX4, 0446T, 99454	patient physicologic monitoring equipment package	EQ392	$1,000.00	$1,000.00	0%	0	2,320,898
G2082	Esketamine (56 mg vial)	SH109	$772.41	$834.20	8%	1	4,344
G2083	Esketamine (84 mg vial)	SH110	$1,158.62	$1,251.31	8%	1	32,155
111 codes	pack, basic injection	SA041	$10.45	$12.73	22%	-	-
306 codes	pack, cleaning and disinfecting, endoscope	SA042	$22.40	$25.36	13%	-	-
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%	-	-
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%	-	-
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$4.01	-20%	-	-
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$2.26	-17%	-	-
239 codes	pack, pelvic exam	SA051	$20.16	$14.38	-29%	-	-
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$6.50	35%	-	-

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$7.49	37%	-	-
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$6.53	41%	-	-
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$10.93	50%	-	-
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$9.48	53%	-	-
38 codes	pack, urology cystoscopy visit	SA058	$94.68	$75.67	-20%	-	-
120 codes	pack, drapes, ortho, large	SA080	$37.30	$33.33	-11%	-	-
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%	-	-
145 codes	pack, ophthalmology visit (w-dilation)	SA082	$3.52	$3.12	-11%	-	-
119 codes	pack, protective, ortho, large	SA083	$10.86	$12.16	12%	-	-
27 codes	pack, protective, ortho, small	SA084	$5.99	$6.71	12%	-	-

TABLE 23: CY 2026 NEW INVOICES

CPT/HCPCS Codes	Item Name	CMS Code	Average Price	No. of Invoices	NF Allowed Services
37X09	Iliac IVL Catheter	SD380	3,450.00	3	374
37X09, 37X26	IVL generator	EQ413	15,000.00	1	1,779
37X10, 37X11, 37X12, 37X13, 37X14, 37X18, 37X19, 37X20, 37X21, 37X22	Drug coated balloon	SD382	2,343.33	3	41,255
37X14, 37X22	Drug eluting stent	SD383	1,900.00	1	9,110
37X18, 37X20, 37X22, 37X24, 37X35, 37X37, 37X39, 37X41	Embolic protection for atherectomy	SD384	2,862.00	1	63,494
37X26	FemPop IVL Catheter	SD381	4,700.00	3	1,405
37X31, 37X32, 37X33, 37X34, 37X39, 37X40, 37X41, 37X42	drug eluting stent, tibial	SD379	2,750.00	4	2,643
52XX2	Optilume BPH Prostatic Dilation Kit	SA138	5,900.00	10	1

CPT/HCPCS Codes	Item Name	CMS Code	Average Price	No. of Invoices	NF Allowed Services
55705, 5XX00, 5XX01, 5XX02, 5XX03, 5XX04, 5XX07	Disposable Prostate Core Biopsy Needle	SC110	43.85	1	58,849
5XX00, 5XX01, 5XX04	Transrectal Ultrasound Biopsy Guide	SD376	17.31	1	45,735
5XX01, 5XX03, 5XX04, 5XX07, 5XX10	UroNav system	ER127	181,998.45	1	21,540
5XX02, 5XX03, 5XX07	Transperineal Ultrasound Biopsy Guide	SD373	237.00	1	11,287
5XX08, 5XX09	Transrectal MRI-compatible -150mm fully automatic biopsy gun	SD374	180.00	1	1,213
5XX08, 5XX09	Transrectal MRI-compatible needle guide	SD375	150.00	1	1,213
64X11	IB-Stim device kit	SA139	1,195.00	4	0
64X11	Adhesive dot 10mm	SK135	0.19	1	0
647XX	Kit, UltraguideCTR	SA140	1,099.00	3	75
77X08	Orthovoltage Treatment Delivery System	ER128	498,961.00	1	11,912
91XX2	Anorectal expulsion balloon	SD377	35.25	2	13,451
91XX2	Sheath, catheter	SD378	39.00	2	13,451
922X1	Dark Adaptometer, Second Generation	ER126	61,758.00	1	0
99XX4, 99454	digital remote physicologic monitoring device app	SD385	6.62	1	2,320,580
9XX01	Scalp Cooling Cap/Kit	SA141	1,800.00	6	2
No codes	pack, angiography	SA142	68.26	1	-
No codes	Digital mental health device (insomnia)	SD386	800.00	4	-

TABLE 24: CY 2026 NO PE REFINEMENTS

HCPCS	Description
0596T	Temp fml iu vlv-pmp 1st insj
0597T	Temp fml iu valve-pmp rplcmt
27465	Shortening of thigh bone
27466	Lengthening of thigh bone
27715	Revision of lower leg
27XX0	Osteot femur imed lngth dev
27XX1	Osteot tibia imed lngth dev
28750	Fusion of big toe joint
28755	Fusion of big toe joint
33340	Perq clsr tcat l atr apndge
33880	Evasc rpr ta ndgft cov lsa
33881	Evasc rpr ta ndgft xcov lsa
33883	Delayed plmt prox xtn prosth
33886	Delayed plmt dstl xtn prosth
33XX2	Evasc rpr ta dplmt mltpc sys
35XX1	Bpg crtd-clat crtd
37X02	Revsc evasc ivt angio sf ea

HCPCS	Description
37X04	Revsc evsc ivt angio cplx ea
37X06	Revsc cvasc ivt stent sf ea
37X08	Revsc evasc ivt st cplx ea
37X09	Iv lithotrp ivt w/in sm art
37X11	Revsc evasc fpvt angio sf ea
37X13	Rvsc evsc fpvt angio cplx ea
37X15	Revsc evasc fpvt stent sf ea
37X17	Revsc evasc fpvt st cplx ea
37X19	Revsc evsc fpvt athrc sf ea
37X21	Rvsc evsc fpvt athrc cplx ea
37X23	Rvsc evsc fpvt st athr sf ea
37X25	Rvsc evsc fpvt st ath cpx ea
37X26	Iv lithotrp fpvt w/in sm art
37X28	Revsc evsc tpvt angio sf ea
37X30	Rvsc evsc tpvt angio cplx ea
37X32	Revsc evasc tpvt st sf ea
37X36	Revsc evsc tpvt athrc sf ea
37X38	Revsc evsc tpvt athr cplx ea
37X40	Rvsc evsc tpvt st athr sf ea
37X44	Revsc evasc imvt angio sf ea
37X46	Revsc cvsc imvt angio cpx ea
4XX04	Gstr rstcv px trnsorl esg
52500	Revision of bladder neck
52601	Prostatectomy (turp)
52630	Remove prostate regrowth
52649	Prostate laser enucleation
52XX1	Trurl rbtc wtrjt rescj prst8
55705	Bx prst8 any approach nonimg
55706	Prostate saturation sampling
55840	Extensive prostate surgery
55842	Extensive prostate surgery
55845	Extensive prostate surgery
55866	Laps surg prst8ect rpbic rad
558X1	Lap srg prst8ct lymph nod bx
558X2	Lap srg prst8ct bi pl lmphad
5XX00	Bx prst8 trct us guided
5XX01	Bx prst8 trct us w/mri fus 1
5XX02	Bx prst8 tprnl us guided
5XX03	Bx prst8 tprn us w/mri fus 1
5XX04	Bx prst8 trct mri-us 1st
5XX07	Bx prst8 tprnl mri-us 1st
5XX08	Bx prst8 in-bore ct/mri bx 1
5XX09	Bx prst8 in-bore ct/mri 1
5XX10	Bx prst8 ea add mri-us/ct/mr
5XX11	Abltj ire prst8 1+ tum perq
61624	Tcat perm occls/embolj cns
62XX0	Dcmprn prq rmv lig flv 1lmbr
62XX1	Dcmprn prq rmv lig flv addl
647XX	Dcmprn median nrv carpl tunl
64X10	Rmvl bat modulj sys pg only
64X11	Perq elec nrv field stimj cn
64XX5	1st opn implt bat modulj sys
64XX6	Revj/rplcmt bat mod sys lead
64XX7	Revj/rplcmt bat mod sys pg
64XX8	Rmvl bat modulj sys tot sys
64XX9	Rmvl bat modul sys lead only

HCPCS	Description
70496	Ct angiography head
70498	Ct angiography neck
70XX1	Cta h&n c+ w/noncontrast img
70XX2	Ct cere prfu alys c+w/ct/cta
70XX3	Ct cere prfu aly c+wo ct/cta
75894	X-rays transcath therapy
75898	Follow-up angiography
75XX6	Quan&char c athrosclrtc plaq
76872	Us transrectal
92284	Dx dark adaptation exam i&r
922X1	Scr dark adaptation meas i&r
96380	Admn rsv monoc antb im cnsl
96381	Admn rsv monoc antb im njx
99091	Collj & interpj data ea 30 d
99453	Rem mntr physiol param setup
99473	Self-meas bp pt educaj/train
99474	Self-meas bp 2 readg bid 30d
9XX02	Mchnl sclp cool prep plmt
9XX03	Mchnl sclp cool after chemo

F. Evaluation and Management (E/M) Visits

1. Evaluation and Management (E/M) Visit Complexity Add-On

In the CY 2024 PFS final rule (88 FR 78970 through 78982), we finalized separate payment for the office/outpatient evaluation and management (O/O E/M) visit complexity add-on code, HCPCS code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).*

In the CY 2024 PFS final rule, we noted that the O/O E/M visit complexity add-on code ''reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M visit services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high-risk disease) and to address the majority of a patient's health care needs with consistency and continuity over longer periods of time.'' (88 FR 78970 through 78971). We explained in the CY 2024 PFS final rule that it is the relationship between the patient and the practitioner that is the determining factor for when the add-on code should be billed. The add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship. The first part of the code descriptor, the ''continuing focal point for all needed health care services,'' describes a relationship between the patient and the practitioner when the practitioner is the continuing focal point for all health care services that the patient needs. The second part of the add-on code also describes a relationship involving medical services that are part of ongoing care related to a patient's single, serious condition or a complex condition. There is previously unrecognized but important cognitive effort of utilizing the longitudinal relationship in making a diagnosis, developing a treatment plan, and weighing the factors that affect a longitudinal doctor-patient relationship. The practitioner must decide what course of action and choice of words in the visit itself would lead to the best health outcome in the single visit while simultaneously building up an effective, trusting longitudinal relationship with the patient. Weighing these various factors, even for a seemingly simple condition, makes the entire visit inherently complex, which is what this add-on code is intended to capture (88 FR 78973 through 78974).

Interested parties have recommended that CMS either establish separate payment for an evaluation and management inherent complexity add-on code specific to home-based visits or expand use of the O/O E/M visit complexity add-on code HCPCS code G2211 to be reported alongside home and residence E/M visits furnished to beneficiaries in nursing facilities, assisted living facilities, and the beneficiary's home. Interested parties have explained that home-based primary care practices provide access to primary care services for patients who otherwise would not be able to leave the house to see a primary care practitioner, and include the development of longitudinal, ''high-touch'' relationships with their patients.

In the CY 2024 PFS final rule (88 FR 78818, 78971), we stated that the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with separate payment for HCPCS code G2211 (85 FR 84569, 87 FR 69588), and that we finalized work RVUs for the nursing facility E/M visit codes (87 FR 69604 through 69606) and the home or residence services code family (87 FR 69608 and 69609) subsequently in the CY 2023 PFS final rule. We stated that we may nevertheless consider in future rulemaking whether home or residence evaluation and management services bear unrecognized resource costs and whether HCPCS code G2211 should be applicable to home or residence E/M visits. We have noted that the application of the add-on code is not based on the characteristics of particular patients (even though the rationale for valuing the code is based on recognizing the typical complexity of patient needs), but rather the relationship between the patient and the practitioner (88 FR 78973). In part, HCPCS code G2211 recognizes the resource costs involved in building trust in a long-term practitioner-patient relationship that are

not reflected in the valuation of the O/O E/M code set. The same appears to be true about the home and residence evaluation and management code set. Building trust as part of a longitudinal practitioner-patient relationship may be particularly significant in the context of home and residence E/M visits. Typically, home visits occur at least monthly and people with serious illness may receive weekly visits. These visits involve developing and following through on a longitudinal care plan with proactive contacts regarding all of a person's health care needs. The follow-through based on a trusting practitioner/patient relationship is critical to keeping patients stable and preventing exacerbations. For this reason, we believe it is appropriate to extend the application of HCPCS code G2211 to home and residence E/M visits at this time. Therefore, we are proposing to allow HCPCS code G2211 to be billed as an add-on code with the home or residence evaluation and management visits code family (CPT codes 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350). The HCPCS code G2211 descriptor would read as follows, ''*(Visit complexity inherent to evaluation and management* associated with *medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-*on code, *list separately in addition to home or residence or* office/outpatient *evaluation and management* service*, new* or *established))*''.

G. Enhanced Care Management

1. Integrating Behavioral Health Into Advanced Primary Care Management (APCM)

In the CY 2025 PFS final rule (89 FR 97859 through 97902), we finalized separate coding and payment for Advanced Primary Care Management (APCM) services (HCPCS codes G0556, G0557, and G0558).

TABLE: 25 APCM CODES

Code	G0556	G0557	G0558
Population	For beneficiaries with one chronic condition or fewer	For beneficiaries with multiple (two more more) chronic conditions	For beneficiaries who are a Qualified Medicare Beneficiaries with multiple (two or more) chronic conditions
Long Descriptor	*Advanced primary care management services for a patient with one chronic condition [expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline], or fewer, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:* ● *Consent;* ++ *Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.* ++ *Document in patient's medical record that consent was obtained.* ● *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*	*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:* ● *Consent;* ++ *Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.* ++ *Document in patient's medical record that consent was obtained.* ● *Initiation during a qualifying visit for new*	*Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:* ● *Consent;* ++ *Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.* ++ *Document in patient's medical record that consent was obtained.* ● *Initiation during a qualifying visit for new*

Code	G0556	G0557	G0558
	• *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;* • *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;* • *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;* • *Overall comprehensive care management;* ++ *Systematic needs assessment (medical and psychosocial).* ++ *System-based approaches to ensure receipt of preventive services.* ++ *Medication reconciliation, management and oversight of self-management.* • *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan with typical care plan elements when clinically relevant;* ++ *Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;* • *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;* ++ *Ensure timely exchange of electronic health information*	*patients or patients not seen within 3 years;* • *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;* • *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;* • *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;* • *Overall comprehensive care management;* ++ *Systematic needs assessment (medical and psychosocial).* ++ *System-based approaches to ensure receipt of preventive services.* ++ *Medication reconciliation, management and oversight of self-management.* • *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;* ++ *Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;* • *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*	*patients or patients not seen within 3 years;* *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;* • *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;* •*Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;* • *Overall comprehensive care management;* ++ *Systematic needs assessment (medical and psychosocial).* ++ *System-based approaches to ensure receipt of preventive services.* ++ *Medication reconciliation, management and oversight of self-management.* • *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;* ++ *Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;* *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

Code	G0556	G0557	G0558
	with other practitioners and providers to support continuity of care. *++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.* *● Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;* *● Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;* *++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital*	*++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.* *++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.* *● Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;* *● Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;* *++ Ensure access to patient-initiated digital*	*++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.* *++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.* *● Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;* *● Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;* *++ Ensure access to patient-initiated digital*

Code	G0556	G0557	G0558
	online assessment and management and E/M visits (or e-visits). • *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;* • *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;* • *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology*).	*communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).* • *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;* • *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;* • *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).	*communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).* • *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;* • *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;* • *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology*)

In the CY 2017 PFS final rule (81 FR 80230), we began making separate payment to practitioners who provide behavioral health integration (BHI) services to patients using the Psychiatric Collaborative Care Model (CoCM) (a specific model of care provided by a primary care team consisting of a primary care provider and a health care manager who works in collaboration with a psychiatric consultant) using HCPCS codes G0502, G0503, and G0504.

In the CY 2018 PFS final rule (82 FR 53077 through 53078), these codes were replaced by CPT codes 99492 (Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies), 99493 (Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment), and 99494 (Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure)), respectively.

In the CY 2017 PFS final rule (81 FR 80230), we also began making separate payment to practitioners who provide general BHI services to patients, using HCPCS code G0507. BHI is a term that refers broadly to collaborative care that integrates behavioral health services with primary care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. In the CY 2018 PFS final rule (82 FR 53077 through 53078), HCPCS code G0507 was replaced by CPT code 99484.

CPT code 99484 is for care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes,

facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team.

Patients with chronic health conditions are ''more likely to have related behavioral health concerns and find it easier to improve chronic conditions when these concerns are also addressed.'' [54] Integrating behavioral health with primary care has been shown to improve outcomes like reduced depression severity, and enhancing patient's experience of care.[55] In the CY 2025 PFS final rule (89 FR 97897), we summarized comments that we had received on our APCM services proposals discussing the importance of behavioral health on overall health and urging us to consider including behavioral health in future rulemaking as it relates to advanced primary care, citing the growing need for fully integrated physical and behavioral health. In our response, we agreed with commenters that behavioral health integration services are complementary to APCM services and that behavioral health is important in the context of overall health. We stated that we will take comments recommending strategies for further integration into consideration for future rulemaking. We further stated that we continue to be interested in the use of behavioral health integration services as they relate to advanced primary care and welcome input from interested parties, including how evolving changes in practice may warrant reconsideration of payment and coding policies.

We believe that the physicians and practitioners who furnish APCM services should be able to provide BHI services and CoCM without needing to document their time spent performing the service because this would help facilitate a more holistic, team-based approach to care coordination and reduce burden. Otherwise, the practice would need to develop a time documentation system for BHI and CoCM, but not APCM. Functionally, we also believe that many practices that develop the interdisciplinary teams to provide advanced primary care are also the ones most likely ready to furnish BHI and CoCM services, so alignment in billing requirements would streamline processes. Therefore, for CY 2026, we are proposing to create optional add-on codes for APCM services that would facilitate providing complementary BHI services by removing the time-based requirements of the existing BHI and CoCM codes. We believe that removing the time-based requirements will reduce burden on practitioners by reducing the documentation requirements for billing. By reducing the documentation requirements, we also believe primary care practitioners may be more likely to offer and furnish BHI and CoCM services, which would improve access to BHI and CoCM for primary care patients. These proposed optional add-on codes for APCM services would be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner. In the CY 2024 PFS final rule (88 FR 78939), we summarized comments received for Principal Illness Navigation services that discussed that patients with severe mental illness and substance use disorders may only see behavioral health practitioners regularly, which we believe makes the integration of behavioral health and primary care important for this population to improve access. We are opting to not create an add-on code for CPT code 99494 as this code is for an additional 30 minutes of initial or subsequent psychiatric collaborative care management in a calendar month, and the APCM codes, and proposed add-on codes do not require the counting of minutes in order to bill.

2. Behavioral Health Integration Add-On Codes for APCM (HCPCS Codes GPCM1, GPCM2, GPCM3)

We are proposing the establishment of three new G-codes to be billed as add-on services when the APCM base code (HCPCS codes G0556, G0557, and G0558) is reported by the same practitioner in the same month. HCPCS code GPCM1, an add-on code based on CPT code 99492, HCPCS code GPCM2, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and HCPCS code GPCM3, an add-on code for general behavioral health integration services based on CPT code 99484. We are not proposing to create an add-on code for CPT code 99494, as that code describes additional time, and these codes do not require the counting of minutes.

Our proposed code descriptors are listed below.

HCPCS code GPCM1: Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately and in addition to the Advanced Primary Care Management code).

HCPCS code GPCM2: Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are

[54] https://integrationacademy.ahrq.gov/about/integrated-behavioral-health#:~:text=Integrated%20behavioral%20health%20offers%20many,these%20concerns%20are%20also%20addressed.

[55] Balasubramanian, Bijal, Deborah Cohen, Katelyn Jetelina, Miriam Dickinson, Melinda Davis, Rose Gunn, Kris Gowen, Frank DeGruy 3rd, Benjamin Miller, Larry Green. ''Outcomes of Integrated Behavioral Health with Primary Care.'' J Am Board Fam Med. 2017 Mar–Apr;30(2):130–139.doi: 10.3122/jabfm.2017.02.160234.

prepared for discharge from active treatment (list separately and in addition to Advanced Primary Care Management code).

HCPCS code GPCM3: Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team (list separately and in addition to Advanced Primary Care Management code).

3. Valuation of Behavioral Health Integration Add-on Codes for APCM Services

In consideration that the services described by the proposed add-on codes are meant to be directly comparable to the existing CoCM and BHI codes, we propose a direct crosswalk to the current work RVU values of CPT code 99492 for HCPCS code GPCM1 (work RVU 1.88), CPT code 99493 for HCPCS code GPCM2 (work RVU 2.05), and CPT code 99484 for HCPCS code GPCM3 (work RVU 0.93). We also propose a direct crosswalk to the current direct PE inputs for CPT codes 99492 (non-facility RVU 2.48, facility RVU 0.80), 99493 (non-facility RVU 1.93, facility RVU 0.86), and 99484 (non-facility RVU 0.66, facility RVU 0.30), to HCPCS codes GPCM1, GPCM2, and GPCM3, respectively. We welcome comments on this approach.

4. Request for Information Related to APCM and Prevention

Having a usual source of primary care can be positively associated with better receipt of recommended prevention services [56] and effective management of chronic disease,[57] which per the Trump Administration's Executive Order, ''Establishing the President's Make America Healthy Again Commission,'' [58] is a top priority for CMS. APCM coding and payment has represented CMS' recent efforts to promote team-based primary care. In the CY 2025 PFS final rule (89 FR 97863), commenters recommended that cost sharing be eliminated for APCM services, indicating that any amount of cost sharing could be prohibitive and may limit the uptake of APCM services. A few commenters suggested that APCM services are preventive services that should be exempt from beneficiary cost sharing.

At the time, we responded to comments stating that CMS did not see how APCM fit within the benefit categories for preventive services. After further consideration and analysis, there are some service elements of APCM that are substantively similar to certain aspects of the ''personalized prevention plan services'' described under section 1861(hhh)(1) of the Act. For example, the personalized prevention plan includes a health risk assessment, which includes identification of chronic diseases, injury risks, modifiable risk factors, and urgent health needs. This is substantively similar to the service element of APCM that requires an overall systematic needs assessment (which includes both medical and psychosocial needs). The personalized prevention plan includes ''improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management,'' which is substantively similar to the APCM service element of ''oversight of self-management.'' However, as APCM is a bundle of different care management and communication technology-based services, there are other service elements of the APCM codes that may be covered under Medicare Part B and carry cost sharing obligations.

The blending of prevention and treatment services makes intuitive sense for those familiar with advanced primary care practices— which must simultaneously balance ensuring patients receive their needed preventive services and treatment services. Indeed, effective care management often means balancing prevention and treatment in the life an individual patient. For example, for a patient with a recent history of a Deep Venous Thrombosis (DVT) on anticoagulation medication, a primary care team must often balance whether or not to hold the patient's anticoagulation in order for the patient to receive a colonoscopy (where removal of a polyp while the patient is on anticoagulation can lead to excessive bleeding).[59] The primary care team must balance the relative risks of holding the anticoagulation medication, with the relative risks of delaying cancer screening, for the optimal health and wellbeing of the patient.

Given these factors, we are seeking comments on how CMS should consider application of cost sharing for APCM services, particularly, if we were to include preventive services within the APCM bundles. How should we account for cost sharing if APCM includes both preventive services and other Part B services? Should CMS consider including the Annual Wellness Visit, depression screening, or other preventative services in the APCM bundle, and if so, which services and why?

Should CMS consider other changes to APCM or additional coding to further recognize the work of advanced primary care practices in preventing and managing chronic disease?

Additionally, we have often described how primary care teams are central to the relative success of Medicare Shared Savings ACOs. In 2023, as in previous years, ACOs comprised of larger proportions of primary care clinicians had significantly higher net per capita savings than ACOs comprised of smaller proportions of primary care clinicians.

Should CMS consider new payments to Shared Savings Program ACOs for prospective monthly APCM payments to be delivered to primary care practices that satisfy the APCM billing requirements, with the payments reconciled under the ACO benchmark?

If so, how should CMS consider consent and other features of APCM in these contexts?

Should CMS consider other updates to APCM payments or Shared Savings Program policies that would drive increased participation of primary care practitioners in ACOs?

[56] Blewett, Lynn, Pamela Jo Johnson, Brian Lee, and Peter Scal. When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services. Journal of General Internal Medicine. Volume 23, pages 1354–1360. Published May 28, 2008.

[57] Luo, Jiajun, Muhammad Kibriya, Paul Zakin, Andrew Craver, Liz Connellan, Saira Tasmin, Tamar Polonsky, Karen Kim, Habibul Ahsan, Briseis Aschebrook-Kilfoy. ''Urban Spatial Accessibility of Primary Care and Hypertension Control and Awareness on Chicago's South Side: A Study From the COMPASS Cohort. Circ Carvdiovasc Qual Outcomes. 2022 Sep; 15(9):e008845. Doi: 10.1161/CIRCOUTCOMES.121.008845. Epub 2022 Sep 6.

[58] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

[59] O'Donnel, Michael and Seth A. Gross. ''Management of Anticoagulation and Colonoscopy.'' Current Treatment Options in Gastroenterology. Volume 19, pages 1–13(2021). Published January 16, 2021.

I. Policies To Improve Care for Chronic Illness and Behavioral Health Needs

1. Updates to Payment for Digital Mental Health Treatment (DMHT) and Comment Solicitation on Payment Policy for Software as a Service (SaaS)

a. Updates to Payment for DMHT

In the CY 2025 PFS final rule (89 FR 97923 through 97928), we established Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. We use the term ''DMHT device'' to include the term digital cognitive behavioral therapy we used in prior rulemaking (88 FR 79012 through 79013) and in general to refer to software devices cleared, approved, or granted De Novo authorization by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health. We use the terms ''behavioral health conditions'' and ''mental disorders'' interchangeably and to mean psychiatric disorders as referenced in FDA regulation, 21 CFR 882.5801. This includes substance use disorders. The FDA definition of devices encompasses certain software intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.[60] As the field of innovative products including digital therapeutics and computerized behavioral therapy devices for behavioral health treatment develops and expands the FDA continues to apply a risk-based framework to review and classify computerized behavioral therapy devices.

Effective January 1, 2025, we finalized three HCPCS G-codes for DMHT devices, to be billed by physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness: G0552 *(Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan);* HCPCS code G0553 *(First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month);* and HCPCS code G0554 *(Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month).*

Additionally, we finalized the conditions of payment for these codes. To be payable under the PFS, the DMHT device must have been cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or granted De Novo authorization by FDA and in each instance classified at § 882.5801. In addition, the billing practitioner must incur the cost of the DMHT device furnished to the beneficiary, and the furnishing of the DMHT device must be incident to the billing practitioner's professional services in association with ongoing behavioral health treatment under a plan of care by the billing practitioner. Furthermore, we finalized that the billing practitioner must diagnose the patient with a mental health condition and prescribe or order the DMHT device. We are clarifying here that the patient must have a mental health condition diagnosis, but the billing practitioner does not need to be the practitioner who made the diagnosis. The patient could then use the DMHT device in settings according to how the device has been classified by FDA for use at § 882.5801, which could include the home or an office or other outpatient setting if consistent with the FDA classification for use. Also, payment may only be made for DHMT devices for mental health treatment in accordance with the use indicated in their FDA classification at § 882.5801. We continue to be vigilant about waste, fraud and abuse as we develop payment policy for devices that may function like DMHT devices but whose technology platforms may differ from those of DMHT devices classified at § 882.5801. We seek to ensure that DMHT devices are not only safe for patients but also beneficial for patients. Our objective in requiring that DMHT devices be classified at § 882.5801 as a condition of payment was to set guardrails within our payment policy for patient safety and benefit. While partly in recognition of our inability to evaluate every DMHT device, in this way we limited payment to devices which are required to comply with the special controls requiring clinical data to validate the model of behavioral therapy as implemented by the device. While presently use cases for insomnia, substance use disorder, depression and anxiety have been classified by the FDA at 21 CFR 882.5801, future use cases are not necessarily limited to these.

It is possible that additional DMHT devices for other use cases with similar characteristics may be classified under this code section.

We anticipate that updating our payment policies will be an iterative process relating first to behavioral health treatment and by extension to chronic conditions. Behavioral health conditions are some of the most prevalent chronic diseases in the country. Among adults aged 18 or older in 2023, 22.8 percent (or 58.7 million people) had any mental illness and 48.5 million people aged 12 or older (or 17.1 percent) had a substance use disorder (SUD) in the past year. These behavioral health conditions are often chronic in nature. Individuals with Major Depressive Disorder, for example, often have recurrent episodes throughout their lives.[61]

The technologies and platforms for digital therapeutics are evolving rapidly. We are at an early stage of Medicare payment for DMHT devices as supplies furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. In considering the next stage in the development of our payment policy, we have been reviewing interested parties' recommendations to make payment for FDA authorized devices under other classifications, including Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions under 21 CFR 876.5960; Biofeedback device under 21 CFR 882.5050; Digital

[60] Sec. 201(h)(1) of the Federal Food, Drug, and Cosmetic Act.

[61] *https://www.samhsa.gov/data/sites/default/files/NSDUH%202023%20Annual%20Release/2023-nsduh-main-highlights.pdf.*

therapy device to reduce sleep disturbance for psychiatric conditions under 21 CFR 882.5705; Digital therapy device for Attention Deficit Hyperactivity Disorder under 21 CFR 882.5803; and Computerized behavioral therapy device for the treatment of fibromyalgia symptoms to be codified at 21 CFR 882.5804. We note that Medicare coverage of biofeedback is limited by a long-standing national coverage determination. See, Medicare National Coverage Determinations Manual Chapter 1, Part 1 (Sections 10–80.12) Coverage Determinations, Section 30.1, Biofeedback, *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part1.pdf.*

We are proposing to expand our payment policies for HCPCS codes G0552, G0553, and G0554 to also make payment for DMHT devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each instance classified at § 882.5803 Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD). The § 882.5803 classification is for software intended to provide therapy for ADHD or any of its individual symptoms as an adjunct to clinician supervised treatment. Comparable to the special controls for device classification § 882.5801 Computerized behavioral therapy device for psychiatric disorders, the § 882.5803 device classification's special controls require the use of a validated measure to evaluate effectiveness of the device to provide therapy for ADHD or any of its individual symptoms. The special controls for device classification § 882.5801 require that clinical data must be provided to describe a validated model of behavioral therapy for the psychiatric disorder; and to validate the model of behavioral therapy as implemented by the device. Comparable to the § 882.5801 device classification, the § 882.5803 device classification is intended to provide therapy as an adjunct to clinician supervised treatment. We believe that it is important to expand our coding and payment policies to include such devices classified at § 882.5803 to more fully reflect the range of behavioral health disorders treated by FDA-authorized products. We also propose that all the conditions of payment for HCPCS codes G0552, G0553, and G0554 finalized in the CY 2025 PFS final rule would apply to DMHT devices classified at § 882.5803. Additionally, we welcome comments on whether we should establish coding and payment policies for devices classified under the following FDA regulation sections that were recommended to us by interested parties: Computerized behavioral therapy devices for treating symptoms of gastrointestinal conditions at § 876.5960; Digital therapy devices to reduce sleep disturbance for psychiatric conditions at § 882.5705; and Computerized behavioral therapy device for the treatment of fibromyalgia symptoms to be codified at § 882.5804.

Medicare FFS claims data for HCPCS codes G0552, G0553, and G0554 have remained low in volume since we established these codes in the CY 2025 PFS final rule. We understand there may be several reasons for this. We are aware per interested parties and commenters that a condition of payment that we established for these codes, that the billing practitioner is incurring the cost of furnishing the DMHT device to the patient, may not align with direct to consumer delivery and payment models that existed before the final rule was issued.

At this time, we do not believe we can appropriately price all the DMHT devices for which we would make payment under our current policies and proposals, and therefore, we are not proposing any changes to the existing contractor-priced status for HCPCS code G0552. As we have noted, the technologies and DMHT therapies are evolving rapidly. We recognize our payment policy, too, will evolve. Given the dynamic nature of the development of these devices and the variation in methods of action for potential technology platforms, we do not have sufficient information needed to establish national pricing for devices described by HCPCS code G0552 at this time. We recognize that the ongoing nationwide behavioral health workforce shortage combined with increasing demand for behavioral health care services may limit access to behavioral health services for some Medicare beneficiaries.[62] We recognize that digital therapeutic devices may offer innovative means to access certain behavioral health care services. We acknowledge that the field of digital therapeutics is evolving and continue to solicit comments from the public on this topic, including the CPT Editorial Panel. We continue to aim to both provide access to vital behavioral health services and gather further information about the delivery of digital behavioral health therapies, their effectiveness, their adoption by practitioners as complements to the behavioral health care they furnish, and their use by patients for the treatment of behavioral health conditions. We continue to welcome information and may consider national pricing through future rulemaking.

We are seeking comments on the possibility of establishing for CY 2026 additional separate coding and payment for a broader based set of services describing digital tools used by practitioners intended for maintaining or encouraging a healthy lifestyle, as part of a mental health treatment plan of care. Specifically, we are seeking information about clinical practice involving use of such tools. On what reliable evidence do practitioners inform their clinical judgment that use of such digital tools is warranted or beneficial to their treatment of the patient? What role do these digital tools typically have within plans of behavioral health treatment? What appropriate crosswalks would we consider for the purposes of nationally pricing a code to describe digital tools that do not require FDA clearance, approval or authorization and therefore do not entail the development costs of FDA clearance, approval or authorization or meet other conditions of payment for HCPCS code G0552, primarily that the practitioner must bear the cost of the DMHT device as a supply incident to their services. For example, we could consider the inputs assigned to CPT code 98016 (Brief communication technology-based service (for example, virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5 to 10 minutes of medical discussion) or CPT code 99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5 to 10 minutes). Since the resource costs reflected in the practice expense should be lower for services involving digital tools that do not require FDA clearance, approval, or authorization or meet the condition of payment that the billing practitioner bears the cost of supplying the DMHT device for HCPCS code G0552, we anticipate that the corresponding valuation for any additional coding would be appropriately lower than G0552. We welcome comments on these potential crosswalks or any other services that

[62] *https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand.*

may best approximate the resource costs involved in cases where practitioners furnish a digital tool as part of a mental health treatment plan of care and furnish initial education and onboarding, per course of treatment that augments a behavioral therapy plan, and monthly treatment management services directly related to the patient's use of these digital tools. We also welcome comments on these potential crosswalks or any other services that may best approximate the resource costs involved in cases where practitioners do not furnish the digital tool and do not furnish initial education and onboarding for the tool, but nonetheless incorporate use of the tool as part of a mental health treatment plan of care.

Additionally, we are requesting comments on other related digital device policies for our consideration in future rulemaking. Specifically, we received a request from an interested party to create a new add-on G code to existing CPT codes 96112, 96113, 96116, 96121, 96130, 96131, 96132, and 96133 (code descriptors can be found in Table 26), for physicians' or non-physician practitioners' psychological/neuropsychological evaluations so they may report administration of an FDA authorized eye-tracking technology to aid in the diagnosis of Autism Spectrum Disorder (ASD) in pediatric patients, including staff time with the patient, data submission and output.

The interested party stated that the device collects data based on the clinical presentation of a patient, then an analysis algorithm is applied to the collected data to generate output. The interested party raised concerns that currently there are delays and waitlists to obtain diagnostic evaluations for children at risk for ASD. Their solution is to use this ASD diagnosis tool at the point of care after a parent or physician identifies a risk of ASD in a child. According to the interested party, this digital device can help reduce ASD diagnosis delays to be seen by a diagnostic specialist. The interested party is requesting the following code descriptor, *Algorithm-driven neurological assessment for likelihood of Autism Spectrum Disorder (ASD) diagnosis, and of ASD-measures' severity (for example, social disability, verbal and non-verbal ability), derived from validated quantitative analysis of looking behavior,* and recommends for CMS to either establish a national rate for the add-on code using a crosswalk to CPT code 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), CPT code 93247 (External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report), or to allow contractor pricing.

We are seeking comments from the public regarding whether creating an add-on G code and contractor pricing is needed for the administration of an FDA authorized eye-tracking technology and other technology to aid in the diagnosis of ASD in pediatric patients; or whether it would be more appropriate to go through the CPT Editorial Panel process to obtain a Category III CPT code for this treatment.

TABLE 26: PSYCHOLOGICAL/NEUROPSYCHOLOGICAL EVALUATION CODES

CPT Code	Long Descriptor
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)

b. Comment Solicitation on Payment Policy for Software as a Service (SaaS)

In recent years, there have been rapid developments in the use of software-based technologies to support clinical decision-making in the outpatient and physician office settings, some of which may be devices requiring FDA, clearance, approval, or authorization. We refer to these software-based technologies as software as a service (SaaS). As the data used in our PE methodology has aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology. As described in section II.B of this proposed rule, PE resources typically involved in furnishing services are characterized as either direct or indirect costs. Direct costs involved in furnishing a service are estimated for each code and include clinical labor, medical supplies, and medical equipment. Indirect costs include administrative labor, office expenses, and all other expenses. Indirect PE is allocated to each service based on physician work, direct costs, and a specialty-specific indirect percentage. The source of the specialty specific indirect percentage was the Physician Practice Information (PPI) Survey, last administered in 2007 and 2008, when emerging technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware may not have been typical. Thus, these costs are not well accounted for in the PE methodology. While we have received updated PPI survey data from the AMA that did incorporate information on the practice costs associated with SaaS and AI services, this information would only reflect the impact of SaaS and AI on the PE/hr associated with a given medical specialty, rather than providing insight into the direct costs associated with use of this technology.

Furthermore, as described in section II.B.5 of this proposed rule, due to several limitations with the data, we are

not proposing to implement the PE/HR data or cost shares from the AMA's PPI Survey data for CY 2026 ratesetting. Consistent with our PE methodology and as we have stated in past PFS rulemaking (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment. However, beginning with payment for Fractional Flow Reserve Computed Tomography (Heartflow) in the CY 2022 PFS final rule (86 FR 65041) CMS has made intermediate, service-specific policies to allow for PFS payment of SaaS and AI applications in certain circumstances.

We consider several distinct issues when evaluating SaaS technologies. First, we have observed wide variations in the purported costs of clinically similar SaaS technologies. The various costs that manufacturers consider when pricing their technologies, including research and development and software maintenance, are often not publicly verifiable. Additionally, due to the novel and evolving nature of these technologies, there are rarely existing medical items or services that can be utilized for comparison purposes to determine clinical and resource similarity. Finally, while there has been a rapid increase in the development and coding of services incorporating these technologies in recent years, there is a very limited amount of Medicare claims data for these services.

As this technology has continued to evolve and diversify, interested parties have stated that the lack of a consistent payment policy for SaaS and AI devices is an impediment to patient access when these devices are otherwise cleared, approved, or authorized by the FDA. Interested parties have requested that CMS consider the development of a payment policy for these devices that is stable and consistent across settings of care, payment systems, and types of services incorporating SaaS and AI devices. Additionally, as we are interested in paying accurately for the management of chronic disease and primary care services, we are seeking to understand how the use of SaaS and AI technology affects those services and how to incorporate these costs into our current strategy for paying for evolving models of care delivery, such as Advanced Primary Care Management and risk-based payment arrangements generally. Therefore, we are requesting public comments on how we should consider paying for SaaS under the PFS, including:

- What factors should we consider when paying for SaaS?
- What has the experience been of risk-based payment arrangement participants with incorporating SaaS under their payment arrangements?
- Have risk-based payment arrangements reflected the underlying value of SaaS to the practice of medicine?
- Given the limitations of the PE methodology to account for this kind of technology, what alternative pricing strategies should CMS use to accurately pay for SaaS and AI devices under the PFS? For example, should CMS continue its current practice, as referenced in section II.E.23. of this proposed rule, of crosswalking values from the OPPS established payment amounts for the technical components of services incorporating SaaS and AI? Or should we integrate OPPS geometric mean costs for these devices into our ratesetting methodology as we are proposing to do in this proposed rule for RPM and RTM services, or set payment rates relative to OPPS rates as we are proposing to do for radiation oncology services? See sections II.E.24. and 30. this proposed rule.
- How should CMS value the physician work associated with utilizing and interpreting the clinical outputs associated with SaaS and AI devices?
- Is there an alternative data source outside of the limited Medicare claims data currently available and hospital invoices provided by manufacturers, which may not fully depict total hospital acquisition costs, that can accurately reflect the costs of the SaaS?
- How are these technologies used in the treatment of chronic disease?
- How may CMS best evaluate the quality and efficacy of SaaS and AI technologies?

We welcome input from interested parties on these questions as well as any additional suggestions that would enhance our ability to provide accurate and consistent payment for procedures incorporating SaaS. We note that there is a comment solicitation in the CY 2026 OPPS proposed rule regarding SaaS devices furnished in hospital outpatient departments and ASCs.

2. Prevention and Management of Chronic Disease—Request for Information

Six in ten Americans have at least one chronic disease, and four in ten have two or more chronic diseases. Many preventable chronic diseases are caused by a short list of risk behaviors, including smoking, poor nutrition, physical inactivity, and excessive alcohol use.[63] In 2023, among adults aged 18 or older, 22.8 percent (or 58.7 million people) had any mental illness (AMI) in the past year.[64] Although Medicare Part B covers many preventive services,[65] as defined in section 1861(ddd)(3) of the Act, Medicare preventive services have some restrictions.[66]

Per the Trump Administration Executive Order, ''Establishing the President's Make America Healthy Again Commission,'' [67] the Administration is directing our focus towards understanding and drastically lowering chronic disease rates, including thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety. Furthermore, the Executive Order directs that agencies must ensure the availability of expanded treatment options and the flexibility for health insurance coverage to provide benefits to support beneficial lifestyle changes and disease prevention. As such, focusing on the prevention and management of chronic disease is a top priority for us.

We are broadly soliciting feedback to help us better understand how we could enhance our support management for prevention and management of chronic disease. Specifically, we are requesting commenters consider the following information:

- How could we better support prevention and management, including self-management, of chronic disease?
- Are there certain services that address the root causes of disease, chronic disease management, or prevention, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? If so, please provide specific examples.
- Are there current services being performed to address social isolation and loneliness of persons with

[63] Centers for Disease Control. ''Chronic diseases in America.'' Available from: *https://www.cdc.gov/chronic-disease/about/index.html#:~:text=Six%20in%2010%20Americans%20have,inactivity%2C%20and%20excessive%20alcohol%20use.*

[64] Highlights for the 2023 National Survey on Drug Use and Heath, *https://www.samhsa.gov/data/sites/default/files/NSDUH%202023%20Annual%20Release/2023-nsduh-main-highlights.pdf.*

[65] *https://www.medicare.gov/coverage/preventive-screening-services.*

[66] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c18pdf.pdf.*

[67] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

Medicare, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? If so, what evidence has supported these services, and what do these services entail? What services have been delivered by Medicare providers or community-based organizations, including area agencies on aging and other local aging and disability organizations? What has been the impact?

- Are there current services being performed that improve physical activity, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? How should CMS consider provider assessment of physical activity, exercise prescription, supervised exercise programs, and referral, given the accelerating use of wearable devices and advances in remote monitoring technology?
- Should CMS consider creating separate coding and payment for intensive lifestyle interventions, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set, and how should these interventions be prioritized? If so, what evidence has supported these services, and what do the services entail? How would additional coding and payment be substantively different from coding and payment for Intensive Behavioral Therapy?
- Should CMS consider creating separate coding and payment for medically-tailored meals, as an incident-to service performed under general supervision of a billing practitioner? If so, what would be the appropriate description of such a service, and under what patient circumstances (that is, after discharge from a hospital)? Do community-based organizations providing medically tailored meals currently employ a physician, nurse practitioner, physician assistant, or other practitioner who could both bill Medicare and supervise a medically-tailored meal service? Should CMS consider allowing billing providers to refer to community-based organizations to deliver and ensure quality of medically-tailored meals while under general supervision (please see § 410.26(a)(3) for further information about general supervision) of the referring billing provider? If CMS were to create separate coding and payment for medically-tailored meals, how should CMS ensure integrity of the service being delivered?
- Please provide information on whether we should consider creating separate coding and payment for FDA-cleared digital therapeutics that treat or manage the symptoms of chronic diseases an incident-to service performed under the general supervision of a billing practitioner. Please see the CY 2025 PFS final rule (89 FR 97923 through 97928) for reference as to how we created new coding and payment for FDA-cleared digital mental health treatments (DMHTs).
- Are there technical solutions that would enhance the uptake of the annual wellness visit (AWV), or the improving accessibility, impact, and usefulness of the AWV? How can CMS better support practitioners and beneficiaries related to the AWV? Should CMS consider moving some of the required components of the AWV to optional add-on codes of the AWV instead, with the intent of decreasing burden, improving uptake, and allowing practitioners to select additional AWV elements that may be more relevant to particular patients?
- The Administration for Community Living (ACL) has defined evidence-based programs,[68] which have demonstrated impact in effectively treating chronic disease, preventing disease, and helping older adults and people with disabilities to adopt healthy behaviors, improve their health status, reduce disability and injury, and reduce their use of hospital services and emergency room visits. In addition to programs impacting chronic disease management and prevention, there are evidence-based health programs that address older adult falls, mental health, physical activity, and more. Fifty-six State units on aging that work with over 600 area agencies on aging (AAAs) and their networks of service providers receive formula grants from ACL to administer programs, but the need exceeds available federal funding. Are there certain existing or new Physician Fee Schedule codes and payment, or Innovation Center Models, that could better support practitioner provision of successful interventions through partnerships between health care entities, AAAs, community care hubs, and other local aging and disability organizations? If so, please provide specific examples.
- In consideration that there are significantly more types of coding and payment that describe procedures in the physician fee schedule, please provide feedback regarding whether this detracts from the codes describing services that address underlying health behaviors, chronic disease management, and prevention.

Aligning with this initiative to focus on the prevention and management of chronic disease, we are considering whether to create additional coding and payment for motivational interviewing. Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific health goal and exploring the person's own reasons for change within an atmosphere of acceptance and compassion.[69] Compared to traditional advice-giving, motivational interviewing is more successful at improving a patient's underlying health behaviors that contribute to chronic disease, including but not limited to smoking, substance use, physical activity, nutrition, and adherence to medication and other treatments. Multiple meta-analyses have demonstrated that motivational interviewing has demonstrated statistically significant improvements in reduction of alcohol consumption, reduction in substance use in people with dependency or addiction, increased physical activity participation,[70] increased weight loss, and reduction in blood pressure.[71] Motivational interviewing has been adapted and integrated into many settings, including primary care facilities, emergency departments, behavioral health centers, and criminal justice and social service agencies.[72] We are considering whether to develop separate coding and payment for motivational interviewing, which could also be performed under general supervision of the billing practitioner, in order to better account for the time and resources involved in furnishing this care. Furthermore, we understand that in many practices, health coaches can help support the provision of motivational interviewing services. We note that the Category III CPT codes

[68] Administration for Community Living. ''Health Promotion.'' *https://acl.gov/programs/health-wellness/disease-prevention.*

[69] Miller, W.R. & Rollnick, S. (2013) Motivational Interviewing: Helping people to change (3rd Edition). Guilford Press.

[70] Frost, Helen et al. ''Effectiveness of Motivational Interviewing on Adult Behaviour Change in Health and Social Care Settings: a Systematic Review of Reviews.'' Available from: *https://pubmed.ncbi.nlm.nih.gov/30335780/.*

[71] VanBuskirk, Katherine, Julie Loebach Wetherell. ''Motivational interviewing with primary care populations: a systematic review and meta-analysis.'' Available from: *https://pubmed.ncbi.nlm.nih.gov/23934180/.*

[72] SAMHSA, Treatment Improvement Protocol 35: Enhancing Motivation for Change in Substance Abuse Treatment Updated 2019, *https://library.samhsa.gov/sites/default/files/tip-35-pep19-02-01-003.pdf.*

(0591T, 0592T, and 0593T) for health coaching are currently contractor-priced, and have a January 2030 sunset date. However, health coaches do not have a Medicare benefit category and therefore cannot bill Medicare directly (a new benefit category requires statutory change) but could potentially operate as clinical staff under general supervision incident-to a physician service if new coding and payment were constructed in this way.

We are soliciting feedback from the public regarding motivational interviewing and health coaches. Specifically, we are requesting commenters consider the following information:

- Please provide information on whether we should create separate coding and payment for motivational interviewing, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment.
- What is the best definition and description of motivational interviewing?
- What types of clinical staff should be able to perform motivational interviewing under the general supervision of a billing practitioner?
- How long does a session of motivational interviewing typically last? If we were to create coding and payment for motivational interviewing, what should the time-based requirements of the code be?
- We heard from interested parties that in many clinics, health coaches perform services under general supervision, and that there may be substantive overlap with motivational interviewing. To what extent are the services performed by health coaches encompassed by motivational interviewing?
- What training is required to effectively perform motivational interviewing? Are there agreed upon national training or certification standards for health coaches? If so, what are they? Do states have separate training or certification standards for health coaches?
- To what extent would health coaches be able to perform motivational interviewing incident-to billing practitioners under general supervision? Please see § 410.26(a)(3) for further information about general supervision.
- In what clinical situations are motivational interviewing and health coaching most commonly performed? What are the clinical characteristics of a patient where motivational interviewing and health coaching would be medically reasonable and necessary?
- Can motivational interviewing and health coaching appropriately be performed via audiovisual or audio-only synchronous telecommunication?
- What has been the experience of providers and payers utilizing the codes 0591T (Health and well-being coaching: face-to-face, individual initial assessment), 0592T (Individual follow-up session, at least 30 minutes), and 0593T (Group session, two or more individuals, at least 30 minutes)? If the CPT committee were to create permanent codes with staff able to operate under the general supervision of a billing practitioner, would this capture the time and resources to perform health coaching?
- To what extent would new coding for motivational interviewing or health coaching better support some of the evidence-based programs funded and overseen by ACL that effectively manage or prevent chronic disease?

We welcome feedback from stakeholders and the public on how we could better support management of chronic disease and prevention, including whether we should create separate coding and payment for motivational interviewing, along with overlap between motivational interviewing and health coaches for consideration for future rulemaking.

3. Community Health Integration and Principal Illness Navigation for Behavioral Health

a. Practitioner Types

In the CY 2024 PFS final rule (88 FR 78920), we finalized G-codes to reflect new coding and payment for services describing Community Health Integration (CHI) services (HCPCS codes G0019 (*Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month*) and G0022 (*Community health integration services, each additional 30 minutes per calendar month*)), provided by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner. We also finalized Principal Illness Navigation (PIN) services (HCPCS codes G0023 (*Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month*) and G0024 (*Principal Illness Navigation services, additional 30 minutes per calendar month*); G0140 (*Principal Illness Navigation—Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month*) and G0146 (*Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month*)), provided by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist. In the CY 2025 PFS final rule (89 FR 97822), we clarified that when we refer to ''certified or trained auxiliary personnel'' in the following codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes clinical social workers (CSWs).

Marriage and family therapists (MFTs) and mental health counselors (MHCs) have a similar statutory benefit category as CSWs and may also connect individuals with community-based resources to address unmet social needs that affect the diagnosis and treatment of medical problems. Like CSWs, MFTs and MHCs can bill Medicare directly for services they personally perform for the diagnosis or treatment of mental illness and substance use disorders, but are not authorized by statute to bill under the PFS for services that are provided by auxiliary personnel incident to their professional services. CHI and PIN services are typically provided by auxiliary personnel supervised by the billing practitioner, and MFTs and MHCs could serve as auxiliary personnel, as the codes do not limit the types of auxiliary personnel that can perform CHI and PIN services incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1). MFTs and MHCs could not directly bill Medicare under the PFS for CHI and PIN services if they were provided by auxiliary personnel, as they are not authorized to supervise, bill, and be paid directly by Medicare for services that are provided by auxiliary personnel incident to their professional services. As we stated previously in the CY 2024 PFS final rule (88 FR 78926), ''the codes do not limit the types of other health care professionals, such as registered nurses and social workers, that can perform CHI services (and PIN services, as we discuss in the next section) incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of

auxiliary personnel at § 410.26(a)(1).'' We are clarifying that when we refer to ''certified or trained auxiliary personnel'' in the following HCPCS codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes MFT and MHCs. We are clarifying that, like CSWs, MFTs and MHCs can bill Medicare directly for CHI and PIN services they personally perform for the diagnosis or treatment of mental illness. Additionally, CMS required for auxiliary personnel performing CHI and PIN under general supervision, that in the absence of state level certification or training requirements, CMS required training to perform the services. We are further clarifying that if CSWs, MFTs, and MHCs are performing the services as auxiliary personnel under the general supervision of a billing practitioner, in the absence of state-level requirements, that they meet the certification or training requirements to perform all CHI and PIN service elements. This is relevant in the cases where a CSW, MFT, or MHC are performing CHI and PIN under the general supervision of a billing practitioner for a medical problem that is not considered a mental illness. For CHI and PIN services, as with all incidents to services, it is the billing practitioner's responsibility to ensure that all payment rules and applicable State requirements are met including licensure, certification, and/or training. This does not mean that the billing practitioners are required to provide the licensure, certification, and/or training themselves, but rather that they must ensure that the Medicare criteria for billing and payment of CHI and PIN services are met.

Individuals who personally furnish or serve as auxiliary personnel for CHI and PIN services must meet all other service requirements associated with these codes. We welcome comments on this clarification.

b. Initiating Visits

In the CY 2024 PFS final rule (88 FR 78923), we finalized allowing E/M services (other than a low-level E/M visit done by clinical staff), including an E/M service that is part of a transitional care management (TCM) service and an annual wellness visit (AWV) service to serve as the initiating visit for CHI services. We received comments requesting for CPT codes 90791 (Psychiatric diagnostic evaluation) and 96156 (Health behavior assessment, or re-assessment (that is, health-focused clinical interview, behavioral observations, clinical decision making)) to be allowed to serve as initiating visits, but we determined at the time that these services would be better captured and better serve the needs being addressed with the PIN service elements. We have continued to analyze the uptake of CHI services and believe that these services may fit the need for additional initiating CHI visits, as utilization data is showing that CHI services are being used to address SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat mental illness.

For CSWs, MFTs, and MHCs to bill Medicare directly for CHI services personally performed for the diagnosis or treatment of mental illness, we are proposing to allow for CPT code 90791 (Psychiatric diagnostic evaluation) or the Health Behavior Assessment and Intervention (HBAI) services that CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 (and any subsequent HBAI codes) to serve as initiating visits for CHI, as we believe these codes are the most analogous codes to the E/M codes that are currently used as initiating visits for CHI that are utilized by practitioners in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness. All other policies for CHI initiating visits also apply to CHI services furnished by CSWs, MFTs, and MHCs. Please see the 2024 PFS final rule (88 FR 78921 through 78932) and 2025 PFS final rule (89 FR 97821 through 97824) for additional information regarding CHI services and CHI initiating visits. We welcome comments on this proposal.

4. Technical Refinements To Revise Terminology for Services Related to Upstream Drivers of Health

a. Policies To Improve Care for Chronic Illness and Behavioral Health Needs

(1) Social Determinants of Health Risk Assessment (HCPCS Code G0136)

In the CY 2024 PFS final rule (88 FR 78932 through 78937), we finalized coding and payment for HCPCS code G0136 (*Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5 to 15 minutes*). After further review of utilization information, we have come to believe that the resource costs described by HCPCS code G0136 are already accounted for in existing codes, including but not limited to E/M visits. Therefore, we are proposing to delete this code for CY 2026. Accordingly, we are proposing to remove this code from the Medicare Telehealth Services list.

Additionally, we are proposing conforming regulation text updates at 42 CFR 410.15. We are proposing to revise § 410.15(a) as follows: in paragraph (a), by revising the definition of First annual wellness visit providing personalized prevention plan services by removing subparagraph (xiii) and redesignating subparagraph (xiv) as (xiii); and, in revising the definition of Subsequent annual wellness visit providing personalized prevention plan services by removing subparagraph (xi) and redesignating subparagraph (xii) as (xi).

(2) Community Health Integration Services (HCPCS Codes G0019)

In response to the CY 2024 PFS proposed rule, we received several comments requesting that CMS revise some of the language used in the Community Health Integration (CHI) (HCPCS codes G0019) code descriptor to better fit the purpose of CHI services. Some of the examples that commenters provided as an alternative to ''social determinants of health'' included: ''social drivers of health, drivers of health, or health-related social needs.'' Many of these commenters noted that other CMS programs use the term social drivers of health and requested that CMS use consistent naming conventions (88 FR 78933). After further consideration of the code descriptors, we are proposing to replace the term ''social determinants of health (SDOH)'' with the term ''upstream driver(s)''. We have determined that the term ''upstream driver(s)'' is more comprehensive and includes a variety of factors that can impact the health of Medicare beneficiaries. The term ''upstream driver(s)'' encompasses a wider range of root causes of the problems that practitioners are addressing through CHI services. This type of whole-person care can better address the upstream drivers that affect patient behaviors (such as smoking, poor nutrition, low physical activity, substance misuse, etc.) or potential dietary, behavioral, medical, and environmental drivers to lessen the impacts of the problem(s) addressed in the initiating visit.

We are proposing the following changes to HCPCS codes G0019, and we will make conforming revisions to codes describing similar services to reflect the updated terminology, including services furnished by RHCs, FQHCs, and OTPs.

G0019—Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address upstream driver(s) that are significantly limiting ability to

diagnose or treat problem(s) addressed in an initiating E/M visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the upstream driver(s) and the problem(s) addressed in the initiating E/M visit.*

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services to address upstream driver(s).

Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the upstream driver(s), and educating the patient on how to best participate in medical decision-making.

- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the upstream driver(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the upstream driver(s), and adjust daily routines to better meet* diagnosis *and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

J. Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Other Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at § 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

Fee for service (FFS) Medicare Parts A and B also make payment for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We also added several examples of clinical scenarios that are considered to meet that standard under §411.15(i)(3) and amended that regulation to add more examples in the CY 2024 PFS final rule (88 FR 79022 through 79029) and in the CY 2025 PFS final rule (89 FR 97936 through 97945).

b. Submissions Received Through Public Submission Process

In the CY 2023 PFS final rule, we established a process whereby we accept and consider submissions from the public (the ''public submission process'') to assist us to identify additional dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered services (87 FR 69663 through 69688). We thank all those who submitted recommendations through this process. We received seven submissions from various organizations and individuals on or before February 10, 2025.

Most of the submissions recommended that we consider clinical scenarios involving beneficiaries with diabetes mellitus when contemplating payment under Medicare for dental services that are inextricably linked to other covered services. Four submitters had similar themes in their submissions that expressed the concern that the absence of treatment of chronic dental infections could complicate covered medical treatment for the management of diabetes-associated retinopathy and nephropathy. Two submitters were focused on their view of how important it is to improve oral health through treatment of oral infections like periodontitis and preventive dental care, as they asserted these dental services are related to the successful prevention and treatment of diabetic retinopathy. These two submitters were specifically concerned about beneficiaries who are at risk for diabetes-related retinopathy and vision loss or who have diabetes-related retinopathy and vision loss.

One submitter explained that their submission's purpose was not to nominate a new clinical scenario for consideration for CY 2026 rulemaking, but instead was to provide an update on their ongoing research efforts in response to CMS' previous questions about the connection between autoimmune disease and oral health. The submitter referred to their nomination for CY 2025 rulemaking and CMS' respective request for comment

which is discussed in the CY 2025 PFS proposed rule (89 FR 61760 through 61762). The letter emphasized that patients with autoimmune diseases often experience oral and dental complications, which can be exacerbated by immunosuppressive therapies. The submitter stated that they are currently analyzing Medicare claims data and commercial insurance data to demonstrate the positive impact of dental care on patients undergoing immunosuppressive treatment. They explained that they are particularly focused on investigating the relationship between regular preventive dental visits and systemic infection rates for those with Sjogren's disease.

Since CY 2023, we have discussed our commitment to review submissions we receive through the public submissions process. We have also expressed our intention to continue to engage in discussions with the public on a wide spectrum of issues relating to Medicare payment for dental services that may be inextricably linked to other covered services. For CY 2026, we are not making any proposals in response to the submissions that we received and will take the information and recommendations submitted into consideration for the future.

K. Payment for Skin Substitutes

A. Background

The CY 2014 Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period describes skin substitutes as ''. . . a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers . . .'' (78 FR 74930 through 74931). When a procedure utilizing a skin substitute product is performed, providers bill one or more Healthcare Common Procedure Coding System (HCPCS) codes to describe the preparation of the wound, the use of at least one skin substitute product, and application of the skin substitute product through suturing or various other techniques. Specifically, CPT codes 15271 through 15278 describe the application of skin substitutes to various size wounds and anatomical locations.

Recently, several novel industry practices have come to our attention, likely driving substantial and unusual increases in the number of available skin substitute products, the sales and distribution structure for these products, and the rapidity of products changing manufacturer ownership. These industry changes are causing a significant increase in spending under Medicare Part B for skin substitute products in the non-facility setting. According to Medicare claims data, Part B spending for these products rose from approximately $250 million in 2019 to over $10 billion in 2024, a nearly 40-fold increase, while the number of patients receiving these products only doubled. Increases in payment rates and launch prices for skin substitutes, especially newer products, account for the majority of observed Medicare spending increases on these products. Of note, as part of its workplan, the U.S. Department of Health and Human Services' Office of the Inspector General announced in November 2024 plans to review Medicare Part B claims for skin substitutes to identify payments that were at risk for noncompliance with Medicare requirements with an expected issue date of fiscal year 2026.[73]

We outlined our HCPCS Level II coding and payment policy objectives for skin substitutes in the CY 2023 PFS proposed rule (87 FR 46249) because we concluded it would be beneficial for interested parties to understand our priorities as we work to create a consistent approach for the suite of products we have referred to as skin substitutes. As discussed in the CY 2023 PFS proposed rule, we have a number of objectives related to refining our Medicare policies in this area, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) employing a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material, so we can incorporate payment methodologies that are more consistent; and (4) promoting clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have requested that CMS address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the non-facility setting; however, interested parties have also indicated that further alignment of our policies across the non-facility and hospital outpatient department settings would reduce confusion.

[73] *https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000894.asp.*

On April 25, 2024, the Medicare Administrative Contractors (MACs) released a proposed Local Coverage Determination (LCD) to provide appropriate coverage for skin substitute grafts used for chronic non-healing diabetic foot and venous leg ulcers. The MACs issued the collaborative proposed Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD to make sure that Medicare covers, and people with Medicare have access to, skin substitute products that are supported by evidence that shows that they are reasonable and necessary for the treatment of diabetic foot and venous leg ulcers in the Medicare population and that coverage aligns with professional guidelines for appropriately managing these wounds. All of the MACs have delayed the effective date of the final local coverage determinations for cellular and tissue-based products for wounds (CTPs, or skin substitutes) in diabetic foot ulcers and venous leg ulcers, moving the implementation date across all MAC jurisdictions to January 1, 2026. For details, please see the final LCD, L36377, titled: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers at: *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36377&ver=19.* We note that additional coverage determinations may apply to skin substitute products.

The Medicare statute, regulations, and manual provisions empower the Medicare program to determine if a product is reasonable and necessary for the treatment of a beneficiary's condition and safe and effective, not experimental or investigational, and appropriate and therefore eligible for coverage under Part B. (*See,* for example, 42 U.S.C. 1395l(e), 1395y(a)(1)(A), 42 CFR 411.15(k)(1), 424.5(a)(6), Medicare Program Integrity Manual § 3.6.2.2, Medicare Benefit Policy Manual ch. 15, §§ 50.4.1–50.4.3, and Medicare Program Integrity Manual, ch. 13 §§ 13.5.3, 13.5.4.) The inclusion of a product in this payment rule does not necessarily imply that a determination has been made by CMS or its contractors that it is reasonable and necessary and meets the other preconditions to Medicare coverage. Similarly, the use of short descriptors and associated FDA regulatory categories[74] may reflect current FDA

[74] The term ''FDA regulatory categories'' is used in this Proposed Rule when referring to the basis for CMS's proposed payment policies but is not intended to reflect or imply that the products

regulation but are not intended to imply that FDA has determined that a product meets any specific FDA statutory or regulatory requirements. FDA's statutory and regulatory framework, including, for example, FDA's findings that a product is ''safe and effective,'' is not controlling of Medicare's determination under its own authorities of whether a product is ''reasonable and necessary'' for an individual patient and meets all preconditions for Medicare coverage and payment. FDA does not make Medicare coverage or payment determinations, nor do FDA statutes and regulations govern Medicare coverage or payment determinations. However, CMS has determined that, when it is setting payment rates on a prospective basis, a different inquiry and set of considerations apply and that it makes sense to consider how FDA regulates products that CMS considers to be skin substitutes.

We continue to believe that our existing payment policies are unsatisfactory, unsustainable over the long term, and rooted in historical practice established two decades ago prior to significant evolutions in medical technology and practice. After hosting a town hall [75] to provide an opportunity for public input, including discussion of potential approaches to the methodology for payment of skin substitute products, as well as reviewing several years of comments in response to CY rulemaking in 2023, 2024, and 2025 on this subject, we have developed a proposal that addresses our stated objectives as well as many of the comments we have received.

B. Medicare Part B Payment for Skin Substitutes

1. Payment for Skin Substitutes When Used During a Covered Application Procedure Under the PFS in the Non-Facility Setting

CMS has historically considered skin substitutes to be biologicals for payment purposes under Medicare Part B. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA) established payment methodology for drugs and biologicals under section 1847A of the Act. Under this methodology, a vast majority of drugs and biologicals separately paid under Medicare Part B are paid at the Average Sales Price (ASP) plus six percent. Section 303(c) of the MMA, titled ''Payment reform for covered outpatient drugs and biologicals,'' amended Title XVIII of the Act by adding new section 1847A of the Act. In part, this section established the use of the ASP to determine the payment limit for drugs and biologicals described in section 1842(o)(1)(C) of the Act (that is, drugs or biologicals billed by a physician, supplier, or any other person and not paid on a cost or prospective payment basis) furnished on or after January 1, 2005. Because Medicare is currently paying for most skin substitutes as biologicals using the methodology under section 1847A of the Act, each skin substitute product receives a unique billing code (typically, a Level II HCPCS code) and payment limit.

Section 401 of Division CC, Title IV of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) (CAA, 2021) amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires certain manufacturers without a Medicaid drug rebate agreement, such as certain manufacturers of skin substitutes, to report ASP data to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Because most skin substitutes are currently paid as biologicals using the methodology described in section 1847A of the Act, manufacturers of these products are currently required to report their ASP data to CMS every quarter. Prior to this, section 1927(b)(3)(A)(iii)(I) of the Act only required manufacturers with a Medicaid drug rebate agreement to report ASP data to CMS for drugs or biologicals described in section 1842(o)(1)(C) of the Act.

Section 1847A of the Act also includes several relevant definitions. While the definition of ''single-source drug or biological'' provided at section 1847A(c)(6)(D) includes ''a biological,'' sections 1847A(c)(6)(H) and (I) of the Act offer more insight into the meaning of the term for purposes of this section. Subparagraph (I) defines the term ''reference biological product'' as a biological product licensed under section 351 of the PHS Act. Subparagraph (H) defines the term ''biosimilar biological product'' as ''a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act.''

Section 1927 of the Act, which is referred to multiple times in section 1847A of the Act, also references section 351 of the PHS Act when referencing biologicals. The title of section 303 of the MMA, which added section 1847A to the Act, refers to ''covered outpatient drugs,'' defined in section 1927(k)(2) of the Act. Subparagraph (B) adds biological products to this definition when those products are licensed under section 351 of the PHS Act, among other requirements.

In the CY 2022 PFS final rule, to address the need to establish a payment mechanism for synthetic skin substitutes in the physician office setting and to be responsive to feedback received from commenters, we finalized an approach for payment of each synthetic skin substitute for which we had received a HCPCS Level II coding application. We finalized that those products would be payable in the physician office setting and billed separately from the procedure to apply them using HCPCS A-codes (86 FR 65120).

2. Payment for Skin Substitutes Under the Outpatient Prospective Payment System (OPPS)

Prior to CY 2014, all products considered to be skin substitutes were separately paid under the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931). In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products furnished in the hospital outpatient setting into their associated application procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

discussed within this Proposed Rule are characterized as such or grouped together by FDA.

[75] CMS Skin Substitutes Town Hall, which was held virtually on January 18, 2023. More information regarding the CMS Skin Substitutes Town Hall such as links to recording and transcripts is available at *https://www.cms.gov/medicare/payment/fee-schedules/physician/skin-substitutes#:~:text=The%20CMS%20Skin%20Substitutes%20Town,Physician%20Fee%20Schedule%20(PFS).*

Skin substitutes assigned to the high-cost group are described by CPT codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Claims billed with primary CPT codes 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high-cost group, and claims billed with primary HCPCS codes C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low-cost group (78 FR 74935). The graft skin substitute administration add-on codes, which include ''each additional 25 sq cm'' in the description (that is, CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278), are packaged into the payment rates for the primary administration codes.

For CY 2025, each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2025, the payment rate for APC 5053 (Level 3 Skin Procedures) is $612.13, the payment rate for APC 5054 (Level 4 Skin Procedures) is $1,829.23, and the payment rate for APC 5055 (Level 5 Skin Procedures) is $3,660.97. Table 27 lists the APC assignments and CY 2025 payment rates for the HCPCS codes describing the skin substitute application procedures. This information is also available in Addenda A and B of the CY 2025 final OPPS/ASC rule with comment period (the Addenda A and B are available on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

TABLE 27: CY 2025 APC ASSIGNMENTS FOR SKIN SUBSTITUTE APPLICATION HCPCS CODES

APC	APC Title	HCPCS Codes	Final CY 2025 OPPS Payment Rate
APC 5053	Level 3 Skin Procedures	C5271, C5275, C5277	$612.13
APC 5054	Level 4 Skin Procedures	C5273, CPT codes 15271, 15275, 15277	$1,829.23
APC 5055	Level 5 Skin Procedures	CPT code 15273	$3,660.97

Beginning in CY 2016, we adopted a policy where we determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC), which is calculated as the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days, exceeding the PDC threshold. We assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high-cost group. We assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976). We also assign skin substitutes with pass-through payment status to the high-cost category.

We assign skin substitutes with some pricing information but without claims data for which to calculate a geometric MUC or PDC to either the high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we use the wholesale acquisition cost (WAC) plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we use 95 percent of the average wholesale price (AWP) to assign a skin substitute to either the high-cost or low-cost category.

In the CY 2021 OPPS/ASC final rule with comment period, after the first entirely synthetic skin substitute products were introduced into the market, we revised our description of skin substitutes to include both biological and synthetic products (85 FR 86064 through 86067). Any skin substitute product that is assigned to a code in the HCPCS A2XXX series is assigned to the high-cost skin substitute group, including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series are assigned to the low-cost category until pricing information is available to compare to the MUC and PDC thresholds (89 FR 94247).

In the CY 2014 OPPS/ASC final rule, we also noted that several skin substitute products are applied as either liquids or powders per milliliter or per milligram and are employed in procedures outside of CPT codes 15271 through 15278. We stated that these products ''. . . will be packaged into the surgical procedure in which they are used.'' (78 FR 74930 through 74931).

We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that, under the OPPS, these items cannot be assigned to either the high-cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 (85 FR 86066).

C. Current FDA Regulation of Products CMS Considers To Be Skin Substitutes

The FDA regulates products that CMS considers to be skin substitutes based on a variety of factors, including product composition, mode of action, and intended use. Relevant categories of FDA regulation for skin substitute products include the following:

1. Self-determination Under Section 361 of the PHS Act and the Regulations in 21 CFR 1271 (361 HCT/Ps)

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) are defined in 21 CFR 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples include bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. Pursuant to section 361 of the Public Health Service (PHS) Act, FDA promulgated regulations at 21 CFR

1271, *et seq* that create an electronic registration and listing system for establishments that manufacture HCT/Ps, regulate donor eligibility, and establish current good tissue practice and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps.

A subset of HCT/Ps are those that are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271 (361 HCT/Ps). The FDA has taken a risk-based, tiered approach in regulating HCT/Ps; as the potential risk posed by a product increases, so too does the level of oversight (63 FR 26745). Although FDA is authorized to apply the requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or the PHS Act to those products that meet the definition of drug, biological product, or device, under a tiered, risk-based approach, HCT/Ps that meet specific criteria or fall within detailed exceptions do not require premarket review and approval. HCT/Ps that do not meet all the criteria in 21 CFR 1271.10(a) are not regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. Unless an exception in 21 CFR 1271.15 applies, such products are regulated as drugs, devices, and/or biological products under the FD&C Act and/or the PHS Act and are subject to additional regulation, including applicable premarket review. An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR part 1271 if it meets all of the following criteria (21 CFR 1271.10(a)):

- The HCT/P is minimally manipulated.
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P.
- Either:

++ The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

++ The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function; and

--- Is for autologous use;

--- Is for allogeneic use in a first-degree or second-degree blood relative; or

--- Is for reproductive use.

Establishments that manufacture 361 HCT/Ps, as defined by 21 CFR 1271.3(e), must register and list their 361 HCT/Ps in the FDA's electronic Human Cell and Tissue Establishment Registration System (eHCTERS), but premarket review and approval by FDA is not needed. However, FDA acceptance of an establishment registration and 361 HCT/P listing form does not constitute a determination that an establishment is compliant with applicable FDA rules and regulations, that the FDA has agreed with the manufacturer's self-determination as a 361 HCT/P, or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)). When this proposed rule refers to 361 HCT/Ps, it generally refers to products where an establishment has self-determined that their product is a 361 HCT/P.[76] If an HCT/P does not meet the criteria set out in 21 CFR 1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions in 21 CFR 1271.15, the HCT/P will be regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act (42 U.S.C. 262), and applicable regulations, including 21 CFR part 1271, and premarket review generally is required.

2. 510(k) Premarket Notification Submissions, Premarket Approval Applications, and De Novo Requests

''Devices,'' as defined under 21 U.S.C. 321(h)(1), do not achieve their primary intended purposes through chemical action and are not dependent upon being metabolized for the achievement of their primary intended purposes. Devices may be subject to premarket review through: (1) a 510(k) premarket notification submission (510(k)) in accordance with section 510(k) of the FD&C Act and implementing regulations in subpart E of 21 CFR part 807; (2) a premarket approval application (PMA) under section 515 of the FD&C Act and regulations in 21 CFR part 814; or, potentially, (3) a De Novo classification request (De Novo request) under section 513(f)(2) of the FD&C Act and regulations in subpart D of 21 CFR part 860. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (sections 510(k) and 513(i) of the FD&C Act). Premarket approval is the most rigorous type of review and generally is required for class III medical devices. Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act). De Novo classification is a marketing pathway for novel medical devices for which general controls alone (class I), or general and special controls (class II), provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Devices that are classified into class I or class II through a De Novo request may be marketed and used as predicates for future premarket notification (that is, 510(k)) submissions, when applicable.

3. Biologics License Application

To lawfully introduce or deliver for introduction into interstate commerce a drug that is a biological product, a valid biologics license application (BLA) must be in effect under section 351(a)(1) of the PHS Act, 42 U.S.C. 262(a)(1), unless exempted under 42 U.S.C. 262(a)(3). Such licenses are issued only after showing that the product is safe, pure, and potent. Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products (21 CFR 601.2(d)). Potency has long been interpreted to include effectiveness (21 CFR 600.3(s)).

The definition of the term ''biological product'' in section 351(i) of the PHS Act is: ''a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.'' (42 U.S.C. 262(i)). In contrast to the registration and listing requirements for a 361 HCT/P or the substantial equivalence requirements for 510(k)s, products licensed under section 351 of the PHS Act are required to meet stringent pre- and post-market requirements to ensure the products' safety and efficacy when

[76] We note that establishments may seek feedback from FDA regarding their self-determination analysis and conclusion that a particular product is a 361 HCT/P. See, For example., *https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group*.

marketed. Table 2 lists several other notable differences between the relevant FDA regulatory categories for products CMS considers to be skin substitutes.

TABLE 28: COMPARISON OF FDA CLASSIFICATIONS

Classification	Review Goal Within	FY2025 Standard Application Fee
361 HCT/P	N/A[77] (registration required)	N/A
510(k)[78]	90 Days	$24,335
PMA	180 or 320 days[79]	$540,783
BLA (original application for products requiring clinical data)	10 months[80]	$4,310,002[81]

D. Proposed Payment of Skin Substitute Products Under the PFS and OPPS

1. Separate Payment for Skin Substitute Products as Incident-To Supplies

We have carefully considered our policy objectives, which include: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) employing a uniform approach across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material; and (4) providing clarity for interested parties on CMS skin substitutes policies and procedures. We propose, starting January 1, 2026, to separately pay for the provision of certain groups of skin substitute products as incident-to supplies when, for those products that are coverable under Medicare's rules, they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. This proposal does not apply to biological products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act. While we considered proposing to pay separately for skin substitutes initially under just the PFS in non-facility settings consistent with current practice, one of our primary policy objectives is to ensure a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; and so, we ultimately determined that the suite of products referred to as skin substitutes should be treated in a uniform manner across different outpatient care settings, to the extent permitted by applicable law. The physician, in consultation with his or her patient, decides the site of service for treatment. While many factors are considered as a part of that decision, substantial differences in payment for the application of the same skin substitute product in one site of service versus another, or between similar skin substitute products, should not be one of them. Establishing a consistent framework for how these products are treated within the non-facility and hospital outpatient settings would empower providers to make the best treatment decisions for their patients, ensure equitable access to needed services, and pay appropriately for these services. We also considered bundling payment for skin substitute products in both the PFS and OPPS as part of this proposal. While supplies are generally bundled into the payment of the service in both the physician office and hospital outpatient departments, for many years skin substitute products have been paid separately in the physician office setting, where the majority of these products are currently applied. So, we have determined that bundling payment for skin substitute products with their administration procedures across both settings under this new proposal, before efforts are made to address improper utilization patterns, would be premature. Depending on whether our proposal is finalized, and the outcomes of a final policy, we may consider packaging skin substitute products with the related application procedures in both the hospital outpatient setting and non-facility setting in future rulemaking. We seek comments on our proposal to separately pay for the provision of certain groups of skin substitute products as well as on our proposal to implement this policy in both the non-facility and hospital outpatient settings. For additional details on the OPPS proposal for skin substitutes, please see the CY 2026 OPPS/ASC proposed rule with comment period; the remainder of this policy proposal will focus on implementation under the PFS.

We propose, under the PFS, to pay separately for the use of specific skin substitute products (that is, skin substitute products that are not regulated as biological products under section 351 of the PHS Act) that are eligible for Medicare coverage during a covered application procedure in the non-facility setting as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act. Supplies are a large category of items that typically are either for single use or have a shorter use life span than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in outpatient settings, including certain implantable medical devices. ''Incident-to supplies'' refers to supplies that are furnished as an integral, although incidental, part of the physician's professional services in the course of diagnosis or treatment of an injury or illness (42 CFR 410.26). Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through 15278, and the procedure of treating the wound and applying a covering to the wound is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures. We seek comments on our proposal to separately pay for provision of skin substitutes as incident-to supplies under the PFS in the non-facility setting.

Skin substitutes have historically been paid separately in the non-facility setting as biologicals instead of supplies when used during a covered application procedure. Products CMS considers to be skin substitutes may also meet FDA's

[77] No premarket authorization is required for 361 HCT/Ps.

[78] *https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.*

[79] These numbers include either a review within 180 days for decisions without advisory committee input or a review within 320 days for decisions with advisory committee input, respectively.

[80] PDUFA performance goals call for FDA to review and act on 90 percent of original BLA submissions within 10 months of the 60-day filing date. Other regulatory pathways may have different timelines. See *https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review; https://www.fda.gov/drugs/development-approval-process-drugs.*

[81] *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.*

definition of a biological product, either directly or as an analogous product. However, section 1847A of the Act, which includes the controlling provisions for setting Medicare payment for drugs and biologicals billed by a physician, generally refers to biologicals in ways that do not encompass most skin substitutes. While most skin substitutes are either medical devices regulated under the FD&C Act or products regulated solely under section 361 of the PHS Act, subparagraphs (H) and (I) of section 1847A(c)(6) of the Act only refer to biologicals licensed under section 351 of the PHS Act. Section 1847A of the Act also references section 1927 of the Act, which again refers to section 351 of the PHS Act when referencing biologicals. In addition, to operationalize the payment system, section 1847A of the Act includes extensive references to National Drug Codes, a type of drug identifier published by the FDA and generally not assigned to skin substitutes, which further supports our proposal to stop utilizing 1847A payment methodologies for skin substitutes that are not licensed under section 351 of the PHS Act. For example, section 1847A(b)(4)(A) of the Act directs use of the lesser of the average sales price or wholesale acquisition cost when determining the payment amount for a single-source drug or biological for all National Drug Codes assigned to the drug or biological. The methodology for calculating both the average sales price and the wholesale acquisition cost is described in paragraph (6) of section 1847A(b) of the Act, which describes a process that again specifies the use of National Drug Codes. Because skin substitutes generally do not have National Drug Codes, CMS has operationalized this process for skin substitutes by allowing manufacturers of skin substitutes to self-select an Alternate ID to distinguish between different skin substitute products.[82] However, the use of an alternative identification method is not required by the statute, and the calculation of a payment rate for these products is otherwise not possible.

We note that section 351 and section 361 of the PHS Act are two distinct regulatory frameworks. Section 351 biological products must seek FDA pre-marketing approval (using clinical studies that are required by the applicable section 351 regulations) and are applicable to the prevention, treatment, or cure of a disease or condition. In contrast to the prerequisites for marketing products that fall under section 351 of the PHS Act , no FDA approval or clearance is required for marketing the self-determined 361 HCT/Ps. Section 361 products also do not receive an FDA license of approval for a specific prevention, treatment, or cure of a disease or condition and do not require controlled clinical trials to demonstrate effectiveness. Rather the self-determined 361 HCT/Ps are limited to intended uses that reflect homologous use for that particular product.

In light of our careful review of the applicable statutory provisions governing skin substitute products paid under the ASP methodology under 1847A of the Act, the different FDA regulatory frameworks used for these products, and the skyrocketing increase in Medicare spending for such products, we are proposing to pay separately for specific skin substitute products (other than products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act) that are eligible for Medicare coverage during a covered application procedure in the non-facility setting as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act.

One purpose of the new proposed policy is to limit some of the current profiteering practices occurring in this industry. For example, as reflected in CMS's ASP pricing files, we have observed a dramatic increase in launch prices. It is unclear how these prices could be attached to realistic changes in resource costs as many of these new products are minimally manipulated tissues. Our proposed policy is likely to disincentivize this practice, as well as several other novel industry practices that have come to our attention by preventing exploitation of skin substitute pricing under section 1847A of the Act, overuse of expensive skin substitute products, and waste resulting from use of more-expensive skin substitute products over clinically-appropriate, less-expensive alternatives. Notably, there has not been significant growth in payments for skin substitutes in the OPPS, which unconditionally packages the payment for skin substitute products with their associated application procedures. We note that the relevant statutory provisions, when considered together, do not require all of these kinds of products to be paid as biologicals under section 1847A of the Act. Therefore, under this proposed policy, unless a skin substitute is approved as a drug or as a biological product under section 351 of the PHS Act, in which case we would continue to pay for it consistent with section 1847A of the Act, we would consider it an incident-to supply for payment purposes under the PFS with the definitions and rates described below. For Medicare purposes, we propose to codify the definition of ''biological'' as ''a product licensed under section 351 of the Public Health Service Act'' at §§ 414.802 and 414.902. We seek comments on our proposal to limit application of section 1847A of the Act to skin substitutes that are approved as a drug or as a biological product under section 351 of the PHS Act and our proposed edits to the regulations.

2. Payment Categories Based on FDA Regulatory Category

Paying separately for skin substitutes in the non-facility setting has led to dramatic price increases for these products, as noted above. Grouping similar products or services into a single billing code and using a single payment amount for them, as we do with many services under the OPPS, some services under the PFS, and all multiple-source drugs under section 1847A of the Act, incentivizes hospitals and prescribers to make the most cost-efficient, clinically effective treatment decision. However, we recognize that grouping dissimilar products and/or services to set payment rates can limit beneficiaries' access to appropriate care, especially when some groups encompass products and services with significant clinical and resource variability. In the case of skin substitutes, no single product among the wide range of products stands out as typical; so we have reviewed several methods to group or classify skin substitutes to determine which best reflects clinical and resource similarities between these products.

To reflect relevant product characteristics, we propose to group skin substitutes that are not drugs or biologicals (that is, biological products licensed under section 351 of the PHS Act) using three CMS payment categories based on FDA regulatory categories (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. We have previously noted in rulemaking that CMS has no obligation to categorize products based on the FDA's current regulatory framework (74 FR 60476); but, in this case, we have determined that the FDA regulatory categories provide an appropriate level of distinction for a heterogeneous category of products that exhibit clinical and resource variability that can ultimately improve the accuracy of the relative value units under the PFS. Proposing a payment policy that aligns with FDA's current regulatory framework also

[82] *https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.*

provides for predictability and efficiency for purposes of Medicare payment. Payment for new products, as discussed below, could be achieved quickly and consistently by CMS's capacity to immediately recognize the FDA regulatory categories.

a. 361 HCT/Ps

As described previously, 361 HCT/Ps are a subset of HCT/Ps that are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271 and listed in the FDA's eHCTERS. Currently, registered 361 HCT/Ps generally are dressings intended only to cover and protect a wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap. A structural tissue intended for wound care is generally limited to the homologous use of cover and protect in order to be a 361 HCT/P.[83] Intended uses such as wound treatment, promotion or acceleration of wound healing, or serving as a skin substitute would generally be non-homologous uses of structural tissues. Instead, products for such intended uses (for example, the treatment of wounds) generally are subject to PMA or BLA requirements.

b. Devices Requiring 510(k) Clearance

A 510(k) is a premarket submission made to the FDA generally by the manufacturer of a device to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval. (FD&C Act sections 510(k), 513(i)). Currently, 510(k)-cleared devices that we are considering for purposes of this proposal generally are dressings intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap. When intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound and otherwise meeting the device definition, generally the FDA's Center for Devices and Radiological Health (CDRH) regulates wound dressings composed of natural biomaterials, including animal and human derived tissue as devices, and they are currently subject to 510(k) requirements. At this time, wound dressings have not been 510(k) cleared by FDA for indications such as wound treatment, promotion or acceleration of wound healing, or serving as a skin substitute.[84] Instead, products for such intended uses generally are subject to PMA or BLA requirements.

For the purposes of this policy, we propose to group any skin substitutes authorized through the De Novo pathway with those cleared under 510(k)s. De Novo classification is a marketing pathway for medical devices for which general controls alone (class I), or general and special controls (class II), provide reasonable assurance of safety and effectiveness. While products authorized through the De Novo pathway have no legally marketed predicate device, devices that are classified into class I or class II through a De Novo authorization may be marketed and used as predicates for future premarket notification (that is, 510(k)) submissions, when applicable. Because of this, we would expect skin substitutes authorized through the De Novo pathway and those cleared under 510(k)s to be similar for purposes of this proposal.

c. Products Subject to PMAs

Premarket approval is the most rigorous type of review and generally is required for class III medical devices. Similar to BLA-approved wound care products, PMA-approved wound care products generally are intended to go beyond a simple wound cover to provide some type of direct treatment effect. The FDA has not defined the term ''skin substitute.'' However, the term has been used as a descriptor for certain wound care constructs that are currently approved under a BLA or PMA for treatment of burns or skin ulcers, including ulcers that appear to have failed to heal after standard of care. The intended uses of these products may include scaffold claims, reference to matrix attributes that promote endogenous cell binding, migration, differentiation, or proliferation, and/or activities mediated by matrix-associated regulatory factors that facilitate wound healing. Currently, wound care products intended to interact with the wound to facilitate, promote, or accelerate wound healing generally require approval of a BLA or, in some instances, a PMA. Approval of these products requires demonstration of safety and efficacy for the intended use, which generally requires the performance of clinical studies. So PMA-approved devices can be readily distinguished from 510(k)-cleared devices and 361 HCT/P products, which are intended mainly to cover and protect the wound. They are clinically different, provide different benefits, and would theoretically be used for patients presenting with different clinical scenarios. As discussed, PMA-approved devices also go through a much more rigorous review process before marketing as compared to the substantial equivalence requirements for 510(k)s and lack of premarket review for registered 361 HCT/Ps. This more rigorous review for PMAs, as well as differences in clinical utility, and the associated costs to manufacturers, suggests that the resources involved in furnishing these products could be distinct from 361 HCT/Ps and 510(k)s. We seek comment on our proposal to group skin substitutes into three FDA categories, PMA, 510(k), and 361 HCT/P, to set payment rates.

d. Innovative Products

We note that recognizing innovation for supplies through payment policy is complex. It may be difficult to differentiate a truly innovative product from another that offers no true clinical advance. We seek comments on how to properly recognize innovative products through payment policy under the PFS as we continue to assess how best to identify and value innovative products under the PFS. For example, we seek comments on whether skin substitutes with active pass-through payment status under the OPPS and/or those receiving new technology add-on payments (NTAP) under the IPPS should be paid separately from their FDA category under the PFS. We seek comments on whether these products should meet a substantial clinical improvement standard or whether, consistent with current pass-through policy, a device that has received marketing authorization for an indication covered by FDA's Breakthrough Devices Program would generally represent clinically-relevant innovation sufficient to qualify for a product-specific payment rate. Finally, we seek comments on using either a product's ASP or invoice pricing, similar to how devices with pass-through status are paid in ambulatory surgical centers, or adding a set percentage, similar to the NTAP add-on, to the applicable FDA category's base rate to set payment limits during the period of time that the product is covered by the pass-through and/or NTAP programs.

[83] See *Regulatory Considerations for HCT/Ps: Minimal Manipulation and Homologous Use, July 2020 (pg. 19).*

[84] FDA Executive Summary Prepared for the October 26 & 27, 2022 Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Panel Classification of Wound Dressings with Animal-derived Materials (Section 3). Available at download

3. Alternative Payment Categories

As a conceptually possible alternative to our proposal to group skin substitutes based on FDA regulatory categories for purposes of payment, we considered aligning these products based on their composition, for example, whether they are non-synthetic or synthetic. Two examples provided by interested parties include grouping the products as allografts (for example, amniotic products, cellular products), xenografts (for example, collagen products derived from animals), synthetics (for example, artificial products made from various biomaterials) and grouping the products as human living/cryopreserved tissue, dehydrated human/amniotic tissue, animal xenografts, and synthetics/polymers. However, as noted previously, skin substitutes are a heterogenous group with an increasing intersection between tissue, bioengineered, and synthetic components. With many products now including both non-synthetic and synthetic components, clear categorization of skin substitutes by composition is no longer feasible. This makes this alternative extremely complex to implement because it would be necessary to determine which category would be most appropriate for each individual product based on the components of its composition and an assessment of the importance of each. In addition, it is unclear if grouping products based solely on their composition would provide accurate differentiation with respect to resource or clinical similarity for the purposes of setting an appropriate payment rate.

Other alternatives we considered include grouping all products together to set a single payment rate or creating two or more categories reflecting product cost, similar to the grouping used currently to set payment rates for skin substitutes in hospital outpatient departments. While these options may offer certain operational advantages for their simplicity, neither recognizes the clinical differences among skin substitutes as reflected by their different intended uses. Paying for similar items and services at a comparable rate is a foundational aspect of our payment systems, but hospital outpatient departments and physicians and other practitioners paid under the PFS would instead have a financial incentive to use the least expensive skin substitute or the product offering the greatest discount, which could negatively affect patient outcomes and disincentivize innovation in this space if clinical differences are not recognized and differential payments rates are not set. In addition, dividing products by cost relies on pricing set by manufacturers. Especially in light of the dramatic growth of skin substitutes' ASP-based payment limits, this method is unlikely to accurately reflect skin substitute resource costs or clinical similarity.

We seek comments on whether adding certain subcategories to the three proposed FDA categories would improve clinical or resource similarity. One potential example is creating certain subcategories for payment based on one or more FDA device product codes, which is a categorization process that FDA uses to group similar products together. Other examples that have come to our attention include setting unique payment rates for 361 HCT/Ps based on the number of tissue layers (for example, one layer, two layers, and three or more tissue layers) or entirely synthetic products versus non-synthetic products for 510(k)s. If significant clinical or resource differences were identified between products in one or more of these categories, CMS could create a separate payment grouping for these products for payment purposes.

We also seek comments on whether products that are not in sheet form are appropriately considered skin substitutes for the purposes of providing separate payment under this policy. Examples include gel, powder, ointment, foam, liquid, or injected products listed in the nontraditional units of cc, mL, mg, and cm^3. We request feedback on whether these products could be appropriately used as part of the CPT administration codes in the range 15271 through 15278, despite existing CPT coding guidelines limiting their use, and how these units could be paid using the FDA regulatory category groups. For example, assuming these products were appropriate to administer using the noted CPT administration codes or other administration codes, CMS could include products listed in units of cc, mL, or cm^3 in the applicable FDA categories and equate a single cm^2 unit to each cc, mL, or cm^3 for payment purposes. We seek comments on whether other administration codes could be used to appropriately describe services performed using products with units other than cm^2.

4. Establishing RVUs and Initial Payment Rates

Section 1848(c)(2)(N) of the Act provides authority to establish or adjust practice expense RVUs using cost, charge, or other data from suppliers or providers of services, including information collected or obtained under section 1848(c)(2)(M) of the Act. Section 1848(c)(2)(M) of the Act authorizes the Secretary to collect or obtain information on the resources directly or indirectly related to furnishing services for which payment is made under the PFS fee schedule, and such information may be collected or obtained from any eligible professional or any other source. In addition, it allows the Secretary, as he determines appropriate, to use such information in the determination of RVUs. We are relying on these authorities to propose to establish practice expense RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories discussed above based on the volume-weighted average ASP, with no additional markup, as submitted by manufacturers, when available. We have developed initial payment rates for each group based on the weighted, per-unit average of ASPs for the fourth quarter of calendar year 2024. These initial payment rates are listed in the file titled ''Skin Substitute Products by FDA Regulatory Category'' on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* When ASP was not available, we used the MUC, which we currently use to determine the high-cost/low-cost status for each skin substitute product in the hospital outpatient setting, to calculate the proposed initial rates. While use of hospital cost data departs from the hierarchy of data sources contained in section 1847A of the Act to calculate prices for drugs and biologicals, we note that section 1848(c)(2)(N) of the Act provides authority for us to use this data to establish or adjust practice expense RVUs. In addition, as proposed, skin substitutes in the three FDA regulatory categories would no longer be considered biologicals for the purposes of payment under section 1847A of the Act. We considered using only the MUC data to calculate payment rates for these products. However, when ASP is reported, it may serve as a better estimate of cost across both settings as the ASP reflects sales to physicians as well as hospitals. We seek comments on our proposal to establish PE RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories using ASP, or MUC when ASP is not available, using per-unit averaged pricing data from the fourth quarter of 2024. We also seek comments on whether these calculations, if finalized, should be updated with the most recently

available data at the time the final rule is drafted.

As we are proposing to implement this policy for CY 2026 in a site-neutral manner across both the non-facility setting under the PFS and hospital outpatient setting under the OPPS, we are including all products used in either setting to calculate the rates. However, when product-specific utilization across both settings is used to calculate volume-weighted average payments, the result is an apparent rank order anomaly; despite having a more rigorous regulatory review process and receiving indications to treat and heal wounds, the PMA category has the lowest average payment. We are concerned that use of the novel pricing practices noted above has resulted in a decoupling of actual resource costs from the ASP. To address this, as a short-term measure, we propose to weight the product-specific utilization in calculating the proposed rates using the proportions from only the hospital OPPS data and establish for CY 2026 a single payment rate that would apply to all skin substitute products in the three FDA regulatory categories. We believe the OPPS utilization data may better predict utilization patterns under our proposed policies for non-facility settings because, similar to our proposals, these products are already grouped together for payment purposes under the OPPS. By grouping skin substitutes into high- and low-cost groups in the OPPS, hospitals are incentivized to choose either the lowest-cost, clinically appropriate product in the low-cost group or the lowest-cost, clinically appropriate product in the high-cost group. No similar incentive currently exists in the non-facility setting for physicians and other suppliers billing under the PFS. As the proposed policies are intended to mitigate the problematic incentives associated with current patterns of use in the non-facility setting by establishing payment rates for the products in groups instead of individually, we do not believe it would reflect the expected resource costs involved in providing care if we were to base the initial rates on utilization data from the non-facility setting that may be skewed by incentives that would no longer exist under our proposals. For these reasons, we are proposing to initially use hospital outpatient utilization to weight how much each product's price contributes to the proposed payment rates for skin substitutes cleared through the 510(k) pathway, self-determined to be 361 HCT/Ps, or approved under a PMA. We seek comments on the use of the hospital outpatient product utilization patterns to set payment rates for these products under the PFS. We are also proposing for CY 2026 to establish the same initial rate for each group of skin substitutes, including 510(k)-cleared products, registered 361 HCT/Ps, and approved PMAs. To ensure we are not underestimating the resources involved in using these products in furnishing care, we are proposing to use the highest of the calculated volume-weighted average payment amounts for 510(k)s, 361 HCT/Ps, and PMAs to set initial payment valuations. As the 361 HCT/Ps have the highest volume-weighted average payment amount, this average payment rate is reflected in the proposed initial payment rate below. However, we note that, in future notice and comment rulemaking, we intend to propose using claims data to set payment rates for products in these three categories, which would likely result in payment valuations that diverge based on the updated data. Another alternative is to set the payment rate for products in these categories at the volume-weighted average for all three categories, resulting in a lower initial payment rate for all three groups of products. We seek comment on our proposal to use the 361 HCT/P volume-weighted average payment amount to set the initial payment rates for products in all three categories as well as the alternative of using a pooled average of the three categories to set the initial payment rates.

Alternatively, while the ASP pricing files show that skin substitutes across all three of the FDA regulatory categories have increased in cost substantially since 2019, unlike the self-determined 361 HCT/Ps and 510(k)-cleared devices, there has not been a substantial increase in the number of skin substitutes with approved PMAs. Consequently, it is possible that the non-facility utilization of the skin substitutes with approved PMAs is not as distorted as the utilization of the other kinds of skin substitutes. Setting a separate payment rate for this category using combined product utilization patterns (from both OPPS and non-facility settings), would result in a higher initial payment rate for the PMA category. This would rationally order the FDA regulatory categories, based on clinical considerations and some indicators of resource cost, until pricing data removed from these aberrant financial incentives can be incorporated. We seek comments on this alternative policy option.

Under the PFS, payment rates are determined based on work RVUs, PE RVUs, and MP RVUs multiplied by their respective GPCI adjusters and then converted into dollars through multiplication by the conversion factor. For skin substitutes that would be valued and paid as incident-to supplies under our proposal, the practitioner work associated with the application of the skin substitute is already accounted for in the valuation of the application codes themselves (CPT codes 15271–15278), so we are not proposing work RVUs for the codes that describe the products involved in furnishing the application service. Rather than using the established PE methodology to derive PE RVUs from work, direct PE inputs, and the PE/HR data (as described in section II.E of this proposed rule), we are instead proposing to use our authority under sections 1848(c)(2)(M) and (N) of the Act to establish PE RVUs for these supplies using rates calculated from a combination of OPPS cost data and ASP data weighted by OPPS volume. For the specific PE RVUs, please see Addendum B of this proposed rule available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For malpractice RVUs, we generally believe that the malpractice resources are already reflected in the MP RVUs associated with the application codes, but because the standard PFS methodologies assign a minimum of .01 MP RVUs to all codes except add-on codes (75 FR 73276.), we are proposing an MP RVU of 0.01 for these supplies consistent with the rounding convention We also seek comments on whether we should consider treating the codes describing skin substitute products as add-on codes to the current CPT application codes. This would more clearly indicate that the only skin substitute products to be paid for and treated as supplies by Medicare are those used in conjunction with the already existing CPT administration codes. If we were to treat these codes as add-on codes to the application codes, we would effectuate this by assigning a global indicator of ZZZ to the skin substitute codes under the PFS. If we were to finalize these codes as add-on codes, we would assign 0 MP RVUs to them, consistent with existing policy regarding add-on codes.

The proposed PE and MP RVUs would result in an initial payment rate of approximately $125.38/cm^2 for skin substitute products in all three FDA regulatory categories (including PMA-

approved devices, 361 HCT/Ps, and 510(k) cleared devices) prior to the application of the geographic adjustments. Again, the proposed PE and MP RVUs are available in Addendum B of this proposed rule. We seek comments on these proposed initial values.

We determined these proposed values using product pricing and volume for skin substitutes from paid claims with dates of service in the fourth quarter of 2024 because it is the most recent, substantially complete quarter of data. For professional claims, we excluded claims without a positive line-level allowed amount, so that we did not inadvertently include volume without presumed costs in the calculation. In addition, in reviewing the ASP pricing files from the first quarter of 2017 through the first quarter of 2025, the most complete ASP reporting is in the fourth quarter of each year. To determine the payment rates, we first used a product's ASP if it was available. If the ASP rate was missing, we used the 2024 MUC for the HCPCS code. We then calculated a single rate for each FDA category by taking the volume-weighted average of the rates for the applicable codes using the hospital outpatient utilization to weight each category. We note that if rather than using the final quarter of CY 2024, we alternatively, were to use pricing and volume from all four quarters of 2024 to determine proposed rates, the rate for all categories would be approximately $114.87/cm^2. Using a pooled payment rate across all three categories would result in a rate of approximately $65.85/cm^2, while splitting the categories to pay the PMA category using the combined product utilization patterns and the 510(k) and 361 HCT/P categories using the OPPS utilization patterns would result in rates of approximately $259.47/cm^2 and $125.38/cm^2 respectively. We seek comments on our proposed process to calculate initial payment rates as well as these alternatives.

We propose to maintain the current structure of HCPCS codes for skin substitutes, including a process to introduce new product-specific codes and propose initial valuation based on the typical resource costs (that is, those reflected in ASP and MUC data) of the groups associated with each skin substitute's HCPCS code. For a complete list of codes and FDA categories, please see file titled ''Skin Substitute Products by FDA Regulatory Category'' available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Individual HCPCS coding remains necessary to provide identification on claims and track each product's cost. This will also allow effectuation of any applicable coverage policies and improve our ability to determine if any refinements in payment categories would be appropriate in future rulemaking. For the most part, the resources for incident-to supplies are included in the total RVUs of a procedural code or are packaged under the OPPS. However, this proposed approach is not entirely novel, since Medicare pays for various components of services through the use of separate HCPCS codes and/or payment modifiers. The most obvious examples of these kinds of payment and coding splits occur in diagnostic tests and radiation treatment services, but there are also many examples in the PFS of add-on codes with RVUs primarily driven by the costs of particular items, including disposable supplies. In this case, the full range of resource costs for the services would not be included in the RVUs or payment amount for a single code but rather spread across several codes, namely a base code and one or more add-on codes. In this case, the application base codes would be reported with an add-on or multiple add-on HCPCS codes associated with skin substitutes. For example, CPT code 15271 (application of skin substitute graft, leg or ankle) would be reported with a PE-only add-on code that includes the resources involved in using the skin substitute product. (Such PE-only codes are designated with a PC/TC indicator of 3 and are only paid under the PFS in the non-facility setting. The same HCPCS code would be separately reportable in the hospital outpatient setting but not paid under the PFS.)

We propose that new HCPCS codes describing skin substitutes would be categorized based on whether they are PMA-approved, 510(k)-cleared, or self-determined 361 HCT/Ps and the RVUs that apply to that category would be applied to the new code at the next quarterly update. Any change to the RVUs associated with each group would be subject to annual notice and comment rulemaking. Currently, HCPCS Level II coding applications are submitted and reviewed during the quarterly and biannual coding cycles. We post our coding determinations for drugs and biologicals on a quarterly basis, and do not routinely review those applications at a HCPCS public meeting. For non-drugs and non-biologicals, we post our coding decisions on a biannual basis. For our biannual cycles for non-drugs and non-biologicals, we post preliminary coding determinations then invite feedback on those preliminary coding determinations at a biannual HCPCS public meeting; final coding determinations are posted following the HCPCS public meeting. CMS has been reviewing skin substitutes marketed as 361 HCT/Ps in the quarterly drugs and biologicals coding cycle and 510(k)-cleared skin substitutes in the biannual, non-drugs and non-biologicals coding cycle. Beginning January 1, 2026, we propose to review HCPCS Level II coding applications for all skin substitutes marketed as 361 HCT/Ps through our biannual coding cycle for non-drugs and non-biological products, rather than on a quarterly basis. Skin substitutes that received a 510(k) clearance, PMA approval, or a granted De Novo request would continue to be evaluated in the biannual HCPCS Level II coding cycles. Therefore, under this proposal, CMS would evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles. Should any products come to market under the BLA, NDA, or ANDA pathways that could potentially be considered skin substitutes, CMS would instead review them in a quarterly HCPCS Level II drugs and biologicals coding cycle. Before a code is assigned, not otherwise classified (NOC) codes would be used and the CMS MACs would assign the appropriate payment based on the product's FDA regulatory category.

If skin substitutes that are not licensed under section 351 of the PHS Act are no longer paid as biologicals using the methodology under section 1847A of the Act, as proposed, then the manufacturers of these products would no longer be required to report ASP data to CMS under section 1847A(f)(2) of the Act. However, as noted above, when ASP data is reported, it may serve as a better estimate of resources across the hospital outpatient and non-facility settings than hospital outpatient MUC data. We propose to update the rates for the skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. However, we have concerns that using a single, scheduled quarter of ASP data to set payment rates could encourage gaming. We seek comments on the use of a longer timeframe, such as the most recently available four calendar quarters, to set payment rates in future years. In the event ASP is not available for a particular product, we propose to use the MUC data. If MUC is not available, we propose to use the product's WAC or 89.6 percent of AWP

if WAC is also unavailable, similar to other products for which ASP is used to calculate a payment rate.[85] Once updated use patterns reflecting this policy are available to calculate rates, we propose using all relevant products and the combined product utilization patterns (OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three categories. We seek comments on our proposed methodology to set and update the payment rates for skin substitutes as well as the rates themselves.

5. Summary

To implement this policy, we propose, starting January 1, 2026, to separately pay for skin substitute products as incident-to supplies in both the non-facility and hospital outpatient settings. We propose to create three groups to pay for skin substitutes based on their FDA regulatory categories: PMA, 510(k), and 361 HCT/P, and would include each skin substitute in the applicable category based on its FDA approval, clearance, or self-determination, unless a skin substitute is licensed under section 351 of the PHS Act, as described earlier in this section, in which case the payment methodology under section 1847A would continue to apply. We propose calculate initial payment rates for skin substitute products in each of the three FDA regulatory categories using the volume-weighted average ASP for skin substitute products in each group as submitted by manufacturers, when available, and the MUC when ASP is not available. We propose to use the hospital outpatient utilization patterns to set the payment rates for all three categories of skin substitutes, which we propose to pay at a single rate for CY 2026. For CY 2026, the proposed PE and MP RVUs would result in an initial payment rate of approximately $125.38/cm^2 (prior to the application of the geographic adjustments) for PMA approvals, 510(k)s, and self-determined 361 HCT/Ps. We propose to accomplish this by maintaining the current HCPCS codes for skin substitutes and then applying this rate to each code. We propose to update the rates for the skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates, though we are seeking comments on whether a single quarter is most advisable. In the event ASP is not available for a particular product, we propose to use the hospital outpatient MUC data. If MUC is not available, we propose to use the product's WAC or 89.6 percent of AWP if WAC is also unavailable. We propose to include all skin substitute products used across both settings as well as the combined product utilization patterns, as soon as data is available that reflects the results of this policy, to determine a weighted average per-unit cost by group to set the payment rates for each of the three categories. We are also seeking comments on how to best integrate this data into updated PE RVUs for years subsequent to CY 2026. Specifically, we are seeking comment on whether we should apply PE scaling factors to the data (that is, volume-weighted ASP or MUC) in order to optimize relativity with other PFS services and supplies once these products are incorporated into PFS data used for rate setting. We propose to evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles. Finally, we propose to codify the definition of ''biological'' as ''a product licensed under section 351 of the Public Health Service Act'' at §§414.802 and 414.902.

L. Strategies for Improving Global Surgery Payment Accuracy

1. Background

CMS establishes valuation and payment for approximately several thousand physician services as ''global surgical packages'' (herein 'globals') under the PFS. Each package includes a surgical procedure defined by the HCPCS code as well as related services, for example, pre and immediate post-operative care on the day of the procedure, care related to complications, and discharge services, and post-operative evaluation and management (E/M) services typically provided during postoperative periods of specified lengths called ''global periods.'' Currently, CMS pays for approximately 5,500 globals covering 0-, 10- and 90-day postoperative periods. Of the 5,500 total global surgical procedures, approximately 4,200 have either a 10- or 90-day global periods and nearly all of these 4,200 globals have at least one post-operative E/M visit included as part of their respective global surgical packages. Global surgical packages apply to the practitioner performing the procedure and, in the case of group practices, to the entire practice. Practitioners outside of those performing the procedure (or in the same group practice) can separately bill for post-operative and other care related to a global surgical procedure.

Taking into consideration findings from OIG reports that practitioners were performing fewer post-operative visits than Medicare assumed when valuing globals as well as our internal analysis, we finalized a policy in the CY 2015 PFS final rule to transition all globals with 10-day and 90-day global periods to have 0-day global periods. This change would allow practitioners to bill separately for any post-operative visits (or other care related to the procedure, for example, care for complications) furnished after the day of the procedure to be billed as standalone services. However, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), prohibited CMS from implementing this finalized policy and required that we collect data on the number and level of post-operative visits provided to enrollees as part of global periods and use this information to improve the valuation of globals.

In response to the MACRA requirements, CMS developed a claims-based reporting system and required practitioners in nine states and in practices of 10 or more National Provider Identifiers (NPIs) to report post-operative visits falling with global periods using no-pay HCPCS code 99024. We also initiated a research contract with RAND to analyze the collected data, to conduct a survey-based study on the level of post-operative visits, and to model different approaches to use the collected data and other information to improve the accuracy of valuation for global surgical services (see 81 FR 80212 through 80222 for more detailed discussion).

We recognize that, in some cases, a practitioner may only furnish the procedure component of a global surgical package, while in others, a practitioner may only provide post-operative care. In these cases, we rely on a set of transfer of care modifiers to split the fixed overall valuation of global surgical packages between providers. CMS broadened the scope for required reporting of transfer of care modifier -54 (*Surgical care only*) in the CY 2025 PFS Final Rule as part of an iterative process to improve global package valuation and therefore payment. Previously, this modifier could only be attached to global procedures with a 10 or 90-day global period when a patient's transfer of care was formally documented by both the surgeon and one or more post-operative care practitioners. In internal analyses, CMS found modifier -54 was used only rarely in aggregate and was concentrated in a small number of

[85] 89.6 percent of AWP was calculated by first reducing the usual 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup.

ophthalmologic and cardiology procedures. Beginning January 1, 2025, and onward, modifier -54 must be reported in all cases where the surgeon does not intend to provide post-operative care, including but not limited to cases where both the surgeon and another practitioner both formally document the transfer of care as under the previous policy (see 89 FR 97961 through 97967 for that discussion).

For CY 2025, we also finalized a new add-on code, HCPCS code G0559, for post-operative care services furnished by a practitioner other than the one who performed the surgical procedure (or another practitioner in the same group practice). This add-on code will more appropriately reflect the time and resources involved in these post-operative follow-up visits by practitioners who were not involved in furnishing the surgical procedure however may see the patient for postoperative care (see 89 FR 97968 through 97971 for that discussion).

2. Strategies To Address Global Package Valuation

We noted in the CY 2025 PFS final rule that our proposal to broaden the required use of the transfer of care modifiers was a first step in an iterative process towards improving the accuracy of global surgical service valuation and payment. We are considering next steps to improve the valuation and payment for these services. We are continuing to consider approaches to establishing the payment allocations for portions of the global package when the transfer of care modifiers are used. Furthermore, we are considering approaches to specifically use information reported to CMS on the number and level of post operative visits to improve global surgical service valuation as required by Section 1848(c)(8)(C) of the Act.

We requested comments in the CY 2025 proposed rule on how best to determine the appropriate shares used to split total global surgical package valuations into discrete portions for the purposes of determining valuation (and therefore payment) in transfer of care scenarios. We sought comment on potential approaches to revise these shares and how they could better reflect current medical practice and conventions for post-operative follow-up care. We sought to identify a procedure-specific, data-driven method for assigning shares to portions of the global package valuation to more appropriately align the resources involved in each portion to payment rates. We stated in the CY 2025 PFS proposed rule that we would appreciate and carefully consider recommendations from interested parties, including the AMA RUC, on what those shares should be and other relevant information. We also stated in the proposed rule that CMS could use data collected over nearly a decade on the observed number of post-operative visits furnished to patients as part of global surgical packages as the basis for calculating new data-driven shares. We note that we received few comments in response to our comment solicitation.

Currently, Medicare pays surgeons a fixed share of a global procedure's valuation when billed with specified modifiers, specifically, modifier -54. These ''procedure shares'' are based on long-standing assumption and are clustered at certain values, for example, 79 percent, 80 percent, or 81 percent for roughly half of procedures with 90-day global periods and 90 percent for most procedures with 10-day global periods (the remaining approximately 20 percent and 10 percent for 90-day and 10-day procedures, respectively, account for post-operative care). We believe that the use of these distinct portions of the global package will help us to best align valuation—and therefore payment—to the practitioner who is performing a specific portion of the global surgical service.

We heard from commenters that the current component percentages published in the PFS were developed using magnitude estimation and cross-specialty scaling and that there is not any reverse engineering of work and time that can be performed to develop a better percentage of pre-, intra- and post-operative work than what is currently published in the PFS. Given the fact that both PFS global surgical procedures and relative valuations have changed since the inception of the PFS, we believe there may be better ways to provide the correct apportionments to the global surgical packages. Furthermore, clinical practice including post-operative care has changed dramatically over the decades since the inception of the current shares. We did not update procedure shares in the CY 2025 PFS final rule.

We are again soliciting public comments on strategies to improve the accuracy of payment for global surgical packages, specifically related to the procedure shares. We are seeking public comments on what the procedure shares should be based on for the 90-day global packages. We are also seeking comments and stakeholder input as to current practice standards and division of work between surgeons and providers of post-operative care. Currently, there is no clear basis for the current procedure shares, and this will allow for stakeholder input as to what those procedure shares should be.

In accordance with MACRA, we have been collecting data on post-operative visits furnished as part of global surgical packages and the extent to which these furnished post-operative visits align with the number of post-operative visits assumed by CMS when valuing global surgical services. For procedures with 90-day global periods and 2023 dates of service, our internal analysis shows that only 28 percent of post-operative visits considered by CMS during global surgical service valuation were actually provided to enrollees as part of global surgical packages. Our internal findings and RAND's published analyses have consistently shown that only a fraction of ''expected'' post-operative visits are provided. Absent evidence to the contrary, which CMS has not identified despite several solicitations for comments from the public (89 FR 97961 through 97962), our interpretation is that many post-operative visits considered during the valuation of global surgical packages are not provided as part of these packages. This presents an opportunity to use information from claims-based reporting of post-operative visits to develop procedure shares that better reflect current practice patterns. Using this data, as established through notice and comment rulemaking (81 FR 80212 through 80222), we considered several options regarding how the procedure shares could be updated, based on the data that was analyzed. These options are available in the file titled ''Estimated Procedure Shares Under Procedure-Only Modifier -54, Surgical Services with 90-day Global Period'' on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

As we continue to contemplate how to pay more accurately for global surgical packages, and specifically in consideration of how the procedure shares could be updated, we identified three alternatives to the status quo assumed procedure shares (that is, the share of a global surgical package valuation assigned to the surgeon when modifier -54 is reported) for global surgical packages. Each alternative uses information available in claims data to calculate new HCPCS code-specific procedure shares. Each alternative also calculates procedure shares as the ratio of procedure work RVUs (defined as the sum of intraservice work and other work on the day of the procedure (that is, pre-service work) as indicated on the

Physician Time File to total global surgical package work RVUs. The Physician Time File and Addendum B are both located under the Download files for this proposed rule at: *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.* The approaches differ in the way we would calculate procedure work RVUs, and more specifically, intraservice work as a component of procedure work RVUs.

Under the first approach, we would calculate procedure work RVUs by subtracting work RVUs assigned to each post-operative visit listed in the Physician Time File for a global procedure HCPCS code from the total valuation of the global surgical package. Under the second approach, we would calculate procedures' work RVUs by subtracting the work RVUs for post-operative visits provided as part of global surgical packages. To do so, we would multiply the number of post-operative visits typically provided for the global procedure HCPCS code (defined as the median count of post-operative visits reported to CMS using no-pay code 99024 among procedures without overlapping global periods with other global surgical services) by the average valuation per post-operative visit calculated for the mix (that is, number and level) of post-operative visits for the global procedure HCPCS code as listed in the Physician Time File. Under the third approach, would calculate procedure RVUs as the product of total physician time (in minutes) for each global procedure HCPCS code from the Physician Time File and the ratio of physician time (in minutes) assigned to post-operative visits for the code in the Physician Time File to total physician time.

In the CY 2025 PFS final rule, we expanded the scope for modifier -54 (surgical care only) to include all scenarios where the surgeon does not expect to provide post-operative care. The scope for modifier -55 (post-operative care only) was not changed. As a result, the post-operative share of total global surgical package valuation can only be billed with modifier -55 when transfers of care are formally documented by the surgeon and another practitioner.

Looking at 2023 claims data, RAND's analyses suggest the current procedure shares do not reflect the real-world division of work between surgeons and providers of post-operative care. Across all CY 2023 90-day global procedures and weighted by procedure volume, the procedure share under our current assumed procedure shares would have been 82 percent, on average, assuming all procedures were billed with modifier -54. Under the procedure shares calculated based on the actual number of visits furnished in global surgical periods (determined using information from claims-based reporting of post-operative visits), the average procedure share would have been 91 percent, with 85 percent of procedures having higher procedure shares under this approach compared to CMS' current assumptions.

We are seeking comments on the best approach to utilize going forward, specifically on the CPT code 99024-based approach. Of these approaches, the first (in terms of work RVUs) and third (in terms of physician time minutes) rely on Physician Time File counts of the number and level of post-operative visits assumed to occur as part of global surgical packages. Based on prior analyses (see 89 FR 97961), these counts are substantially inflated. Of all Physician Time File assumed visits and for 2023 global surgical procedure volumes, only 2 percent of visits following procedures with 10-day global periods and 28 percent of visits following procedures with 90-day global periods were provided to patients as part of global surgical packages. For this reason, we believe the resulting procedure shares under these approaches are too low and would lead to payments to surgeons that do not reflect the time and resources involved in furnishing the procedure component of global surgical services. In contrast, the second approach (using post-operative visit counts from claims-based reporting) reflects real-world, observed patterns of post-operative care. Furthermore, the second approach allows for routine, transparent updating of procedure shares over time. In contrast, shares could be updated under the first and third approaches only when global surgical services are revalued, and even then, with the limitation noted previously that the resulting visit counts by E/M service level are often substantially too high.

We are seeking comments on replacing the current procedure shares using the second approach described above (that is, with procedure work RVUs calculated using counts of post-operative visits reported using no-pay CPT code 99024).

Additionally, in our internal review of the percentages assigned for the pre-operative, surgical care, and post-operative portions of the global packages, we found that there are a small number of codes that do not have any assigned percentages in our files even though these codes are identified as global packages. We are again seeking comments on whether we should consider, first, whether these codes are appropriately categorized as 90-day global package codes, and if so, we are seeking comments on what the assigned percentages should be for each portion of the service.

M. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: work, practice expense (PE), and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource-based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary, adjust RVUs no less often than every 5 years. As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor (RF) was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) specialty-level risk values derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk values derived from Medicare claims data of the weighted average risk values of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk value based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we discussed this methodology and finalized a policy to begin conducting annual MP RVU updates to

reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the three most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data but would remain unchanged between the 5-year reviews.

In the CY 2018 PFS proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors used in the calculation of MP RVUs prior to the next required 5-year update (CY 2020) using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however, the proposal was ultimately not finalized for CY 2018.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. In the CY 2020 PFS final rule (84 FR 62606 through 62615), we implemented the fourth review and update of MP RVUs, and we also conducted the statutorily required 3-year review of the GPCIs. The MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Therefore, to increase efficiency, we finalized a policy to align the update of MP premium data and specialty-level risk factors with the update to the MP GPCIs. We finalized a policy to review, and if necessary, update the MP RVUs at least every 3 years, similar to our review and update of the GPCIs.

In the CY 2023 PFS final rule, we conducted the statutorily required review of the MP RVUs and GPCIs (87 FR 69634 through 69641). We refer to this review and update of the MP RVUs as the ''CY 2023 update.'' As part of this review, we finalized a methodological improvement to move from MP risk factors to a MP risk index. The risk index is calculated as a ratio of the specialty's national average premium to the volume-weighted national average premium across all specialties. We finalized this methodological improvement to increase consistency with the calculation of MP RVUs, so that changes in the MP risk index reflect changes in payment, as opposed to changes relative only to the specialty with the lowest national average premium.

2. Methodology for the Proposed Revision of Resource-Based Malpractice (MP) RVUs

a. General Discussion

We calculated the MP RVUs that we are proposing for CY 2026 using updated MP premium data obtained from state insurance rate filings. The methodology used to calculate the CY 2026 resource-based MP RVUs largely parallels the process used in the CY 2023 update with continued improvements to our data collection process. To calculate the MP RVUs, we obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk values for the various specialties that furnish a particular service. Because MP premiums vary by state and specialty, we weigh the MP premium data geographically and by specialty. We calculated the MP RVUs we are proposing using four data sources: data on MP insurance premium rates presumed to be in effect as of December 31, 2023; CY 2023 Medicare payment and utilization data; higher of the CY 2025 final work RVUs or the clinical labor portion of the direct PE RVUs; and CY 2025 GPCIs. We used the higher of the CY 2025 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2026 proposed MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2023 update, we calculated the proposed MP RVUs using specialty-specific MP premium data because they represent the expense incurred by practitioners to obtain MP insurance as reported by insurers. For CY 2026, we obtained the most current MP insurance premium data available, reflecting rates with a presumed effective date of no later than December 31, 2023, from insurers with the largest market share in each state. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) 2023 market share report. This annual report provides state-level market share for entities that provide premium liability insurance (PLI) in a state. Premium data was downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating states. For non-SERFF states, data was downloaded from the state-specific website (if available online) or obtained directly from the state's alternate access to filings. For SERFF states and non-SERFF states with online access to filings, we used the 2023 market share report to select insurance companies. These market share filings were the most current data available during the data collection and acquisition process.

MP insurance premium data was collected from all 50 States and the District of Columbia. We made efforts to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection, and therefore, we used filings from the previous update. Consistent with the CY 2023 MP RVU update, we did not collect filings for the other U.S. territories: American Samoa, Guam, Virgin Islands, or Northern Mariana Islands. We collected MP insurance premium data for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. We made adjustments to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the state's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

In the CY 2020 PFS final rule (84 FR 62607 through 62610), we finalized methodological improvements that expanded the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs. Premium data were included for all physician and nonphysician practitioner (NPP) specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all States, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all States.

b. Proposed Methodological Refinements

For the CY 2026 update, we are not proposing any major methodological refinements to the development of MP premium data. However, we have continued to refine the universe of specialties subject to imputation and sources of imputation for each specialty. For the CY 2023 update, premium data for the specialties of Geriatric Medicine, Hospitalist, Internal Medicine, Medical Oncology, Pain Management, and Preventive Medicine were augmented with some imputed data, but sufficient data was collected for these specialties during this CY 2026 update such that imputation was unnecessary. Additionally, Allergy/Immunology was previously used as the imputation source for both Osteopathic Manipulative Medicine and Addiction Medicine. For this CY 2026 update, more clinically similar specialties were used as the imputation source for these specialties.

c. Steps for Calculating Proposed Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 PFS final rule with comment period (79 FR 67591), along with the methodological improvements established in the CY 2023 PFS final rule (87 FR 69634 through 69641). The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk index of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area MP premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2018 to 2022 American Community Survey (ACS) 5-year estimates). This contrasts with the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the 2025 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of MP claims if they occur. To account for the presence of different classes in the MP premium data and the task of mapping these premiums to procedures, we calculated a distinct risk index for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several methods for calculating average premiums by specialty.

Developing Distinct Service Risk Groups: We determined that there was sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 17 specialties. These specialties are listed in Table 29. The CY 2026 update uses the same structure of specialty/service risk group as the CY 2023 update. For all other specialties (those that are not listed in Table 29) that typically do not distinguish premiums as described above, a single risk index value was calculated, and that specialty risk index value was applied to all services performed by those specialties.

TABLE 29: SPECIALTIES SUBDIVIDED INTO SERVICE RISK GROUPS

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Cardiac Electrophysiology (21), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93) Unknown Physician Specialty (99)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Step (3): Calculate a risk index for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk index. These risk index values are calculated by dividing the national average premium for each specialty by the volume-weighted national average premium across all specialties. Risk index values less than one correspond to specialties with relatively lower malpractice risk than average, and values greater than one correspond to specialties with relatively higher malpractice risk. The volume-weighted national average premium was calculated as the sum of the product of the national average premium and total CY 2023 PE and work RVUs for each specialty/service risk group, then dividing by total CY 2023 PE and work RVUs across all specialties.

(a) Technical Component (TC) Only Services

For the CY 2020 update of the MP RVUs (84 FR 62606 through 62615), we finalized that we would assign a risk factor of 1.00, which was the lowest physician specialty risk factor (allergy/immunology), to TC-only services due to a lack of sufficient professional liability premium data. For the proposed CY 2023 update of the MP RVUs (87 FR 46016), our expanded data

collection efforts resulted in sufficient premium data such that we could directly assign a risk value for TC- only services without the need for mapping. However, due to a technical error, we continued to assign a 1.0 risk factor for all TC-only services which resulted in an incorrect calculation of the proposed MP RVUs for TC-only services. In the CY 2023 PFS final rule (87 FR 69641), we finalized a correction to this ratesetting error for the 2023 update of the MP RVUs that again mapped TC-only services to allergy/immunology, which had a risk index value of 0.430. We stated that using this risk value will correct the identified error, while also maintaining as much stability as possible for TC-only services so that there is not a major shift in value from current MP RVUs for the technical and professional components.

For this CY 2026 update of the MP RVUs, we are proposing to map TC-only services to the specialty allergy/immunology, which now has a risk index value of 0.427. Mapping the TC-only services to the specialty allergy/immunology would be consistent with the CY 2020 and 2023 updates of the MP RVUs and maintain stability in our ratesetting process. We request comments regarding the risk index value for TC-only services. Table 30 shows the risk index values by specialty type and service risk group.

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TABLE 30: CY 2026 Risk Index by Specialty and Service Risk Group

Medicare Specialty Code and Name	2026 Service Risk Group	2026 Risk Index
01-General practice	NO SURG	0.723
01-General practice	SURG	1.438
01-General practice	OB	1.707
02-General surgery	ALL	3.074
03-Allergy/immunology	ALL	0.427
04-Otolaryngology	NO SURG	0.711
04-Otolaryngology	SURG	1.679
05-Anesthesiology	ALL	0.967
06-Cardiology	NO SURG	0.815
06-Cardiology	SURG	2.754
07-Dermatology	NO SURG	0.492
07-Dermatology	SURG	1.135
08-Family practice	NO SURG	0.726
08-Family practice	SURG	1.494
08-Family practice	OB	1.716
09-Interventional Pain Management	ALL	1.190
10-Gastroenterology	NO SURG	0.867
10-Gastroenterology	SURG	1.290
11-Internal medicine	ALL	0.793
12-Osteopathic manipulative medicine	ALL	0.590
13-Neurology	NO SURG	0.968
13-Neurology	SURG	4.845
14-Neurosurgery	ALL	4.845
15-Speech Language Pathology	ALL	0.012
16-Obstetrics/gynecology	NO SURG	0.992
16-Obstetrics/gynecology	SURG	2.018
16-Obstetrics/gynecology	OB	3.686
17-Hospice & Palliative Care	ALL	0.780
18-Ophthalmology	NO SURG	0.505
18-Ophthalmology	SURG	0.918
19-Oral surgery (dental only)	ALL	1.313
20-Orthopedic surgery	ALL	2.451
21-Cardiac Electrophysiology	NO SURG	0.815
21-Cardiac Electrophysiology	SURG	2.763
22-Pathology	ALL	0.655
23-Sports Medicine	ALL	0.740
24-Plastic and reconstructive surgery	ALL	2.136
25-Physical medicine and rehabilitation	ALL	0.600
26-Psychiatry	ALL	0.475
27-Geriatric Psychiatry	ALL	0.475
28-Colorectal surgery	ALL	1.657
29-Pulmonary disease	ALL	0.971
30-Diagnostic radiology	ALL	1.099
31-Intensive Cardiac Rehab	ALL	0.815
32-Anesthesiologist assistants	ALL	0.264
33-Thoracic surgery	ALL	2.895

Medicare Specialty Code and Name	2026 Service Risk Group	2026 Risk Index
34-Urology	NO SURG	0.830
34-Urology	SURG	1.480
35-Chiropractic	ALL	0.154
36-Nuclear medicine	ALL	0.602
37-Pediatric medicine	ALL	0.705
38-Geriatric medicine	NO SURG	0.682
38-Geriatric medicine	SURG	1.649
39-Nephrology	NO SURG	0.713
39-Nephrology	SURG	1.143
40-Hand surgery	ALL	1.964
41-Optometry	ALL	0.046
42-Certified nurse midwife	ALL	1.021
43-CRNA	ALL	0.269
44-Infectious disease	ALL	0.910
45-Mammography screening center	ALL	0.016
46-Endocrinology	NO SURG	0.770
46-Endocrinology	SURG	1.430
47-Independent Diagnostic Testing Facility	ALL	0.016
48-Podiatry	NO SURG	0.452
48-Podiatry	SURG	0.982
62-Psychologist	ALL	0.064
63-Portable X-ray supplier	ALL	0.014
64-Audiologist	ALL	0.015
65-Physical therapist	ALL	0.034
66-Rheumatology	ALL	0.674
67-Occupational therapist	ALL	0.024
68-Clinical psychologist	ALL	0.064
69-Clinical laboratory	ALL	0.016
70-Multispecialty clinic or group practice	ALL	0.714
71-Registered Dietician/Nutrition Professional	ALL	0.192
72-Pain management	ALL	1.128
75-Slide Preparation Facilities	ALL	0.016
76-Peripheral vascular disease	ALL	2.938
77-Vascular surgery	ALL	2.938
78-Cardiac surgery	ALL	2.754
79-Addiction medicine	ALL	0.484
80-Licensed clinical social worker	ALL	0.022
81-Critical care (intensivists)	ALL	1.201
82-Hematology	ALL	0.750
83-Hematology/oncology	ALL	0.782
84-Preventive medicine	ALL	0.544
85-Maxillofacial surgery	ALL	1.452
86-Neuropsychiatry	ALL	0.475
90-Medical oncology	ALL	0.746
91-Surgical oncology	ALL	2.664
92-Radiation oncology	ALL	0.918
93-Emergency medicine	NO SURG	1.478
93-Emergency medicine	SURG	2.854
94-Interventional radiology	ALL	1.501
98-Gynecologist/oncologist	ALL	2.664
99-Unknown physician specialty	NO SURG	0.714
99-Unknown physician specialty	SURG	1.229
C0-Sleep Medicine	ALL	0.909
C3-Interventional Cardiology	ALL	2.725
C6-Hospitalist	ALL	0.940

Medicare Specialty Code and Name	2026 Service Risk Group	2026 Risk Index
C7-Advanced Heart Failure & Transplant Cardiology	ALL	0.815
C8-Medical toxicology	ALL	1.478
C9-Hematopoietic cell transplantation and cellular therapy	ALL	0.799
E1-Marriage and family therapist (MFT)*	ALL	0.022
E2-Mental health counselor (MHC)*	ALL	0.022
E3-Dental anesthesiology*	ALL	0.954
E6-Oral and maxillofacial pathology*	ALL	0.609
E7-Oral and maxillofacial radiology*	ALL	1.083
F1-Orofacial pain*	ALL	1.121

*Note: CMS specialty codes denoted with an asterisk (*) were established for billing purposes effective January 1, 2024. This is the first update for which risk index values have been calculated for these specialties.

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Step (4): Calculate MP RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This percentage was then multiplied by each respective specialty's risk index value as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk index reflecting the weighted MP costs across all specialties furnishing that procedure. The service specific risk index was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

For low volume services codes, we finalized in the CY 2018 PFS final rule (82 FR 53000 through 53006) a proposal to apply the list of expected specialties instead of the claims-based specialty mix for low volume services to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services (which also includes no volume services); these are defined as codes that have 100 allowed services or fewer. These service-level overrides are used to determine the specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2026, we are soliciting public comment on the list of expected specialties. The proposed list of codes and expected specialties is available on our website under downloads for the CY 2026 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource-based MP RVUs are equal to the total current resource-based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we discuss specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We are proposing to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We note that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we propose to also exclude for the purpose of calculating MP RVUs is available in section II.B. of this final rule, Determination of Practice Expense Relative Value Units. The resource-based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2026 PFS rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work currently represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type is detailed in section VII. of this proposed rule, the Regulatory Impact Analysis.

Additional information on our methodology for updating the MP RVUs is available in the ''Interim Report for the CY 2026 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' which is available on the CMS website under the downloads section of the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

N. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate

Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS below in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in Frontier States (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which has been extended by many successive amendments to the statute. The 1.0 floor for the work GPCI under section 1848(e)(1)(E) of the Act was most recently extended by section 2206 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4, enacted March 15, 2025) through September 30, 2025 (that is, for services furnished no later than September 30, 2025). Therefore, as proposed, the CY 2026 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for Frontier States are permanent, and therefore, are reflected in the CY 2026 proposed GPCIs.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, since more than 1 year has passed since the previous GPCI update was implemented in CY 2023 and 2024, we are proposing to phase in ½ of the proposed GPCI adjustment in CY 2026 and the remaining ½ of the adjustment for CY 2027.

We have completed our review of the GPCIs and are proposing new GPCIs beginning for CY 2026 in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS locality's proposed work, PE, and MP GPCIs using the share of total RVUs that each component accounts for in the actual Medicare utilization from CY 2023. While we do not actually use GAFs in computing the PFS payment for a specific service, they are a useful metric for purposes of comparing overall costs and payments across fee schedule areas. The actual effect of GPCIs on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those reflected in the GAF.

See Addenda D and E to this proposed rule for the CY 2026 proposed GPCIs and summarized GAFs. These Addenda are available on the CMS website under the supporting documents section of the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89 and increased the number of Statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23 additional localities, increasing the total number of PFS localities from 89 to 112. Subsequently, we operationalized a technical refinement to retire several California localities that were no longer operationally necessary, resulting in a reduction of unique California localities from 32 to 29 from CY 2024 on. We refer readers to the discussion of this technical refinement in the CY 2023 (87 FR 69621 through 69625) and 2024 (88 FR 78985 through 78987) PFS final rules, and the section below. As a result, the current 109 payment localities include 34 Statewide areas (that is, only one locality for the entire State) and 72 localities in the other 16 States, with 10 States having two localities, two States having three localities, one State having four localities, and three States having five or more localities. The remainder of the 109 PFS payment localities are comprised as follows: the combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We note that the localities generally represent a grouping of one or more constituent counties.

The current 109 fee schedule areas, also referred to as payment localities, are defined alternatively by State boundaries (Statewide areas for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate geographically adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a State. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). The changes to the proposed CY 2026 GPCIs for each locality reflect the updated resource cost data in each area to better adjust PFS payments for geographic cost differences compared to national average costs. We note that the changes in the proposed GPCIs reflect

the statutory floors and limitations on variation discussed above that may advantage some rural localities. We describe the data sources and methodologies we use to calculate each of the three GPCIs below in this section. Additional information on the CY 2026 GPCI update is available in an interim report, ''Interim Report for the CY 2026 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for nine professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), formerly known as Occupational Employee Statistics (OES), wage data as a replacement for the 2000 Census data. The BLS OEWS data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OEWS wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OEWS is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OEWS data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs; for the CY 2017 GPCI update, we used updated BLS OEWS data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs; for the CY 2020 GPCI update, we used updated BLS OEWS data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs; and for the CY 2023 GPCI update, we used updated BLS OEWS data (2017 through 2020) as a replacement for the 2014 through 2017 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OEWS data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed below, the employee wage component and purchased services component of the PE GPCI). Therefore, for the CY 2026 GPCI update, we used updated BLS OEWS data (2020 through 2023) as a replacement for the 2017 through 2020 data to compute the proposed work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2023), we used 2017 through 2020 BLS OEWS data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OEWS is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the CY 2026 GPCI update, we used updated BLS OEWS data (2020 through 2023) as a replacement for the 2017 through 2020 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI. In calculating the CY 2026 GPCI update for the office rent index component of the PE GPCI, we used the 2018 through 2022 American Community Survey (ACS) 5-year estimates as a replacement for the 2015 through 2019 ACS data.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). To ensure that premium data are homogenous and comparable across geographic areas, data were collected for policies with uniform coverage limits of $1 million per occurrence and $3 million aggregate ($1 million/$3 million). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million/$3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2023 GPCI update, we used

premium data presumed in effect as of December 31, 2020. The CY 2026 MP GPCI update reflects premium data presumed in effect no later than December 31, 2023. We note that we finalized a few technical refinements to the MP GPCI methodology in CY 2017 and refer readers to the CY 2017 (81 FR 80270) PFS final rule for additional discussion of those.

d. GPCI Cost Share Weights

For the CY 2026 GPCIs, we are proposing to continue to use the current 2006-based MEI cost share weights for determining the proposed PE GPCI values. Specifically, we use the cost share weights to weight the four components of the PE GPCI: employee compensation, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses, as shown in Table 31. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017, CY 2020, and CY 2023 GPCI updates.

We note that we proposed and finalized to rebase and revise the MEI cost share weights for CY 2023, and we refer readers to the detailed discussion in section II.M. of the CY 2023 PFS final rule (87 FR 69688 through 69710). Due to the concurrent rebasing and revision of the MEI cost share weights during the CY 2023 GPCI update, we proposed and finalized to maintain the use of the 2006-based MEI cost share weights for the CY 2023 GPCIs, thus delaying the implementation of the rebased and revised 2017-based MEI cost share weights for this purpose. We refer readers to our discussion about using the rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and for the purposes of updating the GPCIs in the CY 2023 PFS final rule (87 FR 69414 through 69415, 69619 through 69620, and 70212 through 70218). In those sections, we discussed our considerations for updating the MEI cost share weights for the RVUs and the GPCIs and the potential redistributive impact that making such a change would have had on PFS payments. We have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI, which was most recently done for CY 2023; however, in light of the overall impacts of making this change and in the interest of maintaining stability in payments, we proposed and finalized to maintain the use of the currently used 2006-based MEI cost share weights for the CY 2023 final PE GPCIs. For the CY 2026 GPCI update, we have the same concerns about the potential redistributive effects that implementing the 2017-based MEI would have on PFS payments. Additionally, we have received data from the American Medical Association's (AMA) Physician Practice Information [86] (PPI) and Clinician Practice Information [87] (CPI) Surveys, however, these data lack the specific breakdown of practice expense that we would need to consider its use to weight the four components of the PE GPCI for CY 2026, including Office Rent and Purchased Services, which are reported in an aggregate buckets of general overhead costs and other expenses in the survey data. We refer readers to section VII. of this proposed rule for more discussion regarding a possible derivation of cost share weights for use in the PE GPCI from the PPI and CPI Survey.

We also note that maintaining the 2006-based MEI cost share weights for the CY 2026 GPCI update preserves consistency in the data used to update both the GPCI and PFS ratesetting inputs for CY 2026. We refer readers to section VII. of this proposed rule for additional discussion on this issue and the estimated impacts as it relates to PFS ratesetting and the GPCI update for CY 2026. We also refer readers to the discussion regarding the PPI and CPI survey data in section II.B. of this proposed rule. In addition, we direct readers to the CY 2011 PFS final rule (75 FR 73256) where we similarly delayed implementation of updated MEI cost share weights in response to commenters' concerns about our separate, ongoing analysis that would inform future GPCI changes and the reallocation of labor-related costs from the medical equipment and supplies and miscellaneous component to the employee compensation component of the PE GPCI.

In the CY 2011 PFS final rule (75 FR 73256), we acknowledged that we typically update the GPCI cost share weights concurrently with the most recent MEI rebasing and revision, but in consideration of the commenters' concerns in response to the proposed rule, we did not use the revised cost share weights for the CY 2011 GPCIs and instead finalized the implementation of the rebased and revised MEI cost share weights through subsequent rulemaking. We invite comments on the 2017-based MEI cost share weights and the weights based on PPI and CPI Survey data for purposes of alternatives considered for the CY 2026 GPCIs and PFS ratesetting, given the estimated impacts discussed in section VII. of this proposed rule. We are also soliciting comments on how best to proceed with implementation of the 2017-based MEI cost share weights or PPI and CPI Survey weights in the future. More specifically, we are seeking comment on how best to incorporate updated cost share weights into the PE GPCI if we were to implement them outside the statutorily required triennial update in which we phase in all aspects of the GPCI update through the previously discussed 2-year (½ in each year) phase-in required by section 1848(e)(1)(C) of the Act. Section 1848(e)(1)(C) of the Act requires that, if more than one year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, specifically, we are seeking comment on potentially incorporating the updated cost share weights into the CY 2027 GPCIs. We note that we would not be required by statute to phase in the adjustment over 2 years as specified in section 1848(e)(1)(C) of the Act because, in CY 2027, no more than one year would have elapsed since this CY 2026 GPCI adjustment. Therefore, we are also seeking comment on whether it would be appropriate to use a multi-year transition to incorporate updated cost share weights for purposes of the PE GPCI and PFS ratesetting as we have done in the past when incorporating other new data into the PFS payment methodology (for example, the clinical labor update), or if, because updated cost share weights only impact the composition of the PE GPCI, such a transition would not be warranted. If we were to instead apply updated cost share weights for purposes of the PE GPCI and PFS ratesetting for CY 2028 or later, we would be required under section 1848(e)(1)(C) of the Act to phase in the GPCI adjustments over 2 years. We are seeking comments on whether, in that case, it would be appropriate to similarly apply a transition to implement updated cost share weights for purposes of PFS ratesetting as well, and refer readers to section II.B and VII. of this proposed rule for more discussion regarding the alternatives considered and impacts of a phase-in of updated cost share weights in PFS ratesetting. The proposed CY 2026 GPCI cost share weights are displayed in

[86] *https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.*

[87] *https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.*

Table 31. We note that the 2017-based MEI cost share weights as finalized in section II.M. of the CY 2023 PFS (87 FR 69688 through 69708) final rule are also displayed in Table 31 for awareness regarding potential future rulemaking and GPCI updates. As previously discussed, the PPI and CPI Survey data lack the specific breakdown of practice expense that we would need to consider its use to weight the four components of the PE GPCI for CY 2026, therefore, we refer readers to section VII. of this proposed rule for more discussion regarding a possible derivation of cost share weights for use in the PE GPCI from the PPI and CPI Survey for awareness regarding potential future rulemaking and GPCI updates.

TABLE 31: PROPOSED GPCI COST SHARE WEIGHTS FOR CY 2026

Expense Category	Current and CY 2026 Proposed GPCI Cost Share Weights (2006-based MEI)	2017-based MEI Cost Share Weights*
Work	50.866%	47.522%
Practice Expense	44.839%	51.129%
- Employee Compensation	16.553%	25.450%
- Office Rent	10.223%	5.683%
- Purchased Services	8.095%	13.419%
- Equipment, Supplies, Other	9.968%	6.576%
Malpractice Insurance	4.295%	1.349%
Total	**100.000%**	**100.000%**

*As finalized in the CY 2023 PFS final rule (87 FR 69688 - 69708)

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in Frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be Frontier States. In general, a Frontier State is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a Frontier State, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2026 PFS proposed rule. The qualifying states are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we will apply a 1.0 PE GPCI floor for these states in CY 2026.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-state locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously

in the rest-of-state locality or locality 3 and are now in MSAs were a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We note that while the phase-in for transition areas is no longer applicable, the hold harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two former unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties—San Francisco, San Mateo, Alameda, and Contra Costa counties—across three former unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers; and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. In light of the foregoing, for CY 2023, we proposed and finalized to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we proposed and finalized to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to four, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we noted that we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty). The refinement finalized in the CY 2024 PFS final rule (88 FR 78985 through 78987) ultimately changed the number of distinct fee schedule areas for payment purposes in California from 32 to 29. We noted that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we needed to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. We note that these changes do not have any payment implications under the PFS.

h. Alternatives Considered Related to List of Occupation Codes Used in the Work GPCI Calculation

As explained in the Work GPCIs section above, we utilize a refined list of occupation groups and codes from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) data to calculate the work GPCI. Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OEWS data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs. For the CY 2023 GPCI update, we reviewed the occupation codes and groups used to capture geographic variation in professional wages to assess other potential codes and groups that could be used in addition to the current selections to calculate the work GPCI, with significant consideration given to the extent to which the data exist in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). Based on our review and commenters' response to the proposals, we finalized the addition of two new occupation groups (and their corresponding occupation codes), Management Occupations and Business and Financial Operation Occupations, to the preexisting seven occupation groups, and four new occupation codes to the pre-existing Computer, Mathematical, Life, and Physical Science group, and three occupation codes to the pre-existing Social Science,

Community and Social Service, and Legal group in the CY 2023 PFS final rule (87 FR 69621 through 69625). The practical effect of the addition of these occupation groups and codes on the work GPCI was minimal because the statute at section 1848(e)(1)(A)(iii) of the Act requires that the work GPCI reflect only one quarter of cost differences, but their inclusion added meaningful data regarding the geographic variation in professional wages for CY 2023.

In the CY 2023 PFS final rule (87 FR 69631), some commenters stated that our methodologic changes to the work GPCI occupation groups and codes create unnecessary complexity and limited transparency. The commenters stated that CMS did not provide an impact analysis or criteria for inclusion (that is, how well it correlated as a proxy) other than significant consideration to the extent to which the data exist in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). The commenters stated that, without further explanation, two additional occupation groups were added to the previous seven occupation groups, which increased the greater than 100 current occupation codes by 60. One commenter believed that it is unlikely that the cumulation of so many professions will accurately reflect the relative difference in work of a single profession such as a physician; the commenter stated that, if one were to compare the BLS OEWS data file used for the work GPCI with that of the healthcare provider dataset, there is a discordance. The commenters agreed that the healthcare provider dataset should not be used for developing the work GPCI due to circularity, but believe it could be used to validate the proposed work GPCIs and to identify a much smaller subset of professions that would act as more reliable proxies than what was proposed. The commenters urged CMS to apply a smaller number of professions to the work GPCI, as they thought that doing so would result in a more reliable and accurate proxy for physician work, and provide more information about the correlation between physician work and the proxy professions to allow the public to verify its accuracy.

In response to commenters, we noted that we do not claim the proxy professions themselves, or the absolute wages of the proxy professionals are correlated to physician wages, but rather, that the geographic variation in proxy professional wages is similar to the geographic variation in physician wages.

We believed that there would be similar geographic variation if one were to compare the BLS OEWS data used for the work GPCI with data from a healthcare provider dataset. We continue to believe in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals across an array of industries vary. Further, we welcomed opportunities to discuss data sources that can be used to validate the work GPCI, similar to the analysis that we performed for residential and commercial rent data used for the office rent index for CY 2023.

For CY 2026, we analyzed the potential effect of using a consolidated set of occupation codes on the work GPCI and compared that effect to changes in work GPCI values that would occur utilizing the standard set of occupation codes, as finalized for CY 2023. We acknowledge that the use of a more parsimonious set of occupations could be an improvement if it results in essentially the same work GPCI values with increased simplicity and clarity for interested parties. We explored approaches to condense the list of occupation codes used in a more systematic manner, with the establishment of inclusion criteria for an occupation code such as level of education attainment and data completeness. For our analysis, we identified 274, 157 and 90 occupation codes with at least 50 percent, 75 percent, and 90 percent having a Bachelor's Degree or higher, excluding occupation codes in Group 29 that are paid on the Fee Schedule, respectively from the May 2023 OEWS data. We then applied various data completeness criteria thresholds to these occupation codes with wage data for at least 50 percent, 75 percent, and 90 percent of U.S. counties, resulting in the number of occupation codes displayed below in Table 32.

TABLE 32: DATA EXISTENCE FOR CODES THAT MEET VARIOUS EDUCATION ATTAINMENT THRESHOLDS: AT LEAST 50%, 75% OR 90% WITH A BACHELOR'S DEGREE OR HIGHER, EXCLUDING GROUP 29 OCCUPATION CODES THAT ARE PAID ON THE FEE SCHEDULE

	Bachelor's Degree or higher ≥ 50%		Bachelor's Degree or higher ≥ 75%		Bachelor's Degree or higher ≥ 90%	
# of Codes	274		157		90	
	Number	Percent	Number	Percent	Number	Percent
Codes with wage data for at least 50% of U.S. counties	112	41%	57	36%	23	26%
Codes with wage data for at least 75% of U.S. counties	69	25%	31	20%	8	9%
Codes with wage data for at least 90% of U.S. counties	45	16%	19	12%	4	4%

* Note: Prosthodontists (1) 29-1024 is not in the MSA-level data file that is used for analyzing data completeness. Wage data is only available at the national level in file "all_data_M_2023.xlsx". Therefore, the starting # of codes is 273, 156 and 89.

Of these scenarios with various thresholds of the education attainment and data completeness inclusion criterion, we investigated two scenarios compared to the standard CY 2026 GPCI: (1) occupation codes with at least 75 percent of Bachelor's Degree or Higher excluding Group 29 and wage data for at least 50 percent of U.S. counties, resulting in a list of 57 occupation codes and (2) occupation codes with at least 75 percent of Bachelor's Degree or Higher excluding Group 29 and wage data for at least 75 percent of U.S. counties, resulting in a

list of 31 occupation codes from the May 2023 OWES data. Under these two scenarios, the work GPCIs result in changes relative to current CY 2025 work GPCI values that are nearly identical to those under the standard CY 2026 GPCI update, as shown below in Table 33.

TABLE 33 Distribution of Work GPCI Change Under Consolidated Occupation Code Lists, Transition Values for CY 2026 Compared to CY 2025 Values

SIZE OF CHANGE IN MEASURE	Standard CY 2026 GPCI Update # of Payment Areas	BACH 75 DATA 50 # of Payment Areas	BACH 75 DATA 75 # of Payment Areas
< -10%	0	0	0
-10% to < - 4%	0	0	0
-4% to < -1.5%	13	12	13
-1.5% to < -0.5%	36	37	37
-0.5% to < 0.5%	53	54	53
0.5% to < 1.5%	7	6	6
1.5% to < 4%	0	0	0
4% to < 10%	0	0	0
10% or more	0	0	0

Standard CY 2026 GPCI Update: reflects changes to occupation codes as described in Interim Report, using the same approach as in previous updates

BACH 75 DATA 50: includes occupation codes with ≥75% Bachelors' degrees (or higher) and data available for ≥50% of U.S. counties

BACH 75 DATA 75: includes occupation codes with ≥75% Bachelors' degrees (or higher) and data available for ≥75% of U.S. counties

Based on the two scenarios' changes relative to current CY 2025 work GPCI values that are nearly identical to those under the standard CY 2026 GPCI update, we are seeking comment on the potential to establish clear inclusion criteria for occupation codes for the calculation of the work GPCI in future GPCI updates. We note that a smaller, standardized list of occupation codes that meet rigorous and clearly established thresholds for education attainment and data completeness would aid transparency in the work GPCI and be responsive to the commenters' requests.

Similar to the finalized addition of occupation groups and codes for the CY 2023 GPCI update, the practical effect of limiting the occupation groups and codes on the work GPCI would be minimal because the statute at section 1848(e)(1)(A)(iii) of the Act requires that the work GPCI reflect only one quarter of cost differences, but the limitation could aid transparency and allow for a greater degree of precision when tracking changes in geographic variation in professional wages across GPCI update years.

i. Proposed GPCI Update Summary

As explained in the Background section above, section 1848(e)(1)(C) of the Act mandates the periodic review and adjustment of GPCIs. For each periodic review and adjustment, we publish the proposed GPCIs in the PFS proposed rule to provide an opportunity for public notice and comment and allow us to consider whether any revisions in response to comments are warranted prior to implementation. The proposed CY 2026 updated GPCIs that we propose for the first and second year of the 2-year phase-in, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our website under the supporting documents section of the CY 2026 PFS proposed rule web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

We note that in recent GPCI updates, commenters have stated that there is a lack of transparency into the GPCI data and methodology used to derive the GPCIs. In response to the CY 2023 PFS proposed rule, one commenter stated that they cannot accurately validate CMS' GPCI calculations because there is little transparency and access to the data and methods used. The commenter stated that they submitted a comment on the CY 2022 PFS proposed rule urging CMS to provide more transparency into the GPCI calculations in general, including a more detailed description of the step-by-step methodology and the specific data files used to derive the GPCIs. In addition to making the RVUs by county available, the commenters also suggested CMS to make available the source data for the work GPCI by county, the source data for each component of the practice expense GPCI, and all budget neutrality adjustments and calculations.

The commenters stated that CMS provided these data prior to 2020 and that they used it to reproduce and validate the CMS methodology for calculating the GPCIs each year. In the CY 2023 PFS final rule, in response to these comments, we referred readers to the step-by-step instructions provided in the final report, ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* We also referred readers to Table 4.A.1: Summary of Elements Required for GPCI Calculation in the final report, and the previous discussion, for the data sources used for the work GPCI and each component of the practice expense GPCI. As noted in the proposed and final rules for each GPCI update, we discuss the years and timeframes of data used from each source. We note that we provide web links to the publicly-available data sources used in the GPCI updates, the methodological parameters, as well as an overview of how we develop each GPCI component in the interim and final reports published with

each proposed and final rule containing a GPCI update. This practice is consistent with previous updates. We also note that the budget neutrality adjustment and statutory floors applied after the budget neutrality adjustment are detailed in the note, ''CY 2023 GPCI Update Note_County_Data,'' on our website located under the supporting documents section for the CY 2023 PFS proposed and final rules at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* We also reminded commenters that, in response to the commenters' concerns expressed in rulemaking for the CY 2020 GPCI update, we included more detailed steps in the final report, ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Phys Fee Sched_v19Feb2020'', which is available on the CMS website under the downloads section of the CY 2020 PFS final rule to assist interested parties in navigating these data. Additionally, as part of our ongoing commitment to transparency, we post the county-level data that we use to develop the proposed GPCIs, which allows interested parties to further examine and replicate our GPCI methodology. This file is also available on the CMS website on our website under the Downloads section, titled ''CY 2023 Proposed Rule GPCI County-Level Data File.'' We believe that we sufficiently addressed previous commenters' concerns for the CY 2023 GPCI update in the proposed and final rules and aforementioned CY 2020 and CY 2023 interim and final reports, but we are seeking comment related to any additional information specific to what data was provided prior to 2020 that is no longer provided. Based on a comparison of data and information in the interim and final reports, as well as the data file downloads, we have not identified any information or data that we have discontinued since 2020, as commenters have claimed. We are open to any feedback related to specific information and data that would aid transparency in a GPCI update.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (hereinafter referred to as ''the Infrastructure Act'') amended section 1847A of the Act to add a provision requiring manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as ''refundable drug'') for calendar quarters beginning January 1, 2023.

The calculation of the refund is codified at § 414.940(c). For a new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

- The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;
- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2023 PFS final rule, we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69731). In the CY 2024 PFS final rule (88 FR 79047 through 79064), we finalized an increased applicable percentage for two categories of drugs with unique circumstances, codified at § 414.940(d). These categories include: certain drugs with a low-volume dose (that is, where the volume removed from the vial or container containing the labeled dose does not exceed 0.1 mL or falls between 0.11 mL and 0.4 mL); and orphan drugs furnished to fewer than 100 unique beneficiaries. Drugs with an increased applicable percentage are listed on the CMS website.[88]

b. Application for Increased Applicable Percentage

Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary to increase the applicable percentage for a refundable drug that has unique circumstances through notice and comment rulemaking. In the CY 2024 PFS final rule (88 FR 79057 through 79060), we finalized an application process (CMS–10835, OMB 0938–1435) by which manufacturers could apply for an increased applicable percentage for a drug and may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We explained that manufacturers could benefit from a formal process through which they can provide information, including that which may not be publicly available, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of its unique circumstances.[89] [90] We finalized the application deadline of February 1 of each year, adopted a deadline of August 1 for the FDA-approval of the drug and the deadline for notifying and submitting the FDA-approved label to CMS of September 1 of the year before the year in which the increased applicable percentages would apply. We codified this process in regulation at § 414.940(e). The application process requires the applicant to provide a written request comprising FDA-approved labeling for the drug; justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage. Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage beginning as of the following January 1. The collection of information requests associated with the application process (CMS–10835, OMB 0938–1435) would remain unchanged under this proposed rule.

We received two applications for increased applicable percentage for consideration in the CY 2026 PFS proposed rule. Both applicants submitted the information required under § 414.940(e)(1), including, as applicable, the FDA-approved labeling for the drug, justification for consideration for increased applicable

[88] *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs.*

[89] *https://www.cms.gov/files/document/drugs-increased-applicable-percentage.pdf.*

[90] *https://cms.gov/files/document/orphan-drugs-increased-applicable-percentage-calendar-quarters-2023.pdf.*

percentage, and justification for the requested applicable percentage.

The first application for increased applicable percentage for CY 2026 is from the manufacturer of Leukine® (sargramostim),[91] who has resubmitted a request for a 72 percent applicable percentage after applying in the previous year. Leukine® is a leukocyte growth factor with five FDA-approved indications in hematological malignancies and one indication for post-radiation exposure to increase white blood cell counts. The applicant's submitted FDA-approved labeling for the drug did not include the adjuvant uses described in the application (further described below in this paragraph) due to ongoing cancer vaccine adjuvant trials. The applicant reemphasizes that multiple sponsors are in late-stage development, with a total of 22 Phase II and Phase III clinical trials, an increase from 16 reported in the previous year, investigating Leukine® as a vaccine adjuvant for oncology indications, specifically to stimulate the immune response of dendritic cells when used alongside these vaccines. Cancer treatment vaccines differ from the vaccines that protect against viruses, such as the influenza virus. Instead of preventing disease, cancer treatment vaccines aim to stimulate the immune system to attack existing cancer cells in the body.[92] The applicant states that it has no ownership stake in the development of these cancer treatment vaccines and does not possess control or influence over the design and execution of the clinical trials. The estimated completion dates for Phase III clinical trials vary, with the earliest expected in late 2025 [93] and the latest in March 2029.[94] The adjuvant use of Leukine® in predetermined dosage is distinct from its six FDA-approved indications, all of which have dosages that are based on body weight or body surface area (BSA). The adjuvant use dosages of Leukine® in clinical trials are generally much smaller than dosages for indications in the FDA-approved labeling. The smallest dose of Leukine® used for vaccine adjuvant purposes of which the applicant is aware (that is, 70 mcg) would lead to as much as 72 percent of the drug being discarded from a single-dose 250 mcg lyophilized vial, which is the only size available commercially. The applicant suggests that if use of these small doses were to become more common for an approved indication, the percentage of discarded units could increase the discarded drug refund amount that could be owed by the applicant, even though the applicant lacks control or knowledge of the potential variability of the discarded amounts that may occur if Leukine® were used for such purposes. If another manufacturer were to seek FDA approval for adjuvant use of sargramostim but was not involved in its production, the available single-dose 250-mcg vial presentation of Leukine® would likely not be optimized for the small doses being studied in these trials.

As part of CMS's review of the application, we analyzed existing claims data from the first quarter of 2018 through the last quarter of 2024 and found the percentage of units discarded for the HCPCS code for Leukine® (J2820) ranged from 1.2 percent to 3.8 percent, which is below the applicable percentage of 10 percent. In addition to the low overall discard rate, the percentage of units discarded showed a standard deviation of less than 1 percent across quarters. This is notably lower than the 6.21 percent average standard deviation observed for rarely utilized orphan drugs, as reported in the CY 2024 PFS final rule (88 FR 52393). The low standard deviation indicates minimal quarter-to-quarter variation, with the percentage of units discarded tightly clustered around a 2.2 percent mean. For context, approximately two-thirds of the quarterly percentage values for units discarded fall within one percentage point above or below the mean, highlighting the consistency and stability of the trend over the 7-year period. Therefore, although the applicant suggests otherwise, this data does not follow a statistical distribution similar to that considered for rarely-utilized orphan drugs meeting the criteria in § 414.940(d)(5), which may not have a normal statistical distribution from quarter to quarter, potentially resulting in highly variable refund amounts as compared with the variability of drugs administered to a higher number of beneficiaries. Since we did not yet know the impact of a new adjuvant indication with a type of immunotherapy commonly referred to as cancer vaccines [95] on the current percentage of units discarded, we did not propose an increased applicable percentage in the CY 2025 PFS proposed rule. Additionally, because it was not yet known whether sargramostim would be approved for additional indications and dosages, as indicated in the information provided by the applicant, and the available data did not provide enough information for CMS to determine whether Leukine® had unique circumstances that would prompt an increase in the applicable percentage, we did not propose an increase in the applicable percentage for the drug in the CY 2025 PFS proposed rule. The applicant agreed with CMS' rationale for this decision.

Because we are maintaining our determination from the CY 2025 PFS proposed rule, we are not proposing an increase in the applicable percentage for Leukine® at this time. The applicant may reapply in a future application cycle when more information, such as FDA-approved labeling reflecting new indications or dosages, becomes available.

The second application is from the manufacturer of Jelmyto® (mitomycin for pyelocalyceal solution) [96] who is requesting an additional 10 percent increase to the 35 percent applicable percentage finalized in the CY 2023 PFS final rule (87 FR 69727 through 69731), bringing the total applicable percentage to 45 percent. Jelmyto® is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG–UTUC), a rare cancer with approximately 7,000 new annual cases [97] in the United States. According to the applicant, Jelmyto® dosing ranges from 20 mg to 60 mg per single treatment, with the specific dose determined by kidney volume measurements obtained through pyelography.[9] In the CY 2023 PFS final rule, we stated that Jelmyto®, a drug reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, may leave a substantial amount adhering to the vial wall due to its viscosity, and making it non-extractable. This viscosity results from proprietary reverse-thermal technology (RTGel®), which enables the drug to transition from a chilled liquid at instillation into a gel at body temperature. We determined that a 35 percent applicable percentage was appropriate—accounting for 25 percent lost to adhesion (that is, an 80 mg package with maximum extractable dose of 60 mg results in at least 25 percent being discarded) and an additional 10 percent to align with drugs without unique circumstances for patients requiring less than the maximum dose of 60 mg. We disagreed that an

[91] *https:/www.accessdata.fda.gov/drugsatfda__docs/label/2022/103362s5249lb1.pdf.*

[92] *https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html.*

[93] *https://clinicaltrials.gov/study/NCT04229979.*

[94] *https://clinicaltrials.gov/study/NCT05100641.*

[95] *https://www.cancerresearch.org/treatment-types/cancer-vaccines.*

[96] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211728s010lbl.pdf.*

[97] *https://www.urologyhealth.org/urology-a-z/u/upper-tract-urothelial-carcinoma-(utuc).*

applicable percentage greater than 35 percent should be applied to such hydrogel products, because we believe that 25 percent accounts for the hydrogel that adheres to the vial, and because we have allowed for an additional 10 percent of drug to be discarded before any refund would be owed. This 35 percent applicable percentage was codified at § 414.940(d)(2), with broad support from commenters, for drugs that are both reconstituted with a hydrogel and subject to variable dosing based on patient-specific characteristics.

The applicant contends that the current 35 percent applicable percentage does not account for drug loss due to kidney volume variations and different administration routes, both of which the applicant claims meet the patient-specific characteristics outlined in § 414.940(d)(2). Since kidney volume cannot be determined until the pharmacy has prepared the drug and the patient is ready for administration of the initial treatment, the applicant states that patients with smaller-than-average kidney volumes may lead to a higher amount of drug being discarded. Additionally, the amount of Jelmyto® discarded may increase when providers choose antegrade (via nephrostomy tube) administration over the more common retrograde (via ureteral catheter) administration, as the greater drug delivery efficiency of the antegrade route may result in a lower dose required, leading to more of the drug being discarded. The choice of administration route must be determined on an individual basis, considering multiple factors, including but not limited to the risks and benefits of each route, previous history of failed administration attempts, tolerance to anesthesia, anatomical variations in the urinary tract, patient preference, and the patient's clinical presentation at the time of drug administration.[98] [99] [100] These patient-specific characteristics, combined with the requirement for hydrogel reconstitution, were considered when establishing the current 35 percent applicable percentage.

In the CY 2024 PFS final rule (88 FR 79057), we stated that we do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, BSA-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act. Consistent with that statement, we generally do not consider dose variations due to patient- or condition-specific characteristics to be unique circumstances for the same reason. That is, manufacturers can optimize the availability of products for these circumstances to minimize discarded amounts. Therefore, we do not consider the drug loss due to patient-specific characteristics, such as variation in kidney volume and factors leading to antegrade administration, to be unique circumstances, and we are not proposing an increase in the applicable percentage of 45 percent for the drug. Consistent with the CY 2023 PFS final rule, we propose that the applicable percentage for Jelmyto® continue to be 35 percent.

We welcome comments on these applications for increased applicable percentage.

2. Average Sales Price: Price Concessions and Bona Fide Service Fees (§ 414.804 and 414.802)

a. Background

Drugs payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those furnished via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and other drugs for which coverage is specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment limits for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. If CMS determines a payment limit for a drug, it is published in the ASP pricing file or Not Otherwise Classified (NOC) pricing file, which are both updated quarterly.

The calculation of payment limits for such drugs payable under Part B is done on a quarterly basis using the manufacturer's ASP (as defined in § 414.902), as applicable, using methodology in section 1847A of the Act. Manufacturers are required to report ASP data to CMS under sections 1847A(f)(2) and 1927(b)(3) of the Act and are instructed to calculate the manufacturer's ASP in accordance with section 1847A(c) of the Act and § 414.804(a).

As part of that calculation of the manufacturer's ASP, required under section 1847A(c)(3) of the Act and § 414.804(a)(2), manufacturers must deduct price concessions such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program). Section 1847A(c)(3) of the Act also provides that, ''[f]or years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.'' The Secretary implemented an interim rule adopting those statutory categories of price concessions in 2004 (69 FR 47488). In 2006 the Secretary finalized policies for how the manufacturer's ASP is calculated, which required manufacturers to deduct all price concessions from ASP at § 414.804(a)(2). While price concessions are deducted from the manufacturer's ASP (that is, price concessions will lower the resulting manufacturer's ASP), bona fide service fees (BFSFs) are not considered price concessions and, therefore, are not deducted when calculating the manufacturer's ASP (see § 414.804(a)(2)(ii)). In other words, BFSFs do not lower the manufacturer's ASP because they are not part of the calculation.

In the Calendar Year (CY) 2007 Physician Fee Schedule (PFS) final rule (71 FR 69665 through 69678) Medicare finalized a definition of BFSF for the purposes of calculating the manufacturer's ASP at § 414.802. The definition finalized in that final rule states that the term ''BFSFs'' means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. In the CY 2007 PFS final rule, we stated that the BFSF definition provides an appropriate safeguard against the potential risk for inappropriately

[98] *https://bjui-journals.onlinelibrary.wiley.com/doi/full/10.1111/bju.15925.*

[99] *https://www.sciencedirect.com/science/article/pii/S2405456923001232.*

[100] *https://www.jelmyto.com/hcp/pdf/jelmyto-antegrade-instillation-overview.pdf.*

inflated ASPs. We stated that if a manufacturer has determined that a fee paid meets the other elements of the definition of ''bona fide service fee,'' then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity. Further, we stated (71 FR 69669) that in the absence of specific guidance in the Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices. We stated that these assumptions may be submitted along with the ASP data.

Accurate assessment and reporting of price concessions and BFSFs are essential to correctly calculating the manufacturer's ASP. Improperly classifying price concessions as BFSFs would artificially increase the manufacturer's ASP resulting in Medicare overpayments and higher coinsurance amounts paid by beneficiaries.

In December of 2022, the Office of Inspector General (OIG) published a report entitled ''Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices'' (hereinafter referred to as the December 2022 OIG report).[101] That report recommended CMS actively review current guidance related to areas identified in the report and determine whether additional guidance would ensure more accurate and consistent ASP calculations. One area identified was how bundled sales price concessions should be incorporated into the manufacturer's ASP calculation. Manufacturers noted they would like additional guidance regarding whether unbundling a bundled arrangement should include just the discounts contingent on purchase or performance or all discounts that are part of the arrangement, how to treat bundled sales that include covered and noncovered products, and how manufacturers should identify and reallocate discounts with sales that may be considered bundled across time periods.

This report also recommended CMS give particular consideration to guidance regarding BFSFs. Manufacturers surveyed in the report expressed that there could be inconsistencies and differences in how manufacturers interpret the BFSF definition. For example, manufacturers noted that CMS has not defined the term fair market value (FMV) for the purposes of the BFSF. The report states that CMS should provide additional guidance on the methodology that manufacturers should use to assess FMV and clarify a timeframe after which manufacturers should reassess the FMV of BFSFs.

In addition to the recommendations from the December 2022 OIG report, we have concern that certain costs could be classified as BFSFs when they should instead be classified as a price concession in some instances. Further, we are concerned that certain costs that are classified as BFSFs may not represent the FMV for the service. Lastly, the current policy that manufacturers may presume none of the fees are passed on in whole or in part may allow for certain costs to be misclassified when reasonable inquiry would demonstrate that fees are indeed passed on. Such occurrences would likely impact the accuracy of ASP data that is reported to CMS each quarter.

For these reasons, in this proposed rule, we are proposing policies to provide additional guidance on two aspects of the calculation of manufacturer's ASP. First, we are proposing regulatory text to specify when certain fees are considered price concessions and on how manufacturers should allocate pricing for drugs sold under a bundled arrangement. Second, we are proposing to revise the definition of BFSFs by (1) specifying the methodology that should be used to determine FMV and the time period after which manufacturers should reassess the FMV; and (2) further explaining what CMS considers to be sufficient evidence of whether or not a fee is passed on in whole or in part to an affiliate,[102] client, or customer of an entity. We are also proposing that in the absence of specific guidance, manufacturers be required to submit any reasonable assumptions they utilize for manufacturer's ASP calculations (which is currently voluntary), including documentation of the methodology used to determine fair market value and periodic reviews of fair market value. We propose that manufacturers must also submit a warranty or certification from the recipient of the fee that it is not passed on in whole or in part to an affiliate, client, or customer of an entity. Finally, in this proposed rule, we will provide certain non-exhaustive examples of fees that CMS considers to be price concessions and not BFSFs.

The goal of these proposed policies is to avoid inaccurate calculation of the manufacturer's ASP that is used to determine Part B drug payment limits. These proposed policies also will clarify how certain costs should be considered under newer pharmaceutical business practices that may not have been considered when Medicare last finalized the definition of BFSFs in 2007.

b. Price Concessions

As discussed in the background section, the statute requires that the manufacturer's ASP include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program).

Manufacturers can offer certain price concessions as part of bundled arrangements in which price concessions are treated as discounts that are tied to the purchase of the same drug or item or multiple drugs or items. They can also be discounts contingent on certain performance requirements, such as achievement of market share. In addition, price concessions as part of a bundled arrangement may include only Part B drugs or may include both Part B drugs and other products or services. These price concessions within bundled arrangements are accounted for in the calculation of the manufacturer's ASP.

We discussed bundled price concessions and considered how manufacturers could apportion such discounts to calculate the manufacturer's ASP in the CY 2007 PFS final rule (71 FR 69673 through 69676). We stated that given the potentially wide range of bundling arrangements that might exist, based on the information we had about such arrangements, we could not determine at that time whether there is a universal approach for treating bundled price concessions in the manufacturer's ASP calculation that would address all potential structures of bundling arrangements in a manner that would achieve our goal of ensuring the accuracy of the ASP payment methodology and preventing inappropriate financial incentives. Then, in the Medicare Payment Advisory Commission's (MedPAC) January 2007 Report to Congress, ''Impact of Changes in Medicare

[101] Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Price, Office of Inspector General, U.S. Department of Health and Human Services. December 2022. *https://oig.hhs.gov/documents/evaluation/3215/OEI-BL-21-00330-Complete%20Report.pdf*.

[102] Affiliate meaning the affiliate of an entity that is receiving the fee that is providing the service.

Payments for Part B Drugs,'' [103] they discussed the issue of allocation of bundled price concessions for purposes of calculating the manufacturer's ASP, noting that ''some manufacturers offer provider discounts for one of their products contingent on purchases of one or more other products.'' In light of MedPAC's recommendation that CMS address the ASP reporting requirements for bundled products and our discussion of bundled price concessions in the CY 2007 PFS rulemaking, we stated in the CY 2008 PFS proposed rule (72 FR 38150 through 38151) that we believe specific guidance in the ASP context is warranted to ensure consistency in ASP reporting across manufacturers and to enhance the accuracy of the ASP payment system. We stated at that time that we found MedPAC's suggestion not to defer further guidance in this area compelling with respect to the potential that manufacturers may make differing assumptions in the absence of specific guidance on how to allocate bundled price concessions in the context of ASP. However, in the CY 2008 PFS final rule (72 FR 66256 through 66258), based on comments recommending a delay and to better understand the concerns stated by the commenters, we did not finalize the regulatory language changes we proposed in the CY 2008 PFS proposed rule at that time. However, we explained that in the absence of specific guidance, manufacturers may make reasonable assumptions in their calculation of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and their customary business practices.

In the 2007 Prescription Drugs final rule (72 FR 39144 through 39145), Medicaid finalized a definition of the term ''bundled sale'' for the purpose of calculating the average manufacturer price (AMP) and best price, which is codified at § 447.502. The definition was revised in the CY 2016 Covered Outpatient Drugs final rule (81 FR 5181 through 5183) and the 2020 Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements final rule (85 FR 87022 through 87024). The current definition states that a bundled sale means any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. The definition further states: (1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement; (2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle; and (3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale.

We are aware that many manufacturers currently utilize portions of the Medicaid definition of bundled sales to identify any bundled arrangements for the purposes of their ASP calculations. In addition, we noted in the CY 2008 PFS final rule (72 FR 66257 through 66258), that most commenters supported an appropriately consistent approach for the treatment of bundled price concessions with both AMP and ASP calculations. We also stated our intention at that time to remain consistent, as appropriate, with the final policy adopted in the 2007 Prescription Drugs final rule (72 FR 39144 through 39145).

As discussed in the background section, the December 2022 OIG report recommended that CMS consider providing additional guidance with regard to how bundled sales price concessions should be incorporated into the manufacturer's ASP calculation. The report stated specifically that one manufacturer requested additional guidance pertaining to bundled sales discounts for the following:

- Whether unbundling a bundled arrangement should include just the discounts contingent on purchase or performance requirements or all discounts that may be part of the underlying arrangement.
- How to treat bundled sales that include both covered products and noncovered products (that is, products for which there is no government price reporting obligation).
- How manufacturers should identify and reallocate discounts associated with sales that may be considered bundled across time periods. The manufacturer stated that CMS guidance on these types of temporal bundling will be critical because they will play an important role in the implementation and evaluation of value- and outcomes-based arrangements, which may require assessing the efficacy of a drug over multiple reporting periods.

Therefore, in this proposed rule, we propose to add a definition of the term bundled arrangement to § 414.802, similar to that which was proposed in the CY 2008 PFS proposed rule. Specifically, we are proposing the definition to state ''Bundled Arrangement means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs or biologicals been purchased separately or outside the bundled arrangement.'' We also propose adding subparagraphs (iii) and (iv) at § 414.804(a)(2) to provide manufacturers with additional guidance on how to allocate discounts under bundled arrangements, which aligns with Medicaid's definition of bundled sale further described later in this section. This proposal aligns with our previously stated intent to remain consistent, as appropriate, with Medicaid's policy for calculating AMP and aligns with supportive comments discussed in the CY 2007 and 2008 PFS final rule discussions on this topic.

Second, to address the suggestion that the agency determine whether additional guidance would be appropriate for the areas described in the December 2022 OIG report for how to account for unbundling a bundled arrangement, we note that Medicaid's definition of ''bundled sale'' at § 447.502 directs that discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. In other words, as noted in 81 FR 5181 through 5183, the ''unbundling'' of both contingent and non-contingent discounts is appropriate because ''all

[103] Impact of Changes in Medicare Payments for Part B Drugs, Medicare Payment Advisory Commission. January 2007. *https://www.govinfo.gov/content/pkg/GOVPUB-Y3_M46_3-PURL-LPS78409/pdf/GOVPUB-Y3_M46_3-PURL-LPS78409.pdf.*

the discounts'' in the bundled arrangement should be proportionally allocated. We propose to adopt this approach for the calculation of the manufacturer's ASP because of our stated intent for consistency with policies for AMP. Consistent application of this policy by all manufacturers reduces the opportunity for improper manipulation of the ASP calculation, providing greater certainty to CMS of the integrity of the submitted ASP. We are, therefore, proposing the same regulatory language be added to § 414.804(a)(2) under paragraphs (iii) and (iv).

Third, to address the suggestion that the agency determine whether additional guidance would be appropriate for the areas described in the December 2022 OIG report for how to allocate discounts for bundled sales, we propose that for bundled sales containing both Medicare Part B-covered and non-covered products, manufacturers allocate discounts proportionally as described in the previous paragraph. However, we have heard from interested parties that this method may not be sufficient to cover all cases and could potentially result in inaccurate ASPs. Bundled arrangements may vary depending upon the number and type of products included in a bundling arrangement, whether the price concessions are contingent on the purchase of only one product, the purchase of multiple products, or the inclusion of one or more products on a formulary, and the timing of the price concessions. For example, a different allocation method may be needed to account for variable costs per product in the bundled arrangement. We solicit comment on if there are other methods of allocating discounts in these circumstances that would more accurately represent ASP.

Finally, to address the suggestion that the agency determine whether additional guidance would be appropriate for the areas described in the December 2022 OIG report as it relates to how to reallocate discounts associated with sales that may be considered bundled across time periods (for example, outcomes-based arrangements or value-based purchasing arrangements), we are *not* proposing to adopt the portion of the Medicaid definition of bundled sale stating that value-based purchasing arrangements may qualify as a bundled sale because we are continuing to evaluate how value-based purchasing arrangements should be considered for drugs payable under Medicare Part B. We solicit comments on how discounts associated with sales that may be considered bundled across time periods could be accounted for in the manufacturer's ASP calculation.

We solicit comments on this proposal.

c. Bona Fide Service Fees

As described in the background section above, currently, the term ''BFSFs'' means fees paid by a manufacturer to an entity, that (1) represent FMV (2) for a bona fide, itemized service actually performed on behalf of the manufacturer (3) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (4) that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.[104] A fee must meet all four conditions of the definition to be considered a BFSF rather than a price concession to be deducted from ASP. We are proposing two changes to the BFSFs regarding (1) what is considered FMV and (2) proposing what evidence is required to be provided by a manufacturer to show that a fee is not passed on in whole or in part to an affiliate, client, or customer of an entity, whether or not the entity takes title to the drug. In addition, we are proposing an addition to the list of price concessions to include when certain fees paid by a manufacturer are presumed to be price concessions.

(1) Fair Market Value

One element of the definition of BFSFs specifies that the fees must represent FMV for the service. To date, we have not issued guidance on a specific method that manufacturers must use to determine whether a fee represents FMV. In the CY 2007 PFS final rule (71 FR 69666 through 69670), we stated that the appropriate method or methods for determining whether a fee represents FMV may depend upon the specifics of the contracting terms, such as the activities the entity will perform and the agreed-upon mechanism for establishing the payment (for example, percentage of goods purchased). We stated in that final rule that we believe manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining FMV of drug distribution services for which they contract. Therefore, we did not mandate the specific method manufacturers must use to determine whether a fee represents FMV for purposes of excluding BFSFs from the calculation of ASP.

As discussed in the background section above, the December 2022 OIG report identified BFSFs as an area where CMS could provide additional guidance to manufacturers and further stated that manufacturers expressed that competitors may be taking disparate approaches when applying CMS's four-part test to make these determinations. In some cases, BFSFs that are very high could mask price concessions that are passed on by the entity performing the bona fide service so that the product's ASP can remain high. Conversely, certain fees that are BFSFs could be incorrectly classified as a price concession to reduce the manufacturer's ASP and mask price increases that could be faster than the rate of inflation for purposes of the Medicare Prescription Drug Inflation Rebate Program. Consequently, we recommend additional guardrails to ensure that BFSFs are correctly identified, and that the manufacturer's ASP is not manipulated to be artificially increased or decreased.

Accordingly, in this proposed rule, we are (1) proposing revisions to the definition of BFSFs at § 414.802 that retains the existing four prong test (as described in the background section) and adds proposed requirements for the standards and the methodology that should be used to determine the FMV for such fees; (2) the time period after which manufacturers should reassess the FMV; and (3) any FMV analysis of fees that vary directly with the amount of drug sold or price of a manufacturer's drug must be conducted by an independent third party that does not have a conflict of interest.

Based on the structure or arrangement of certain fees that meet the definition of BFSF, we propose additional requirements for the standards and methodology that should be used to determine FMV. Specifically, we propose that for fees paid by a manufacturer to an entity that do not vary directly with the amount of drug sold or price of a manufacturer's drug, that the FME must be determined either based on comparable market transactions that generally reflect current market conditions or the cost of the service plus a reasonable markup to the total cost.

We propose that, for fees paid by a manufacturer to an entity that vary directly with the amount of drug sold or price of a manufacturer's drug, the FMV must be determined by using the cost of the service and adding a reasonable markup to the total cost. If any material portion of cost data is not available, manufacturers should follow a market-based approach based on verifiable market data until such time as sufficient cost data becomes available. In addition,

[104] 42 CFR 414.802.

we propose that under such circumstances that the FMV assessment must be conducted by an independent third-party valuator. This means that the valuator must not have any financial relationship (other than the arrangement to conduct FMV analyses) with either party to the arrangement and no stake in the outcome of the valuation. The FMV analysis must be documented with a clear explanation, including a description of the methodology used.

Regarding FMV assessments, we propose manufacturers conduct periodic updates of any FMV analyses for service arrangements that are ongoing, at a frequency no less than the renewal frequency of the agreement (that is, annually for annual renewals). Documentation of this update should be included in the reasonable assumption documentation that corresponds with the quarter when the update is conducted. Implementing standards and defining the methodology manufacturers must use to determine FMV will better establish uniform industry practices and provide the desired clarity requested by manufacturers in the December 2022 OIG report.

We solicit comments on this proposal.

(2) Fees Presumed To Be Price Concessions

We are proposing revisions to § 414.804(a)(2) to specify when certain fees should be presumed to be price concessions. Specifically, we propose that if fees paid by a manufacturer to an entity vary directly with the amount or price of a manufacturer's drugs (that is, the fees paid are (i) percentage-based fees or (ii) flat fees or fixed fees that are designed in such a way as to approximate percentage-based fees), such fees are presumed to be price concessions to be deducted from the calculation of the manufacturer's ASP unless such manufacturer determines such fees to be FMV using a cost-based approach which may be further validated with market-based data.

(3) Evidence

Another element of the BFSF definition specifies that the BFSF must not be passed on, in whole or in part, to a client or customer of an entity. When finalizing the CY 2007 PFS final rule (71 FR 69669 through 69670), we stated that there may be significant barriers that limit a manufacturer's ability to determine whether a fee that otherwise meets the definition of BFSF is passed on, in whole or in part, to a client or customer of any entity. We noted in the preamble section of that rule that we believe that it is essential to retain the ''not passed on'' element in the definition of BFSFs given that the ''not passed on'' element is a key factor in distinguishing a price concession from a BFSF because, if a fee that is passed on is excluded from the ASP calculation, then there is a greater risk of the ASP being inappropriately inflated. We stated that if a manufacturer has determined that a fee paid meets the other elements of the definition of ''bona fide service fees,'' then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.

There may be certain fees that a manufacturer classifies as BFSFs for the purposes of calculating the manufacturer's ASP that should actually be considered price concessions and, therefore, deducted from the manufacturer's ASP. In the December 2022 OIG report, manufacturers reported inconsistent practices in the treatment of BFSFs. As such, we propose that it is no longer appropriate that a manufacturer may presume, in absence of any evidence or notice to the contrary, that a fee paid is not passed on to an affiliate, client, or customer of any entity. This proposed revision to the definition specifies that, in addition to a client or customer of any entity, that the fee also shall not be passed on to an affiliate, which means an affiliate of an entity that is receiving the fee the tis providing the service. We propose the addition of the word affiliate to more comprehensively address the type of arrangements that may exist between certain entities.

In addition, we propose that the manufacturer be responsible for obtaining a certification or warranty from the entity receiving the fee stating that such fee will not be passed on to an affiliate, client, or customer of any entity. We are proposing to add new subparagraph § 414.804(a)(5)(iii) requiring manufacturers to provide certification letters from any recipient of a BFSF that the fee is not passed on in whole or in part to an affiliate, client or customer of an entity, whether or not the entity takes title to the drug.

We also propose to revise § 414.804(a)(5) to add additional data submission requirements. This paragraph currently states that the manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter. We are proposing to add a header to this section titled ''Submission Requirements'' and remove ''The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.'' We are also proposing to add three paragraphs (i, ii, and iii). The proposed text would be revised to state that manufacturers must submit the following to CMS within 30 days of the close of the quarter:

- The manufacturer's average sales price, which must be calculated by the manufacturer every calendar quarter. The first quarter submission must be submitted by April 30, 2004.
- Effective January 1, 2026, reasonable assumptions for calculation of the manufacturer's ASP including the fair market value analysis for bona fide service fees, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices, including documentation of the methodology used to determine fair market value and periodic reviews of fair market value.
- Effective January 1, 2026, certification letter from the recipient of a bona fide service fee (as defined under § 414.802) as evidence that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity, whether or not the entity takes title to the drug.

These data submission requirements, if finalized, would be effective for sales occurring January 1, 2026, and after and that data would be due to CMS by April 30, 2026, and used in the July 2026 pricing file. The newly proposed certification letter should be submitted in the current portal and uploaded under reasonable assumptions. Lastly, manufacturers must maintain and submit to CMS a copy of the FMV analysis, confirming it was conducted in a timely manner, documentation (such as a certification letter from the recipient of the fee) that the fee is not passed on in whole or in part to an affiliate, client or customer of an entity, whether or not the entity takes title to the drug, and documentation (such as a mutual representation in the relevant services agreement) that both parties have agreed to represent the payment as a BFSF in a consistent manner to all third parties, including any affiliates, clients, and governmental agencies.

We solicit comment on this proposal.

(3) Further Guidance on the BFSF Definition

In the CY 2007 PFS final rule (71 FR 69667 through 69668), we discussed the option of providing a list of bona fide

services. However, many commenters at that time were opposed to establishing a list of bona fide services because it would require ongoing refinement for manufacturers to accurately calculate ASP. In that final rule, we did not establish a list of bona fide services because we wanted to avoid inadvertently limiting the scope of what could constitute a bona fide service. We continue to believe that constructing an exhaustive list could be prohibitive over time. However, in this proposed rule, we are proposing some specific, non-exhaustive examples of fees and how they should be considered in the calculation of manufacturer's ASP.

First, we note that certain payments by drug manufacturers to drug distributors, which lower the price that distributors and purchasing physicians pay, appear to be price concessions. In 2024, the Department of Justice filed a complaint against a manufacturer alleging the company engaged in fraudulent drug price reporting practices by classifying payments to distributors to cover credit card processing fees as BFSFs instead of price concessions.[105] The manufacturers' payment allegedly enabled the purchasers of the product to use credit cards to purchase drugs from the distributor without incurring an additional fee that would otherwise be charged, while also taking advantage of the benefits of using credit cards, such as ''cash back'' and other credit card rewards. This type of arrangement would lower the price of the drug to both the distributor and the distributors' customers and the manufacturers' payments should be classified as price concessions, which are deducted from ASP, not BFSFs.

Second, as discussed in our Autologous Cell-based Immunotherapy and Gene Therapy Payment proposal, we also propose that any payment by the manufacturer to an entity for tissue procurement is not considered a BFSF for the purposes of calculating the manufacturer's ASP since this is an integral part of the manufacturing process for autologous cell-based immunotherapy or gene therapy and should be included in the price of the product.

Third, certain fees for data sharing services about the product appear to exceed the FMV for the service or are not for bona fide services because the data is required for legal compliance and audit purposes under the services agreement (such as complete and timely data to validate that a rebate or discount has been earned or is not duplicative prior to its payment by the manufacturer). If a manufacturer pays an entity for providing data back to the manufacturer about the product being sold, that fee should be assessed for FMV as discussed previously in this section and we propose a certification or warranty from the entity providing the service that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity. As proposed previously in this section, we propose that such certification or warranty should be submitted by the manufacturer to CMS as part of the quarterly ASP data submission.

Lastly, certain fees paid for distribution services appear to exceed the FMV for the service. Similar to data sharing services, if a manufacturer pays an entity for distributing their product, the fee should be assessed for FMV, and we propose a certification or warranty should be provided by the entity providing the service that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity. As proposed previously in this section, we propose that such certification or warranty should be submitted by the manufacturer to CMS as part of the quarterly ASP data submission.

We solicit comment on these proposals.

d. Summary

In summary, we are proposing to add a definition of bundled arrangement at § 414.802 and to update § 414.804(a)(2) to provide guidance to manufacturers regarding pricing of bundled price concessions. We are also proposing new regulatory text at § 414.804(a)(2)(i) to specify when certain fees are considered price concessions. We propose revisions to the definition of BFSFs at § 414.802 to specify: (1) standards and the methodology that should be used to determine FMV for such fees; (2) the time period after which manufacturers should reassess the FMV; and (3) that any FMV analysis regarding BFSFs that vary directly with the amount of drug sold or price of a manufacturer's drug must be conducted by an independent third party that does not have a conflict of interest. Further, we propose revising § 414.804(a)(5) to update requirements for ASP data submissions as they relate to reasonable assumptions and evidence that BFSFs are not passed on. Finally, we are proposing a non-exhaustive list of certain fees that we either do not consider BFSFs or may not be in line with FMV.

3. Average Sales Price: Units Sold at Maximum Fair Price

The Act establishes the Medicare Drug Price Negotiation Program (the ''Negotiation Program'') to negotiate a maximum fair price (MFP)[106] for certain high expenditure, single source drugs payable under Medicare Part B and covered under Part D (each, a ''selected drug''). For the initial price applicability year 2026, CMS reached agreement on a negotiated price for all 10 selected drugs covered under Part D. Then, for initial price applicability year 2027, CMS selected an additional 15 drugs covered under Part D. For the third year of the Negotiation Program, initial price applicability year 2028, CMS will select for negotiation up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D.

Beginning in initial price applicability year 2028, for selected drugs payable under Part B, section 1847A(b)(1)(B) of the Act sets the Medicare Part B payment limit during the price applicability period as 106 percent of MFP. Payment limits are published on the ASP drug pricing file, which is updated quarterly. For selected drugs with a negotiated price for initial price applicability year 2026 and 2027 that have utilization under Medicare Part B, we clarify that the Part B payment limit will not be based on the MFP unless it is selected for renegotiation, pursuant to section 1194(f)(3) of the Act and as discussed in section 130.2 of the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of sections 1191 through 1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028; [107] and there is an agreed-upon renegotiated MFP.

Manufacturers of drugs payable under Part B are required to report the manufacturer's ASP to CMS each quarter as described in sections 1927(b)(3) and 1847A(f) of the Act, even when a drug is a selected drug with an MFP, including a renegotiated MFP. The statute directs that the manufacturer's ASP include sales to all purchasers in the United States (section 1847A(c)(1) of the Act) with two exempted categories of sales: (1) sales exempt from best price under section 1927(c)(1)(C)(i) of the Act; and (2) sales that are merely nominal in

[105] United States Files Complaint Against Regeneron Pharmaceuticals Alleging Fraudulent Drug Price Reporting, District of Massachusetts, United States Attorney's Office. April 2024. *https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-regeneron-pharmaceuticals-alleging-fraudulent-drug.*

[106] Defined at section 1191(c)(3) of the Act.

[107] See: *https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.*

amount as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, as limited by section 1927(c)(1)(D) of the Act. Units of drugs sold at MFP do not fall in either of those categories. In addition, units sold at MFP are expressly included in the determination of best price, as stated in section 1927(c)(1)(C)(ii)(V) of the Act. Therefore, since the statutory language does not expressly or implicitly exempt units of Medicare Part B or Part D MFP sales from the calculation of the manufacturer's ASP, we clarify in this proposed rule that units of selected drugs sold at MFP are included in the calculation of the manufacturer's ASP described in section 1847A(c) of the Act effective January 1, 2026.

The file used for publishing payment limits for drugs covered under Part B is usually referred to as the ''ASP drug pricing file'' likely because most drugs listed on the file have a payment limit based on the ASP (usually 106 percent of ASP). However, the file also contains the payment limits based on other pricing metrics. For example, several provisions in section 1847A of the Act require that the payment limit be based on a pricing metric other than ASP under specific circumstances, including the following:

- When the Wholesale acquisition cost (WAC) is less than ASP for a single source drug or biological (section 1847A(b)(4) of the Act);
- When ASP exceeds the widely available market price (WAMP) or average manufacturer price (AMP) (section 1847A(d) of the Act); and
- For a selected drug, 106 percent of MFP (section 1847A(b)(1) of the Act).

In such circumstances, only the actual payment limit is published on the pricing file (and no ASP information is displayed).

4. Autologous Cell-Based Immunotherapy and Gene Therapy Payment

a. Background

Medicare Part B covers many cellular immunotherapies and gene therapies that are FDA-approved under a biologics license application (BLA) as incident to drugs and biologicals under section 1861(s)(2) of the Act, which are paid under section 1847A of the Act (typically, at ASP plus 6 percent). Cell-based autologous therapies are a particular subset, which require cells to be collected from the patient, altered to create the intended therapy, and then administered to the same patient for treatment of a condition. These steps generally include cell collection from the patient via apheresis (including leukapheresis), surgical removal, biopsies or other means, the cells are immediately transported at very low temperatures to a manufacturing site for genetic engineering and/or other steps (for example, activation, cell expansion, and/or quality testing). After the manufacturing steps are complete, the final product is transported back to the healthcare provider or treatment facility to be administered to the patient.

For example, for Chimeric Antigen Receptor (CAR) T-cell therapy, T-cells are collected from the patient via leukapheresis and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the same patient to attack certain cancerous cells. For other autologous cell-based therapy, the preparatory and manufacturing steps follow a similar general process.

Many studies show that the manufacturing steps for these therapies have a very high cost of goods sold (COGS), including very high proportion of labor costs in manufacturing, which ultimately leads to a high final cost of the therapy.[108] [109] Some also note that the acquisition of raw materials, including tissue procurement, and quality-related activities are other top contributors to the COGS for autologous cell-based therapies. As technologies advance, there has been continued research to scale cell-based therapies, including a possible shift to allogeneic cell therapy, in which cell collection would be from healthy donors or stem cells. Manufacturing allogenic cell-based therapy would allow the therapy to be ready ahead of time instead of the multiple-week wait time between cell collection and administration of the treatment for allogeneic therapies.[110] [111] [112] Throughout research and discussions of cell-based therapies, tissue procurement is a key consideration in the discussion of the COGS. This further distinguishes all types of tissue procurement, whether it be for allogenic or autologous therapies, are part of the COGS and part of the manufacturing process for the products.

As technologies for autologous cell-based immunotherapies and gene therapies continue to advance, we aim for payment policies amongst these therapies to be consistent. Therefore, in this proposed rule, we are proposing policies for how Medicare pays for the manufacturing steps across all types of autologous cell-based immunotherapies and gene therapies and proposing how these steps should be considered by manufacturers when submitting ASP data to CMS.

b. Payment

Medicare payment for the manufacturing steps to CAR T-cell therapies have previously been discussed in rulemaking, specifically in the CY 2019, 2020, and 2021 Medicare hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rules and the CY 2025 Physician Fee Schedule (PFS) final rule. In the 2019 OPPS/ASC final rule (83 FR 58904 through 58908), we finalized policies for payment of four Level III CPT codes (0537T through 0540T). We finalized that CPT codes describing (1) harvesting of blood-derived T lymphocytes, (2) preparation of T lymphocytes for transportation, cryopreservation, and storage, and (3) preparation of the CAR T-cell therapy for administration are not payable under OPPS. We stated that these codes describe various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. We noted that the billing and payment codes for the CAR T-cell therapies include leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals. In that final rule, we also finalized to pay separately for the Level III CPT code describing the administration service for CAR T-cell therapy. This policy was reiterated in the CY 2020 and 2021 OPPS/ASC final rules (84 FR 61231 through 61234 and 85 FR 85949 through 85951, respectively).

[108] Yonatan Y. Lipsitz, William D. Milligan, Ian Fitzpatrick, et al, A roadmap for cost-of-goods planning to guide economic production of cell therapy products, Cytotherapy,Volume 19, Issue 12, 2017, Pages 1383–1391.

[109] Brian Canter, Sabine Sussman, Stephen Colvill, Nitzan Arad, Elizabeth Staton, Arti Rai, Introducing biosimilar competition for cell and gene therapy products, *Journal of Law and the Biosciences,* Volume 11, Issue 2, July–December 2024, lsae015, *https://doi.org/10.1093/jlb/lsae015.*

[110] Caldwell KJ, Gottschalk S, Talleur AC. Allogeneic CAR Cell Therapy-More Than a Pipe Dream. Front Immunol. 2021 Jan 8;11:618427. doi: 10.3389/fimmu.2020.618427. PMID: 33488631; PMCID: PMC7821739.

[111] Abbasalizadeh, S., Pakzad, M., Cabral, J.M.S., & Baharvand, H. (2017). Allogeneic cell therapy manufacturing: process development technologies and facility design options. *Expert Opinion on Biological Therapy,* 17(10), 1201–1219. *https://doi.org/10.1080/14712598.2017.1354982.*

[112] Pigeau GM, Csaszar E, Dulgar-Tulloch A. Commercial Scale Manufacturing of Allogeneic Cell Therapy. Front Med (Lausanne). 2018 Aug 22;5:233. doi: 10.3389/fmed.2018.00233. PMID: 30186836; PMCID: PMC6113399.

In September 2023, the CPT Editorial Panel deleted four Level III codes (0537T through 0540T) and created four new Level I codes (38225 through 38228) that describe only the steps of the complex CAR–T Therapy process performed and supervised by physicians: CPT code 38225 *(Chimeric antigen receptor T-cell (CAR–T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR–T cells, per day);* 38226 (*Chimeric antigen receptor T-cell (CAR–T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)*); 38227 (*Chimeric antigen receptor T-cell (CAR–T) therapy; receipt and preparation of CAR–T cells for administration*); 38228 (*Chimeric antigen receptor T-cell (CAR–T) therapy; CAR–T cell administration, autologous*). In the CY 2025 PFS final rule (89 FR 97779 through 97780), we finalized the policy to continue to bundle payment under the PFS for CAR–T services described under CPT codes 38225, 38226, and 38227. We stated that bundling payment is appropriate for these codes to align with OPPS policies to not pay separately for each step used to manufacture a drug or biological. In that final rule we also finalized to pay separately for CPT code 38228 (the service of CAR T-cell therapy administration), which aligns with OPPS policy.

To date, payment for procedures that are required for manufacturing other autologous cell-based immunotherapies and gene therapies (that are not CAR T-cell therapies) have not been explicitly addressed. As discussed in the background section above, the tissue procurement step for all autologous cell-based therapies is a pivotal part of the manufacturing process and a key component of the overall cost of the product, that is, COGS. In addition, if certain therapies could be scaled in a way that they could be allogenic in nature, we see that the tissue procurement step would even more clearly be considered a manufacturing step.

Therefore, in this proposed rule, we propose that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself. This proposal continues the current payment policies for CAR T-cell therapies as discussed earlier in this section and extends the same payment policy to other autologous cell-based therapies. In our evaluation of each therapy, there are similar sequences of steps as we described in the background section. Consistent with previous rulemaking, we propose that Medicare not pay separately for each step used to manufacture an autologous cell-based immunotherapy or gene therapy. In other words, Medicare does not pay separately for the collection of raw materials or labor associated with the collection of raw materials for a drug or biological that are essentially part of the COGS. Payment for the raw materials and any labor associated with collection of the raw materials is included in the payment of the drug or biological itself, using the billing and payment code for the product.

We solicit comments on the proposal to continue this policy for CAR T-cell therapies and extension of the policy to other autologous cell-based immunotherapy or gene therapies.

c. Average Sales Price

Payment limit calculations for drugs payable under Part B are done on a quarterly basis using the manufacturer's ASP (as defined in § 414.902) using methodology in section 1847A of the Act. Manufacturers are required to report ASP data to CMS under sections 1847A(f)(2) and 1927(b)(3) of the Act. Manufacturers are instructed to calculate the manufacturer's ASP in accordance with section 1847A(c) of the Act and § 414.804(a). To date, we have not addressed how manufacturers of autologous cell-based immunotherapy or gene therapy should account for the procedures for the collection of cells used to manufacture the product into the calculation of the manufacturer's ASP.

As discussed in section III.A.3.a. of this proposed rule, the COGS and manufacturing process for an autologous cell-based immunotherapy or gene therapy include tissue procurement (that is, the collection of cells from the patient). Consistent with the proposal in the previous section that preparatory procedures required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself, we also propose that, beginning January 1, 2026 (that is, data reflecting sales beginning on that date), any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that are paid by the manufacturer be included in the calculation of the manufacturer's ASP. We also propose that any payment by the manufacturer to an entity for tissue procurement is not considered a bona fide service fee for the purposes of calculating the manufacturer's ASP since this is an integral part of the manufacturing process for autologous cell-based immunotherapy or gene therapy and should be included in the price of the product.

We solicit comment on this proposal.

d. Summary

In summary, we propose that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself and that, beginning January 1, 2026, any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that were paid for by the manufacturer be included in the calculation of the manufacturer's ASP.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background on RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405 subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse that is furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically

necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount per visit. As of April 1, 2021, all RHCs are subject to statutory upper payment limits determined in accordance with section 1833(f) of the Act, as amended by section 130 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148)), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were initially designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. These nearly all-inclusive rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket reduced by a productivity adjustment. For CY 2025, we rebased and revised the 2017-based FQHC market basket to reflect a 2022 base year (89 FR 98023 through 98032).

2. Payment for Care Coordination Services

a. Background

In the last several years of rulemaking, we have expanded the scope of care coordination services (formerly referred to as care management services) that are billable using HCPCS code G0511. More recently, in the CY 2025 PFS final rule, we unbundled the individual HCPCS codes that make up G0511 (89 FR 97999 through 98000). We have also been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result, established codes and separate payment to independently recognize and pay for these important services. As stated in the CY 2016 PFS Final Rule (80 FR 71080 through 71088), the care coordination included in services, such as office visits, does not always adequately describe the non-face-to-face care management work involved in primary care and similar care relationships. We noted that payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

Over the last decade, we have updated RHC and FQHC payment policies as appropriate, and we remain committed to improving how Medicare payment recognizes the resources involved in furnishing covered services that encompass aspects of advanced primary care furnished by interprofessional care teams and typically concentrating on the delivery of appropriate preventive care to patients and the management of individuals' chronic conditions as they progress over time. As a result, we reaffirmed our support of primary care and recognized care management as one of the critical components of primary care by implementing significant changes aimed at better capturing the resources required for care management services, including chronic care management (CCM), principal care management (PCM), general behavior health integration (BHI), chronic pain management (CPM), transitional care management (TCM), remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), community health integration (CHI), principal illness navigation (PIN), PIN-peer support services and Advanced Primary Care Management (APCM). For RHCs and FQHCs, we established payment for these suites of care coordination services outside of the RHC AIR and FQHC PPS. That is, payment is made in addition to the otherwise billable visit.

In the CY 2025 PFS final rule (89 FR 97870 through 97874), we discussed how we established coding and payment under the PFS for a newly defined set of APCM services described and defined by three new HCPCS G-codes. This new coding reflects the recognized effectiveness and growing adoption of the advanced primary care approach to care. It also encompasses a broader range of services and simplifies the billing and documentation requirements, as compared to existing care management codes. The finalized coding for APCM incorporated elements of several existing care management services into a bundle that we have already considered to be care coordination services paid separately to RHCs and FQHCs using HCPCS code G0511 (for example, CCM and PCM). In addition, the coding for APCM incorporated elements of communication technology-based services (CTBS) into a bundle that we have already considered to be virtual communications paid separately to RHCs and FQHCs using HCPCS code G0071. Therefore, to allow RHCs and FQHCs the ability to simplify the billing and documentation requirements associated with furnishing APCM services we finalized in the CY 2025 PFS final rule to allow RHCs and FQHCs to bill for these services and receive separate payment.

Further, the APCM code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner (NPP) is used to meet time thresholds for billing. In the CY 2025 final rule, we finalized and adopted the three new APCM codes G0556, G0557, and G0558.

RHCs and FQHCs are required to use the more specific coding, that is, the three HCPCS G-codes listed above when furnishing APCM. These services are paid in addition to the otherwise billable visit under the RHC AIR methodology or FQHC PPS because we believe that they are similar to the other care coordination services, such as, CCM, PCM, and RPM. That is, APCM involves non-face to-face care coordination of which the costs associated with these services are not captured in the RHC AIR or FQHC PPS rate. Similarly to the care coordination services, payment for APCM is based on the PFS national non-facility rate. It is important to note that if RHCs and FQHCs furnish APCM services, the HCPCS codes for APCM are per calendar month bundles. Consequently, if the RHC/FQHC furnishes APCM then they would not bill for certain other individual care coordination services. For further discussion on duplicative services and concurrent billing restrictions regarding APCM policies, please refer to the CY 2025 PFS final rule (89 FR 97710).

b. Integrating Behavioral Health Into Advanced Primary Care Management (APCM)

In the CY 2018 PFS final rule, we established requirements and separate payment for general Behavioral Health Integration (BHI) and Psychiatric Collaborative Care Model (CoCM) services furnished in RHCs and FQHCs (82 FR 53169 through 53180). General BHI and Psychiatric CoCM services are based on a model of behavioral health integration that enhances usual primary care by adding two key services to the primary care team: care management support for patients receiving behavioral health treatment and regular psychiatric inter-specialty consultation. In the CY 2018 PFS final rule, we also initiated the use of HCPCS codes G0511 and G0512 to pay for general care coordination services and CoCM services, respectively.

As discussed in section II.G.1. of this proposed rule, we recognize that patients with chronic health conditions are ''more likely to have related behavioral health concerns and find it easier to improve chronic conditions when these concerns are also addressed.'' [113] Integrating behavioral health with primary care has been shown to improve outcomes like reduced depression severity, and enhancing patient's experience of care. [114] We explain that in response to comments received for CY 2025 rulemaking, for services paid under the PFS, we are proposing to create optional add-on codes for APCM services that would facilitate providing complementary BHI services.

As discussed previously in this section, we adopted the coding for the defined set of APCM services described and defined by HCPCS codes G0556, G0557, and G0558 to allow RHCs and FQHCs the ability to simplify the billing and documentation requirements associated with furnishing APCM services (89 FR 98010 through 98012). In addition, and similarly to the discussion in section II.G of this proposed rule, since RHCs and FQHCs that fulfill the requirements to bill for APCM services must comply with requirements that ensure the integrity of the services provided, we believe that these settings should also be able to provide BHI and CoCM with simpler billing and documentation requirements. Therefore, for CY 2026, in alignment with the PFS and goals associated with APCM services, we are proposing to adopt the add-on codes for APCM that would facilitate billing for BHI and CoCM services when RHCs and FQHCs are providing advanced primary care. We believe allowing for the use of these add-on codes would encourage RHCs and FQHCs to provide complementary BHI services, thereby improving access to BHI and CoCM for primary care patients in the RHC and FQHC settings. For further discussion regarding the optional add-on codes, please see section II.G.2 of this proposed rule.

In the CY 2025 PFS final rule (89 FR 98010), commenters suggested that we consider unbundling HCPCS code G0512, similarly to what we did with HCPCS code G0511. That is, unbundle the services that comprise HCPCS code G0512 and permit billing of HCPCS codes 99492, 99493, and 99494. Commenters explained that allowing RHCs and FQHCs to report the dedicated CPT codes would support and encourage the adoption of CoCM in these settings. In addition, since we are proposing use of add-on codes for APCM services to facilitate payment of BHI and CoCM services when they are furnished by RHCs and FQHCs providing advanced primary care services, we believe that we would also need to unbundle HCPCS code G0512 to effectuate that policy. RHCs and FQHCs that are furnishing BHI and CoCM as advanced primary care services would not be able to bill for certain other individual CPT codes, such as, 99492, 99493, and 99484.

Therefore, we are proposing to require RHCs and FQHCs to report the individual codes that make up the CoCM HCPCS code, G0512 beginning January 1, 2026. Similar to what was finalized in the CY 2025 PFS final rule (89 FR 98000 through 98010) for the general care management HCPCS code G0511, HCPCS code G0512 would no longer be payable when billed by RHCs and FQHCs; instead, RHCs and FQHCs will be required to bill the individual CPT and HCPCS codes that make up HCPCS G0512. The current list of base codes and add-on codes that make up G0512 are listed in Table 34, titled ''Psychiatric Collaborative Care Model HCPCS Codes and Descriptors.'' Payment for these services will be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We are proposing to revise § 405.2464(c) to reflect our proposal on payment of CoCM services for RHCs and FQHCs.

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[113] *https://integrationacademy.ahrq.gov/about/integrated-behavioral-health#:~:text=Integrated%20behavioral%20health%20offers%20many,these%20concerns%20are%20also%20addressed.*

[114] Balasubramanian, Bijal, Deborah Cohen, Katelyn Jetelina, Miriam Dickinson, Melinda Davis, Rose Gunn, Kris Gowen, Frank DeGruy 3rd, Benjamin Miller, Larry Green. ''Outcomes of Integrated Behavioral Health with Primary Care.'' J Am Board Fam Med. 2017 Mar–Apr;30(2):130–139.doi: 10.3122/jabfm.2017.02.160234.

TABLE 34: PSYCHIATRIC COLLABORATIVE CARE MODEL HCPCS CODES AND DESCRIPTORS

HCPCS Code	Short Descriptors	Long Descriptors
99492	1st psych collab care mgmt.; CoCM First Month, 70 minutes per calendar month	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and that the treating physician or other qualified health care professional directs, with the following required elements: • Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional. • Initial assessment of the patient, including administering validated rating scales, with the development of an individualized treatment plan • Review by the psychiatric consultant with modifications of the plan, if recommended. • Entering patient in a registry and tracking patient follow-up and progress using the registry, with proper documentation, and participation in weekly caseload consultation with the psychiatric consultant. • Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.
99493	Sbsq psyc collab care management; CoCM Subsequent Months, 60 minutes per calendar month	Follow up psychiatric collaborative care management, first 60 minutes in a following month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: • Tracking patient follow-up and progress using the registry, with proper documentation • Participation in weekly caseload consultation with the psychiatric consultant. • Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers. • Other review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations supplied by the psychiatric consultant. • Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies. • Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission

HCPCS Code	Short Descriptors	Long Descriptors
		of symptoms, other treatment goals and prepare for discharge from active treatment.
99494	1st/subesq psyc collab care; Add-on CoCM (any month), each additional 30 minutes per calendar month.	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and that the treating physician or other qualified health care professional directs (list separately from the code for the primary procedure).
G2214	Init/sub psych care m 1st 30; Initial or subsequent psychiatric collaborative care management, 30 minutes of behavioral health care manager time per calendar month.	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional: • Tracking patient follow-up and progress using the registry, with proper documentation; participation in weekly caseload consultation with the psychiatric consultant. • Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers. • Other review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations supplied by the psychiatric consultant. • Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies. • Monitoring of patient outcomes using validated rating scales. • Relapse prevention planning with patients as they achieve remission of symptoms, or other treatment goals and prepare for discharge from active treatment.

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c. Payment for Communication Technology-Based Services (CTBS) and Remote Evaluation Services—HCPCS Code G0071

In the CY 2019 PFS final rule (83 FR 59683 through 59688), we established requirements and separate payment for certain CTBS and remote evaluation services in RHCs and FQHCs. Effective January 1, 2019, RHCs and FQHCs are paid for HCPCS code G0071 (Virtual Communication Services), when HCPCS code G0071 is on an RHC or FQHC claim, either alone or with other payable services, and at least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who has had an RHC or FQHC billable visit within the previous year, and the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment. At that time, HCPCS code G0071 comprised individual HCPCS codes G2012 (CTBS) and G2010 (remote evaluation services). For respective CTBS code descriptors, please refer to Table 35 in this section. The payment rate for HCPCS G0071 was set at the average of the PFS national non-facility payment rates for HCPCS code G2012 and HCPCS code G2010 for remote evaluation services.

(1) Updates to CTBS and Remote Evaluation Services Under the PFS

In the CY 2021 PFS final rule (85 FR 84532 through 84533), for practitioners billing under the PFS, we discuss additional policies as they relate to CTBS services. One of which was the establishment of HCPCS code G2250, which allows billing of CTBS by certain non-physician practitioners (NPPs), consistent with the scope of these practitioners' benefit categories, who cannot independently bill for evaluation and management (E/M) services. At the time of the CY 2021 PFS rulemaking we did not address the applicability of

G2250 for RHC and FQHC purposes. However, we acknowledge that the code descriptor for HCPCS code G2250 mirrors that of the existing HCPCS code G2010 in that both codes describe the remote assessment of recorded video and/or images submitted by an established patient (for example, store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment. Since HCPCS code G2250 describes remote evaluation services similarly to HCPCS code G2010 and certain non-physician practitioners are recognized as RHC and FQHC practitioners, we propose to consider HCPCS code G2250 as billable for separate payment when this service is furnished in an RHC or FQHC. Please see below for more detail on the proposals for CY 2026.

In CY 2025 PFS final rule (89 FR 97791 through 97794), for practitioners billing under the PFS, we discuss how the CPT Editorial Panel established new CPT code 98016 describing a brief virtual check-in encounter that is intended to evaluate the need for a more extensive visit (that is, a visit described by one of the office/outpatient E/M codes). We stated that the code descriptor for CPT code 98016 mirrored the existing HCPCS code G2012, which is described as a brief communication technology-based service, for example, virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5 to 10 minutes of medical discussion). We further stated that given the similarity between CPT code 98016 and HCPCS code G2012, we finalized the replacement of HCPCS code G2012 with CPT 98016. That is, HCPCS code G2012 was terminated effective December 31, 2024. We inadvertently did not discuss the applicability of this code termination to RHCs and FQHCs; however, given our alignment with the PFS, beginning January 1, 2025 for HCPCS code G0071, CPT code 98016 was used for purposes of computing the payment rate.

(2) Proposal for CY 2026 for CTBS and Remote Evaluation Services

As we stated previously in section III.B.2.a. of this proposed rule, APCM includes elements of CTBS and remote evaluation services, however in the CY 2025 PFS final rule, we did not address how there are potential duplicative services with APCM and these services for RHCs and FQHCs (89 FR 98010 through 98012). Similarly with unbundling of G0512, we believe that we would also need to unbundle HCPCS code G0071 to better effectuate the payment policy for APCM. RHCs and FQHCs that are furnishing CTBS or remote evaluation services as advanced primary care services would not be able to bill for certain other individual CPT codes, such as, G2010, G2250, and 98016. Therefore, we are proposing to require RHCs and FQHCs to report the individual codes that make up HCPCS code G0071 beginning January 1, 2026. Payment for these services will be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We are proposing to revise § 405.2464(e) to reflect our proposal for payment of CTBS and remote evaluation services for RHCs and FQHCs.

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TABLE 35: CODE DESCRIPTORS FOR COMMUNICATION TECHNOLOGY-BASED SERVICES AND REMOTE EVALUATION SERVICES

HCPCS Code	Short Descriptors	Long Descriptors
G0071	Communication Services by RHC/FQHC 5 minutes	Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between an rural health clinic (RHC) or Federally qualified health center (FQHC) practitioner and RHC or FQHC patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an RHC or FQHC practitioner, occurring in lieu of an office visit; RHC or FQHC only.
G2010	Remote image submit by patient	Remote evaluation of recorded video and/or images submitted by an established patient (for example, store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment).
G2012	Discontinued - Brief check in by MD/QHP	Brief communication technology-based service, for example, virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5 to 10 minutes of medical discussion.

HCPCS Code	Short Descriptors	Long Descriptors
G2250	Remote image submitted by patient, non-E/M	Remote assessment of recorded video and/or images submitted by an established patient (for example, store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.
98016	Brief communication technology-based service	Established patient brief communication technology-based service with 5 to 10 minutes of medical discussion.

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d. Aligning With the PFS for Care Coordination Services

(1) Background

Under the PFS, certain care management/coordination services are categorized as designated care management services and assigned general supervision for purposes of ''incident to'' billing. As we discuss in the CY 2017 PFS final rule (81 FR 80238), generally, we do not believe it is clinically necessary for the individuals on the team who provide these services other than the treating practitioner (namely, clinical staff) to have the treating practitioner immediately available to them at all times, as would be required under a higher level of supervision. We also discussed how the regulations under § 410.26(b), at that time, provided for an exception to assign general supervision to CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are generally non-face-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner (who is also the supervising practitioner) is not physically present; and the CPT codes comprise solely (or to a significant degree) non-face-to-face services provided by clinical staff (81 FR 80255).

For practitioners billing under the PFS, in an effort to better define general supervision and to assign general supervision not only to CCM services and the non-face-to-face portion of TCM services, but also to the then proposed codes., we amended §§ 410.26(a)(3) and 410.26(b). We amended § 410.26(a)(3) to better describe general supervision in the context of these services, and amended § 410.26(b) to assign general supervision to ''designated care management services'', stating that we will designate such services through notice and comment rulemaking (81 FR 80255 through 80256). We state at § 410.26(b)(5) that designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

Since CY 2017, when new care management/coordination services are proposed under the PFS, we also propose to add the new codes, when applicable, to the list of designated care management services for which we allow general supervision. Each year along with the proposed rule and the final rule we have published the codes for designated care management services assigned general supervision as supporting documentation. For example, for the CY 2025 PFS final rule, the file is titled ''CY 2025 Final Rule List of Designated Care Management Services.''

(2) RHC and FQHC Care Coordination Services

As we discuss in section III.B.2.a. of this proposed rule, over the last several years we have been increasing our focus on care coordination. These services have evolved to focus on preventing and managing chronic disease, improving a beneficiary's transition from the hospital to the community setting, or on integrative treatment of patients with behavioral health conditions. Care coordination services are typically non-face-to-face services that do not require the skill level of an RHC or FQHC practitioner. We have acknowledged that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved and may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries.

We have noted previously that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC (80 FR 71081). Therefore, we have proposed payment policies for RHCs and FQHCs that complement the new services for care coordination established under the PFS to align use of the RHC and FQHC resources for those services with a separate payment.

Over the last decade, the number of new care coordination services established under the PFS has increased. As these services are proposed, we review and evaluate the new care coordination codes each year as established under the PFS to determine their applicability to RHCs and FQHCs. Our general process is to review the descriptor and policies under the PFS for each new HCPCS code to determine if the services are provided face-to-face with a practitioner or auxiliary personnel with a patient, or have some face-to-face component with a practitioner or auxiliary personnel or are strictly non-face-to-face; that is, the care coordination services are being performed behind the scenes and not in

the presence of the patient. If the new care coordination service met the non-face-to-face criteria for RHCs and FQHCs, we would propose in the proposed rule adding it to the list of care coordination services that can be paid separately from a billable visit for RHCs and FQHCs. For a detailed history on the payment for care coordination services, please see section III.B.2. of the CY 2025 PFS final rule (89 FR 97998 through 98010).

The increase in frequency of this complementary rulemaking has prompted us consider operational efficiencies that we believe could result in more transparency and clarity in determining applicable care coordination services for RHCs and FQHCs. In the CY 2025 PFS final rule (89 FR 98012), we solicited comment on how we can improve the transparency regarding which HCPCS codes are considered care coordination services. Our goal is to classify care coordination services established under the PFS that extend to RHCs and FQHCs. We stated that we believe establishing a streamlined policy regarding which services are separately paid for RHCs and FQHCs versus which services are included as part of the visit creates transparency. In addition, we believe establishing a policy where codes are communicated and updated through subregulatory guidance such as manuals, website pages, and change requests may be more efficient.

Only a few commenters responded to our request for information on how we can improve transparency and predictability regarding which HCPCS codes are considered care coordination services. These commenters agreed with a streamlined approach and that communicating these updates through sub-regulatory guidance would be more transparent and efficient. Commenters stated that by distinguishing services that are separately payable from those services included in a visit, we would provide RHCs and FQHCs the clarity needed to accurately submit claims for Medicare reimbursement.

In response to the comment solicitation, we propose adopting services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs. We believe this proposal would improve transparency and efficiency for RHCs and FQHCs since these services and their designation as care management services go through notice and comment rulemaking. In addition, as discussed under §§ 405.2413 and 405.2415, service and supplies furnished incident to TCM and care coordination services can be furnished under general supervision.

As discussed previously in this section, under the PFS, when new care management/coordination services are proposed under the PFS, we also propose to add the new codes, when applicable, to the list of designated care management services for which we allow general supervision. Each year, along with the proposed rule and the final rule, we have published the codes for designated care management services assigned general supervision as supporting documentation. For example, for the CY 2025 PFS final rule, the file is titled ''CY 2025 Final Rule List of Designated Care Management Services.'' Under our proposal, services designated as care management services and added to the list of designated care management services could also be furnished in RHCs and FQHCs and paid separately as described in § 405.2464(c). Interested parties can look for opportunities to review and comment on new services in the respective sections of the PFS proposed and final rules. When services are finalized under the PFS, we propose to update RHC and FQHC sub-regulatory guidance to reflect the new care coordination services. We expect that this will occur, that is, we would adopt any new care management services that are proposed and finalized in the CY 2027 PFS rule and displayed on the list of the designated care management services to be care coordination services for RHCs and FQHCs.

Any new care coordination HCPCS codes will be paid separately from the RHC AIR methodology or FQHC PPS at the national non-facility PFS payment rate, either alone or with other payable visits. We note that some of the current RHC and FQHC care coordination services are not listed on the current list of designated care management service, however, we will continue to make separate payments for these RHC and FQHC care coordination services as they have been previously adopted through notice and comment rulemaking. These services include CCM, PCM, BHI, CPM, RPM, RTM, CHI, PIN and PIN-peer support services, and APCM.

We seek comment on whether the proposed process to align with the care coordination services paid under the PFS as care management services is sustainable moving forward or is there a more effective approach for adopting new care coordination codes established under the PFS as care management codes that would improve transparency and efficiency for RHCs and FQHCs.

3. Services Using Telecommunications Technology

a. Background

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136, March 27, 2020) directed the Secretary to establish payment for RHC and FQHC services that are provided as Medicare telehealth services by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by section 3704 of the CARES Act, required that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID–19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. We established payment rates for these services furnished by RHCs and FQHCs based on the average PFS payment amount for all Medicare telehealth services, weighted by volume in a Special Edition Medicare Learning Network Article (SE20016). We subsequently finalized a policy to extend use of this payment methodology for these services through CY2025.

Section 303 of the Consolidated Appropriations Acs (CAA), 2022, section 4113(c) of CAA, 2023, section 3207(c) of the American Relief Act, 2025, and section 2207(c) of the Full-Year Continuing Appropriations and Extensions Act, 2025 each subsequently extended these flexibilities. Most recently, section 2207(c) of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(m)(8) of the Act to continue payment for RHC and FQHC services as Medicare telehealth services through September 30, 2025.

In addition to the statutory and associated rulemaking changes noted previously, we established various flexibilities related to use of telecommunications technology through rulemaking; for example, in the CY 2022 PFS final rule with comment period (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in-person) encounter between an RHC or FQHC patient and

an RHC or FQHC practitioner, and we revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder.

We also revised § 405.2469, to add a supplemental wraparound payment to be made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. We noted that these changes aligned with similar changes for Medicare telehealth services for behavioral health paid under the PFS. We also noted that this change would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

In addition, in the CY 2022 PFS final rule (86 FR 65210 and 65211), we revised the regulations at §§ 405.2463 and 405.2469 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record. In the CY 2025 PFS final rule, we announced that we would continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026. However, subsequent to the publication of the CY 2025 PFS final rule, section 2207(d) of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4, March 15, 2025) legislated the in-person visit requirement for mental health visits following September 30, 2025; we are implementing conforming regulatory changes as discussed in section III.B.3.d. of this proposed rule.

As an additional regulatory flexibility, in the CY 2025 PFS final rule (89 FR 98013 through 98017), we extended our policy to deem the presence of the physician (or other practitioner) to include virtual presence for the purposes of direct supervision through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

b. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. See section II.D.2 of this proposed rule for the discussion regarding direct supervision for services provided using telecommunications technologies under the PFS.

In the CY 2024 PFS final rule (88 FR 79067), we explained that extending this definition of direct supervision for RHCs and FQHCs under our regulations at §§ 405.2413, 405.2415, 405.2448, and 405.2452 through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. In addition, we were concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2024, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID–19. We also believed that RHCs and FQHCs would need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Similar to services furnished in physician office setting, RHC and FQHC services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care coordination services which may be furnished under general supervision. For CY 2024 we continued to define ''immediate availability'' as including real-time audio and visual interactive telecommunications through December 31, 2024, and solicited comment on whether we should consider extending the definition of ''direct supervision'' to permit virtual presence beyond December 31, 2024; specifically, we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have had in regard to this policy. In the CY 2025 final rule, (89 FR 98015) we finalized our policy to maintain the virtual presence flexibility on a temporary basis, that is, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025 as such a policy continues to support access and preserve workforce capacity.

(1) Proposal for CY 2026 Regarding Direct Supervision in RHCs/FQHCs

We have considered information from interested parties, particularly in response to the CY 2024 PFS proposed rule where we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have regarding this policy.

As discussed in the CY 2025 final rule (89 FR 98014 through 98015), in response to our proposal to extend this definition through the end of 2025, commenters strongly supported the proposal to allow virtual direct supervision through real-time audio/video communications technology in RHCs and FQHCs, citing benefits such as reduced inefficiencies, improved accessibility, better alignment with other outpatient providers, and enhanced healthcare delivery without compromising patient safety or program integrity.

Given the information presented by interested parties on safety and effectiveness, we think direct supervision provided via two-way real time audio-video telecommunications technology meets the statutory requirements specific to RHCs and FQHCs at section 1861(aa)(2)(B) of the Act regarding necessary physician supervision and guidance. We note that in section II.D.2 of this proposed rule, we propose to permanently adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26, except for services that have global surgery indicators of, 010, or 090. These indicators are defined in IOM Pub. 100–04, chapter 23, section 50.6 as 010 ''Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable'' and 090 ''Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount''. These are services that describe a surgical service as well as its post-operative period of either 10 days, or 90 days, respectively.

In the interests of aligning our approach toward direct supervision for RHCs and FQHCs with that discussed in section II.D.2. of this proposed rule, we believe that we should permanently adopt this flexibility in RHCs and FQHCs as it continues to support access and preserve workforce capacity. However, as we discuss in IOM Pub. 100–02, chapter 13, section 40.4, the Medicare global billing requirements do not apply to RHCs and FQHCs, and global billing codes are not accepted for RHC or FQHC billing or payment. Since services that have global surgery indicators are not applicable in the RHC and FQHC settings, we are proposing revisions at § 405.2401(b) to define ''Direct Supervision'' to mean that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

c. Payment for Medical Visits Furnished via Telecommunications Technology

Widespread use of telecommunications technology to furnish services during the PHE has illustrated interest within the medical community and among Medicare beneficiaries in furnishing and receiving care through the use of technology beyond the PHE. During the PHE, RHCs and FQHCs, much like other health care providers, had to change how they furnish care to meet the needs of their patients. RHCs and FQHCs heavily utilized the temporary authority to be paid for their services when provided as Medicare telehealth services during the PHE. Eliminating flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology for over 5 years and resuming payment solely for in-person, face-to-face medical visits, would cause disruptions in access to services from RHC and FQHC practitioners. This would be particularly problematic for the underserved populations that these settings furnish services to since it could fragment care. We believe that we need to preserve the flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology temporarily and to do so through an approach that these settings are familiar with to mitigate burden while we consider how to incorporate services furnished through telecommunications technology on a more permanent basis.

For these reasons, in the event that Congress no longer authorizes payment to be made for telehealth services furnished via a telecommunications system by RHCs and FQHCs using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS, we are proposing, on a temporary basis, to facilitate payment for non-behavioral health visits (hereafter referred to in this discussion as ''medical visit services'') furnished via telecommunications technology using an approach that closely aligns with this methodology. Like the methodology we used during and after the PHE, RHCs and FQHCs would continue to bill for RHC and FQHC medical visit services furnished using telecommunications technology, including services furnished using audio-only communications technology, by reporting HCPCS code G2025 on the claim. Since the costs associated with medical visit services furnished via telecommunications technology are not included in the calculations for the RHC AIR methodology and FQHC PPS, we believe, similar to the methodology described in section 1834(m)(8) of the Act, that we need to propose a proxy that would represent such resources used when furnishing these services. Therefore, we propose to continue to calculate the payment amount for these services billed using HCPCS code G2025 based on the average amount for all Medicare telehealth services paid under the PFS, weighted by volume for those services reported under the PFS. We believe that continuing to use this weighted average is appropriate during this interim period while we contemplate permanent policies for these services since there is a wide range of payment rates for the Medicare telehealth services paid under the PFS. As discussed in the CY 2025 final rule (89 FR 98015 through 98016), we believe that RHCs and FQHCs generally furnish services that are similar to and at a frequency the same as physicians and other practitioners paid under the PFS. While we do not have actual cost information, we believe that this weighted average is an appropriate proxy since it addresses certain resource costs experienced by professionals and would mitigate any potential over or under payments. Costs associated with these services would continue to not be used in determining payments under the RHC AIR methodology or the FQHC PPS.

We believe that the proposed approach would preserve the telecommunication technology flexibility under which RHC and FQHC services have been furnished for over 5 years and would not impact access to care for Medicare beneficiaries who currently benefit from these services while CMS contemplates next steps. We note that this is a stopgap approach to preserve access concerns temporarily. The same rationale that led us to propose and finalize this policy last year applies again now given that congress has again extended this flexibility following publication of last year's final rule; we beleive that our regulatory approach toward inclusion of these services furnished via telecommunications technology will continue to apply after the end of the statutory requirement that they be included. In addition, we believe that continuing this payment methodology on a temporary basis through December 31, 2026 would provide flexibility to respond to any future statutory changes.

(1) Alternative Proposal Considered for Payment of Medical Visits Furnished via Telecommunication Technology

We considered reevaluating the regulations regarding face-to-face visit requirements for encounters between a beneficiary and an RHC or FQHC practitioner in light of contemporary medical practices. That is, we considered proposing a revision to the regulatory requirement that an RHC or FQHC medical visit must be a face-to-face (that is, in-person) encounter between a beneficiary and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time, audio and video telecommunications technology. This would result in payment for services furnished via telecommunication technology to be made under the RHC AIR methodology and under the FQHC PPS, similar to how we revised the regulations for mental health visits. We believe interested parties may prefer the per visit payment that aligns with the RHC AIR or FQHC PPS. However, we did not propose this alternative because we determined that it would have unintended consequences, especially in cases where the RHC AIR or FQHC PPS per-visit rates would be significantly higher than the PFS rate that would apply if other entities furnished the same service to the same beneficiary in the same location.

We believe that continuing to pay temporarily for RHC and FQHC services furnished via telecommunication technologies in the same manner as we have done over the past several years preserves the flexibility for RHCs and FQHCs to continue access to care, mitigates administrative burden, and mitigates potential program integrity concerns. However, we are soliciting comment on the alternative proposal we considered. That is, revising the definition of a visit to include interactive, real-time, audio/video telecommunication technology which would result in a capitated payment under the RHC AIR methodology or FQHC PPS.

d. Proposal for Conforming Regulatory Text Changes

Subsequent to the publication of the CY 2025 PFS final rule, section 2207(d) of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended sections 1834(y)(2) and 1834(o)(4)(B) of the Act by extending the delay of in-person requirements for mental health services furnished through telecommunication technology for RHCs and FQHCs, respectively, through September 30, 2025. We are therefore proposing to make conforming regulatory text changes based to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we propose to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we propose to amend paragraph (d). Both of these provisions would require that, beginning October 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

C. Ambulatory Specialty Model (ASM)

1. Overview of Proposed Ambulatory Specialty Model

a. Introduction

Under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center) in section 1115A(b) of the Act, we are proposing the implementation and testing of the Ambulatory Specialty Model (ASM), a new mandatory alternative payment model with 5 performance years that would begin January 1, 2027 and end December 31, 2031. ASM would test whether adjusting payment for specialists based on their performance on targeted measures of quality, cost, care coordination, and meaningful use of certified electronic health record (EHR) technology (CEHRT) results in enhanced quality of care and reduced costs through more effective upstream chronic condition management.

To enhance quality of care and lower the costs of care, ASM would be established as a mandatory model focused on the care provided by select specialists to Medicare beneficiaries with the chronic conditions of heart failure and low back pain. Under the model, clinicians would be required to report a select set of measures and activities clinically relevant to their specialty type and the chronic condition of interest. These measures and activities would assess quality, cost, interoperability, and care coordination practices, all of which are necessary for effective upstream chronic condition management. To incentivize improvements in quality and care coordination, CMS would assess the clinician's performance on those measures and activities relative to their peers, who are also participants of the model and of a similar specialty type treating the same chronic condition.

ASM falls within a larger framework of activities initiated by the Innovation Center to focus on high-volume, high-cost chronic conditions and direct engagement of specialists in value-based payment. The Innovation Center recently announced its new strategy based on three strategic pillars for improving the health of Americans and protecting taxpayers: preventing disease through evidence-based practices, empowering people with information to make better decisions, and driving choice and competition.[115]

In line with the updated Innovation Center principles, this proposed rule proposes a new mandatory model that would improve beneficiary and provider engagement, incentivize preventive care, and increase financial accountability for certain specialists. The model would build upon lessons learned from previous Innovation Center models and the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program. We believe the model would answer the call to create a more cohesive and efficient health system that enhances the quality of care and reduces costs over time. To promote preventive care, the model would incentivize specialists who are ASM participants to ensure that their patients have a regular source of primary care and are screened to help identify risks and early signs of chronic conditions. This model would also seek to prevent deterioration of and complications associated with established chronic conditions. To empower patients, the model would promote direct accountability for quality. By featuring patient-reported outcome measures in the proposed quality ASM performance category, this model encourages patients to report their improvement or decline in function, which directly impacts clinician payment and further incentivizes clinicians to incorporate patient voice and experience in clinical care decisions. We believe a focus on

[115] CMS Innovation Center, CMS Innovation Center 2025 Strategy to Make America Healthy Again, May 2025. *https://www.cms.gov/priorities/innovation/about/strategic-direction#:~:text=Three%2DPronged%20Approach,served%20by%20the%20Innovation%20Center.*

patient-reported measures elevates patient voice, leading clinicians to be more responsive to the patient's response to treatment, while also addressing the significant spending that results from functional impairment. These measures also provide a pathway for clinicians to have conversations about non-medical, lifestyle-based interventions with their patients. This proposed model is intent on removing the onus from patients to act as the go-between among clinicians they see for their care by incentivizing clinicians to coordinate care for their patients more seamlessly. Patients would be able to focus on solutions to their health, rather than resolving information and guidance they have received from multiple clinicians.

Finally, the model would require the participation of individual clinicians rather than organizations to encourage competition and create a level playing field for solo and small practices. By evaluating clinicians individually, ASM removes the unequal reporting and scoring benefits that have been previously afforded to consolidated health systems and group practices. This form of mandatory participation would bring transparency, accountability, and comparability at the clinician-level, helping to identify clinicians within large, consolidated health systems or provider networks providing low-value care.

Low-value care refers to services that: (1) may offer limited or no clinical benefit to a patient; or (2) may present risks of harm that outweigh the potential benefit. By requiring the participation of individual clinicians, we believe this model would reduce spending that represents low-value services and major cost-drivers for heart failure and low back pain (for example, unnecessary imaging, surgeries, hospital admissions). Ultimately, this model aims to drive competition among similar specialists with a targeted assessment of their performance relative to their peers in the treatment of a specific chronic condition and protect taxpayers by reducing low-value services by holding specialists accountable for the cost of services clinically related to their role in managing care.

We have designed ASM with a focus on clinicians who commonly treat patients in the ambulatory setting, develop longitudinal relationships with patients, and co-manage beneficiaries with primary care clinicians. In addition, we considered those who treat chronic conditions that are likely to benefit from improved integration between specialty and primary care to maximize opportunities for incentivizing high-value care and tertiary prevention. Specifically, we propose to focus the model on the chronic conditions of heart failure and low back pain, as they have previously established episode-based cost measures (EBCMs) specified for the MIPS cost performance category.

The EBCMs were developed with specialists and stakeholders through an extensive, collaborative process that, by design, focused on conditions with a large share of Medicare spending, a high number of responsible clinicians, and opportunities for care improvement. Based on recent estimates, heart failure and low back pain, in particular, account for 3.5 and 2.7 percent total Medicare Part A and B spending.[116] These are significantly higher than other chronic conditions with EBCMs, which account for less than one percent of Medicare Part A and B spending, except for diabetes, which accounts for 4.2 percent of spending.[117] In contrast, many Medicare beneficiaries with type 2 diabetes are capably managed by primary care physicians as the quarterback of their care with input from consulting specialists. Consequently, we do not believe it would be an appropriate chronic condition for this specialty care model.

ASM would be a mandatory model that begins on January 1, 2027 and ends December, 31, 2033. There would be 5 performance years, beginning January 1, 2027 and ending December 31, 2031. Final data submission of measures and activities would be in CY 2032, with final model payment adjustments in CY 2033.

To measure clinician performance in ASM, we would establish a mandatory set of measures and activities for physicians that meet the proposed ASM participant eligibility criteria described in section III.C.2.c.(3). of this proposed rule. ASM aims to assess the performance of ASM participants providing care for Medicare beneficiaries with the targeted chronic conditions at the individual clinician level. Specifically, ASM would test whether adjusting Medicare Part B payments for covered professional services based on measures of quality, cost, care coordination, and CEHRT results in enhanced quality of care and reduced costs through more effective upstream chronic condition management.

ASM would leverage components of the existing MIPS Value Pathway (MVP) framework, as appropriate, to meaningfully engage specialists in improving the quality of care for high-volume, high-cost chronic conditions and better integrate specialists in primary care. MVPs are one MIPS reporting option that provides a smaller set of measures to choose from that are most relevant to a condition or specialty. Currently, for MIPS, CMS assesses the performance of each MIPS eligible clinician on measures and activities CMS has specified for a CY performance period/MIPS payment year for four performance categories: quality, cost, clinical practice improvement activities, and meaningful use of CEHRT (referred to as ''Promoting Interoperability''). In accordance with section 1848(q) of the Act, CMS calculates a composite performance score (a ''final score'' as defined at § 414.1305) from 0 to 100 points for each MIPS eligible clinician. Then, CMS compares each MIPS eligible clinician's final score to the performance threshold established in prior rulemaking for that CY performance period/MIPS payment year to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act. For the applicable MIPS payment year, CMS would calculate and apply to each MIPS eligible clinician: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment factor for each MIPS eligible clinician, CMS accounts for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act.

By applying these budget neutrality and scaling factor requirements, CMS's calculations of positive MIPS payment adjustment factors for each MIPS eligible clinician are limited by CMS's calculations of negative MIPS payment factors for each MIPS eligible clinician. In other words, CMS's estimated amounts of positive MIPS payment adjustment factors for MIPS eligible clinicians performing above the performance threshold must be offset by CMS's estimated amounts of negative MIPS payment adjustment factors for MIPS eligible clinicians performing below the performance threshold. In MVPs, however, clinicians still have flexibility to select which measures to report. Under MIPS, a clinician's performance is assessed against all MIPS clinicians, regardless of reporting

[116] Quality Payment Program, 2025 Summary of Cost Measures, December 2024. *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3129/2025-mips-summary-cost-measures.pdf.*

[117] Ibid.

option, specialty type, or the services they provide.

As CMS discussed in a 2024 Request for Information (RFI) (89 FR 61596),[118] we expect that a more targeted approach where clinicians are evaluated: (1) on required reporting of a set of relevant performance measures; and (2) among clinicians furnishing similar sets of services, would produce scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement would also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. This targeted approach would include reporting or required collection of patient-reported outcome measures that assess the change in a beneficiary's functional status over the course of the episode, ensuring clinicians prioritize the same goals as their patients. Furthermore, equipped with more specialty-relevant performance information, we expect clinicians would be more likely to invest resources in pursuit of better outcomes and improved care coordination, ultimately resulting in better care for patients. To test this more targeted approach, this proposed mandatory model leverages the existing MVP policies, deviating from MVP policies in specific ways, as applicable.

First, unlike the voluntary measure and activity selection permitted under the MVP reporting option, ASM would require clinicians to report on a set of measures and activities clinically relevant to their specialty type and the chronic condition. of interest. This would ensure a more analogous comparison between clinicians. Second, while clinicians reporting under MVPs are scored against the entire pool of MIPS clinicians, ASM would assess performance against only those clinicians treating the same chronic condition. Each clinician would receive a performance score based on the measures and activities included in the four ASM performance categories (which are based on the MIPS performance categories)—quality, cost, improvement activities, and Promoting Interoperability. In section III.C.2.d. of this proposed rule, we describe the proposed requirements in the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories.

Third, we would use a different approach, compared to MVPs, for aggregating the ASM performance categories to calculate a final score and determine the ASM payment adjustment. This approach would broaden the distribution of final scores and increase the magnitude of payment adjustments, which we believe would incentivize performance improvements that would lead to more effective upstream chronic condition management. We refer readers to the CY 2022 PFS final rule for additional details on the MVP performance category weighting § 414.1365(e). As described in section III.C.2.e. of this proposed rule, we would focus on value and variation in clinician performance by primarily measuring performance on quality and cost performance categories for calculating the ASM final score. We also understand the importance of the improvement activities and Promoting Interoperability performance categories and would apply potential negative scoring adjustments for non-reporting or poor performance. We are also considering additional positive scoring adjustments for clinicians in small practices participating in the model and for ASM participants treating a large proportion of medically complex patients. We refer readers to sections III.C.2.c., III.C.2.d., and III.C.2.e. of this proposed rule for additional details on the proposed policies related to ASM participant eligibility criteria, the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories, and ASM final scoring calculations.

To ensure savings in the financial impacts for the model, ASM would also retain a percentage of the payments rather than distributing all funds as clinicians' payment adjustments. ASM participants would receive neutral, negative, or positive payment adjustments on future Medicare Part B payments for covered professional services based on their performance during an ASM performance year. As is done under MIPS, clinicians participating in ASM would continue to bill Medicare under the traditional FFS system for services furnished to Medicare FFS beneficiaries. MIPS eligibility criteria described under 42 CFR 414.1305 are not factored into the ASM participant eligibility criteria described in section III.C.2.c.(3). of this proposed rule. However, MIPS eligible clinicians participating in this model would be exempt from MIPS reporting requirements for any ASM performance year that they are included in ASM.

b. Background

Health care is becoming more fragmented as Medicare beneficiaries are increasingly seeing a greater number of specialists on a more regular basis. At the same time, the volume of primary care visits has remained relatively constant.[119] [120] Primary care teams must now coordinate with more specialists than ever before,[121] despite persistent barriers to specialist access for certain patients.[122] [123] We believe there are opportunities to improve coordination between specialists and primary care providers (PCPs) and increase beneficiary engagement in care decisions, particularly with respect to preventing the onset and progression of disease.

Although the Innovation Center has tested models that address the integration of primary and specialty care for chronic conditions that may benefit from greater collaboration and create opportunities for preventive care, these models have been largely focused on behaviors and practice patterns in primary care.[124] This proposed model test elects to focus on the behaviors and practice patterns in specialty care for those treating chronic conditions and would be the first Innovation Center

[118] Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Medicare Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments.

[119] Barnett ML, Bitton A, Souza J, Landon BE. Trends in Outpatient Care for Medicare Beneficiaries and Implications for Primary Care, 2000 to 2019 [published correction appears in Ann Intern Med. 2022 Oct;175(10):1492]. Ann Intern Med. 2021;174(12):1658–1665. doi:10.7326/M21–1523.

[120] Lori Timmins, PhD, Carol Urato, MA, Lisa M. Kern, MD, MPH, Arkadipta Ghosh, PhD, Eugene Rich, MD. Primary Care Redesign and Care Fragmentation Among Medicare Beneficiaries. The American Journal of Managed Care, March 2022, Volume 28, Issue 3.

[121] The CMS Innovation Center's strategy to support person-centered, value-based specialty care. 2022. Retrieved from *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.*

[122] McConnell KJ, Charlesworth CJ, Zhu JM, Meath THA, George RM, Davis MM, Saha S, Kim H. Access to Primary, Mental Health, and Specialty Care: A Comparison of Medicaid and Commercially Insured Populations in Oregon. J Gen Intern Med. 2020 Jan;35(1):247–254. doi: 10.1007/s11606–019–05439–z. Epub 2019 Oct 28. PMID: 31659659; PMCID: PMC6957609.

[123] Romaire MA, Haber SG, Wensky SG, McCall N. Primary care and specialty providers: an assessment of continuity of care, utilization, and expenditures. *Med Care.* 2014;52(12):1042–1049. doi:10.1097/MLR.0000000000000246.

[124] See the evaluation reports of the Comprehensive Primary Care Plus (CPC+) model, which ran from 2017 to 2021, *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.* See also the evaluation reports of the Primary Care First (PCF) model, which began in 2021 and will end December 31, 2025, *https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options.*

model to use the MVP framework as the foundation for a model test.

We believe the MVP framework has many benefits. First, the MVP framework advances value-based care by narrowing the available measure set based upon clinician specialty, medical condition, or patient population, which allows for meaningful comparisons to be made across providers and relevant feedback to be available to participants on their performance, strengthening the foundation for accountability in specialty care. The MVPs utilize a cohesive set of measures and activities focused on performance in rendering care for a particular specialty or clinical condition. Second, we believe that meaningful comparisons of performance combined with a payment methodology that includes more significant Medicare Part B payment adjustments, would encourage meaningful specialty care engagement with primary care clinicians to both prevent and manage the onset of chronic conditions. Third, we intend to test ASM's more targeted approach to performance assessment, as described in the introduction section of this proposed rule, so it may provide a foundation to potentially expand this approach to other specialist cohorts treating other chronic conditions. While there are 21 MVPs for the CY 2025 performance period/2027 MIPS payment year spanning numerous specialties, CMS has a goal of creating additional MVPs relevant to the practices of 80 percent of MIPS eligible clinicians. The MVP reporting option, with its focused set of measures and activities aligned around specific specialties or conditions, provides a framework for applying ASM's targeted approach to other specialist cohorts treating other chronic conditions. Using an existing framework that is agnostic to specialty type, as opposed to creating multiple unique models that are each narrowly defined by a condition or specialty, would allow the Innovation Center to take a more inclusive and unified approach to increasing specialist engagement in value-based payment.

Using MVPs as a framework to test a chronic condition model, ASM would increase the number of specialists in value-based care arrangements and hold them accountable for ensuring beneficiaries have a regular source of primary care. Through required improvement activities and measures, the model would also encourage specialty care providers to actively engage with both beneficiaries and PCPs to improve care transitions and make certain their patients are receiving preventive care, such as screening for obesity and depression. When primary and specialty care providers collaborate across care settings, together they can deliver accountable care that best meets patients' needs and preferences.

2. Provisions of Proposed Ambulatory Specialty Model

a. Definitions

We propose at 42 CFR 512.705 to define certain terms for ASM. We describe these proposed definitions in context throughout section III.C.2 of this proposed rule. We propose to codify the definitions and policies of ASM at 42 CFR part 512 subpart G (proposed § 512.705 through § 512.780). In addition, we propose that the definitions contained in the standard provisions for mandatory Innovation Center models at subpart A of part 512 would also apply to ASM, unless expressly stated otherwise in the proposed policies set forth at § 512.705 through § 512.780. We seek comments on these proposed definitions for ASM.

b. Proposed Length of Model Test

We propose at § 512.705 to define the ''ASM test period'' as the 7-year period from January 1, 2027, to December 31, 2033, that includes all ASM performance years and ASM payment years as described in Table 36. We propose at § 512.705 to define ''ASM performance year'' as a 12-month period beginning on January 1 and ending on December 31 of each year during the first 5 calendar years of ASM test period. We propose at § 512.705 to define an ''ASM payment year'' as a calendar year in which CMS applies the ASM payment multiplier to Medicare Part B payments based on the final score achieved by that ASM participant for the ASM performance year 2 years prior.

Like MIPS, we propose that an ASM payment year occurs 2 calendar years following the ASM performance year that determines the ASM participant's final score that then determines their payment adjustment factor applied in that ASM payment year. For instance, the CY 2027 ASM performance year would correspond to the CY 2029 ASM payment year to allow time for ASM participants to submit required data for each of the ASM performance categories as described in section III.C.2.d of this proposed rule and for CMS to score submitted data for the ASM performance categories, calculate final scores, and determine payment adjustments as discussed in sections III.C.2.d., III.C.2.e, and III.C.2.f of proposed rule. Final data submission of measures and activities would be in CY 2032, with final model payment adjustments in CY 2033. This timeline aligns with MIPS in that those who report traditional MIPS or MVPs receive an adjustment to their Medicare Part B fee-for-service payments 2 years after the corresponding MIPS performance period based on a total score calculated from reported measures and activities across the MIPS performance categories (see §§ 414.1305, 414.1320, 414.1365, and 414.1405(e)). We believe 5 ASM performance years followed by 5 ASM payment years would allow sufficient time for ASM participants to invest in care delivery transformation and for CMS to evaluate the impact of the model's payment adjustments.

TABLE 36: ASM PERFORMANCE YEARS AND ASM PAYMENT YEARS

Calendar Year	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031	CY 2032	CY 2033
ASM Performance Year (PY)	X	X	X	X	X		
ASM Participant Data Submission		Report for PY 2027	Report for PY 2028	Report for PY 2029	Report for PY 2030	Report for PY 2031	
Final Score & ASM Payment Adjustment Factor Calculation		Released for PY 2027	Released for PY 2028	Released for PY 2029	Released for PY 2030	Released for PY 2031	
ASM Payment Years			Payment adjusted for PY 2027	Payment adjusted for PY 2028	Payment adjusted for PY 2029	Payment adjusted for PY 2030	Payment adjusted for PY 2031

We propose an ASM start date of January 1, 2027. We alternatively considered proposing an ASM start date as January 1, 2026, but given the rulemaking process, an earlier start date would not have given ASM participants enough time to prepare for participation in ASM.

We believe that the ASM test period of 7 years, as opposed to a shorter duration, is necessary to obtain sufficient data to compute a reliable impact estimate and to analyze the data from the Model to determine the next steps regarding potential expansion or extension of the Model. Further, we believe that a test period of 7 years is necessary to address and mitigate any potential implementation issues or unintended consequences. For a discussion of the proposed evaluation approach, please see section III.C.2.l of this proposed rule.

We invite public comments on the proposed ASM test period of 7 years. We also seek comment on the proposed ASM start date of January 1, 2027.

c. Proposed ASM Participants

(1) Proposed Mandatory Participation

We believe that requiring clinicians to participate in the model test is necessary to eliminate selection bias, yield generalizable results, and ensure an evaluable comparison group. Voluntary participation in Innovation Center models has demonstrated that those electing to voluntarily participate are more likely to have the infrastructure and experience to succeed under the model. Moreover, in a voluntary model, when the opportunity for financial gain is reduced or uncertain, participant attrition increases. We believe requiring participation in ASM would prevent this type of selection bias.

Mandatory participation in ASM would also ensure a sufficient volume of participants to produce a necessarily diverse, representative evaluation of clinicians providing specialty care to Medicare beneficiaries with heart failure or low back pain. We believe ASM could highlight inefficient care utilization patterns and potentially inform quality improvement and care coordination incentives for application in the Quality Payment Program, the MVP reporting option, and future Innovation Center models. Finally, mandatory participation would generate a statistically robust test of ASM with results that are reliable, generalizable, and able to support potential model expansion. Therefore, we propose at § 512.710(a)(1) that participation in ASM would be mandatory for all clinicians who meet the ASM participant eligibility criteria at § 512.710(b).

Specifically—

- 2027 ASM performance year: ASM participants would be measured for performance and exempted from MIPS participation, if applicable, during CY 2027; report and be scored during CY 2028; and receive payment adjustments for CY 2027 performance in CY 2029;
- 2028 performance year: ASM participants meeting ASM participant eligibility criteria for the 2028 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2028; report and be scored during CY 2029; and receive payment adjustments for CY 2028 performance in CY 2030;
- 2029 ASM performance year: ASM participants meeting ASM participant eligibility criteria for the 2029 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2029; report and be scored during CY 2030; and receive payment adjustments for CY 2029 performance in CY 2031;
- 2030 ASM performance year: ASM participants meeting ASM participant eligibility criteria for the 2030 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2030; report and be scored during CY 2031; and receive payment adjustments for CY 2030 performance in CY 2032; and
- 2031 ASM performance year: ASM participants meeting ASM participant eligibility criteria for the 2031 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2031; report and be scored during CY 2032; and receive payment adjustments for CY 2031 performance in CY 2033.

We propose at § 512.710(a)(1) that once a clinician meets the ASM participant eligibility criteria, they would be considered an ASM participant for the duration of the model. We propose at § 512.710(a)(2) that clinicians would be exempt from MIPS reporting for any ASM performance year that they meet ASM participant eligibility criteria and, therefore, must meet ASM model requirements. However, for any model year that a previously selected ASM participant does not continue to meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year, the ASM participant would not be required to submit data in accordance with § 512.720, as proposed, would not be scored in accordance with § 512.745, as proposed, and would not receive an ASM payment adjustment in accordance with § 512.750. In addition, because the proposed Medicare waiver at § 512.775 only waives the requirements of section 1848(q) of the Act, and its implementing

regulations for an ASM performance year that ASM participants meets the ASM participant eligibility criteria, the ASM participant would be required to satisfy any MIPS reporting obligations and would receive a MIPS payment adjustment two years later, in accordance with current regulations, for any performance year that they do not meet the ASM participant eligibility criteria. Because ASM participants would potentially be subject to MIPS for any ASM performance year that they do not meet the ASM participant eligibility criteria, ASM payment adjustments may be applied during an ASM payment year during which an ASM participant is not actively participating in ASM and is instead participating in MIPS.

We invite public comments on our proposal at § 512.710(a) to require mandatory participation in ASM, exempt ASM participants from reporting under MIPS for only those years that they meet ASM participant eligibility criteria.

(2) Proposed ASM Participants

We propose that certain clinicians who treat heart failure and low back pain would be required to participate in ASM. We propose at § 512.705 to define the term ''ASM participant'' to mean an individual clinician who, for at least one ASM performance year, satisfies the ASM participant eligibility criteria described in section III.C.2.c.(3). of this proposed rule and has been selected for participation in the model as described in section III.C.2.c.(5). of this proposed rule. For ASM specifically, we propose at § 512.705 to define ''clinician'' as any ''eligible professional'' defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination. We propose at § 512.705 to define ''ASM heart failure participant'' as an ASM participant who meets the ASM participant eligibility criteria related to heart failure and ''ASM low back pain participant'' as an ASM participant who meets the ASM participant eligibility criteria related to low back pain (discussed later in this section of this proposed rule). We note that the definition of ''model participant'' contained in § 512.110 should be interpreted to include each ASM participant.

We propose to define an ''ASM targeted chronic condition'' at § 512.705 as a medical condition that is a core focus of ASM; that is, heart failure or low back pain. We propose to define an ''ASM cohort'' as a group of ASM participants who treat the same ASM targeted chronic condition; specifically, we propose an ASM heart failure cohort and an ASM back pain cohort for this model. We propose to define the ''ASM heart failure cohort'' to be composed of all ASM heart failure participants and the ''ASM low back pain cohort'' to be composed of all ASM low back pain participants. We note that the proposed ASM cohorts would not include nonphysician practitioners (NPP) because NPPs would not meet the ASM participant eligibility criteria as proposed at § 512.710(b), which states that only clinicians assigned one of the specialty codes at § 512.710(d) may be ASM participants. Medicare does not currently assign specialty codes to NPPs; therefore, NPPs would not satisfy this criterion.

We also considered defining an ASM participant as a group of clinicians within a single practice, provided each clinician individually meets the proposed ASM participant eligibility criteria. However, the inclusion of a group of specialists would result in fewer ASM participants overall and would add complexity to comparing performance across the ASM performance categories and determining final scores. We also believe that a group-based approach to ASM participation may not reflect the variable arrangements of care teams, as clinicians may also work outside the group, across multiple service locations and teams. Under this alternative group-level scenario, we would need to provide the ASM participant with a list of clinicians who individually meet the ASM participant eligibility criteria for an applicable ASM performance year. In this case, each eligible clinician on an ASM participant's clinician list would be considered a downstream participant in ASM, and the ASM participant would be required to contractually bind all downstream participants to comply with all laws pertaining to any patient-identifiable data requested from CMS and the terms of any agreement with CMS, as a condition of receiving and maintaining data from the ASM participant.

We also considered whether the ASM participant under this alternative participant identification approach would be permitted to add or remove clinicians during an ASM performance year. We believe the addition of model policies and processes to account for individual clinician changes would increase operational complexity and the administrative burden of ASM participants if defined under this alternative group-based definition.

We seek comments on our proposed definitions at § 512.705. We also seek comments on adopting an alternative group participation policy and, if so, whether groups should be allowed to add or remove clinicians during a performance year.

(a) ASM Heart Failure Cohort

We propose at § 512.710(d)(1) for the ASM heart failure cohort to only select clinicians who have been assigned a specialty code of cardiology on the plurality of their Medicare Part B claims, provided they meet all applicable ASM participant eligibility criteria under § 512.710(b) for an ASM performance year. We understand that other clinicians may treat heart failure. However, only cardiologists would be required to participate in the model. Cardiologists commonly provide care to Medicare beneficiaries with heart failure and are well-positioned to improve outcomes by ensuring patients are optimized on guideline-directed medical therapy. We believe ASM would incentivize cardiologists to work with a primary care team to engage beneficiaries in addressing the root cause of their illness through lifestyle changes and preventing acute episodes.

In addition to the cardiology specialty code, we considered including clinicians identified by additional cardiac specialty codes, as Medicare uses distinct specialty codes for cardiac electrophysiology, intensive cardiac rehabilitation, cardiac surgery, interventional cardiology, and advanced heart failure and transplant cardiology. Depending on the etiology of heart failure, some beneficiaries may receive care from interventional cardiologists and cardiac electrophysiologists. However, as proceduralists, these specialists do not commonly participate in the longitudinal management of beneficiaries with heart failure and have limited ongoing interactions with primary care.[125] We also considered including cardiologists who specialize in adult congenital heart disease and advanced heart failure and transplant cardiology because these subspecialists often take over as primary managers of care. However, they do not generally co-manage patients or share responsibilities with primary care. Furthermore, they treat a particularly complex patient population, which makes comparing their performance to other cardiologists difficult. For these reasons, we do not propose to include clinicians with specialty codes other than cardiology as ASM participants.

We seek comment on our proposal at § 512.710(d)(1) to only include in the ASM heart failure cohort clinicians with

[125] Sokos G, Kido K, Panjrath G, et al. Multidisciplinary Care in Heart Failure Services. *J Card Fail.* 2023;29(6):943–958. doi:10.1016/j.cardfail.2023.02.011.

a cardiology specialty code on the plurality of their Medicare Part B claims. We also seek comments on including subspecialist cardiology codes in the ASM heart failure cohort.

(b) ASM Low Back Pain Cohort

We identified several nonsurgical and surgical specialties that commonly manage, treat, and maintain long-term relationships with patients with low back pain in the ambulatory setting. Both nonsurgical and surgical specialists offer meaningful, conservative (that is, less invasive) treatment options.[126] However, some low back pain treatments, including spinal fusion for the treatment of non-complex low back pain, contribute to low-value care.[127] For this reason, we believe including the specialists who most commonly perform these procedures is prudent for this model.

While surgical specialists are proceduralists, they are also commonly involved in the longitudinal management of Medicare beneficiaries with low back pain. Nevertheless, to ensure ASM would meet its goal of comparing like participants, we examined whether it would be appropriate to include nonsurgical and surgical specialists in the same ASM cohort.

We stratified 2023 EBCM data by beneficiaries who underwent surgery on their spine and who had complex low back pain and found that, across all specialty types, more than 80 percent of beneficiaries with episodes for low back pain did not undergo spine surgery (83.8 percent for neurosurgery; 90.8 percent for orthopedic surgery), as demonstrated in Table 37.

TABLE 37: Volume distribution of low back pain episodes by specialty types in CY2023

Surgical Status	Complex Low Back Pain	Anesthesiology	Interventional Pain Management	Neurosurgery	Pain Management	Physical Medicine & Rehabilitation	Orthopedic Surgery
No spine surgery	Yes	68.6%	67.4%	60.0%	67.1%	58.7%	46.9%
No spine surgery	No	27.8%	29.0%	23.8%	29.4%	38.1%	43.9%
Spine surgery	Yes	3.1%	3.1%	13.3%	2.9%	2.5%	6.5%
Spine surgery	No	0.5%	0.6%	3.0%	0.6%	0.8%	2.7%

Because orthopedic surgeons and neurosurgeons primarily treat low back pain non-surgically, we believe it is acceptable to include both surgical and nonsurgical specialists in the ASM low back pain cohort. Moreover, the EBCM episode volume eligibility criteria as described in section III.C.2.c.(3)(b) of this proposed rule would screen out specialists who are not treating low back pain longitudinally in the outpatient setting.

We propose at § 512.710(d)(2), for the ASM low back pain cohort, to select clinicians with a specialty type of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, and physical medicine and rehabilitation, provided they meet all applicable ASM participant eligibility criteria for an ASM performance year. We note that there may be some overlap between pain management, interventional pain management, and anesthesiology. However, we propose to include all three specialty designations to ensure we include anesthesiologists that have not yet updated their subspecialty with Medicare and those anesthesiologists treating low back pain without pursuing fellowship training.

Although other clinicians do treat low back pain, we propose that only those listed would be required to participate in ASM. We considered other specialties who could trigger higher volumes of low back pain episodes. For example, chiropractors and physical therapists work closely with both primary care and specialists to treat low back pain, often providing first-line therapy. However, we believe the selected specialties are better positioned to direct and be held accountable for the longitudinal management of low back pain that may employ a variety of modalities.

We seek public comments on our proposal at § 512.710(d)(2) to only include in the ASM low back pain cohort clinicians with a specialty code of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, or physical medicine and rehabilitation on the plurality of their Medicare Part B claims. We seek comments on alternative low back pain-related specialty types that we considered including the ASM low back pain cohort.

(3) ASM Participant Eligibility Criteria

In selecting participants for ASM, we seek to ensure (1) we include a sufficient volume of clinicians treating Medicare beneficiaries for the same clinical condition in the ambulatory setting; (2) there is a reasonable expectation that participants can be measured under the model and held accountable for the care provided to Medicare beneficiaries with heart failure and low back pain; (3) the selected clinicians have the operational capacity to meet the ASM performance requirements described in section III.C.2.d of this proposed rule; and (4) the model test results would be statistically valid, reliable, and generalizable to specialty types included in ASM nationwide should the model test be successful and considered for expansion under section 1115A(c) of the Act.

Therefore, we propose at § 512.705 to define ''ASM participant eligibility criteria'' as the set of criteria defined at § 512.710(b) that CMS uses to determine whether a clinician is selected to participate in ASM. We propose at § 512.710(b) that clinicians who meet all of the following ASM participant eligibility criteria would be required to participate in ASM:

- Is a clinician who bills claims under the Medicare Physician Fee Schedule.
- Is identified by TIN/NPI as a selected specialty type.
- Meets the EBCM episode volume threshold applicable to an ASM targeted chronic condition.
- Is located in one of the selected mandatory geographic areas.

[126] Steinmetz A. Back pain treatment: a new perspective. Ther Adv Musculoskelet Dis. 2022 Jul 4;14:1759720X221100293. doi: 10.1177/1759720X221100293. PMID: 35814351; PMCID: PMC9260567.

[127] Buchbinder R, Underwood M, Hartvigsen J, Maher CG. The Lancet Series call to action to reduce low value care for low back pain: an update. Pain. 2020 Sep;161 Suppl 1(1):S57–S64. doi: 10.1097/j.pain.0000000000001869. PMID: 33090740; PMCID: PMC7434211.

At § 512.705, we propose to define ''mandatory geographic area'' to mean a core-based statistical area (CBSA) or metropolitan division as defined by the Office of Management and Budget (OMB) and selected by CMS under the terms of § 512.710(f). We note that the proposed mandatory geographic areas may include rural areas as defined by MIPS at § 414.1305, which is a ZIP code designated as rural by the Health Resources and Services Administration's Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

We note that, as is the case in MIPS, clinicians practicing in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) who provide services that are billed exclusively under the RHC or FQHC payment methodologies would not be selected to participate in ASM. This is because FQHCs and RHCs receive All-Inclusive Rate (AIR) or Prospective Payment System (PPS) payments and do not submit claims under the Medicare Physician Fee Schedule. However, if these clinicians, separately, provide and bill for services under the Physician Fee Schedule, they would be required to participate in ASM provided they meet the ASM eligibility requirements. Clinicians who provide services at Critical Access Hospitals (CAHs) that are paid under Method I would be required to participate if they meet the ASM eligibility requirements, given that such services are paid under the Medicare PFS. Clinicians who provide services at CAHs that are paid under Method II, and meet all ASM eligibility requirements, would only be required to participate in ASM if they have not reassigned their billing rights to the Method II CAH; that is, if the clinician continues to submit professional claims through the PFS. This is because when a clinician reassigns their billing rights to a Method II CAH, the CAH bills those services through institutional claims. Under MIPS, we use both professional and institutional claims to trigger EBCMs and include clinicians who have reassigned their billing rights to a Method II CAH. However, in contrast to MIPS, ASM, as proposed, would only use professional claims to trigger EBCMs, and, therefore, would not include clinicians who have reassigned their billing rights to a Method II CAH.

We seek comments on the proposed ASM participant eligibility criteria at § 512.710(b).

(a) ASM Participant and Specialty Type Identification

As discussed in section III.C.2.c.(2) of this proposed rule, we propose at § 512.710(d) that only a certain subset of clinicians who treat heart failure and low back pain would be required to participate in this model. To identify ASM participants, we propose to adopt the Quality Payment Program policies for identifying clinicians and clinical specialty.

(i) ASM Participant Identification

Medicare claims are processed using TINs, which may represent an individual clinician or may represent a hospital or group practice. Because we propose that ASM would evaluate performance at an individual clinician level, TIN alone would not be useful for ASM. Individual providers are, however, identifiable by their unique NPI. When TIN and NPI are used together, CMS is able to identify and evaluate individual providers. NPI-level participation also aligns with the Innovation Center's goal of creating a level playing field for all clinicians and removing unequal benefits afforded to consolidated group practices and health systems.

The Quality Payment Program identifies MIPS eligible clinicians for the individual participation option, defined at § 414.1305, by a combination of TIN and NPI, (hereafter TIN/NPI). We believe this method is also the best method of identifying clinicians in ASM.

Using TIN/NPI for identifying ASM participants would offer several advantages. First, direct comparison of specialist performance between similar clinicians is a central feature of ASM. Participation at the TIN/NPI level puts the specialist as the unit of comparison, allowing for more meaningful assessment among peers. This level of participation would also produce more granular performance analysis and useful feedback for clinicians. Second, we also propose to use TIN/NPI to determine whether clinicians meet the other ASM participant eligibility criteria. Specifically, TIN/NPI would be used to ensure that each ASM participant has met the episode volume criteria for the EBCMs and for assigning clinicians to mandatory geographic areas described later in this section of this proposed rule. This approach would maintain consistency between participant identification and performance assessment within ASM and mirrors the methodology used in the Quality Payment Program. Finally, identifying ASM participants at the TIN/NPI level would enable us to identify claims for a single provider who works at more than one location or organization and, therefore, bills under multiple TINs.

We recognize that an individual clinician may assign their billing rights to multiple TINs (that is, practice across multiple TINs). Such an arrangement would have implications on how we identify ASM participants. For example, if a clinician's NPI is associated with two TINs and meets the ASM participant eligibility criteria for both TINs, then we would consider each TIN/NPI combination to be a separate ASM participant that must separately meet model requirements and report required data. Accordingly, we would separately assess performance and determine payment adjustments for each unique TIN/NPI combination, as described in sections III.C.2.d.(1).(b) and III.C.2.f. of this proposed rule. If an NPI is associated with two TINs but only meets the ASM participant eligibility criteria for one TIN/NPI combination, the clinician would only be considered an ASM participant under that one TIN/NPI combination.

We also considered selecting a single TIN/NPI combination to be the ASM participant in the case that a clinician meets ASM eligibility requirements under more than one TIN/NPI combination. Under that scenario, we would have selected the TIN/NPI combination with the majority of EBCM-triggered episodes for a given ASM cohort (see section III.C.2.c.(3).(b) for further discussion on EBCM as part of the ASM participant eligibility criteria). However, this alternative could adversely affect participant volume and exclude appropriate beneficiary episodes.

We believe that identifying ASM participants at the TIN/NPI level drives direct accountability so that outcomes are clearly attributed to ASM participants. Identifying ASM participants at the TIN/NPI level would allow for a like-to-like performance assessment of clinicians who meet ASM participant eligibility criteria. We believe this performance comparison approach would provide granular and actionable insights into best practices and specialty care delivery.

Therefore, we propose to identify clinicians for ASM by the same method used by the Quality Payment Program. Specifically, we propose to use TIN/NPI to identify clinicians as ASM participants.

We seek public comment on our proposal at § 512.710(b)(2) that ASM participants would be identified at the TIN/NPI level. We also seek comments

on the alternative method of using TIN-level specialty type for identifying ASM participants, as well as selecting a single TIN/NPI combination as an ASM participant in the case that a clinician meets ASM eligibility requirements under more than one TIN/NPI combination.

(ii) Participant Exclusion due to Change in TIN During an ASM Performance Year

We recognize that ASM participants may change practices (as reflected by a change in TIN) during an ASM performance year. In such circumstances, we would need to determine whether the ASM participant must continue to meet model requirements for the original TIN, for the new TIN, or would no longer be required to meet model requirements under either TIN for that ASM performance year. We propose at § 512.710(c)(1) that an ASM participant who, during an applicable ASM performance year, no longer assigns their billing rights to the TIN CMS used to identify them as an ASM participant must notify CMS of such change within 30 days of the change in a form and manner determined by CMS. We propose at § 512.710(c)(2) that an ASM participant who notifies CMS of a change in TIN during an ASM performance year would no longer be required to meet ASM requirements, including data submission requirements described at § 512.720, for the applicable ASM performance year and would instead be subject to MIPS reporting obligations, if applicable. We also propose that the waivers, including the MIPS waiver, established at § 512.775 would no longer apply beginning on the date we determine the clinician is no longer required to meet model requirements for the applicable ASM performance year. If the ASM participant fails to notify CMS within 30 days of no longer assigning billing rights to the original TIN in the form and manner determined by CMS, then the ASM participant would be required to meet the data submission requirements described at § 512.720 for the applicable ASM performance year.

Given our proposal to determine whether clinicians meet ASM participant eligibility criteria for each ASM performance year, we believe that we would naturally identify the movement of individual clinicians to a different TIN between ASM performance years. However, if an ASM participant reassigns their billing rights to a new TIN during an ASM performance year, CMS would not have sufficient data for the new TIN/NPI combination to determine if the ASM participant continues to meet all ASM participant eligibility criteria. For example, we would not have timely EBCM data available for the new TIN/NPI combination to determine if the ASM participant meets the 20 EBCM episode volume criterion (discussed in section III.C.2.c.(3).(b) of this proposed rule) under the new TIN. Without complete data to evaluate whether the ASM participant continues to meet the ASM participant eligibility criteria, we propose, for that ASM performance year, the ASM participant would not be required to submit data in accordance with § 512.720, as proposed, would not be scored in accordance with § 512.745, as proposed, and would not receive an ASM payment adjustment in accordance with § 512.750. Because the proposed Medicare waiver at § 512.775 only waives the requirements of section 1848(q) of the Act, and its implementing regulations for an ASM performance year that ASM participants meets the ASM participant eligibility criteria, the ASM participant would be required to satisfy any MIPS reporting obligations and would receive a MIPS payment adjustment two years later, in accordance with current regulations.

We intend to monitor TIN changes in each ASM cohort within each ASM performance year and across the ASM model test period. If CMS determines that changes to this policy are warranted for future ASM performance years, we would propose those changes through notice and comment rulemaking.

We considered requiring an ASM participant who reassigns their billing rights to a new TIN during an ASM performance year to continue to meet all model requirements for the applicable ASM performance year under the new TIN/NPI combination. As ASM focuses on specialty care related to specific chronic conditions, we considered that the ASM participant would likely continue to furnish services related to ASM targeted chronic conditions under the same specialty type and trigger applicable EBCM episodes during the remainder of the applicable ASM performance year. As discussed in sections III.C.2.d.(3) and III.C.2.e.(2).(b) of this proposed rule, in the case that an ASM participant under a new TIN/NPI combination does not trigger at least 20 episodes during the remainder of the applicable ASM performance year, the ASM participant would not receive a final score. Accordingly, they would receive no payment adjustments in the corresponding ASM payment year as described at § 512.750(d). However, if an ASM participant under a new TIN were to: (1) receive quality and cost ASM performance category scores discussed in sections III.C.2.d.(2).(i) and III.C.2.d.(3).(g) of this proposed rule, and (2) meet the requirements to receive a final score as discussed in section III.C.2.e.(2) of this proposed rule, then we believe it would be appropriate to determine an ASM payment adjustment factor and ASM payment multiplier for the ASM participant under the new TIN/NPI combination. We ultimately decided to not propose this policy because we believe that conforming to the policy set forth in section III.C.2.c.(1), which requires an ASM participant to satisfy any MIPS reporting obligations when they no longer meet ASM participant eligibility criteria, would avoid adding unnecessary complexity to the model.

We also considered not requiring an ASM participant to notify CMS if the change in TIN occurs during an ASM performance year and continuing to require the ASM participant to meet all model requirements under the original TIN/NPI combination for the applicable ASM performance year. However, we believe that it would be challenging for the ASM participant to access the necessary data to meet the data submission requirements if no longer affiliated with the original TIN. Therefore, we do not believe it would be appropriate to hold an ASM participant in this situation accountable for ASM requirements under the original TIN.

We seek comments on our proposal at § 512.710(c) to exclude ASM participants who change TIN during an applicable ASM performance year from ASM reporting requirements for that year of the model. We also seek comments on the alternatives of requiring the ASM participant to meet model requirements under their new TIN, as well as the alternative of requiring the ASM participant to meet model requirements and data submission requirements under the original TIN/NPI combination that identified them as an ASM participant.

(iii) ASM Specialty Identification

To ensure that all clinicians meeting the specialty requirements described at § 512.710(d) are included in the model, we propose to define ''specialty type'' based on the specialty code indicated on the plurality of a clinician's Medicare Part B claims during the period described in section III.C.2.c.(5) of this proposed rule. Specifically, we plan to use the same specialty codes used for the Quality Payment Program to identify

MIPS eligible clinicians as defined at § 414.1305.[128]

The specialty codes used on Medicare Part B claims are not reported by clinicians but are assigned to claims by the Medicare Administrative Contractors (MACs) and derived from the clinician-reported specialty designations that are entered in the Provider Enrollment, Chain, and Ownership System (PECOS) as part of the Medicare provider enrollment application. Because a clinician's specialty code could change during an ASM performance year, we propose to use the specialty code assigned to the majority of a clinician's Medicare Part B claims for determining specialty type for ASM.

We also considered using PECOS specialty designation alone for the purpose of determining specialty type for ASM. However, the PECOS specialty codes are self-reported, and a single clinician may list more than one primary specialty, which may make it unreliable as a single source for identifying a clinician's primary specialty. We stated in the CY 2023 PFS final rule that given the strong alignment between PECOS data and claims data and our historical use of claims data to identify a clinician's specialty, we believe that Medicare Part B claims data would be the best data source to use to identify a clinician's specialty (87 FR 70039).[129] Moreover, given that the Quality Payment Program uses Medicare claims data, we do not want to create inconsistencies between specialty types for ASM and MIPS. We also considered using the Health Care Provider Taxonomy Codes, which categorize the type, classification, and/or specialization of health care providers. These codes offer more specificity than PECOS (87 FR 70039) and are used when applying for an NPI from the National Plan and Provider Enumeration System (NPPES). However, they are not verified for accuracy.[130] We have previously elected not to use the Health Care Provider Taxonomy Codes for MIPS because of uncertainty regarding the reliability of NPPES as a data source for MIPS eligibility determinations (87 FR 70039). We analyzed the congruence between specialty designations made for the purposes of MIPS and those reported in NPPES for the proposed specialty types for each of ASM's targeted chronic conditions. Our analysis found a high degree of congruence between the two specialty type codes, likely because we provide a crosswalk of the Health Care Provider Taxonomy Codes and Medicare Specialty Codes that can be used by a clinician when they enroll in Medicare through PECOS.[131] Given the alignment between these coding systems, we believe that remaining consistent with the specialty type determination methodology used by the Quality Payment Program is important for potential scalability of ASM.

We seek comments on our proposal at § 512.710(d) to identify specialty type based on the specialty code indicated on the plurality of a clinician's Medicare Part B claims. We also seek comments on using PECOS specialty codes alone and Health Care Provider Taxonomy Codes for the purpose of determining specialty type for ASM.

(b) Episode-Based Cost Measure (EBCM) Episode Volume

We believe that ASM participant eligibility criteria must appropriately identify clinicians who furnish a sufficient volume of services related to ASM targeted chronic conditions and who can be appropriately evaluated on costs related to the ASM targeted chronic conditions. We propose to identify ASM participants using the volume of services related to heart failure and low back pain furnished by clinicians who have a specialty designation that corresponds with the proposed specialty types discussed in III.C.2.c.(2). of this proposed rule. Only clinicians with the proposed specialty types that furnish a volume of services above a specific threshold related to the applicable ASM targeted chronic condition would be identified as ASM participants. That is, not all clinicians with the proposed specialty types related to heart failure and low back pain would be required to participate in ASM.

We propose to use MIPS EBCMs to determine volume, rather than assessing volume based on claims for individual services. Specifically, the volume of attributed episodes from EBCMs related to the ASM targeted chronic conditions would serve as the data source by which we evaluate the volume of furnished episodes for ASM. We propose at § 512.710(e)(1) to identify ASM heart failure participants using the volume of episodes attributed to a TIN/NPI in accordance with the heart failure EBCM as specified under MIPS. We propose at § 512.710(e)(2) to identify ASM low back pain participants using the volume of episodes attributed to a TIN/NPI in accordance with the low back pain EBCM as specified under MIPS. We refer readers to section III.C.2.c.(5). of this proposed rule on the proposed processes and specific years of data that we would use to assess EBCM volume to identify ASM participants.

EBCMs assess Medicare resource use for a specific condition or procedure based on only those costs that occur as part of an attributed clinician's care management. CMS uses claims data from Medicare Parts A and B, and some Medicare Part D data, if applicable, to construct the EBCMs. An episode is initiated when a clinician submits a professional claim for at least two separate services, provided to a single beneficiary, that are clinically related to the chronic condition being assessed. Although the episode is initiated and attributed to a particular clinician, the episode includes all Medicare Part A and B services for the length of the episode, as defined by the measure specifications (88 FR 79339 through79347). Therefore, regardless of who provides the care, an episode includes all services related to a beneficiary's condition, routine care services, and consequences of care, and excludes services that are clinically unrelated to the targeted condition of the measure.[132]

To attribute episodes to practices and clinicians, CMS first attributes episodes to a TIN when it performs two services indicating care for a particular condition for a single beneficiary within a certain number of days (for example, 180 days); both professional claims must have diagnosis codes for the relevant chronic condition. CMS then attributes episodes to each clinician (NPI) within the group (TIN) that rendered at least 30 percent of the total number of qualifying services during the episode. For the heart failure EBCM, CMS also checks that the clinician prescribed at least two condition-related prescriptions on different days to two different patients during the calendar year used to construct the episode plus a 1-year lookback period to ensure that attributed clinicians are actually involved in providing ongoing chronic care management.[133] The low back pain EBCM does not use this additional check since the types of clinicians that manage low back pain may may not prescribe the relevant medication,

[128] *https://www.federalregister.gov/d/2022-23873/page-70039.*

[129] *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf.*

[130] *https://data.cms.gov/resources/medicare-provider-and-supplier-taxonomy-crosswalk-methodology.*

[131] *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-provider-and-supplier-taxonomy-crosswalk/data.*

[132] *https://www.cms.gov/files/document/wave-4-measure-development-process-macra.pdf.*

[133] *https://www.cms.gov/files/zip/2024-cost-measure-information-forms-zip.zip-0.*

which could prevent certain clinician types from being attributed episodes.[134]

CMS began development and field testing of the heart failure and low back pain measures in 2022.[135] We finalized the inclusion of the heart failure and low back pain measures to the MIPS cost performance category beginning in the 2024 MIPS performance period/2026 MIPS payment year (88 FR 79319). We also finalized the inclusion of the heart failure EBCM in the Advancing Care for Heart Disease MVP (88 FR 80022 through 80025; 89 FR 99015 through 99019) and the low back pain EBCM in the in the Rehabilitative Support for Musculoskeletal Care MVP (88 FR 80002 through 80007; 89 FR 99050 through 990054).

We believe that the construction of the EBCMs and the existing use of these measures within MIPS and MVPs relevant to ASM targeted chronic conditions make the measures an appropriate data source by which to identify ASM participants that furnish enough services and provide longitudinal care management for Medicare beneficiaries diagnosed with ASM targeted chronic conditions.

We believe that an annual threshold of 20 or more attributed episodes from an EBCM is appropriate for identifying ASM participants that can be held accountable for quality and cost related to ASM targeted chronic conditions. We have defined a case minimum of 20 episodes for the purposes of scoring chronic condition EBCMs in MIPS, including MVP reporting, as specified in § 414.1350(c)(6) (88 FR 79346 through 79348). We believe using a similar 20-episode minimum from the calendar year used for determining ASM participant eligibility increases the likelihood that an ASM participant would trigger and be attributed at least 20 episodes within a given ASM performance year. Using a 20-episode threshold would increase the likelihood that they could be scored on the applicable EBCM during the relevant ASM performance year, as described in section III.C.2.d.(3).(g) of this proposed rule.

We also considered using an EBCM episode threshold greater than 20 episodes. For example, we considered the effects of using a 30-episode or 50-episode threshold. In our analysis of calendar year 2023 data, we found that a 30-episode threshold would decrease the number of potentially eligible ASM participants by 43 percent for heart failure and 35 percent for low back pain relative to the 20-episode threshold. We found that a 50-episode threshold would decrease the number of potentially eligible ASM participants by 76 percent for heart failure and by 65 percent for low back pain relative to the 20-episode threshold. We believe that the smaller number of potentially eligible ASM participants under a higher EBCM episode threshold would make for a less reliable model test.

We considered but are not proposing to add the MIPS low volume threshold of Medicare Part B allowed charges for covered professional services, Medicare patients that receive Medicare Part B covered professional services, and the number of Medicare Part B services provided for individual MIPS eligible clinicians as defined at § 414.1305 as part of the ASM participant eligibility criteria. Adding the MIPS low volume threshold would mean that clinicians would have to meet the MIPS eligibility determinations as defined at § 414.1305, as well as all other ASM participant eligibility criteria, to be identified as an ASM participant. We considered using the same low volume threshold for individual MIPS eligible clinicians given the use of the MVP framework for selecting measures for ASM and to identify ASM participants that furnish a sufficient volume of services related to ASM targeted chronic conditions. Given the importance of using EBCM episode volume to identify ASM participants, we found that inclusion of the MIPS low volume threshold in our ASM participant eligibility criteria would add a secondary service volume criterion. We estimate that the inclusion of the MIPS low volume threshold on top of the EBCM episode volume threshold could potentially decrease the number of ASM participants by more than 50 percent. We believe that the use of the EBCM 20-episode threshold would be a more appropriate criterion for identifying ASM.

We seek public comments on our proposals at § 512.710(e) to use the heart failure EBCM as specified under MIPS to identify potential ASM heart failure participants and the low back pain EBCM as specified under MIPS to identify potential ASM low back pain participants. We also seek comments on our proposal that clinicians who have 20 or more heart failure EBCM episodes attributed in accordance with the heart failure EBCM as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year would meet the ASM participation eligibility criterion at § 512.710(b)(3) and clinicians who have 20 or more low back pain EBCM episodes attributed in accordance with the low back pain EBCM under MIPS during the calendar year 2 years prior to the applicable ASM performance year would similarly meet the ASM participation eligibility criterion at § 512.710(b)(3). We also seek comment on specifying a higher episode volume threshold and using the MIPS low volume threshold of Medicare Part B allowed charges for covered professional services for identifying clinicians who provide a sufficient volume of services.

(4) Mandatory Geographic Areas

(a) Identification of Geographic Areas

We propose at § 512.710(f) that only clinicians in certain selected areas would be required to participate in the model. As proposed in § 512.710(f), the proposed unit of selection is CBSAs except in cases where OMB has divided large metropolitan statistical areas (MSAs) into metropolitan divisions. For these MSAs, we propose to use these metropolitan divisions in place of the CBSA. Using metropolitan divisions rather than large MSAs would enable more precise matching of intervention and control groups by using geographic units of more comparable size, which would improve the statistical validity of our evaluation approach.

OMB Bulletin 23–01, issued on July 21, 2023, states that there are 935 CBSAs in the United States and Puerto Rico. OMB delineates MSAs and micropolitan statistical areas, which are referred to collectively as CBSAs. The general concept of the MSA and micropolitan statistical area is that of a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration with that core. MSAs contain at least one urban area of 50,000 or more population; micropolitan statistical areas contain at least one urban area of at least 10,000 and less than 50,000 population.

If specified criteria are met, an MSA containing a single core with a population of 2.5 million or more may be subdivided into metropolitan divisions, which function as distinct areas within the larger metropolitan statistical area. CBSAs are composed of entire counties. There are 393 MSAs, of which 13 are subdivided into 37 metropolitan divisions, and 542 micropolitan statistical areas in the United States and Puerto Rico, as of July 2023.

We also considered using the following geographic areas as the geographic unit from which ASM

[134] *https://www.cms.gov/files/zip/mips-chrcondition-episode-based-cost-measures-attribution-methodology-2023-zip.zip.*

[135] *https://www.cms.gov/files/document/wave-4-measure-development-process-macra.pdf.*

participants are identified: (1) certain ZIP Codes based on their Hospital Referral Regions (HRR); or (2) certain states. We considered selecting based on HRRs for ASM. HRRs represent regional health care markets for tertiary medical care and are defined by determining where most patients were referred for major cardiovascular surgical procedures and for neurosurgery. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. While HRRs may sufficiently reflect referral patterns for heart failure episodes of care, they are less appropriate for low back pain episodes. Therefore, we decided that using CBSAs and metropolitan divisions as a geographic unit is preferable over HRRs for this model.

We also considered selecting states as the geographic unit of selection for ASM. However, we concluded that CBSAs and metropolitan divisions would provide a more granular unit of analysis, allowing for better matching of comparison areas. Additionally, selecting states would greatly reduce the number of independent geographic areas subject to selection under the model, and thus would decrease the statistical power of the model evaluation. Finally, CBSAs and metropolitan divisions straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care.

We propose that we would select the CBSAs and metropolitan divisions through the stratified random sampling methodology described later in this section of this proposed rule to participate in ASM. Although CBSAs are revised periodically, we propose to use the CBSA and metropolitan division designations in OMB Bulletin 23–01 issued on July 21, 2023 as the CBSA designations for purposes of selecting participants for this model, regardless of whether such CBSA designations have changed since July 21, 2023, or would change at some point during the ASM test period. We believe that this approach would best maintain the consistency of the ASM participants in the model, which is crucial for our ability to evaluate the effects of the model test on quality of care and changes in Medicare spending.

As discussed later in this in section III.C.2.c.(4).(e) of this proposed rule, we propose in § 512.710(f)(4) to use the ZIP Codes of the service locations of each clinician as discussed in section III.C.2.c.(4).(e) of this proposed rule to assign each clinician to a single CBSA or metropolitan division. Each clinician that CMS determines falls under the selected CBSA or metropolitan division, and that otherwise meets the other eligibility criteria set forth in § 512.710(b), would be required to participate in the model.

Based on our proposal to randomly select CBSAs and metropolitan divisions as ASM's mandatory geographic areas, III.CZIP Codes and other areas not located in a CBSA or metropolitan division would not be included in the ASM selection methodology as discussed in section III.C.2.c.(4).(b) of this proposed rule. We note that Transforming Episode Accountability Model (TEAM), a mandatory episode-based payment model, uses CBSAs as the geographic unit of selection (as defined in § 512.515). We note that the proposed mandatory geographic areas may include some areas considered as rural areas under MIPS, which defines rural areas at § 414.1305 as a ZIP Code designated as rural by the Health Resources and Services Administration's Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

We seek comments on our proposal to use CBSAs and metropolitan divisions as the geographic unit from which ASM participants are identified. We seek comments on our proposal to use the ZIP Codes of the service locations of each clinician as discussed in section III.C.2.c.(4).(e) of this proposed rule to assign each clinician to a single CBSA or metropolitan division, including ZIP Codes designated as rural by HRSA's FORHP using the most recent FORHP Eligible ZIP Code file available. We seek comment on our proposal to require all eligible clinicians within a CBSA or metropolitan division that the Innovation Center selects through the stratified random sampling methodology as part of the intervention group described in section III.C.2.c.(4).(d) in this proposed rule to participate in ASM. Finally, we seek comments on our proposal to use the CBSA and metropolitan division designations in OMB Bulletin 23–01 issued on July 21, 2023 as the CBSA designations for purposes of selecting participants for this model.

(b) Exclusion of Certain CBSAs and Metropolitan Divisions

We propose at § 512.710(f)(1) that we would not consider certain CBSAs or metropolitan divisions for selection. Specifically, we propose at § 512.710(f)(1)(ii) that we would exclude any CBSA or metropolitan division located entirely in U.S. territories due to challenges we would have in finding suitable geographic areas for comparison. We also propose at § 512.710(f)(1)(i) to exclude any CBSAs or metropolitan divisions that do not have any clinicians of the mandated specialty types with at least 20 eligible episodes between January 1, 2024 and December 31, 2024 in accordance with the EBCM episode threshold described in section III.C.3.c.(3).(b). We believe it is unlikely for these CBSAs or metropolitan divisions to have data available for evaluation after the model starts. After applying these criteria, we expect to have approximately 600 CBSA and metropolitan divisions remain available for selection into ASM.

We considered the alternative of excluding from ASM any CBSA or metropolitan divisions located within a state or portion of a state with a commitment to participate in the Advancing All-Payer Health Equity Approaches and Development (AHEAD) model. The AHEAD model is a state-wide CMS Innovation Center model implemented under section 1115A of the Act that aims to increase investment in primary care, provide financial stability for hospitals, and support beneficiary connections to community resources. We decided not to propose these exclusions because ASM would not interact with the payment methodology in AHEAD and may help align a broader set of clinicians towards the goals of AHEAD. We seek comments on our proposal to exclude from selection any CBSA or metropolitan division located entirely in a U.S. territory and any CBSAs or metropolitan divisions that do not have any clinicians of the mandated specialty types with at least 20 eligible episodes between January 1, 2024 and December 31, 2024. We seek comments on the alternative to exclude AHEAD geographies from ASM's mandatory CBSA or metropolitan divisions.

(c) Geographic Selection Methodology

To determine which CBSAs and metropolitan divisions would be included in the model, we propose to use a stratified random sampling method to select approximately 25 percent of CBSAs and metropolitan divisions into ASM following the process described in the following two sections of this proposed rule. We propose at § 512.710(f)(2) to stratify CBSAs and metropolitan divisions into mutually exclusive groups based on 3 CBSA/metropolitan division-level characteristics: average total Parts A and B episode spending, volume of eligible episodes, and metropolitan division status. We propose at § 512.710(f)(2)(i)

through (vi) stratifying eligible CBSAs into six mutually exclusive groups:

- Eligible CBSAs with ''Low'' average total episode spending (as defined below) and ''Low'' eligible episode volume (as defined below);
- Eligible CBSAs with ''Low'' average total episode spending and ''High'' eligible episode volume (as defined below);
- Eligible CBSAs with ''High'' average total episode spending (as defined below) and ''Low'' eligible episode volume;
- Eligible CBSAs with ''High'' average total episode spending and ''High'' eligible episode volume;
- Eligible CBSAs with ''Very High'' eligible episode volume (as defined below);
- Eligible metropolitan divisions.

(i) Average Total Parts A and B Episode Spending

We propose at § 512.710(f)(2) to measure average total Medicare Parts A and B episode spending using claims data from January 1, 2024 to December 31, 2024. One of the main objectives of ASM is to reduce spending, and therefore, it would be important to account for the significant variation in average episode spending across geographic areas. This stratification would help ensure that we can measure any variation in model effects between high and low spending areas. We propose to use a single, pooled measure including spending for both heart failure and low back pain episodes. This would help limit the number of overall strata and we believe would allow for adequate representation of both high spending low back pain areas and high spending heart failure areas, where the potential for savings may be greatest. We propose to categorize CBSAs into two categories based on average total parts A & B episode spending: below the median (''Low'') and at-or-above the median (''High'').

(ii) Volume of Eligible Episodes

We propose at § 512.710(f)(2) to measure eligible episode volume using claims data from January 1, 2024 to December 31, 2024. We expect significant variation in the volume of eligible episodes across areas. This variation may reflect differences in other characteristics that are related to ASM performance. For example, large, active markets with a larger number of specialists may have structural advantages in performing well in ASM compared to smaller, less active markets. The proposed stratification on volume of eligible episodes would help ensure we select an adequate sample of areas with varying levels of specialty activity so that we would be able to identify statistical differences in outcomes across levels of specialty activity. This stratification would also help ensure that selected CBSAs have sufficient episode volume to support a robust evaluation. We propose to use a single, pooled measure including both heart failure and low back pain episodes. This allows us to limit our number of stratification variables and analysis of 2023 episode-level data found that the episode volumes of the two conditions are highly correlated across CBSAs. We propose to categorize CBSAs into three categories based on total episode volume: below median (''Low''), at-or-above median up to the 95th percentile (''High''), and the 95th percentile and above (''Very High''). We propose to stratify out the top 5 percent of CBSAs by episode volume because of the right-skewed nature of the episode volume distribution.

(iii) Metropolitan Divisions

The largest 13 CBSAs are divided into 37 metropolitan divisions. Metropolitan divisions therefore represent a subdivision level compared to CBSAs. Additionally, these metropolitan divisions, all belonging to CBSAs with a core population of 2.5 million or more, may have important characteristics in common beyond episode volume and average total spending. To ensure adequate representation of metropolitan divisions in the sample, we propose to categorize metropolitan divisions into their own stratum.

We considered stratifying by other characteristics, including ACO penetration, supply of PCPs, region, rurality, and participation in the AHEAD model. We seek comments on our proposed selection strata as well as alternatives considered.

TABLE 38: NUMBER OF ELIGIBLE CBSAs AND METROPOLITAN DIVISIONS BY STRATUM (2023 EBCM DATA)

Stratum Number	Average Total Parts A&B Episode Spending	Volume of Eligible Episodes	CBSA or Metropolitan Division?	Selection Probability	Number of CBSAs or Metropolitan Divisions in Stratum
1	Low	Low	CBSA	40%	160
2	Low	High	CBSA	40%	120
3	High	Low	CBSA	40%	124
4	High	High	CBSA	40%	136
5	-	Very High	CBSA	40%	29
6	-	-	Metropolitan Division	40%	31

(d) Stratified Random Selection of Mandatory Geographic Areas

A representative sample of clinicians that meet eligibility requirements for the proposed ASM is necessary for a robust evaluation of the model. Testing the model in this manner would also allow us to learn more about utilization patterns of health care services and how to incentivize the improvement of quality and care coordination for chronic heart failure and low back pain. This learning could potentially inform the Quality Payment Program and the future of the MVP reporting option. Therefore, we are proposing a broad, representative sample of clinicians in multiple geographic areas. We determined that the best method for obtaining the necessarily diverse, representative group of clinicians would be through stratified, random selection. A stratified, randomly selected sample would allow us to ensure statistical

balance across characteristics of interest (for example, average spending and episode volume) and would provide results that applies generally to similar Medicare clinicians that submit FFS claims and treat heart failure or low back pain and would allow for a more robust evaluation of the model. We also believe that there could be broader learnings from ASM that could apply to other conditions and specialists.

At § 512.710(f)(3), we propose to randomly select CBSAs and metropolitan divisions for ASM from the six stratified groups described above at a 40 percent rate (that is, each CBSA and metropolitan division in each stratum has a 40 percent chance of being selected into the model). If 40 percent of a given stratum does not result in a whole number of CBSAs or metropolitan divisions, CMS would round up to the next whole number to ensure that at least 40 percent of areas from each stratum are selected. Table 38 provides an illustrative example of the six stratified groups based on CY 2023 data. We considered using other selection rates but based on preliminary analyses, we believe these selection rates would produce adequate sample size and participant mix for the model test. We refer readers to the regulatory impact analysis in section VII. of this proposed rule for further discussion on the scale of ASM and its estimated financial impact.

We conducted power analyses to identify detectable changes in total and episode spending between a potential group of CBSAs and metropolitan divisions selected for the model and a potential control group of CBSAs using a Type I error of 0.05 and Type 2 error of 0.2 (implying a power of 0.8). The analysis shows that, if 240 eligible CBSAs are selected for ASM, we would be able to detect about a 3.5 percent change in total episode spending if we look at heart failure and low back pain episodes separately. Allowing a higher Type I error of 0.25 and pooling heart failure and low back pain episodes would allow us to detect about a 1.7 percent change in total episode spending.

This model may be underpowered to detect statistically significant changes in total spending. However, the model may be more likely to generate statistically significant savings among certain low-value services or spending categories that are major cost drivers for heart failure and low back pain (for example, imaging, surgeries, hospital admissions). In a case where the model's impact on total spending is ambiguous, significant savings among these categories of spending may provide strong supporting evidence that Medicare saved money overall.

We seek public comments on our proposed approach to random selection of CBSAs and metropolitan divisions from our proposed selection strata as well as all alternatives considered.

(e) Assignment of Geographic Areas to Clinicians

We propose at § 512.710(f)(4) to assign a single CBSA or metropolitan division to each clinician based on the clinician's most common episode-level service location ZIP Code for each ASM performance year. We believe that it would be appropriate to use service location data from EBCM episodes to identify the CBSA or metropolitan division of clinicians' service locations given the use of the EBCMs as part of ASM participant eligibility criteria. As discussed in section III.C.2.c.(3).(b). of this proposed rule, EBCM episodes would help identify ASM participants who render a meaningful volume of services related to ASM's targeted chronic conditions. Using the service location from Medicare Part B claims of rendered services used to construct the episode as the basis for determining the service location of a clinician would keep a consistent and accurate source of data by which to make these geographic assignments. We also considered using the CBSA or metropolitan division related to the ZIP Code of the TIN to which a clinician has assigned billing rights for the purpose of determining whether a clinician furnishes ASM-related services in a mandatory geographic area. We believe that it would not be appropriate use a TIN's ZIP Code since a TIN's ZIP Code does not necessarily correlate to service location, particularly in the case of multi-site practices.

Using episode-level service location ZIP Code assignments, we propose at § 512.710(f)(4) the following process to identify clinician-level CBSA or metropolitan division assignments:

- Identify all EBCM episodes relevant to ASM targeted chronic conditions attributed to a clinician during the calendar year 2 years before the applicable ASM performance year (or during January 1, 2024 through December 31, 2024 for initial CBSA or metropolitan division assignment).
- For each episode, establish a service location ZIP Code. An episode may consist of several Medicare Part B Claims. Not all of the ZIP Codes set forth on the Medicare Part B claims form may be the same. To determine which ZIP Code the episode would be associated with, we propose to review all applicable Medicare Part B claims associated with the episode and identify the Medicare Part B claim line ZIP Code appearing most often. An episode could have an equal number of ZIP Codes on claims associated with the episode. We would break any ties between ZIP Codes by determining the episode's ZIP Code based on the ZIP Code on the claim with the highest total cost indicated by the total standardized allowed amount, or in instances a second tie break is needed, by using the ZIP Code on the claim with the most recent date.
- Match the ZIP Code assigned to each episode to a CBSA or metropolitan division. In other words, determine the CBSA or metropolitan division to which the episode is assigned. To do so, we propose to use ZIP Code and CBSA/metropolitan division crosswalks published quarterly by the U.S. Department of Housing and Urban Development.[136] Some CBSA and metropolitan division share ZIP Codes, meaning a ZIP Code could be assigned to multiple CBSAs and metropolitan divisions. In these instances, to ensure each ZIP Code is linked to a unique CBSA or metropolitan division, we would assign the ZIP Code to the CBSA or metropolitan division where the ZIP Code has the highest proportion of total addresses. For example, if ZIP–A spans CBSA–B and CBSA–C, and ZIP–A has more addresses in CBSA–B, then we would assign ZIP–A to CBSA–B. We would get the proportion of total addresses in each ZIP Code from the ZIP Code to CBSA/metropolitan division crosswalk published by the U.S. Department of Housing and Urban Development.[137] The crosswalk also subdivides the proportion of total addresses into the number of business addresses, residence addresses, and other addresses. If the proportion of total addresses within the ZIP Code is equal across CBSAs or metropolitan divisions (meaning that we cannot use the proportion of total addresses to assign a single CBSA or metropolitan division to the ZIP Code), then we would assign the ZIP Code to the CBSA and metropolitan division (if applicable) with the highest proportion of business addresses (regardless of the number of residence addresses or other addresses). We use business addresses as the tiebreaker since business addresses would represent where clinicians would practice, which aligns with our overall approach for using service location for participant identification.

[136] *https://www.huduser.gov/portal/datasets/usps_crosswalk.html.*

[137] *https://www.huduser.gov/portal/datasets/usps_crosswalk.html.*

• Determine the appropriate CBSA or metropolitan division for each clinician attributed applicable episodes. If the clinician is attributed multiple episodes in multiple CBSAs or metropolitan divisions, we would match the clinician with the CBSA or metropolitan division where the clinician has the most assigned episodes. If a clinician has an equal number of episodes assigned to multiple CBSAs or metropolitan divisions, we would break such a tie by matching the clinician to the CBSA or metropolitan division that has the highest total risk-adjusted spending across all episodes assigned to each CBSA or metropolitan division. If a second tie break is needed, we would match the clinician to the CBSA or metropolitan division that has episodes with the more recent dates. For example, if a clinician has an equal number of episodes in CBSA–B and CBSA–C, but the episodes in CBSA–B collectively have a higher total risk-adjusted spending compared to all episodes in CBSA–C, then the clinician would be matched to CBSA–B.

We seek comments on our proposed process at § 512.710(f)(4) for determining the CBSA or metropolitan division of a clinician for each ASM performance year using EBCM data for the purposes of determining whether a clinician is located within a mandatory geographic area for each ASM performance year.

(5) Proposed Selection and Notification Process for ASM Participants

We propose to identify ASM participants on an annual basis. At § 512.710(g) we propose to identify all clinicians furnishing covered services in accordance with the ASM participant eligibility criteria specified in section III.C.2.c.(3) of this proposed rule using applicable data from 2 calendar years prior to each ASM performance year. We also propose that a clinician selected for participation for any ASM performance year would be considered an ASM participant for the remainder of the model.

We propose at § 512.710(g)(1)(i), for the 2027 ASM performance year/2029 ASM payment year only, to identify preliminarily eligible ASM participants using the ASM participant eligibility criteria and applicable data from calendar year 2024. If ASM is finalized as proposed, we propose to make public the preliminarily eligible ASM participants in a form and manner determined by CMS. We expect to release this information by the end of CY 2025. Then, to finalize the ASM participants for the 2027 ASM performance year/2029 ASM payment year, we propose § 512.710(g)(1)(ii) to confirm that the preliminarily eligible ASM participants continue to meet the ASM participant eligibility criteria using more recent data from calendar year 2025. We propose to make public the selected ASM participants for the 2027 ASM performance year/2029 ASM payment year in a form and manner determined by CMS. We expect to release this information by the end of July 2026, preceding the start of the 2027 ASM performance year/2029 ASM payment year. We believe that notifying preliminarily eligible ASM participants well before the start of the first ASM performance year in 2027 would provide ample time to become familiar with ASM requirements, make practice adjustments, and prepare for reporting of the required measures and data.

We considered not releasing the preliminarily eligible ASM participants for the 2027 ASM performance year/2029 ASM payment year and, instead, only using applicable data from the 2025 calendar year to identify the final ASM participants for the 2027 ASM performance year/2029 ASM payment year. However, this alternative would provide less time for ASM participants to prepare for the first ASM performance year and potentially increase the operational burden for clinicians selected for the model.

If ASM is finalized, as proposed, for each ASM performance year, beginning with the 2028 ASM performance year/2030 ASM payment year, we propose at § 512.710(g)(2)(i) to confirm that ASM participants continue to meet ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. If an ASM participant does not meet the ASM participant eligibility criteria for the upcoming ASM performance year, then they would not be required to participate in ASM for the applicable ASM performance year and would not need to meet applicable reporting requirements of ASM. Further, waivers, including the MIPS waiver, described at § 512.775 would no longer apply to the ASM participant, and the ASM participant must participate in MIPS if applicable.

Beginning with the 2028 ASM performance year/2030 ASM payment year, we propose at § 512.710(g)(2)(ii) to identify additional clinicians not previously identified as ASM participants but who meet the ASM participant eligibility criteria at § 512.710(b) for the upcoming ASM performance year/ASM payment year using data from the calendar year 2 years prior to the applicable ASM performance year.

We propose that CMS would make public the ASM participants for a given ASM performance year annually in a form and manner determined by CMS. We intend to release this information by the end of July in the year preceding the start of the applicable ASM performance year. We believe that the proposed approach of annually identifying clinicians who meet the ASM participant eligibility criteria would ensure we are accurately selecting ASM participants. That is, we would ensure that ASM participants continue to be of the required specialty type and meet the EBCM episode volume thresholds year-over-year. This proposed approach to selecting ASM participants also allows us to account for movement of ASM participants to different practices within mandatory geographic areas and allows new ASM participants into the model over the ASM test period. We also believe that this approach would allow ASM to maintain an appropriate number of ASM participants over the ASM test period to produce a reliable model test.

We considered an alternative approach of establishing a fixed list of ASM participants for all ASM performance years. Under this alternative, we would first identify ASM participants as clinicians that meet the ASM participant eligibility criteria using applicable data from the 2024 calendar year for the 2027 ASM performance year/2029 ASM payment year and release a list of preliminarily eligible ASM participants. We would then finalize the ASM participants for the 2027 ASM performance year/2029 ASM payment year using applicable data from the 2025 calendar year. Beginning in the 2028 ASM performance year/2030 ASM payment year, we would reconfirm that the final ASM participants identified for the 2027 ASM performance year/2029 ASM payment year continue to meet the ASM participant eligibility criteria for each ASM performance year thereafter using applicable data from 2 calendar years before the applicable ASM performance year. Under this alternative, we would not identify new ASM participants over the course of the ASM model test period. Repeatedly reconfirming that the initial ASM participants continue to meet ASM participant eligibility criteria for each ASM performance year would result in attrition of any ASM participant who changes their association with a practice (that is, assigns billing rights to a different TIN) after the first ASM performance year based on our proposed identification of

ASM participants at the TIN/NPI level. Accordingly, we believe that this alternative fixed-list approach would reduce the number of ASM participants over the ASM test period and the magnitude of this potential decrease could undermine the reliability of the model test.

We seek comments on our proposed approach for selecting and notifying ASM participants at § 512.710(g). We also seek comment on only identifying the final ASM participants for the 2027 ASM performance year/2029 ASM payment year using applicable data from the 2025 calendar year and the use of a fixed list of ASM participants for all ASM performance years.

d. Proposed ASM Performance Assessment Approach, Data Submission Requirements, and ASM Performance Category Requirements and Scoring

As discussed earlier in section III.C.1.b. of this proposed rule, we propose to use the MVP framework, including its performance categories, to assess ASM participant performance related to improving quality of care and reducing low-value care related ASM targeted chronic conditions. We believe this framework offers a tested performance assessment framework to use in creating value-based incentives for ASM participants. In this section of this proposed rule, we discuss the performance measures and activities that would be used to assess the performance of ASM participants in four ASM performance categories of (1) quality, (2) cost, (3) improvement activities, and (4) Promoting Interoperability. We propose to define at § 512.705 ''ASM performance category'' as a group of applicable measures or activities used to assess an ASM participant's performance on quality, cost, improvement activities, or Promoting Interoperability. Tying a clinician's performance to certain measures and activities (as discussed below) in these performance categories would support ASM goals, as discussed in section III.C.1 of this proposed rule, of decreasing the cost of care for beneficiaries with ASM's targeted chronic conditions as well as improving quality care as measured through a focused measure set relevant to ASM's clinical specialties and targeted chronic conditions.

- The quality ASM performance category would assess the quality of care ASM participants delivered by measuring health care processes, outcomes, and patient experiences of care with the goal of improving the quality of care for beneficiaries with ASM's targeted chronic conditions.
- The cost ASM performance category would assess the efficiency and cost-effectiveness of care provided to Medicare beneficiaries with ASM targeted chronic conditions with the goal of providing more cost-efficient care to generate cost savings.
- The improvement activities ASM performance category would assess ASM participants in their efforts to make practice improvements that improve population health, enhance patient experiences and outcomes, reduce cost of care, and improve clinician experience. To meet ASM's practice improvement goals, ASM's improvement activities would incentivize practice improvements that would strengthen care management and processes related to ASM's targeted chronic conditions, and incentivize stronger integration between specialist and primary care providers.
- The Promoting Interoperability ASM performance category would assess ASM participants in their efforts to promote patient engagement and electronic exchange of information using CEHRT to enhance quality of care and reduce costs through more effective upstream chronic condition management and care integration related to ASM's targeted chronic conditions. Under ASM, CEHRT should meet the requirements set forth in § 414.1305, except all instances of references to MIPS are to be replaced with references to ASM.

As further discussed below in section III.C.2.d.(2) of this proposed rule, we propose for the quality ASM performance category, cost ASM performance category, and promoting interoperability ASM performance category, to draw measures and activities from specific MVPs related to each of ASM's targeted chronic conditions to identify a cohesive set of vetted and clinically relevant measures and activities that would allow us to appropriately assess ASM participants on the care they deliver related to ASM's targeted chronic conditions. Using the same measures would mean the many ASM participants would already be familiar with required measures and activities proposed in each of the ASM performance categories. proposed in these ASM performance categories. However, as we discuss in sections III.C.2.d.(1) and III.C.2.f of this proposed rule, comparing performance on these measures and activities as measured by ASM performance category and final scores within each ASM cohort would result in payment adjustments based on direct peer-to-peer comparisons of similar specialists. For some ASM performance categories, we propose to include measures from outside of the relevant MVP, such as from the broader inventory of MIPS measures, when we believe there is a clinically justifiable rationale for including such a measure. We propose ASM-specific measures or activities in limited circumstances when we believe there is rationale for assessing performance or creating an incentive for practice improvement specific to ASM's targeted chronic conditions. For example, the improvement activities ASM performance category, as discussed in section III.C.2.d.(4). of this proposed rule, includes ASM-specific improvement activities.

We also discuss how we propose to score each ASM performance category within each of the ASM performance category sections within this section of this proposed rule. While many of the proposed scoring policies draw from MIPS, we are proposing scoring policies that simplify some existing policies. As a mandatory model, simplification of scoring compared to some MIPS and MVP policies would make it easier for the ASM participant to understand how their performance in each of the ASM performance categories contributes to their final score and resulting payment adjustment. As part of this simplification, our proposed scoring policies ensure that each ASM participant would at minimum be measured on quality and cost, with further scoring adjustments based on performance in the improvement activities and Promoting Interoperability ASM performance categories, to determine payment adjustments.

As discussed in section III.C.2.e of this proposed rule, we plan to calculate a final score based on the quality, cost, improvement activities, and Promoting Interoperability performance categories scores for each ASM participant for each ASM performance year. The scores in the quality and cost ASM performance categories would positively impact the ASM final score while performance in the improvement activities and Promoting Interoperability ASM performance categories could result in negative scoring adjustments to the ASM final score.

In the following section III.C.2.d.(1).(a) of this proposed rule, we first discuss the ASM performance assessment approach. We then propose data submission requirements applicable across the ASM performance categories in section III.C.2.d.(1).(b) of this proposed rule. Finally, we propose specific requirements and scoring policies for each of the four ASM performance categories in sections

III.C.2.d.(2) through III.C.2.d.(5). of this proposed rule.

(1) Proposed Performance Assessment and Data Submission Requirements

(a) ASM Performance Categories

We propose at § 512.715(a)(1) through (3) that CMS uses the performance measures and activities described under §§ 512.725(b) and (c), 512.730(b), 512.735(b), and 512.740(b) to assess ASM participants in the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories. As discussed in section III.C.1 of this proposed rule, we believe that these ASM performance categories taken together would improve the quality of care and produce cost savings related to ASM's chronic conditions. Further, we believe that, taken together, the ASM performance categories provide a comprehensive understanding of an ASM participant's management of their beneficiaries' targeted chronic conditions.

We also believe that ASM participants, because of participation in other CMS programs including MIPS, would already be familiar with reporting (1) quality; (2) cost; (3) improvement activities; and (4) Promoting Interoperability performance categories to determine a final score. This proposed structure is similar to the performance assessment approach of other CMS programs like the MIPS reporting option of the Quality Payment Program. MIPS assesses the performance of MIPS eligible clinicians across four performance categories and then determines a MIPS payment adjustment factor that applies to the clinician's Medicare Part B payments for covered professional services finalized at §§ 414.1380(a) and 414.1405(a) and as defined at § 414.1305.

Under the proposed ASM performance categories, the value of care provided to chronic care patients would be assessed through performance in the quality and cost performance categories, supported by performance in the improvement activities and Promoting Interoperability performance categories. Measures and activities CMS selects to assess an ASM's performance across the quality ASM performance category and cost ASM performance category would assess the value of care directly furnished to chronic care patients. Measuring ASM participants' cost and quality performance ensures that Medicare beneficiaries are receiving clinically appropriate, comprehensive, high-value care. The measurement of cost and quality is essential to measuring the value of care provided to Medicare beneficiaries with chronic conditions. The improvement activities ASM performance category incentivizes care coordination and collaboration between specialty medicine and primary care, creating new opportunities for both groups playing vital roles in care management and coordination. And lastly, the Promoting Interoperability ASM performance category enables meaningful EHR use, the reporting of clinical quality measures, including electronic clinical quality measures (eCQMs) and continuous practice-based quality improvement and care transformation.

We believe that ASM's more targeted approach to performance assessment where we would evaluate ASM participants within each ASM cohort across the ASM performance categories—(1) on a set of relevant performance measures that they are required to report; and (2) among clinicians furnishing similar sets of services, would produce final scores and subsequent payment adjustments, as described in section III.C.2.f of this proposed rule, that are more reflective of clinician performance. A more targeted approach to measurement would also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. We believe this insight is necessary to support and incentivize accountable care, increasing beneficiary access to coordinated specialty care. Furthermore, equipped with more specialty-relevant performance information through participation in ASM, we expect clinicians would be more likely to invest resources in pursuit of better outcomes, reducing the incidence of poor outcomes arising from care fragmentation, ultimately resulting in better care for patients.

We propose at § 512.715(a) that, as further described in §§ 512.725, 512.730, 512.735, and 512.740, ASM participants would receive a specific number of points for their performance on each measure or activity within an ASM performance category. CMS assigns the total number of points that a measure or activity may receive. The total score across all four performance categories that an ASM participant may receive is capped at 100 points. The number of points awarded for an ASM's performance on a measure or activity corresponds to the level of performance, the higher the points, the better the performance. We propose to define at § 512.705 ''ASM performance category score'' as the assessment of each ASM participant's performance on the applicable measures and activities for a performance category during an ASM performance year based on the policies proposed at §§ 512.715, 512.725, 512.730, 512.735, and 512.740. As further described below in this section of this proposed rule, CMS would, using an ASM participant's ASM performance category scores across all ASM performance categories, calculate an ASM participant's final score for an ASM performance year/ASM payment year in accordance with § 512.745.

We propose at § 512.715(b)(1) to use Medicare claims data and administrative data to calculate some measures included in the quality and cost ASM performance categories under §§ 512.725 and 512.730. We propose at § 512.715(b)(2) that we use other model-specific data reported by ASM participants to calculate measure or activity scores for the quality, improvement activities, and Promoting Interoperability ASM performance categories under §§ 512.725, 512.735, and 512.740.

We are soliciting feedback from the public on our proposal to assess ASM participant performance across four ASM performance categories: (1) quality; (2) cost; (3) improvement activities; and (4) promoting interoperability. We seek comments on our proposal at § 512.715(a) to set and assign specific points on measures or activities in each ASM performance category and to calculate a final score using point received across all four ASM performance categories as described at § 512.745. Finally, we seek comments on our proposal at § 512.715(b) to use Medicare claims, administrative data, and model-specific data reported by an ASM participant to calculate measure or activity scores used to calculate ASM performance category scores.

(b) Data Submission Requirements

We propose at § 512.720 that ASM participants would be required to submit data on the measures and activities for the quality, improvement activities, and Promoting Interoperability ASM performance categories in accordance with each ASM performance categories described in §§ 512.725, 512.735, and 512.740. As further discussed below, we are proposing to align some data submission requirements under this model with the data submission requirements under MIPS as defined at § 414.1325. We believe that the use of similar processes and ''submission types''—which we propose to define at § 512.705 as the mechanism by which the ASM submitter submits data to us in the form and manner specified by us, including, but not limited to: (1) direct;

(2) log in and upload; and (3) log in and attest—would limit confusion and burden for those ASM participants that have previously participated in MIPS. We also intend to provide further resources on the exact data submission procedures prior to the first data submission deadline for the 2027 ASM performance year.

We propose that ASM participants must submit data at the same level at which they are identified in the model. Since we propose identifying ASM participants at the TIN/NPI level (as outlined in section III.C.2.c.(3).(a).(i). of this proposed rule), we are likewise proposing that each ASM participant would be required to submit data for each ASM performance category at this same TIN/NPI level, unless specifically stated otherwise within the requirements for a particular performance category. Alignment between participant identification and data submission levels is necessary for a mandatory model and supports our goal of making accurate comparisons between similar participants. This approach differs from MIPS, which offers various reporting options (such as group, subgroup, or APM entity as defined in § 414.1305). We have determined that allowing multiple reporting configurations would undermine ASM's design objective of creating clear peer-to-peer performance comparisons for determining payment adjustments.

We recognize that some of the required measures and attestations in each ASM performance category may reflect practice-level activities. We, therefore, considered whether to allow submission of required measures and attestations for the improvement activities and Promoting Interoperability ASM performance categories at the TIN level. We believe that it is more appropriate to align the data submission level across all the ASM performance categories instead of having some ASM performance categories with data submitted at the TIN/NPI level and others at the TIN level. Alignment of submission level across all ASM performance categories supports our goal of making like-to-like performance comparisons to determine payment adjustments.

We are proposing the following data submission requirements at § 512.720(a)(1)(i) through (iii) (the order of the requirements aligns with the order in which similar data submission requirements for MIPS appear in § 414.1325):

- *Quality ASM performance category data submission requirements.* For the quality ASM performance category, we propose at § 512.720(a)(1)(i) that an ASM participant must report at least one required quality measure that is not an administrative claims-based collection type (discussed in sections III.C.2.d.(2).(b) and III.C.2.d.(2).(c) of this proposed rule) and meets the proposed data completeness requirement as discussed in section III.C.2.d.(2).(h).(i) of this proposed rule. The proposed requirements for the quality ASM performance category are similar to those required under MIPS as defined at § 414.1325(1)(i) but with the addition of meeting the data completeness requirement. We believe that the addition of the data completeness requirement ensures that we would have complete data by which to score at least one required quality measure. We also considered that an ASM participant must report complete data for at least two, at least three, or all required quality measures that are not administrative claims-based collection types as the data submission requirement for the quality ASM performance category. However, not reporting all required measures would negatively affect an ASM's participant quality ASM performance category score as discussed in section III.C.2.(d).(i) of this proposed rule. Further, not meeting the data submission requirement for the quality ASM performance category would mean that an ASM participant would receive the maximum negative payment adjustment for the applicable ASM payment year as discussed in section III.C.2.f.(4) of this proposed rule. Setting the minimum data submission requirement as reporting more than one complete quality measure could penalize ASM participants that are unable to report required measures because of extenuating circumstances. We believe that the proposed minimum data submission requirement combined with the proposed scoring policies would provide the appropriate incentive for reporting all required quality measures while ensuring that we can appropriately evaluate quality performance.
- *Improvement activities ASM performance category data submission requirements.* We propose § 512.720(a)(1)(ii) that the data submission requirement for the improvement activities ASM performance category would require that an ASM participant attest to completing or not completing the required ASM improvement activities defined in § 512.735. Unlike MIPS, we are not proposing to include a ''yes'' attestation to the minimum data submission requirements to receive a final score under ASM as defined in § 512.745(b) as it would conflict with how we propose to factor in the ASM improvement activities performance category score into the final score as proposed at § 512.745(a)(1)(iii).
- *Promoting Interoperability ASM performance category data submission requirements.* The proposed requirements for the Promoting Interoperability ASM performance category at § 512.720(a)(1)(iii) align with the MIPS requirements as defined at § 414.1325(1)(iii).
- *ASM performance categories without data submission requirements.* Like the cost performance category or administrative claims-based quality measures under MIPS, we propose at § 512.720(a)(2) that there would be no data submission requirements for the cost ASM performance category or for quality measures that have an administrative claims-based collection type. Like MIPS, performance in the ASM cost performance category and on some quality, measures would be calculated using administrative claims data, which includes claims submitted with dates of service during the applicable ASM performance year that are processed no later than 60 days following the close of the applicable ASM performance year.
- *Data submission types for ASM participants.* We propose at §§ 512.720(b)(1) and (2) that an ASM participant would, like an individual MIPS eligible clinician, be able to submit their ASM data using, for the quality ASM performance category, the direct, login and upload, submission types, and for improvement activities or Promoting Interoperability ASM performance categories, the direct, login and upload, or login and attest submission types as proposed at § 512.720(b). These are the same submission types available under MIPS.
- *Use of multiple data submission types.* Like the policy established under MIPS, we propose at § 512.720(c) that ASM participants would be permitted to submit their ASM data using multiple submission types for any performance category described at § 512.720(b) as applicable; provided, however, that the ASM participant uses the same identifier for all ASM performance categories and all data submissions.
- *Data submission deadlines.* We propose at § 512.720(d) that ASM participants would need to submit all required data and attestations as required for each ASM performance category by March 31 following the close of the applicable ASM performance year, or a later date as specified by CMS. This proposal aligns

with the deadline policy established under MIPS at § 414.325(e). We considered requiring a data submission deadline earlier than March 31 but believed that it would not provide ASM participants with sufficient time to prepare their data submission.

- *Treatment of multiple data submissions.* Like the policy established under MIPS, for multiple data submissions received in the quality and improvement activities ASM performance categories, for an ASM participant submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), we propose at § 512.720(e) to calculate and score each submission received and assign the highest of the scores. We propose at § 512.720(e)(1) that for multiple data submissions received for an individual ASM participant from one or multiple submitters in the same organization, we propose to score the most recent submission. We propose at § 512.720(e)(2) that for multiple data submissions received for the Promoting Interoperability performance category, we propose to calculate a score for each data submission received and assign the highest of the scores. We also propose that data can be submitted on behalf of the ASM participant by an entity or individual designated to submit data to CMS, including a third-party intermediary as described in § 512.720(a), on behalf of the ASM participant. We propose at § 512.705 to use with the definition of third-party intermediary set forth in MIPS at § 414.1305 to align the data submission policies for third party intermediaries between MIPS and ASM.

We seek comments on the proposed data submission requirements and submission types for each ASM performance category, the data submission deadline, and the proposed treatment of multiple data submissions and scoring at § 512.720. We also seek comments on our proposal to require data submission at the level by which we determine ASM participation. We also seek comments on the alternative data submission requirements for the quality ASM performance category that we considered.

(2) Proposed Quality ASM Performance Category

The proposed quality ASM performance category supports the model goals of improving quality of care with a focus on measures that are relevant to ASM clinical specialties and targeted chronic conditions. It also seeks to decrease the cost of care for beneficiaries with ASM-targeted chronic conditions. Measuring quality of care helps identify areas for improvement and ensures that clinical interventions are effective and lead to improved patient outcomes. The importance of the quality ASM performance category is reflected in the weight of the performance category on the final score, discussed in section III.C.2.e.(1) of this proposed rule.

(a) Background

We propose at § 512.725(b) and (c) to use a quality measure set specific to each ASM cohort, one measure set for heart failure and one measure set for low back pain, which would contain condition-specific mandatory measures. Each ASM participant must report all measures specified in Table 39 for their applicable chronic condition, except for the proposed administrative claims-based measures, which would be calculated by CMS based on their submitted claims. These measures would likely stay consistent throughout the duration of the model to support reporting continuity, minimize burden, and ensure a reliable and valid model evaluation. The quality measurement approach in ASM is similar to the MVP reporting option under MIPS in that it limits reporting to a subset of clinically relevant measures. However, while the MVP reporting option allows a clinician to select an MVP and choose which MVP measures to report, the ASM participant would be required to report all quality measures in their respective ASM measure set.

Medicare's payment landscape is continuing to transform, moving away from traditional FFS payments that are not tied to quality and towards value-based models with increased provider accountability. ASM is a continuation of these efforts, strengthening the connection between quality and payment. We aim, in payment models such as ASM, to utilize quality measures that incentivize evidence-based care and prevention, improve patient outcomes, and reduce low-value health care spending.

We propose to avoid making significant changes to these measure sets over the period of model; however, we may propose to add or remove measures through rulemaking if we believe refinements to the measure set are necessary. We may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. We would use notice and comment rulemaking to propose any modifications, such as adding or removing measures for monitoring quality or calculating scores for quality performance. We seek comment on this proposal.

As proposed, ASM is designed to provide financial incentives for measurable improvements in clinical outcomes for beneficiaries. We expect our quality measurement strategy to increase adherence to clinical guidelines, focus attention on outcomes to reduce costs, and enhance the patient experience. Several of the measures also promote prevention, as detailed in Table 39, by mitigating the progression of the chronic diseases that ASM targets and reducing the risk for other comorbid diseases that may exacerbate health issues. Each quality measure proposed contains measures that aim to measure and incentivize improvement in the following three domains: (1) excess utilization, (2) evidence-based care and outcomes, and (3) patient-reported outcomes and experience. Each measure set would include a utilization-focused measure to assess appropriate use of select services in chronic disease management. This measurement area may also indicate where excess or inappropriate utilization is occurring, which aligns with CMS priorities to reduce spending related to unnecessary care, imaging, or procedures. Measures in the evidence-based care and outcomes domain are clinically relevant to the conditions of focus, can meaningfully discern differences in care furnished by ASM participants, and are associated with improved outcomes for patients. Finally, measures related to patient-reported outcomes capture what matters most to patients, and incentivizing ASM participants to be more attuned to the patient experience could drive improvements in functional status among beneficiaries receiving treatment for heart failure and low back pain. We believe that the measures in all three domains are clinically relevant to the conditions of focus and would align with other CMS programs and nationwide measurement efforts.

TABLE 39: Proposed ASM Measure Sets for the ASM Quality Performance Category

Domain	Prevention Category	Measure	Collection Type(s)
Heart Failure			
Excess Utilization	Adverse events and acute care utilization	Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with HF (MIPS Q492)	Claims
Evidence-based Care and Outcomes	Reduction of disease progression	HF: Beta-Blocker Therapy for LVSD (MIPS Q008)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Reduction of disease progression	HF: ACE Inhibitor or ARB or ARNI Therapy for LVSD (MIPS Q005)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Reduction of disease progression	Controlling High Blood Pressure (MIPS Q236)	eCQM MIPS CQM
Patient Reported Outcomes and Experience	Function/health status/wellbeing	Functional Status Assessments for Heart Failure (MIPS Q377)	eCQM
Low Back Pain			
Excess Utilization	Risk reduction/absence of disease	MRI Lumbar Spine for LBP (measure in development)	Claims
Evidence-based Care and Outcomes	Adverse events and acute utilization	Use of High-Risk Medications in Older Adults (MIPS Q238)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Risk reduction/absence of disease	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Risk reduction/absence of disease	Preventive Care and Screening: BMI Screening and Follow-Up Plan (MIPS Q128)	eCQM MIPS CQM
Patient Reported Outcomes and Experience	Function/health status/wellbeing	Functional Status Change for Patients with Low Back Impairments (MIPS Q220)	MIPS CQM

(i) Performance Year for the Quality ASM Performance Category

We propose at § 512.725(a) that the ASM performance year for quality measures would be the full calendar year from January 1 to December 31, and the performance year would occur 2 years prior to an applicable ASM payment year. We believe that setting the ASM performance year for quality measures in this way aligns with MIPS as defined at § 414.1320 and would be easily adoptable for ASM participants.

We seek comments on our proposed approach setting the ASM performance year for quality measures.

(b) Quality Measure Set for the ASM Heart Failure Cohort

We propose at § 512.725(b)(1) through (5) to include the following measures in the heart failure measure set. Each ASM heart failure participant must report each measure using one of the collection types specified in Table 39.

(i) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure (HF) (MIPS Q492)

We propose to include Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure (HF) (MIPS Q492) in the ASM heart failure measure set. By assessing potentially preventable cardiovascular-related hospital admissions, this measure incentivizes clinicians to adopt evidence-based practices in heart failure management, improve care coordination, and enhance the overall quality of care.

A hospital readmission, for any reason, is disruptive to patients and caregivers, costly to the health care system, and puts patients at additional risk of hospital-acquired infections and complications.[138] Readmissions are also a major source of patient and family stress and may contribute substantially to a decline in functional ability, particularly in older patients.[139] Some readmissions are unavoidable and result from inevitable progression of disease or worsening of chronic conditions. Patients with heart failure, particularly those at a more advanced stage, are vulnerable to a range of factors that may increase their risk for cardiovascular-related hospitalizations.[140] Risk of hospitalization may be related to an individual's clinical and social/community risk factors but may also be affected by the quality of care received. Activities that could improve quality of care include the adoption of guideline-directed medical therapy, early intervention for acute symptoms, optimal care coordination across providers, and support for self-management. Policy changes, such as the Medicare Hospital Readmissions Reduction Program, have led to a decrease in readmission rates for both principal and secondary heart failure hospitalizations; however, readmission rates in both groups remain high.[141] We propose to include this measure to continue the momentum on reducing avoidable hospital admissions and readmissions, as well as improve overall

[138] Dhaliwal JS, Dang AK. Reducing Hospital Readmissions. *Nih.gov*. Published June 7, 2024. *https://www.ncbi.nlm.nih.gov/books/NBK606114/*.

[139] Dhaliwal JS, Dang AK. Reducing Hospital Readmissions. *Nih.gov*. Published June 7, 2024. *https://www.ncbi.nlm.nih.gov/books/NBK606114/*.

[140] Malhotra C, Chaudhry I, Yeo Khung Keong, Sim D. Multifactorial risk factors for hospital readmissions among patients with symptoms of advanced heart failure. *ESC heart failure*. 2024;11(2):1144–1152. *doi:https://doi.org/10.1002/ehf2.14670*.

[141] Blecker S, Herrin J, Li L, Yu H, Grady JN, Horwitz LI. Trends in Hospital Readmission of Medicare-Covered Patients With Heart Failure. *Journal of the American College of Cardiology*. 2019;73(9):1004–1012. *doi:https://doi.org/10.1016/j.jacc.2018.12.040*.

quality of care for Medicare patients with heart failure.

In addition, this measure aligns with other quality programs, such as the Quality Payment Program, which includes the measure in the Advancing Care for Heart Disease MVP. Another benefit of the measure is that it is calculated using administrative claims, which reduces reporting burden for the ASM participant.

Furthermore, ASM proposes to use this measure at the TIN/NPI level. We plan to pursue additional testing and analyses to ensure measure validity at this level. To date, this measure has been validated at the TIN level in the MIPS program. Analyses have determined a certain threshold of attributed patients' needs to be met to ensure measure validity; this threshold can be challenging to achieve at the TIN/NPI level in MIPS given the wide range of specialty types that participate. Internal analyses indicate that, given the 20 EBCM episode threshold for participation of cardiologists described in section III.C.2.c.(3)(b) of this proposed rule, meeting this threshold of attributed patients in ASM would not be a significant issue or threat to measure validity. For that reason, we anticipate this measure would be valid and reliable at the TIN/NPI level for ASM participants treating heart failure.

We seek comment on the proposal to include the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with HF (MIPS Q492) measure in ASM and to assess performance at the TIN/NPI level.

(ii) Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008)

We propose to include Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008) in the ASM heart failure measure set. This measure aims to promote the appropriate use of beta-blocker therapy in select patients with heart failure with reduced ejection fraction (HFrEF). It assesses the percentage of patients aged 18 years and older with a diagnosis of heart failure with a current or prior left ventricular ejection fraction (LVEF) ≤ 40 percent who were prescribed beta-blocker therapy either within a 12-month period of being seen in the outpatient setting or at each hospital discharge. Beta-blockers, especially when delivered as part of guideline-directed medical therapy, decrease the risk of major cardiovascular events, reduce mortality and hospitalization in patients with HFrEF, lessen the symptoms of heart failure, improve the clinical status of these patients, and reduce future clinical deterioration associated with heart failure.[142] These improvements are observed in all populations with heart failure of various etiologies, such as patients with or without coronary artery disease (CAD), patients with or without diabetes, older patients, as well as women and across various racial and ethnic groups.[143]

Despite its survival benefits, use of beta blockers in eligible patients remains suboptimal.[144] [145] Nonadherence to medications prescribed for heart failure, including beta-blockers, can be associated with adverse outcomes such as hospital readmission and mortality.[146] [147] By including this measure, we aim to increase the appropriate use of beta-blocker therapy in eligible patients with heart failure. This aligns with the goals of ASM to drive improvements in the quality of care delivered to heart failure patients, particularly in evidence-based pharmacotherapy. In addition, inclusion of this measure aligns with other quality programs, such as the Quality Payment Program, which includes the measure in the Advancing Care for Heart Disease MVP, and the Cardiology Core Quality Measures Collaborative (CQMC) set. We seek comment on the proposal to include Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008) in the ASM heart failure measure set.

(iii) Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005)

We propose to include Heart Failure (HF): Angiotensin-Converting Enzyme (ACEi) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005) in the heart failure measure set. This measure assesses the appropriate use of the specified medicines in patients with heart failure with reduced LVEF. Adherence to this class of medications, especially as part of guideline-directed medical therapy, offers cardioprotective benefits in patients with heart failure and reduces mortality and heart failure-related hospitalizations.[148] [149] Furthermore, McMurray et al. in PARADIGM–HF showed use of angiotensin receptor–neprilysin inhibitor compared to enalapril, an ACEi, not only reduced risk for cardiovascular death and hospitalization related to heart failure, but also decreased the symptoms and physical limitations of heart failure.[150] Similar to beta blockers, optimal dosing and adherence to this group of medication in heart failure patients remains suboptimal.[151] By including this measure, we can incentivize cardiologists participating in the ASM to prescribe evidence-based pharmacotherapy for patients with HFrEF. In addition, inclusion of this measure aligns with other quality measurement efforts, such as the Advancing Care for Heart Disease MVP in the Quality Payment Program and the Cardiology Core Quality Measures Collaborative (CQMC) set. We seek

[142] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[143] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[144] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[145] Kim SE, Byung Su Yoo. Treatment Strategies of Improving Quality of Care in Patients With Heart Failure. *Korean circulation journal.* 2023;53. *doi:https://doi.org/10.4070/kcj.2023.0024.*

[146] Ruppar TM, Cooper PS, Mehr DR, Delgado JM, Dunbar-Jacob JM. Medication Adherence Interventions Improve Heart Failure Mortality and Readmission Rates: Systematic Review and Meta-Analysis of Controlled Trials. *Journal of the American Heart Association.* 2016;5(6). *doi:https://doi.org/10.1161/jaha.115.002606.*

[147] Ho PM, Magid DJ, Shetterly SM, et al. Medication nonadherence is associated with a broad range of adverse outcomes in patients with coronary artery disease. *American Heart Journal.* 2008;155(4):772–779. *doi:https://doi.org/10.1016/j.ahj.2007.12.011.*

[148] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[149] Düsing R. Mega clinical trials which have shaped the RAS intervention clinical practice. *Therapeutic Advances in Cardiovascular Disease.* 2016;10(3):133–150. *doi:https://doi.org/10.1177/1753944716644131.*

[150] McMurray JJV, Packer M, Desai AS, et al. Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. *New England Journal of Medicine.* 2014;371(11):993–1004. *doi:https://doi.org/10.1056/nejmoa1409077.*

[151] Kim SE, Byung Su Yoo. Treatment Strategies of Improving Quality of Care in Patients With Heart Failure. *Korean circulation journal.* 2023;53. *doi:https://doi.org/10.4070/kcj.2023.0024.*

comment on the appropriateness of including this measure in the heart failure measure set.

(iv) Controlling High Blood Pressure (MIPS Q236)

We propose including Controlling High Blood Pressure (MIPS Q236) in the heart failure measure set for ASM because optimal blood pressure management is a critical part of heart failure management and uncontrolled blood pressure can contribute to complications and progression.[152] [153] For example, severe hypertension can result in pulmonary edema (more common in patients with preserved LVEF), requiring urgent treatment to reduce blood pressure.[154] Controlling blood pressure helps reduce the risk of adverse outcomes, such as hospitalizations and mortality related to heart failure.[155] [156] By including this measure, ASM incentivizes cardiologists to optimize blood pressure control, particularly given that patients with heart failure very commonly have a history of hypertension.[157] In addition, this measure complements the two other quality measures for heart failure in ASM, as the use of beta blockers and ACEi/ARB/ARNIs also have favorable effects on heart failure outcomes and lower blood pressure.[158] The complimentary emphasis on blood pressure control and medication management in this measure set may also slow disease progression and function as a form of tertiary prevention in heart failure patients. Furthermore, its inclusion in other quality measure sets, such as the CMS Universal Foundation Measure Set and the Cardiology Core Quality Measures Collaborative (CQMC) set has resulted in more widespread adoption, helping streamline reporting and reduce burden.[159] We seek comment on our inclusion of this measure in the heart failure quality measure set.

(v) Functional Status Assessments for Heart Failure (MIPS Q377)

We propose including Functional Status Assessments for Heart Failure (MIPS Q377) in the heart failure measure set in ASM because patients with heart failure often experience poor functional status and health-related quality of life, both of which tend to decline as the disease progresses. Assessing functional status is crucial for managing the complex health needs of patients who often have multiple comorbidities. Furthermore, standardized assessment of patient-reported health status using a validated questionnaire can be useful for providing incremental information related to patient functional status and prognosis. It is also an independent predictor of hospitalization and mortality.[160] The measure emphasizes the importance of collecting relevant patient-reported health status from heart failure patients, such as functional limitations, symptom burden, and quality of life. It supports the creation of a dynamic conversation between patients and providers regarding care goals and priorities, which we believe can facilitate shared decision-making, empower patients, and incentivize clinicians to incorporate patient voice and lived experience in clinical care activities. This measure is appropriate for ASM as it encourages cardiologists to regularly assess, monitor, and help improve the functional status of their heart failure patients, which are crucial for providing patient-centered care and aligning treatment plans with individual goals and priorities. In addition, this measure aligns with other quality measurement efforts, such as the Advancing Care for Heart Disease MVP in the Quality Payment Program and the Cardiology Core Quality Measures Collaborative (CQMC) set. We seek comment on our inclusion of this measure in the heart failure quality measure set.

We note that the Functional Status Assessments for Heart Failure (MIPS Q377) measure is currently a process measure. We propose that the process measure would be included for the 2027 ASM performance year, while we explore the benefit and applicability of developing a Patient—patient-reported outcome-based performance measure (PRO–PM). The current measure ensures a functional status assessment is completed. A PRO–PM would hold the ASM participant accountable for not only collecting patient-reported data but also improving or slowing progression of decline in functional status over time. We believe this would capture more meaningful changes in patient care. We seek comments on our proposal to include the Functional Status Assessments for Heart Failure (MIPS Q377) measure in ASM, the applicability of the measure as a PRO–PM, and whether the PRO–PM, if available, should be included in the heart failure measure set for future performance years of ASM.

(c) Quality Measure Set for the ASM Low Back Pain Cohort

We propose at § 512.725(c)(1) through (5) to include the following measures in the low back pain measure set. Each ASM low back pain participant must report each measure using one of the collection types specified in Table 39.

(i) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain, Respecified To Be Relevant to ASM Participants Treating Low Back Pain

We propose to include a respecified MRI Lumbar Spine for Low Back Pain measure in the low back pain measure set. We believe this administrative claims-based measure can effectively assess overuse and hopefully incentivize reductions in inappropriate MRI imaging for low back pain. Routine imaging (such as MRI) is not recommended for patients with non-specific low back pain in the absence of certain clinical indicators with concerning features.[161] However, studies have shown that a significant proportion of patients with low back pain undergo imaging, often within the first few weeks of symptom onset,

[152] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[153] Oh GC, Cho HJ. Blood pressure and heart failure. *Clinical Hypertension.* 2020;26(1). *doi:https://doi.org/10.1186/s40885-019-0132-x.*

[154] Ratko Lasica, Lazar Djukanovic, Jovanka Vukmirovic, et al. Clinical Review of Hypertensive Acute Heart Failure. *Medicina (Kaunas Spausdinta).* 2024;60(1):133–133. *doi:https://doi.org/10.3390/medicina60010133.*

[155] The SPRINT Research Group. A Randomized Trial of Intensive versus Standard Blood-Pressure Control. *New England Journal of Medicine.* 2015;373(22):2103–2116. *doi:https://doi.org/10.1056/nejmoa1511939.*

[156] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[157] Messerli FH, Rimoldi SF, Bangalore S. The Transition From Hypertension to Heart Failure. *JACC: Heart Failure.* 2017;5(8):543–551. *doi:https://doi.org/10.1016/j.jchf.2017.04.012.*

[158] Oh GC, Cho HJ. Blood pressure and heart failure. *Clinical Hypertension.* 2020;26(1). *doi:https://doi.org/10.1186/s40885–019–0132-x.*

[159] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS—The Universal Foundation. *New England Journal of Medicine.* 2023;388(9). *doi:https://doi.org/10.1056/nejmp2215539.*

[160] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[161] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020. *https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf*

despite the lack of clear indication.[162] Overuse of imaging for low back pain can lead to unnecessary health care costs and potential patient harm from incidental findings that may prompt further unnecessary testing or procedures.[163] [164] By including this measure in the low back pain measure set, ASM aims to incentivize adherence to evidence-based guidelines and a reduction of unnecessary MRIs for patients with uncomplicated low back pain, particularly in the initial stages of evaluation and management. We believe this could also have a positive impact on patient experience as it reduces time spent at medical appointments and health care costs. Furthermore, as an administrative claims measure, ASM participants would not have to report data for this measure, reducing reporting burden.

MRI Lumbar Spine for Low Back Pain measure was specified for use in Hospital Outpatient Departments at the facility level and was previously included in the Hospital Outpatient Quality Reporting Program (HOQRP) as OP–8 (73 FR 68766).[165] Part of our re-specification efforts would involve ensuring validity and reliability at the TIN/NPI level. We are also exploring the denominator criteria of the measure and potentially redefining the denominator. This potential change is pending further internal analyses to determine whether participants would be able to meet denominator minimum and specification changes and ensure the measure accurately identifies unwarranted MRI usage. We would propose the measure's specifications through notice and comment rulemaking when available and in advance of using the measure in the low back pain cohort.

We seek comment on the re-specification and inclusion of MRI Lumbar Spine for Low Back Pain measure in the low back pain measure set.

[162] Medicare Payment Advisory Commission. Health Care Spending and the Medicare Program: A Data Book. Medicare Payment Advisory Commission; July 2021. Accessed [insert access date]. *https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec7_SEC.pdf.*

[163] Litkowski PE, Smetana GW, Zeidel ML, Blanchard MS. Curbing the Urge to Image. *The American Journal of Medicine.* 2016;129(10):1131–1135. doi:*https://doi.org/10.1016/j.amjmed.2016.06.020.*

[164] Chou R. Diagnostic Imaging for Low Back Pain: Advice for High-Value Health Care From the American College of Physicians. *Annals of Internal Medicine.* 2011;154(3):181. doi:*https://doi.org/10.7326/0003-4819-154-3-201102010-00008.*

[165] Hospital Outpatient Quality Reporting √ Partnership for Quality Measurement. P4qm.org. Published 2025. Accessed April 23, 2025. *https://p4qm.org/taxonomy/term/216.*

(ii) Use of High-Risk Medications in Older Adults (MIPS Q238)

We propose to include the Use of High-Risk Medications in Older Adults (MIPS Q238) measure in the low back pain quality measure set. Older adults with low back pain who receive a prescription for a high-risk medication as part of their treatment plan, may have a range of adverse events, including medication side effects, drug interactions, a prescribing cascade, or hospitalization. Individuals ages 65 and older are more likely to have multiple chronic conditions, increasing their risk for adverse drug effects associated with polypharmacy.[166] Forty percent of individuals 65 and older filled at least one prescription for a potentially inappropriate medication and 13 percent filled two or more, leading to as much as $7.2 billion spent per year on inappropriate medications in older adults[167] [168] Several of the medications included in the measure are prescribed for treatment of musculoskeletal conditions and pain, such as skeletal muscle relaxants and tricyclic antidepressants.[169] [170] [171] Skeletal muscle relaxants may be prescribed as an alternative to conventional pain medication; however, they carry considerable risk of falls and associated morbidity due to common side effects of dizziness, drowsiness, and hypotension. One study found that elderly patients who were using skeletal muscle relaxants were 2.25 times more likely to visit the emergency room for a fall or fracture than elderly patients who weren't prescribed these medications.[172] Similarly, a meta-analysis exploring the risks associated with use of tricyclic antidepressants in elderly patients found a significant increased risk of falls and fracture.[173] In addition to the morbidity and substantial costs associated with falls in the older adult population, falls in a patient with low back pain could significantly worsen their condition and functional status. We believe including this measure in the low back pain measure set could encourage ASM participants to be more cautious in their prescribing of high-risk medications to patients with low back pain and potentially prevent falls and other adverse events that may negatively impact patient outcomes. It also could align clinical practice with efforts to avoid inappropriate describing in older adults, such as the Beers criteria, and deprescribe where appropriate.[174] We believe the measure may promote positive changes in care delivery, such as incorporating regular medication review and reconciliation. This measure could be particularly impactful in ASM given the promotion of specialty and primary care integration as a goal of the model. We seek comments on our inclusion of the Use of High-Risk Medications in Older Adults (MIPS Q238) measure in the ASM low back pain measure set.

(iii) Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134)

We propose to including Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Q134) in the low back pain measure set

[166] Medicare Payment Advisory Commission. Polypharmacy and opioid use among Medicare Part D enrollees. In: Report to the Congress: Medicare and the Health Care Delivery System. June 2015. Chapter 5. Accessed [insert access date]. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf.*

[167] Fick DM, Mion LC, Beers MH, L. Waller J. Health outcomes associated with potentially inappropriate medication use in older adults. *Research in Nursing & Health.* 2008;31(1):42–51. doi:*https://doi.org/10.1002/nur.20232.*

[168] Fu AZ, Jiang JZ, Reeves JH, Fincham JE, Liu GG, Perri M. Potentially Inappropriate Medication Use and Healthcare Expenditures in the US Community-Dwelling Elderly. *Medical Care.* 2007;45(5):472–476. doi:*https://doi.org/10.1097/01.mlr.0000254571.05722.34.*

[169] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020. *https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCar.*

[170] Santandreu J, Francisco Félix Caballero, M Pilar Gómez-Serranillos, González-Burgos E. Association between tricyclic antidepressants and health outcomes among older people: A systematic review and meta-analysis. *Maturitas.* 2024;188:108083–108083. doi:*https://doi.org/10.1016/j.maturitas.2024.108083.*

[171] Castillo S. Inappropriate Use of Skeletal Muscle Relaxants in Geriatric Patients. Uspharmacist.com. Published January 21, 2020. Accessed April 17, 2025. *https://www.uspharmacist.com/article/inappropriate-use-of-skeletal-muscle-relaxants-in-geriatric-patients#:~:text=Skeletal%20muscle%20relaxants%20are%20on,opioids%20in%20the%20geriatric%20population.*

[172] Castillo S. Inappropriate Use of Skeletal Muscle Relaxants in Geriatric Patients. Uspharmacist.com. Published January 21, 2020. Accessed April 23, 2025. *https://www.uspharmacist.com/article/inappropriate-use-of-skeletal-muscle-relaxants-in-geriatric-patients?utm_source=TrendMD&utm_medium=cpc&utm_campaign=US_Pharmacist_TrendMD_0.*

[173] Santandreu J, Francisco Félix Caballero, M Pilar Gómez-Serranillos, González-Burgos E. Association between tricyclic antidepressants and health outcomes among older people: A systematic review and meta-analysis. *Maturitas.* 2024;188:108083–108083. doi:*https://doi.org/10.1016/j.maturitas.2024.108083.*

[174] American Geriatrics Society. American Geriatrics Society 2023 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. *Journal of the American Geriatrics Society.* 2023;71(7). doi:*https://doi.org/10.1111/jgs.18372.*

because patients with chronic pain conditions, such as low back pain, are at an increased risk of developing depression.[175] Comorbid depression can negatively impact quality of life, treatment adherence, and overall health outcomes.[176] Screening for depression and providing appropriate follow-up care is an essential aspect of comprehensive care for patients with low back pain, as depression may exacerbate pain and worsen functional status.[177] Co-occurring depression has also been found to worsen low back pain outcomes and increase health care costs.[178] Effective management of low back pain often requires a multidisciplinary approach to address the physical, psychological, and emotional aspects of the condition. Including this measure in the ASM low back pain measure set would encourage ASM participants treating low back pain to prioritize mental health screening and follow-up care. We believe this would lead to better management of physical and mental health, prevent worsening of a patient's health status, and improve overall outcomes.[179] [180] We seek comment on the proposal to include the Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134) measure in the ASM low back pain measure set.

(iv) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128)

We propose to including the Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128) measure in the low back pain measure set because obesity can predispose patients to and exacerbate chronic low back pain.[181] [182] Incorporating BMI screening and related follow-up into the care of patients with low back pain can improve outcomes by reducing the severity and recurrence of low back pain. The inclusion of this measure in the ASM low back pain measure set would incentivize a more holistic approach to low back pain management, addressing both the physical and lifestyle factors contributing to the condition. We believe ASM participants treating low back pain can play a crucial role in preventing and addressing modifiable risk factors like obesity and providing appropriate follow-up plans for weight management. In addition, this measure aligns with those used in other quality programs, such as the Rehabilitative Support for Musculoskeletal Care MVP in the Quality Payment Program. We seek comments on the proposal to include Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128) in the ASM low back pain measure set.

(v) Functional Status Change for Patients With Low Back Impairments (MIPS Q220)

We propose to include the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) measure in the ASM low back pain measure set. This measure would encourage ASM participants to adopt a more patient-centered and holistic approach to improving functional status and quality of life in patients with low back pain. As a patient-reported outcome measure, the measure tracks changes in a patient's functional status over time, assessing changes and rewarding meaningful improvement with a better measure score for the ASM participant. We believe measuring and improving functional status could increase self-efficacy, improve financial well-being, and lower future medical costs. Measuring a change in functional status can also be used to direct and assess the success of treatment. Furthermore, the adoption of validated objective measurements may enhance the reliability and sensitivity of detecting physical deficits or monitoring posttreatment improvements of low back pain in older adults.[183] Notably, relevant professional organizations and specialty societies recommend the use of functional status surveys to assess and monitor changes in low back pain over time. The American Academy of Orthopaedic Surgeons recommends the use of the Oswestry Disability Index, which can be used to fulfill this measure, as one of its preferred tools for spine care. While AAOS also recommends the Neck Disability Index, it is less relevant to ASM.[184] [185] These functional status surveys include questions related to modifiable lifestyle factors, such as physical activity and social isolation, prompting conversation with patients that can prevent the worsening of comorbid conditions and low back pain. In addition, this measure aligns with other quality programs, such as the Rehabilitative Support for Musculoskeletal Care MVP in the Quality Payment Program and the Core Quality Measures Collaborative Orthopedics set. By holding ASM participants who treat low back pain accountable for this measure, ASM promotes a comprehensive approach to low back pain management, including appropriate assessment, treatment, and monitoring of changes. We seek comment on our proposal to include the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) measure in the low back pain measure set.

(d) Other Measures Under Consideration

(i) Patient Activation Measure (PAM) (MIPS Q503)

We seek comments on whether the Patient Activation Measure (PAM) (MIPS Q503) would be appropriate to include in both the heart failure and low back pain measure sets. Chronic conditions, in general, are influenced by external factors, such as lifestyle, education, nutrition, and activity. Patient activation, which refers to a patient's knowledge, skills, and confidence in managing their health condition, is an important factor in achieving better health outcomes and

[175] Mullins PM, Yong RJ, Bhattacharyya N. Associations between chronic pain, anxiety, and depression among adults in the United States. *Pain Practice.* 2023;23(6). doi:*https://doi.org/10.1111/papr.13220*.

[176] Mullins PM, Yong RJ, Bhattacharyya N. Associations between chronic pain, anxiety, and depression among adults in the United States. *Pain Practice.* 2023;23(6). doi:*https://doi.org/10.1111/papr.13220*.

[177] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.

[178] Wong JJ, Tricco AC, Côté P, et al. Association Between Depressive Symptoms or Depression and Health Outcomes for Low Back Pain: a Systematic Review and Meta-analysis. *Journal of General Internal Medicine.* 2021;37(5). doi:*https://doi.org/10.1007/s11606-021-07079-8*.

[179] Pinheiro MB, Ferreira ML, Refshauge K, et al. Symptoms of Depression and Risk of New Episodes of Low Back Pain: A Systematic Review and Meta-Analysis. *Arthritis Care & Research.* 2015;67(11):1591–1603. doi:*https://doi.org/10.1002/acr.22619*.

[180] Tagliaferri SD, Miller CT, Owen PJ, et al. Domains of chronic low back pain and assessing treatment effectiveness: A clinical perspective. *Pain Practice.* 2019;20(2). doi:*https://doi.org/10.1111/papr.12846*.

[181] Zhang TT, Liu Z, Liu YL, Zhao JJ, Liu DW, Tian QB. Obesity as a Risk Factor for Low Back Pain: A Meta-Analysis. *Clinical Spine Surgery.* 2018;31(1):22–27. doi:*https://doi.org/10.1097/BSD.0000000000000468*.

[182] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.

[183] Wong AY, Karppinen J, Samartzis D. Low back pain in older adults: risk factors, management options and future directions. *Scoliosis and Spinal Disorders.* 2017;12(1):1–23. *doi:https://doi.org/10.1186/s13013-017-0121-3*.

[184] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.

[185] Performance Measures by Orthopaedic Subspecialty. *Aaos.org.* Published 2025. Accessed April 23, 2025. *https://www.aaos.org/quality/research-resources/patient-reported-outcome-measures/performance-measures-by-orthopaedic-subspecialty*.

adherence to treatment plans. For chronic conditions , such as heart failure and low back pain, where self-management and active patient engagement are crucial, assessing and improving patient activation levels could help ASM participants tailor their ability to provide more patient-centered support and education. Including the PAM measure in ASM could incentivize clinicians to prioritize strategies that enhance patient activation, such as shared decision-making, goal setting, and self-management support.[186] Furthermore, higher levels of patient activation have been associated with better health behaviors, such as physical activity, and improved mental health outcomes.[187] We are concerned by the burden on participants and patients that may be introduced by: (1) adding an additional measure to the set, (2) using a patient survey measure, and (3) PAM being a proprietary measure. We seek comments on whether PAM could be applicable to the heart failure and low back pain measure sets.

(ii) Advance Care Plan (MIPS Q047)

We considered including the Advance Care Plan (MIPS Q047) measure in the heart failure measure set. Advance care planning is important for understanding and documenting a patient's wishes regarding their medical treatment, acknowledging that wishes may evolve as circumstances and health status change. Heart failure, depending on stage and other risk factors, can progress unpredictably and rapidly. According to one meta-analysis, survival rates for all patients with heart failure are 95.7 percent at one month, 86.5 percent at 1 year, and 56.7 percent at 5 years, with elderly patients having lower survival rates on average.[188] Having a documented plan in place is necessary to ensure a patient's wishes are followed should they become incapacitated and unable to make care decisions. One study of Medicare beneficiaries with severe illness found that timely advance care planning was associated with significantly less intensive end-of-life care utilization and fewer in-hospital deaths, hospital admissions, intensive care unit admissions, and emergency department visits.[189] Another study on Medicare beneficiaries with heart failure found that beneficiaries who received advance care planning visits had 19 percent lower total end-of-life expenditure compared to those who did not.[190] This measure could encourage ASM participants to have proactive discussions with their patients about end-of-life care, advance directives, and other important decisions related to their treatment plan. However, we decided not to include the measure, as we worry the measure would not result in sufficiently meaningful positive changes for patients to justify the increased burden. Also, we do not believe the cardiologist would be the most appropriate provider to oversee advance care planning in every case, and we want to avoid duplication of effort with PCPs. We seek comments on whether the Advance Care Plan measure could be meaningful if included in the heart failure measure set.

(iii) Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients With Multiple Chronic Conditions (MIPS Q484)

We considered including the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MIPS Q484) measure in the heart failure measure set. We believe evaluating potentially preventable hospital admissions could help assess the quality of ambulatory care provided by cardiologists to patients with multiple chronic conditions, including heart failure. Nearly 90 percent of adults with heart failure have two or more additional chronic conditions, and almost 60 percent have five or more chronic conditions.[191] For heart failure patients with multiple comorbidities, reducing potentially preventable hospitalizations is a key goal for improving outcomes and reducing health care costs. While incentivizing cardiologists to adopt best practices, such as improving care coordination with primary care and enhancing self-management support, is of interest to CMS, this measure is not adequately targeted to heart failure. We also do not consider this measure appropriate for the low back pain measure set, as the condition is less prone to hospital admissions and re-admissions. We seek comments on whether the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MIPS Q484) measure should be considered for inclusion in the heart failure measure set.

(iv) Cardiac Rehabilitation Patient Referral From an Outpatient Setting (MIPS Q243)

We considered including the Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure in the heart failure measure set. This measure assesses the percentage of patients evaluated in an outpatient setting who have qualified for cardiac rehabilitation and were referred to an outpatient cardiac rehabilitation program. As it relates to heart failure, Medicare patients only qualify for a cardiac rehabilitation program if they have stable chronic heart failure, defined as left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks.[192] In these patients, cardiac rehabilitation is a comprehensive intervention that includes exercise training, education, and counseling to improve cardiovascular health and reduce the risk of future cardiac events. For patients with heart failure, meta-analyses on cardiac rehabilitation have shown that it improves functional capacity, exercise duration, and health-related quality of life.[193] Also, cardiac rehabilitation programs have evolved to serve other purposes, such as disease management and prevention centers that assist with medication adherence, weight loss, smoking cessation, and other contributors to heart disease.[194]

[186] Newland P, Lorenz R, Oliver BJ. Patient activation in adults with chronic conditions: A systematic review. *Journal of Health Psychology.* Published online August 23, 2020:135910532094779. *doi:https://doi.org/10.1177/1359105320947790.*

[187] Hosseinzadeh H, Downie S, Shnaigat M. Effectiveness of health literacy- and patient activation-targeted interventions on chronic disease self-management outcomes in outpatient settings: a systematic review. *Australian Journal of Primary Health.* 2022;28(2). *doi:https://doi.org/10.1071/py21176.*

[188] Jones NR, Roalfe AK, Adoki I, Hobbs FDR, Taylor CJ. Survival of patients with chronic heart failure in the community: A systematic review and meta-analysis. *European Journal of Heart Failure.* 2019;21(11):1306–1325. *doi:https://doi.org/10.1002/ejhf.1594.*

[189] Weissman JS, Reich AJ, Prigerson HG, et al. Association of Advance Care Planning Visits With Intensity of Health Care for Medicare Beneficiaries With Serious Illness at the End of Life. *JAMA Health Forum.* 2021;2(7):e211829. *doi:https://doi.org/10.1001/jamahealthforum.2021.1829.*

[190] Brill SB, Riley SR, Prater L, et al. Advance Care Planning (ACP) in Medicare Beneficiaries with Heart Failure. *Journal of General Internal Medicine.* 2024;39(13):2487–2495. *doi:https://doi.org/10.1007/s11606-024-08604-1.*

[191] Dharmarajan K, Dunlay SM. Multimorbidity in Older Adults with Heart Failure. *Clinics in Geriatric Medicine.* 2016;32(2):277–289. *doi:https://doi.org/10.1016/j.cger.2016.01.002.*

[192] Cardiac Rehabilitation Program Coverage. *www.medicare.gov. https://www.medicare.gov/coverage/cardiac-rehabilitation.*

[193] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). *doi:https://doi.org/10.1161/cir.0000000000001063.*

[194] Ades PA, Keteyian SJ, Wright JS, et al. Increasing Cardiac Rehabilitation Participation From 20% to 70%: A Road Map From the Million

By including this measure in the heart failure measure set, CMS could incentivize cardiologists and other clinicians to refer eligible patients with heart failure to cardiac rehabilitation programs, which can potentially improve their long-term outcomes and reduce their risk of hospitalizations. We decided not to include the measure in the heart failure measure set because access to cardiac rehabilitation programs is significantly varied based on region due to factors like limited availability, density, eligibility, or distance, and these factors could negatively affect ASM participants due to no fault of their own.[195] We seek comment on whether the Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure could be meaningful if included in the heart failure measure set.

(v) Falls: Plan of Care

We considered including the Falls: Plan of Care measure in the low back pain measure set. This measure assesses the percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months. The implementation of a falls plan of care for this population could address multiple aspects of patient safety and functional improvement. Such a plan may include assessment of environmental hazards, evaluation of medication side effects, and implementation of appropriate exercise interventions to improve strength, balance, and coordination.[196] For low back pain patients specifically, the plan could incorporate targeted exercises that not only address fall prevention but also support their primary condition management, creating a comprehensive approach to their care. The Falls: Plan of Care quality measure is particularly relevant for the low back pain patient population as these patients may experience altered biomechanics, decreased mobility, and impaired balance, which may significantly increase their risk of falls. Patients with low back pain may also exhibit protective movement patterns and altered postures that, while intended to minimize pain, may compromise their stability and balance. Studies have shown that some elderly patients with a recent history of back pain are at increased risk for falls, with that risk increasing as the number of locations they experience pain in their back increases.[197] [198] Another study found that community-dwelling older adults with chronic pain generally, such as low back pain, were more likely to have fallen in the past 12 months and to fall again in the future.[199] Additionally, low back pain patients may take medications such as muscle relaxants, anti-depressants, or other medications that can affect their balance and coordination, further elevating their fall risk.[200] [201] By including this measure in the low back pain measure set, we could promote ASM participants to assess the risk a patient is at for falls and implement any needed plan or corrective actions to mitigate the issues that may be present. We decided not to include the measure in the low back pain measure set as we are concerned that beneficiaries in ASM may have falls may for reasons, such as syncope, that are less relevant to the care of the ASM participant, and that the incidence of falls is not high enough in this patient population. We seek comments on whether the Falls: Plan of Care measure could be meaningful if included in the low back pain measure set.

(e) Removal and Addition of Quality Measures

While we do not plan to add or remove measures from either cohort's measure set of the ASM test period, there may be circumstances in which it is necessary. We propose at § 512.725(d) that we would add or remove any quality measure for an ASM cohort through notice and comment rulemaking.

We may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. Because the quality measures currently proposed are all part of MIPS, any updates CMS applies to the measures within MIPS would be incorporated into the quality measure sets accordingly.

We seek comments on the proposed approach for removal or addition of quality measures.

(f) Maintenance of Technical Specifications for Quality Measures

We propose at § 512.725(d) to release technical specifications for the required quality measures in a form and manner determined by CMS for each ASM performance year via notice and comment rulemaking. We intend to use the most recent MIPS version of the technical specifications for all applicable measures. For non-MIPS measures, we would release the measure specifications in advance of the ASM performance year in which the specifications would be applicable via notice-and-comment rulemaking. If any changes are made to specifications for MIPS measures, and ASM chooses not to adopt these changes, we propose releasing the measure technical specifications applicable to ASM via notice and comment rulemaking before the start of each ASM performance year.

We seek comments on our proposal to use the most recent MIPS version of technical specifications of quality measures for each ASM performance year. We also seek comment on our intent to release the technical specifications of non-MIPS measures via notice and comment rulemaking, and if it allows adequate time for ASM participants to make any needed adjustments to data collections systems or practice workflows.

(g) Data Submission Criteria for the Quality ASM Performance Category

We propose at § 512.725(e)(1) that ASM participants submitting data for measures with non-administrative claims-based measures would be required to submit data for each measure using one of the measure's collection types identified for each required quality measure as detailed in Table 39. We propose at § 512.725(e)(2)

Hearts Cardiac Rehabilitation Collaborative. *Mayo Clinic Proceedings.* 2017;92(2):234–242. *doi:https://doi.org/10.1016/j.mayocp.2016.10.014.*

[195] Duncan MS, Robbins NN, Wernke SA, et al. Geographic Variation in Access to Cardiac Rehabilitation. *Journal of the American College of Cardiology.* 2023;81(11):1049–1060. *doi:https://doi.org/10.1016/j.jacc.2023.01.016.*

[196] CDC. Outpatient Care—STEADI in Primary Care. STEADI—Older Adult Fall Prevention. Published May 16, 2024. *https://www.cdc.gov/steadi/hcp/clinical-resources/outpatient-care.html.*

[197] Marshall LM, Litwack-Harrison S, Makris UE, et al. A Prospective Study of Back Pain and Risk of Falls Among Older Community-dwelling Men. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* Published online November 16, 2016:glw227. *doi:https://doi.org/10.1093/gerona/glw227.*

[198] Marshall LM, Litwack-Harrison S, Cawthon PM, et al. A Prospective Study of Back Pain and Risk of Falls Among Older Community-dwelling Women. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2016;71(9):1177–1183. *doi:https://doi.org/10.1093/gerona/glv225.*

[199] Stubbs B, Binnekade T, Eggermont L, Sepehry AA, Patchay S, Schofield P. Pain and the Risk for Falls in Community-Dwelling Older Adults: Systematic Review and Meta-Analysis. *Archives of Physical Medicine and Rehabilitation.* 2014;95(1):175–187.e9. *doi:https://doi.org/10.1016/j.apmr.2013.08.241.*

[200] Park H, Satoh H, Miki A, Urushihara H, Sawada Y. Medications associated with falls in older people: systematic review of publications from a recent 5-year period. *European Journal of Clinical Pharmacology.* 2015;71(12):1429–1440. *doi:https://doi.org/10.1007/s00228-015-1955-3.*

[201] Castillo S. Inappropriate Use of Skeletal Muscle Relaxants in Geriatric Patients. *Uspharmacist.com.* Published January 21, 2020. Accessed April 17, 2025. *https://www.uspharmacist.com/article/inappropriate-use-of-skeletal-muscle-relaxants-in-geriatric-patients?utm_source=TrendMD&utm_medium=cpc&utm_campaign=US_Pharmacist_TrendMD_0.*

that for the applicable ASM performance year, each ASM heart failure participant would report all of the measures in the heart failure measure set as described in section III.C.2.d.(2).(b) of this proposed rule and each ASM low back pain participant would report all the measures in the low back pain measure set as described in section III.C.2.d.(2).(c) of this proposed rule.

We seek comments on the proposed form, manner, and timing of quality measures reporting at § 512.725(e).

(h) Data Completeness Requirement and Case Minimums for the Quality ASM Performance Category

(i) Data Completeness Requirement

We propose at § 512.725(f)(1) to set a data completeness requirement of at least 75 percent beginning in the 2027 ASM performance year. Data completeness is essential to ensure that data submitted on quality measures are sufficiently complete to accurately assess each ASM participant's quality performance. The data completeness requirement means that an ASM participant submitting measure data on MIPS clinical quality measures (MIPS CQMs) or eCQMs must submit data on at least a specific percent of their patients that meet the measure's denominator criteria, regardless of payer. Also, the inclusion of eCQMs in ASM measure sets more easily enables submission of data on 100 percent of the patient records in a provider's EHR, making data completeness more achievable. We believe it is important to maintain high data completeness to ensure the most accurate assessment of ASM participants. The CY 2025 PFS final rule set the CY 2025 MIPS performance period/2027 MIPS payment year MIPS data completeness requirement for the quality performance category at 75 percent (89 FR 98383 through 98387). Prior to this, the MIPS data completeness requirement had been periodically increasing from where it started, which was at least 50 percent to where it currently is (89 FR 98383 through 98387). We do not intend to continue to align with MIPS data completeness requirements and instead propose to assess changes to the ASM quality measure data completeness as needed for model-specific purposes. Since some ASM participants would not have previously reported to MIPS and, therefore, may have limited experience and capabilities with quality reporting of this type, we considered data completeness requirement lower than 75 percent for 2027 ASM performance year and then increasing to 75 percent beginning in the 2028 ASM performance year 2028.

We also propose at § 512.725(f)(2) that ASM participants would receive zero ''measure achievement points,'' which we propose at § 512.705 to mean numerical values assigned to an ASM participant's reported performance data that we use to calculate an ASM performance category score, for any required measure that does not meet the proposed data completeness requirement. Meeting the data completeness requirement ensures that the measure represents an appropriate percentage of the clinical population applicable for a given quality measure. Therefore, we believe that not meeting the proposed data completeness requirement for a given required quality measure should result in the ASM participant receiving zero achievement points for that measure.

Finally, we propose at § 512.725(f)(3) that we exclude from an ASM's participant total measure achievement points and total available measure achievement points any required measures meet the respective measure's data completeness requirement, but do not have a benchmark. As discussed later in this section of this proposed rule, we believe that it would not be appropriate to score quality measures for which we cannot determine a benchmark.

We seek comments on the proposed data completeness requirement of 75 percent at § 512.725(f)(1) and whether a different data completeness percentage that we considered would be more appropriate. We also seek comment on our proposal at § 512.725(f)(2) that ASM participants would receive zero measure achievement points for any submitted quality measure that does not meet the data completeness requirement. Finally, we seek comment on our proposal at § 512.725(f)(3) for not scoring measures that meet data completeness requirements but for which we cannot determine a benchmark.

(ii) Minimum Case Requirements

We seek to ensure that ASM participants are measured reliably, therefore, we propose at § 512.725(g)(1) to use 20 cases as the minimum case requirement for each quality measure. We propose at § 512.725(g)(2) that ASM participants that report measures with fewer cases than the case minimum for the measure and meet the data completeness requirement proposed at § 512.725(f)(1) would receive recognition for submitting the measure, but we would not include the measure in the quality ASM performance category scoring as described later in this section of this proposed rule. We believe this case minimum is appropriate as it aligns with the case minimum under MIPS as defined at § 414.1380(b)(1)(iii).

We seek comments on our proposed case minimum for quality measures at § 512.725(g).

(i) Quality Measure Achievement Points and Quality ASM Performance Category Scoring

(i) Quality Measure Achievement Points

We propose at 512.725(h)(1)(i) to assign 1 to 10 measure achievement points to each measure based on how an ASM participant performance compares to measure-specific benchmarks determined as described in section III.C.2.d.(2).(i) of this proposed rule. We propose at § 512.725(h)(1)(iii) that if an ASM participant fails to submit a measure required under the quality ASM performance category, then the ASM participant would receive zero measure achievement points for that measure. We propose at § 512.725(h)(1)(ii) and (iii) that measures reported by ASM participants must have the required case minimum as applicable for each measure, as proposed at § 512.725(g)(1), and meet the data completeness requirement, as proposed at § 512.725(f)(1), to receive a score. For example, if an ASM participant reports a measure that meets the data completeness requirement rule but does meet the required case minimum, then the ASM participant would not be scored on that measure, and that measure score would not be factored into the ASM participant's quality ASM performance category score. An ASM participant who reports a measure that does not meet the data completeness requirement but meets the required case minimum of this proposed rule would receive a score of zero for the measure. An ASM participant who does not report the measure would receive a score of zero for the measure. We propose at § 512.725(h)(1)(iv) that an ASM participant that submits data for the same measure under two different collection types, if applicable, would be scored on the data submission that leads to the greatest number of achievement points for that required measure.

The quality ASM performance category score would be the sum of all the measure achievement points assigned for the scored measures required for the quality ASM performance category divided by the sum of total possible measure achievement points.

We also propose not to score measures for which we could not

determine a benchmark for a given ASM performance year as described in section.III.C.2.d.(2)(i)(ii) of this proposed rule. In this situation, the quality ASM performance category score would not include any measure or measures for which a benchmark could not be determined. We believe that it would be unfair to penalize ASM participants due to a lack of a benchmark.

We seek comments on this proposed quality ASM performance category scoring approach as described at § 512.725(h)(1).

(ii) Benchmarking

For the quality ASM performance category, we propose at § 512.725(h)(2) that the ASM performance standard is a measure-specific benchmark. We propose at §§ 512.725(h)(2)(i)(A) through (C) to determine benchmarks for each quality measure and for each of the measure's collection types using data reported by ASM participants, to the extent feasible, during the ASM performance year, from a previous ASM performance year, or from another period determined by CMS. The benchmark determination is contingent on relevant available data for accurate calculation that is specific to ASM participants. For measures with an administrative claims-based collection type, we propose at § 512.725(h)(2)(iii) to calculate the benchmark using performance on the measure during the current ASM performance year. We believe it is important to determine separate benchmarks for each of a measure's collection types since performance varies by collection type in MIPS.[202] We considered determining one benchmark per quality measure regardless of collection type since having a single benchmark may help ASM participants more readily calibrate their performance. Given the differences in MIPS performance by collection type for measures that we propose to require in ASM,[203] we believe it would be more appropriate to calculate a benchmark for each collection type.

We propose at § 512.725(h)(2)(iv) to determine benchmarks for each measure's collection type using deciles based on the applicable period of data we use to determine the measure's benchmark. Then, we would evaluate an ASM participant's actual measure performance during the ASM performance year to determine the number of measure achievement points that should be assigned based on where the actual measure performance falls within the benchmark. We propose establishing benchmarks using a percentile distribution, separated by decile categories, because it translates measure-specific score distributions into a uniform distribution of ASM participants based on actual performance values. For each set of benchmarks, we propose to calculate the decile breaks for measure performance and assign measure achievement points for a measure based on which benchmark decile range the ASM participant's performance rate on the measure falls between. For example, an ASM participant in the top decile would receive 10 measure achievement points for the measure, and an ASM participant in the next lower decile would receive measure achievement points ranging from 9 to 9.9. We propose to assign partial measure achievement points to prevent performance cliffs for ASM participants near the decile breaks. The partial measure achievement points would be assigned based on the percentile distribution

We propose at §§ 512.725(h)(2)(ii)(A) through (C) that we only calculate benchmarks for measures that have a minimum of 20 ASM participants that report the measure: (1) meeting the data completeness requirement as proposed at §§ 512.725(f)(1) through (2) meeting the required case as proposed at §§ 512.725(g)(1) and (3) a performance rate greater than zero. We propose a minimum of 20 because our benchmarking methodology relies on assigning measure achievement points based on decile distributions with decimals. A decile distribution requires at least 10 observations. We would double the requirement to 20 so that we would be able to assign decimal measure achievement point values and minimize cliffs between deciles. Given the mandatory participation of ASM and the mandatory quality measure sets, we do not anticipate that we would encounter challenges with meeting this proposed minimum of 20 ASM participants reporting a measure to determine a benchmark.

We seek comments on our proposed benchmark determination process as proposed at § 512.725(h)(2) and all alternatives considered.

(iii) Topped-Out Quality Measures

We propose at § 512.725(h)(3) that we would identify topped out measures in the benchmarks for each ASM performance year, based on within-model performance on each measure. We considered but are not proposing an initial policy regarding topped out measures and differential benchmarking for measures with a topped-out status. MIPS defines at § 414.1305 a topped out non-process measure as a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors; MIPS also defines at § 414.1305 a topped-out process measure as measure with a median performance rate of 95 percent or higher. We propose monitoring during initial ASM performance year(s) before designating an ASM measure with topped out status. We would propose using a definition like the definition used by MIPS and the Hospital Value-Based Purchasing (HVBP) Program: a Truncated Coefficient of Variation less than 0.10 and the 75th and 90th percentiles are within 2 standard errors as defined at § 412.164(c)(3) (88 FR 59333); or median value for a process measure that is 95 percent or greater (80 FR 49550). Topped out measures are of concern as it makes it difficult to assess relative performance to most accurately score the quality ASM performance category. However, since all ASM participants reporting one of the two measure sets would only be compared among others also reporting that measure set, and all the measures are mandatory to report, the benefit of selecting a topped-out measure is nullified. In this way, the reasoning for removing topped out measures is also nullified. Several of the measures included in our measure sets are topped out in other programs, such as MIPS, potentially because MIPS participants can select the measures on which they believe they would perform well. It is unclear whether requiring ASM participants to report a measure that is topped out in MIPS would present the same issues typically associated with topped-out measures or if the appearance of being topped out is simply due to voluntary reporting by only the highest performers in MIPS.

We seek comment on our proposal at § 512.725(3) to identify topped out measures in the benchmarks for each ASM performance year, based on within-model performance on each measure, as well as all alternatives considered.

(iv) Calculation of the Quality ASM Performance Score

We propose at § 512.725(h)(4) to sum all quality measure achievement points determined for all measure reported by an ASM participant for an applicable ASM performance year. We would then divide that total achievement points by the total available measure achievement

[202] *https://qpp.cms.gov/resources/performance-data.*

[203] *https://qpp.cms.gov/resources/performance-data.*

points for measures reported by the ASM participant that meets the case minimum requirements as defined at § 512.725(g) to determine an overall quality ASM performance category score, which could not exceed 100 percentage points.

We propose at § 512.725(h)(4)(ii) that if data used to calculate a score for a quality measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the quality measure score would lead to misleading or inaccurate results, then the affected quality measure would be based on data for 9 consecutive months of the applicable ASM performance year. We propose at § 512.725(h)(4)(ii)(A) to consider ''significant changes or errors'' regarding instances in which a quality measure score could not be calculated as changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We further propose at § 512.735(h)(4)(ii)(A) that significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. We also propose at § 512.725(h)(4)(ii)(B) that we would publish a list of all measures scored in a form and manner specified by CMS. Finally, we propose at § 512.725(h)(4)(ii)(C) that if CMS determines sufficient measure data is not available, or that there is the possibility of patient harm or misleading results, a measure would be excluded from a participants score. We believe these proposed policies would appropriately adapt the proposed quality ASM performance category scoring policies so that ASM participants would not be penalized for changes or errors in the measure and associated submitted data that would be outside the control of the ASM participant.

We propose at § 512.735(h)(4)(iii) that an ASM participant would not receive a quality ASM performance category score if the ASM participant meets the quality ASM performance category data submission requirements proposed at § 512.720(a)(1)(i) but does not meet the case minimum requirements for any of the required quality measures in their applicable quality measure set. As discussed in sections III.C.2.e.(2)(b) and III.C.2.f.(4) of this proposed rule, the ASM participant in this situation would not receive a payment adjustment for the applicable ASM payment year. We believe that we should hold all ASM participants accountable to performance on quality. Accordingly, it would be inappropriate to evaluate the performance of an ASM participant that reports complete quality measure data but cannot meet the case minimums for any required measure within the applicable quality measure set since they would not have sufficient case volume by which to evaluate clinical quality.

We seek comments on our proposed approach to calculate measure achievement points for each required quality measure and determine benchmarks for quality measures in the quality ASM performance category. We also seek comment on our proposed approach to monitor for topped out measure status and future considerations for how we should approach and manage identified topped out measures in ASM. Finally, we seek comment on our proposal to calculate the quality ASM performance category score, as well as the proposed exceptions that could prevent the calculation of an individual quality measure score. or an overall performance category score.

(3) Proposed Cost ASM Performance Category

The proposed cost ASM performance category supports the model goals to improve quality care as measured through a focused measure set relevant to ASM's clinical specialties and targeted chronic conditions, while decreasing the cost of care for beneficiaries with ASM's targeted chronic conditions. The cost ASM performance category ensures that Medicare beneficiaries are receiving clinically appropriate, comprehensive, high-value care. The importance of the cost ASM performance category is reflected in the weight of the performance category contribution to the final score, discussed at section III.C.2.e.(1) of this proposed rule.

(a) Background

The cost ASM performance category is one of four ASM performance categories measuring an ASM participant's performance on the care delivered related to ASM's targeted chronic conditions. The cost ASM performance category incentivizes ASM participants to ensure Medicare beneficiaries are receiving clinically appropriate, comprehensive, high-value care. Like the cost performance category under the MVPs, ASM participants in each ASM cohort would be scored on a condition-relevant EBCM. We propose at § 512.730(b) to use two EBCMs specified for the MIPS cost performance category, the Heart Failure EBCM and the Low Back Pain EBCM. As discussed below, while we are proposing to evaluate ASM participants on their performance on these two MIPS cost measures, and are proposing to use the same MIPS cost benchmarking and scoring methodology finalized for the 2024 MIPS performance period defined at § 414.1380(b)(2)(i)(B), we are proposing to use different benchmark ranges.

(b) Performance Year for Cost ASM Performance Category

Beginning with ASM payment year 2029, we propose at § 512.730(a) that the ASM performance year for cost measures would be the full calendar year from January 1 to December 31 that occurred 2 years prior to an applicable ASM payment year. We believe that setting that setting the ASM performance year for cost measures in this way aligns with MIPS as defined at § 414.1320 and would be easily adoptable by ASM participants.

We seek comments on our proposed approach at § 512.730(a) setting the ASM performance year for cost measures.

(c) Cost Measure for the ASM Heart Failure Cohort

For the ASM heart failure cohort, we propose at § 512.730(b)(1) to utilize the heart failure EBCM, a MIPS cost measure specified by CMS through rulemaking, to determine an ASM heart failure participant's cost ASM performance category score.[204] We are proposing the heart failure EBCM, in part, because the Advancing Care for Heart Disease MVP (88 FR 80022 through 80025; 89 FR 99015 through 99019) includes it as one of the mandatory cost measures. The heart failure EBCM evaluates a participant's risk adjusted and specialty-adjusted cost to Medicare for beneficiaries receiving medical care to manage and treat heart failure.[205] We are proposing the heart failure EBCM because the measure quantifies the costs of services that are clinically related to the participant's role in managing care during a heart failure episode. We believe that the heart failure EBCM captures a targeted high-cost patient population, has robust clinician coverage, and can help lower Medicare spending. The heart failure EBCM is a complex, yet feasible, chronic condition measure that

[204] *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

[205] *https://www.cms.gov/files/zip/2024-cost-measure-information-forms-zip.zip-0.*

addresses care delivered to manage heart failure. We believe holding ASM heart failure participants accountable on the heart failure EBCM represents an opportunity to measure reductions in the cost of care for beneficiaries with heart failure.

Additionally, we are proposing this measure and the focus on heart failure, generally, due to the prevalence of heart failure in the Medicare FFS population, and the high costs associated with the management of the disease and its complications. The incidence of heart failure increases with age, rising from 20 per 1,000 individuals aged 65 to 69 to more than 80 per 1,000 individuals over 80 years of age.[206] With an estimated 1 in 5 Americans 40 years and older expected to develop heart failure and 1 in 5 Americans expected to be 65 years or older by 2050, the number of Americans with heart failure is predicted to significantly increase in the future.[207] Further, heart failure was listed as the cause of death on 13.4 percent of all death certificates in the United States in 2018.[208] In addition to its prevalence, heart failure is also costly for the health care system. According to the Centers for Disease Control and Prevention (CDC), heart failure costs the United States $30.7 billion annually, including health care services, medications used to treat heart failure, and lost productivity.[209] A large contributor to heart failure-related health care costs may be inpatient admissions, with one study estimating that roughly 1 in 6 beneficiaries returned to the hospital for admission for heart failure-related reasons within 90 days of their initial discharge.[210]

We seek comments on the proposed use of the heart failure EBCM at § 512.730(b)(1) to score the cost ASM performance category for the ASM heart failure cohort.

(d) Cost Measure for ASM Low Back Pain Cohort

For the ASM low back pain cohort, we propose at § 512.730(b)(2) to utilize the low back pain EBCM to determine an ASM low back pain participant's cost ASM performance category score.[211] The low back pain EBCM evaluates a participant's risk adjusted and specialty-adjusted cost to Medicare for patients receiving medical care to manage and treat low back pain. We are proposing the low back pain EBCM, in part, to align with the Rehabilitative Support for Musculoskeletal Care MVP (88 FR 80002 through 80007; 89 FR 99050 through 990054). We also believe this chronic condition EBCM appropriately captures the costs of services that are clinically related to the participant's role in managing the longitudinal care during a low back pain episode.

We believe that use of the low back pain EBCM would help increase accountability on spending and limit low-value care related to low back pain. Low back pain is highly prevalent and a high driver of spending. For example, an estimated 20 percent of people living in the United States experience low back pain,[212] and a 2020 study found that low back and neck pain contributed the most to health care spending among 154 mutually exclusive diagnoses, at $134.5 billion in 2016.[213] Other studies have also found large increases in resource use for low backpain despite only modest increase in its prevalence and little improvement in patient outcomes,[214] [215] [216] which underscores the need for more precise measure of resource use and quality of care. Given these findings, we believe the low back pain EBCM would be an appropriate measure by which to accurately determine resource use related to low back pain and compare cost-related performance across ASM low back pain participants.

We seek comments on the proposed use of the low back pain EBCM at § 512.730(b)(2) to determine the cost ASM performance category score for the ASM low back pain cohort.

(e) Removal and Addition of Cost Measures

We intend to avoid making significant changes to the cost measure over the ASM test period. However, we propose at § 512.730(c) to add or remove measures through notice and comment rulemaking as discussed at § 512.730(c) if we believe refinements to the measure set are necessary. We may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. Because the cost measures currently proposed are all part of MIPS, any updates CMS applies to the measures within MIPS would be incorporated into the cost ASM measure sets accordingly.

We seek comments on our proposed approach at § 512.730(c) for adding or removing cost measures if necessary.

(f) Minimum Case Requirements

Like under MIPS, as specified in § 414.1350(c)(6) (88 FR 79346 through 79348), we propose at § 512.730(d) that an ASM participant must have at least 20 attributed episodes (that is, cases) at the TIN/NPI level during an ASM performance year for the ASM participant to receive a score on the applicable EBCM. A participant with an unscored EBCM would also remain unscored in their ASM cost performance category score, resulting in a neutral payment adjustment for the applicable ASM payment year because the participant is required to have an ASM cost performance category score to receive a final score as discussed in section III.C.2.e.(2)(b). As discussed in section III.C.2.c.(3)(b) of this proposed rule, we believe that setting a minimum volume threshold during the calendar year 2 years prior to the applicable ASM performance year for the heart failure EBCM and the low back pain EBCM as part of ASM participant eligibility criteria would mean that ASM heart failure participants and ASM low back pain participants would be likely to meet the same episode case minimum during each ASM performance year.

We seek comment on the proposed case minimum of 20 attributed episodes for all cost measures at § 512.730(d) used to score the cost ASM performance category.

[206] Yancy et al. ''2013 ACCF/AHA Heart Failure Guidelines.'' (2013). *https://www.ahajournals.org/doi/pdf/10.1161/CIR.0b013e31829e8776.*

[207] Yancy et al. ''2013 ACCF/AHA Heart Failure Guidelines.'' (2013). *https://www.ahajournals.org/doi/pdf/10.1161/CIR.0b013e31829e8776.*

[208] Centers for Disease Control and Prevention (CDC) ''Heart Failure.'' September 2020. *https://www.cdc.gov/heartdisease/heart_failure.htm.*

[209] Centers for Disease Control and Prevention (CDC) ''Heart Failure.'' September 2020. *https://www.cdc.gov/heartdisease/heart_failure.htm.*

[210] Kilgore et al., ''Economic burden of hospitalizations of Medicare beneficiaries with heart failure,'' Risk Management and Healthcare Policy 10 (2017): 63–70, doi: 10.2147/RMHP.S130341.

[211] *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

[212] Will, Joshua Scott, David Bury, and John Miller, ''Mechanical Low Back Pain.'' American Academy of Family Physicians 98(7) (2018): 421–428.

[213] Dieleman, Joseph, Jackie Cao, and Abby Chapin, ''US Health Care Spending by Payer and Health Condition, 1996–2016.'' JAMA Network 323(9) (2020): 863–884. doi:10.1001/jama.2020.0734.

[214] Luo, Xuemei, Ricardo Pietrobon, Shawn Sun, Gordon Liu, and Lloyd Hey, ''Estimates and Patterns of Direct Health Care Expenditures Among Individuals With Back Pain in the United States.'' Spine 29(1) (2004): 79–86. doi:10.1097/01.BRS.0000105527.13866.0.

[215] Deyo, Richard, Sohail Mirza, Judith Turner, and Brook Martin, ''Overtreating Chronic Back Pain: Time to Back Off?'' J Am Board Fam Med 22(1) (2009): 62–68. doi:10.3122/jabfm.2009.01.080102.

[216] Norman Marcus Pain Institute, ''Pain Facts.'' Last updated 23 January 2012. *https://www.normanmarcuspaininstitute.com/tag/neck-and-shoulder-pain/.*

(g) Cost Measure Achievement Points and Cost ASM Performance Category Scoring

(i) Cost Measure Achievement Points

We propose to follow a similar methodology for establishing and assigning measure achievement points as is used by MIPS. We propose at §§ 512.730(e)(1)(i) and 512.730(e)(1)(ii) that for each cost measure attributed to an ASM participant, CMS assigns the ASM participant 1 to 10 achievement points (including partial points) based on the ASM participant's performance on the cost measure during the ASM performance year compared to the cost measure's benchmark. Achievement points are awarded based on which benchmark range the ASM participant's performance on the measure is in.

(ii) Benchmarking

We propose at § 512.730(e)(2)(i) that CMS bases cost measure benchmarks on cost measure performance of ASM participants during the ASM performance year. To develop reliable cost measure benchmarks, we propose at § 512.730(e)(2)(i)(A) that each benchmark must have a minimum of 20 ASM participants who meet the minimum case volume specified at § 512.730(d) for CMS to determine a benchmark for the cost measure. We propose at § 512.730(e)(2)(i)(B) if a benchmark is not determined for a cost measure, then the measure would not be scored.

We propose at § 512.730(e)(2)(ii) to score each EBCM using 10 benchmark ranges based on the median (that is, 50th percentile) cost of all ASM participants attributed the relevant measure plus or minus standard deviations. We propose at § 512.730(e)(2)(ii) to center the 10 benchmarks ranges at half the measure achievement points achievable for each EBCM. Given that the measure achievement points range from 1 to 10, the ASM participant with the median cost would be assigned 6 EBCM measure achievement points. We would then determine the score ranges applicable to each of the 10 measure achievement points based on standard deviations above and below the median score. We propose to calculate these benchmark ranges separately for each EBCM.

We believe the proposed benchmark ranges, calculated using the median and centered around half of the available points for each EBCM would be dynamic and responsive to changes in average spending per episode assessed by cost measures and performance thresholds for each ASM performance year. We would update the median and standard deviations used to determine cutoffs for benchmark ranges so that they are based on performance within the ASM performance year. To determine the benchmark ranges, we would adhere to the following principles: (1) determine benchmark ranges according to the distribution of the EBCM averages; and (2) ensure distribution of measure achievement points for cost measures is reflective of overall program performance. We refer readers to Table 40 for an example of how the proposed cost scoring methodology could be implemented for a specific cost measure.

TABLE 40: EXAMPLE OF IMPLEMENTATION OF THE PROPOSED COST SCORING METHODOLOGY FOR ASSIGNMENT OF ACHIEVEMENT POINTS FOR PERFORMANCE ON THE HEART FAILURE COST MEASURE

Benchmark Range	Points	Illustrative Methodology for the Bottom of the Benchmark Range ($)
Benchmark Range 1	1 – 1.9	Median cost + (2.5 × standard deviation)
Benchmark Range 2	2 – 2.9	Median cost + (2 × standard deviation)
Benchmark Range 3	3 – 3.9	Median cost + (1.5 × standard deviation)
Benchmark Range 4	4 – 4.9	Median cost + (1 × standard deviation)
Benchmark Range 5	5 – 5.9	Median cost + (0.5 × standard deviation)
Benchmark Range 6	6 – 6.9	Median cost + (0 × standard deviation)
Benchmark Range 7	7 – 7.9	Median cost - (0.5 × standard deviation)
Benchmark Range 8	8 – 8.9	Median cost - (1 × standard deviation)
Benchmark Range 9	9 – 9.9	Median cost - (1.25 × standard deviation)
Benchmark Range 10	10	Median cost - (1.5 × standard deviation)

We propose at § 512.730(e)(2)(ii) to award up to 10 measure achievement points for each EBCM based on which benchmark range an ASM participant's EBCM average corresponds using the following formula:

EBCM Achievement Points = Benchmark Range # + [(measure score, expressed as a dollar amount − bottom of benchmark range)/(top of benchmark range − bottom of benchmark range)].

This scoring methodology for cost measures would align the assignment of measure achievement points for cost measures so that participants with costs near the measure's median (that is, 50th percentile) would not receive a disproportionately low score. Rather participants with costs near the median would receive an individual EBCM score clustered closer to the median.

We also considered using even decile benchmark ranges based on the distribution of each EBCM score. This alternative approach, however, would mean that ASM participants with EBCM averages near the 50th percentile would receive lower cost measure scores. Given the distribution of EBCM averages proposed for ASM, we believe even decile benchmark ranges would create narrow benchmark deciles that would result in a less accurate assessment of cost performance. For these reasons, we believe it would be more appropriate to use the proposed episode-based cost benchmarking and measure scoring methodologies.

We seek comments on our proposed approach for assigning measure achievement points, calculating EBCM benchmarks and scoring each cost measure, as well as all alternatives considered.

(iii) Calculation of the Cost ASM Performance Category Score

We propose at § 512.730(e)(3) that the cost ASM performance category score would be calculated as the sum of the total number of measure achievement points earned by the ASM participant from each required measure divided by the total number of available measure achievement points for each required cost measure, not to exceed 100 percent, for ASM heart failure participants or ASM low back pain participants. As discussed in section III.C.2.d.(3)(g) of this proposed rule, we propose at § 512.730(e)(3)(i) that an ASM participant who does not have 20 attributed episodes during an ASM performance year would not receive a cost ASM performance category score and would not receive a final score as discussed in section III.C.2.e.(b) of this proposed rule.

We believe that this proposed cost ASM performance category score ensures that ASM participants can be appropriately held accountable on spending related to ASM's targeted chronic conditions. This proposed cost ASM performance category scoring methodology means that the cost ASM performance category would be equivalent to the score for the heart failure EBCM for ASM heart failure participants and the low back pain EBCM for ASM low back pain participants since each participant group is only scored on one cost measure.

We propose at § 512.730(e)(3)(ii) that if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the ASM participant's cost performance category score and a cost performance category score is not calculated.

We propose at § 512.730(e)(3)(ii)(A) to define ''significant changes or errors'' regarding instances in which the cost measure score could not be calculated as changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

We propose at § 512.730(e)(3)(ii)(B) that significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, changes to codes (such as ICD–10, CPT or HCPCS codes), the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications.

We also propose at § 512.730(e)(3)(ii)(C) that we would empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We believe these proposed policies would appropriately adapt the proposed cost ASM performance category scoring policies so that ASM participants would not be penalized for changes or errors in the measure and associated submitted data that would be outside the control of the ASM participant.

We seek comments on our proposed methodology for calculating the cost ASM performance category score.

(4) Proposed Improvement Activities ASM Performance Category

The proposed requirements in the improvement activities ASM performance category aim to improve care coordination, increase collaboration between specialty and primary care, and better address upstream drivers of health for patients. These activities support the model goals to improve quality care as measured through a focused measure set relevant to ASM participants. They also support prevention efforts that incentivize ASM participants to ensure that their patients have a regular source of primary care and are screened to help identify early signs of chronic conditions. The improvement activities ASM performance category would be used to determine a potential scoring adjustment to the final score. We refer readers to sections III.C.2.e.(1) and III.C.2.e.(5) of this proposed rule for details on how the scores in the improvement activities scoring adjustment would be applied to the ASM final score.

(a) Background

The improvement activities ASM performance category provides ASM participants with an opportunity to support broader improvements in health care delivery. Improvement activities originated in MIPS to improve care coordination, foster beneficiary engagement, and advance population health management as described at § 414.1355. ASM leverages this structure and proposes at § 512.705 to define ''improvement activities'' as activities relating to care coordination, integration of specialty and primary care, and addressing health-related social needs of patients.

Care coordination helps to ensure that all healthcare providers involved in a patient's care have appropriate access to relevant patient information and are working towards the same care goals. The exchange of up-to-date and detailed patient information among healthcare providers can improve patient outcomes, safety, and support clinical decision making.[217] Integration of specialty and primary care would also positively impact the patient experience. A 2022 study examining fragmentation in ambulatory care for Medicare FFS beneficiaries found that 4 in 10 beneficiaries experience highly fragmented care, with a mean of 13 ambulatory visits across seven practitioners in 1 year.[218] By providing a more seamless and coordinated approach to beneficiary care, providers reduce the need for patients to spend as much time navigating the health care system and lower any undue costs for patients that may be associated with an increased number of clinical visits and services. This approach also can prevent the worsening of disease by ensuring all parties are aware of a patient's needs, aligned with a care plan, and receiving appropriate prevention and screening services. We borrow elements from the care coordination improvement activity subcategory of MIPS to align with activities in which organizations may already be engaged.

Consistent with our model goals, we believe it is important to create a single set of achievable improvement activities that are applicable to all ASM participants. We took several steps to ensure these improvement activities are consistent with our intent to improve meaningful coordination and collaboration. We developed the measures for this ASM performance category based on our review of feedback provided in response to our RFI (89 FR 61596), interviews with interested parties, and an environmental scan of existing practice coordination activities from the Quality Payment

[217] Foy R. Meta-analysis: Effect of Interactive Communication Between Collaborating Primary Care Physicians and Specialists. *Annals of Internal Medicine.* 2010;152(4):247. doi:*https://doi.org/10.7326/0003-4819-152-4-201002160-00010.*

[218] Centers for Medicare & Medicaid Services. CMS Innovation Center's Strategy to Support Person-Centered, Value-Based Specialty Care. CMS.gov Blog. Published October 19, 2023. *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care* (accessed 2/24/25).

Program and other Innovation Center models.[219]

(b) Performance Year for Improvement Activities

Beginning with ASM payment year 2029, we propose at § 512.735(a) that the ASM performance year for improvement activities would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year. We believe that setting the ASM performance year for improvement activities in this way aligns with MIPS as defined at § 414.1320 and would be easily adoptable by ASM participants. We seek comments on this proposal.

(c) Improvement Activities

We propose at § 512.735 the establishment of the improvement activities ASM performance category. We propose at § 512.735(c) to establish the following ASM improvement activities : (1) Improvement Activity 1 (IA–1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening and Improvement Activity 2 (IA–2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements.

(i) Improvement Activity 1 (IA–1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening

In IA–1, we propose at § 512.735(c)(1) to require annual attestations by ASM participants on activities related to enhancing connections to and relationships with primary care. As the first part of IA–1, we propose at § 512.735(c)(1)(i) that ASM participants develop processes and workflows within their practices to identify patients without a PCP and assist them in finding one. Primary care is a vital resource for patients, providing an efficient and accessible level of care. We believe it is essential that the vast majority of patients have a PCP who can coordinate their overall health care needs, manage chronic conditions, and serve as the first point of contact for health concerns. However, some patients may not have a designated PCP, which can lead to fragmented care and suboptimal health outcomes. A 2022 study found that up to a third of Medicare beneficiaries don't see a PCP yearly.[220] Furthermore, we believe that connecting patients with a PCP could help reduce demand on specialists in situations where the patient could more appropriately be treated in the primary care setting. Continuity with a primary care practice or provider also has the potential to reduce costs.[221] We believe specialists can play a crucial role in ensuring that their patients have access to these high-value primary care services. As part of IA–1, we also propose at § 512.735(c)(1)(ii) to require that the ASM specialist always communicate relevant information back to the ASM beneficiary's PCP following the ASM beneficiary's visit with the ASM participant. This exchange of information is important to patient care planning and is an aspect of specialty care and primary care collaboration that has room for improvement.[222]

As the final element of IA–1, we propose at § 512.735(c)(1)(iii) that ASM participants collaborate with PCPs to ensure that their patients have received HRSN screenings. In addition to ensuring access to primary care, we also recognize the importance of addressing patients' upstream drivers of health. These factors, such as housing, food insecurity, transportation, and financial constraints, are common in the Medicare population. One study found that of approximately 68,000 Medicare Advantage patients who responded to a HRSN screening, 33 percent experienced financial strain, 18.5 percent experienced food insecurity, and 17.7 percent had poor housing quality.[223] These unmet needs can significantly impact a patient's well-being and contribute to the development or exacerbation of diseases, lead to unnecessary health care costs, and worsen overall outcomes.[224] HRSN screening also has the opportunity to open a dialogue between the patient and provider about lifestyle factors, such as diet and physical activity. This discussion with the provider and associated education can promote the adoption of a healthier lifestyle, thereby mitigating the presence of new or worsening diseases. Feedback from interested parties has indicated that PCPs are best equipped to conduct HRSN screenings and may have established relationships with community resources to address identified needs. While specialists may not have the resources to conduct HRSN screenings or be the most appropriate provider to address these concerns, we believe they should have some responsibility in ensuring HRSN screenings have been completed, considering unmet social needs can have a direct impact on the medical condition(s) they are managing. If a specialist identifies that a patient has not received an annual HRSN screening, they should communicate this information to the patient's PCP and encourage them to conduct the screening and initiate any necessary follow-up action(s). The specialist may also choose to conduct the screening themselves, as long as they communicate the results and any follow-up actions to the patient's PCP.

(ii) Improvement Activity 1 (IA–1) Specifications

IA–1 Name. Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening

IA–1 Specifications ASM participants must have evidence of processes, workflows, and/or technology that require the ASM participant to: (1) confirm the ASM beneficiary has access to primary care services and, if not, assist the ASM beneficiary in finding a clinician who provides primary care services, (2) communicate relevant information back to the ASM beneficiary's primary care provider following the ASM beneficiary's visit with the ASM participant, and (3) determine whether the ASM beneficiary has received an annual HRSN screening in the primary care setting and, if not, encourage the primary care services provider to conduct the screening or allow the ASM participant to conduct the HRSN screening.

[219] Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments.

[220] Barnett ML, Bitton A, Souza J, Landon BE. Trends in Outpatient Care for Medicare Beneficiaries and Implications for Primary Care, 2000 to 2019. *Annals of Internal Medicine.* Published online November 2, 2021. doi:*https://doi.org/10.7326/m21-1523.*

[221] Yang Z, Ganguli I, Davis C, et al. Physician-versus practice-level primary care continuity and association with outcomes in Medicare beneficiaries. *Health Services Research.* 2022;57(4):914–929. doi:*https://doi.org/10.1111/1475-6773.13999.*

[222] Timmins, Lori, et al. ''Communication Gaps Persist between Primary Care and Specialist Physicians.'' *The Annals of Family Medicine,* vol. 20, no. 4, 1 July 2022, pp. 343–347, *www.annfammed.org/content/20/4/343, https://doi.org/10.1370/afm.2781.*

[223] Long CL, Franklin SM, Hagan AS, et al. Health-Related Social Needs Among Older Adults Enrolled In Medicare Advantage. *Health Affairs.* 2022;41(4):557–562. doi:*https://doi.org/10.1377/hlthaff.2021.01547.*

[224] ROI Calculator for Partnerships to Address the Social Determinants of Health Review of Evidence for Health-Related Social Needs Interventions. (2019). *https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.*

Evidence can include items such as the following:

- Documented workflows or protocols outlining the process for identifying patients without a designated PCP, assisting patients in finding and establishing care with a PCP (such as practice intake forms or integrated into normal practice in the patient's visit), sharing relevant information (test results, treatment plans, follow-up recommendations) with the patient's PCP after each visit, confirming if the patient has completed an annual HRSN screening, or conducting or communicating with the PCP to conduct an annual HRSN screening if it has not been done.
- EHR system configurations or templates, or other health IT tools, that facilitate capturing and documenting the patient's PCP information, generating and sending visit summaries or reports to the PCP, or recording HRSN screening status and prompting follow-up actions.
- Staff training materials or competency assessments related to identifying patients without a PCP and assisting them in finding one, proper documentation and communication of information to the PCP, or inquiring about HRSN screening status and initiating appropriate follow-up.
- Audit trails or reports from the EHR or practice management system demonstrating patients who were identified as not having a PCP and the actions taken, visit summaries or reports sent to the PCP after each patient encounter, or patients who were confirmed to have completed an annual HRSN screening or underwent one or were referred to the PCP for one.

(iii) Improvement Activity 2 (IA–2): Establishing Communication and Collaboration Expectations With Primary Care Using Collaborative Care Arrangements

In IA–2, we propose at § 512.735(c)(2) to require annual attestations by ASM participants on activities related to establishing collaboration expectations with primary care. We believe that formalizing the collaborative relationship between ASM participants and PCPs through a collaborative care arrangement (CCA) is an important step to reduce patient fragmentation of care and ensures vital coordination activities are occurring. As discussed further below, we propose defining ''collaborative care arrangement'' to mean an arrangement that complies with all of the requirements set forth in § 512.771. We also propose to define ''ASM beneficiary'' at § 512.705 as a Medicare FFS beneficiary who is being treated by an ASM participant for a targeted chronic condition. There are several possible aspects to a CCA, but the goal of the CCA is to set forth expectations between the parties to facilitate primary care and specialty care integration for the benefit of the patient while ensuring both parties are held accountable for how they fulfill their duties.

To receive achievement points for IA–2, we propose at §§ 512.735(c)(2)(i) and (ii) that the ASM participant must enter into at least one CCA with a primary care practice that includes at least three of the following five following collaborative elements: data sharing, co-management, transitions in care planning, closed-loop connections, and care coordination integration as proposed at §§ 512.735(c)(2)(ii)(A) through (E). All of these CCA elements support an important prevention framework by promoting a seamless information ecosystem where providers collaborate to detect health risks before they occur and optimize care through communication. These elements also have properties that may overlap in their implementation with each other and IA–1, which together further the goals of the improvement activities ASM performance category.

The sharing of data back to PCPs is crucial for ensuring continuity of care for shared patients. Specialists should have clear processes in place to provide timely updates, test results, treatment plans, and follow-up recommendations to the patient's PCP, even outside the time of a referral between the parties. We also believe this exchange should be bi-directional, so that both entities have a comprehensive understanding of the patient's condition and can provide appropriate follow-up care and management.

Co-management is a collaborative approach where specialists and PCPs work together to provide coordinated care for patients with complex or chronic conditions. Generally, the different types of co-management include consultative co-management, where the specialist provides consultation and recommendations to the PCP who remains the primary manager of the patient's care; shared co-management, where both the specialist and PCP actively participate in managing the patient's care with clearly defined roles and responsibilities; and principal co-management, where the specialist takes the lead in managing the patient's condition while the PCP provides overall coordination and management of other aspects of the patient's care.[225] The benefits of co-management include shared decision-making and treatment planning, consistent monitoring and follow-up of the patient's condition, reduced duplication of tests and procedures, enhanced patient education and self-management support, and better management of comorbidities and potential drug interactions. Additionally, we believe co-management can lead to better health outcomes, improved patient satisfaction, and potentially lower health care costs by reducing fragmentation and unnecessary utilization of health care resources.

Transition in care planning refers to the processes and protocols in place for seamlessly transitioning a patient's care between specialists and PCPs, or between different care settings (for example, hospital to outpatient care).[226] Care planning can include follow-up appointments, medication reconciliation, and clear communication of the treatment plan. We believe effective transitions in care planning can help prevent gaps in care, reduce hospital readmissions, and ensure continuity of care for the patient. It may also involve defining roles and responsibilities for coordinating care, conducting warm handoffs, and ensuring timely follow-up appointments. When meaningfully implemented, it promotes a seamless and coordinated approach to care, where all providers involved have a shared understanding of the patient's needs and can work together to provide high-quality, patient-centered care.

Closed-loop communication and feedback between specialists and PCPs involve establishing a structured and coordinated process for when the patient is referred from primary care to specialty care and back. The model considers this to include elements such as structured referral templates, communication and information sharing, collaborative treatment planning, and shared monitoring of patient outcomes. By coordinating care effectively, providers can identify and address potential issues or gaps in care, reduce duplication of services or tests, and ensure that patients receive appropriate and timely care, ultimately improving quality and preventing

[225] Kuo D, Gifford DR, Stein MD. A typology of specialists' clinical roles. Arch Intern Med. 2009;169(11):1062–1068. doi:10.1001/archinternmed.2009.114.

[226] Smith, Lucia Rojas, et al. *Care Transitions Framework. www.ncbi.nlm.nih.gov,* Agency for Healthcare Research and Quality (US), 1 Mar. 2014, *www.ncbi.nlm.nih.gov/books/NBK196206/.*

unnecessary utilization of health care resources.[227]

Care coordination activities generally refer to efforts by the ASM participant to identify areas of their practice that could be improved by codified workflows or initiatives, as well as establishment of these activities collaboratively with the partnered primary care practice. These innovations support an environment of continuous improvement for practices and positive outcomes for their shared patients.

When selecting primary care practices for CCAs, ASM participants must ensure the CCA is with a primary care practice with whom they share at least one ASM beneficiary. We recommend that the ASM participant explore entering into a CCA with a primary care practice with whom the ASM participant shares a meaningful portion of their Medicare patients, to maximize the impact of the CCA activities. That is, ASM participants should seek to enter into an CCA with another primary care practice with which they share the largest number of ASM beneficiaries. If that is not feasible, then ASM participants should seek to enter into a CCA with a different primary care practice that they share a significant portion of ASM beneficiaries with.

(iv) Improvement Activity 2 (IA–2) Specifications

IA–2 Name. Establishing Communication and Collaboration Expectations with Primary Care Practices using Collaborative Care Arrangements

IA–2 Specifications. Documentation of at least one executed CCA between a primary care practice with which the ASM participant shares ASM beneficiaries, and the CCA must include collaborative efforts related to at least three of the following five elements:

- *Data Sharing.* Setting expectations for bi-directional sharing of patient information between the parties to the CCA, including but not limited to test results, treatment plans, and follow-up recommendations. This is aimed toward population health management of shared patients and is not necessarily coordinated around a specific referral episode. Elements may include: (1) evidence that the ASM participant always sends a report to the referring PCP; or (2) a process for capturing referral information that the ASM participant has a defined method for capturing reports from the primary care provider in the medical record, for example: reports transmitted between EHRs; documents that are electronically scanned and linked to the patient's EHR; or chart documentation of the relevant details of the specialist-patient interaction, such as notes written into a progress note.
- *Co-Management.* Criteria that define co-management approaches, where the parties to the CCA work together to furnish complementary care for patients with complex or chronic conditions. The criteria should clearly set forth the available co-management approaches. Examples of such co-management relationships may include: (1) consultative co-management, (2) shared co-management, or (3) principal co-management.
- *Transitions in Care.* Defined protocols for seamless transitions of care between ASM participants, the primary care practice, or different care settings. Elements may include: (1) patient-centered care transition action plans, such as documented plans from the ASM participant to the PCP, including outpatient follow-up recommendations, medication reconciliation, and any necessary post-transition support; (2) implementation of the transition plan, including documentation of staff involved in the care transition, records of real-time communication between the ASM participant and the primary care practice, and ensuring the primary care practice is included in any follow-up transition communication; or (3) care transition planning processes, which outline steps the ASM participant would take to prepare and implement the patient-centered care transition plan when transferring care to the PCP.
- *Closed-Loop Communication.* Clearly articulated processes enforcing parameters on how ASM beneficiaries may be referred between the parties to an executed CCA. These structured and enhanced referral processes would add efficiency to communications between the parties to the CCA and ensure expectations around what is needed for effective specialty consultation and collaboration. Examples of provisions that should be included are as follows: (1) expectations for the structure, elements, and flow of information and responsibilities between practices during a referral; (2) monitoring of shared ASM beneficiaries through the entire process to ensure proper follow-up, integration of information, and maintenance of beneficiary choice; and (3) integration of information from the closed-loop connection into the ASM beneficiary's plan of care.
- *Care Coordination Integration.* Structured processes to embed care coordination processes into the ASM participant's practice workflow. Such processes may include: (1) activity records documenting the implementation of care coordination activities with the primary care practice, such as meeting minutes on process improvements, workflow diagrams, training syllabi for training staff on new processes, copies of old and new processes on documenting care coordination activities; or (2) outcome measures demonstrating changes attributable to newly implemented care coordination processes.

We seek comments on the goals and specifications of the required improvement activities proposed at § 512.735(b) and (c).

(d) Improvement Activities Data Submission, Achievement Points, ASM Performance Category Scoring

We propose ASM participants must submit data on ASM improvement activities in the form of attestations meeting the submission requirements at § 512.720. We propose at § 512.735(d)(1) and (2) that ASM participants would receive 10 measure achievement points for reporting ''yes'' for each improvement activity specified at § 512.735(c) in accordance with the data submission requirements at § 512.720(a). We would sum the total achievement points for all submitted improvement activities and divide this sum by the total number of available achievement points for the required improvement activities as specified in paragraph § 512.735(c), not to exceed 100 percent.

In our proposals, both improvement activities would be weighted the same, each accounting for half of the potential improvement activities ASM performance category scoring adjustments to the final score. We considered differential weighting, with IA–1 comprising a smaller number of points for the scoring adjustment. The activities in IA–1, such as sharing patient information back to a PCP after a specialist visit, should already be occurring, whereas activities in IA–2, like the creation of a CCA, are less common and potentially more time consuming. We decided to propose to weight the improvement activities equally, each accounting for the same number of potential points in the improvement activities ASM performance category scoring adjustment, acknowledging the burden that these improvement activities may present to practices. For example, if an ASM participant is already conducting

[227] Murray M. Reducing Waits and Delays in the Referral Process. *Family Practice Management.* 2002;9(3):39–42. *https://www.aafp.org/pubs/fpm/issues/2002/0300/p39.html.*

activities that satisfy IA–1 specifications but do not satisfy IA–2 specifications in the 2027 ASM performance year, they would still be awarded 10 measure achievement points and an improvement activities ASM performance category score of 50 percent. We believe IA–1 would be achieved by the vast majority of ASM participants with limited effort, which may lessen the concern of initial improvement activity burden and impact to the ASM participant's overall score. Simultaneously, we want to promote specialty collaboration with primary care, thus if ASM participants do not achieve the expectations in IA–2, the ASM participant would only receive 10 measure achievement points. If ASM participants do not complete the requirements for IA–1 and do not complete the requirements for IA–2, they would receive zero measure achievement points and an improvement activities ASM performance category score of zero percent.

We seek comments on our improvement activities ASM performance category scoring approach at § 512.735(d)(1) and (2) and alternative improvement activity weighting and scoring options.

(5) Proposed Promoting Interoperability ASM Performance Category

Our long-term goal for the Promoting Interoperability performance category is to ensure the meaningful use of CEHRT and information exchange throughout the year, for all data, all clinicians, and all patients. We believe it is important to leverage the Promoting Interoperability ASM performance category for scoring adjustments to the final score, as discussed in section III.C.2.e. of this proposed rule.

(a) Background

This section includes proposals for the performance year for Promoting Interoperability measures, the requirement for CEHRT use and related attestations, data submission criteria and scoring for the ASM Promoting Interoperability performance category. The Promoting Interoperability performance category score would be used to determine the Promoting Interoperability performance category scoring adjustment applied to the final score.

(b) ASM Performance Year for the Promoting Interoperability ASM Performance Category

At § 512.740(a), we propose the ASM performance year for Promoting Interoperability category. Beginning with ASM payment year 2029, the performance year for Promoting Interoperability measures is the minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

Reporting for this period would provide ASM participants with the opportunity to continuously monitor their performance, identify gaps in reporting and identify areas that may require investigation and corrective action. Additionally, this performance period aligns with the MIPS performance period established for the MIPS Promoting Interoperability performance period established at § 414.1320(i)(1). We believe that alignment of the performance period between MIPS and the ASM model supports ASM participant's transition from MIPS to ASM.

We seek comments on our proposal at § 512.740(a) for the 180-day performance period for Promoting Interoperability measures.

(c) Reporting for the Promoting Interoperability Performance Category

We propose at § 512.740(b) to earn a performance category score for the Promoting Interoperability Performance category for inclusion in the final score, an ASM participant must be a meaningful EHR user. A meaningful EHR user means an ASM participant who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, and engages in activities related to supporting providers with the performance of CEHRT. We are proposing to not include additional provisions related to information blocking as defined at 45 CFR 171.103 in the definition of a meaningful EHR user.

The Promoting Interoperability ASM performance category would focus on the safe use and exchange of patient data. Our requirements to demonstrate meaningful CEHRT use through reporting Promoting Interoperability measures are discussed later in this section of this proposed rule.

(i) Required CEHRT Use

We propose our requirement for CEHRT use at § 512.740(b)(1) that ASM participants are required to provide evidence, in a form and manner specified by CMS, demonstrating use of CEHRT to fulfill the Promoting Interoperability measure requirements (as defined by a meaningful EHR user at § 414.1305) and receive a score greater than zero percentage points for the Promoting Interoperability ASM performance category. ASM participants must use certified health IT that meets the definition of CEHRT at § 414.1305 (which references health IT certification criteria finalized at 45 CFR 170.315) to receive a score greater than zero for the Promoting Interoperability ASM performance category. To demonstrate evidence of CEHRT use, ASM participants would be required to provide their EHR's CMS identification ID from the Certified Health IT Product List, available on *HealthIT.gov.*

We believe requiring the use of CEHRT supports the goals of ASM by helping enable: (1) meaningful EHR use, further measured by ASM's proposed Promoting Interoperability measures; (2) reporting of clinical quality measures, including eCQMs; (3) interoperability and data sharing between providers and with patients to drive better patient care, care coordination, and primary and specialty care integration; and (4) continuous practice-based quality improvement and care transformation. To promote standardization, we align with the definition of CEHRT at § 414.1305 used across CMS in other Promoting Interoperability and quality reporting programs. For example, CEHRT use is required for eligible clinicians participating in the MIPS program as stated at § 414.1375(b)(1).

In addition to requiring use of CEHRT, we are also maintaining the requirement ASM participants submit confirmation of the following to earn a score for this category:

- The Office of the National Coordinator for Health Information Technology (ONC) Direct Review attestation at 45 part 170, subpart E.
- The Security Risk Assessment Measure.
- The High Priority Practices Guide of the Safety Assurance Factors for EHR Resilience (SAFER) Guides [228] Measure.

We are proposing to not include the Actions to Limit or Restrict Compatibility or Interoperability of CEHRT attestation in ASM at this time.

We believe maintaining the ONC Direct Review process (45 CFR part 170, subpart E) in ASM increases accountability among certified health IT developers and vendors by ensuring ASM participants' Health IT Module [229] conforms to ONC's Health IT Certification Program requirements not

[228] *https://www.healthit.gov/topic/safety/safer-guides.*

[229] 45 CFR 170.102.

only during implementation of CEHRT, but also while CEHRT is being used during patient care and in care delivery.

The Security Risk Analysis and SAFER measures are designed to optimize the safety of ASM participants' EHR systems. We propose at § 512.740(b)(3)(ii) that an ASM participant must complete the activities included in the Security Risk Analysis measure within the calendar year of the ASM performance year. This aligns with a MIPS requirement for eligible clinicians in MIPS as stated at § 414.1375(b)(2)(ii)(A); ASM participants that previously participated in MIPS are likely familiar with these requirements. The security risk analysis is conducted to protect the security of individually identifiable health information and the systems that are used to create, receive, maintain, or transmit such information. An ASM participant would conduct a security risk analysi [230] in accordance with 45 CFR 164.308(a)(1)(A). As part of the security risk analysis, ASM participants would be required to address the security of electronic protected health information (ePHI) created, received, maintained, or transmitted by CEHRT, including whether it would be reasonable and appropriate in the participants' specific circumstances to encrypt ePHI in their CEHRT in accordance with requirements in 45 CFR 164.306(d)(3) and 45 CFR 164.312(a)(2)(iv), implement security updates as necessary, and correct identified security deficiencies as part of the ASM participant's risk management process.

We also propose at § 512.740(b)(3)(iii) that the ASM participant must confirm the ASM participant's completion of the annual self-assessment under the SAFER Guides measure within the calendar year of the ASM performance year. The High Priority Practices SAFER Guide[231] is used as an annual self-assessment to support consistent safety practices for all EHR users and further enable the electronic exchange of health information. This aligns with a requirement for eligible clinicians in MIPS as stated at § 414.1375(b)(2)(ii)(D).

Together, we believe these measures drive more secure, efficient, and meaningful use of CEHRT and health IT in ASM. Furthermore, given current and historical requirements in the Promoting Interoperability performance category in MIPS, these requirements are likely familiar and already implemented, or readily implementable, for many ASM participants.

We considered the alternative of allowing identified ASM participants without CEHRT to opt-out of participating in ASM. However, we would be concerned an opt-out would: (1) disincentivize the adoption of CEHRT and participation of specialists in value-based payment models, (2) be challenging for CMS to operationalize and audit, and (3) potentially result in a reduction in participant volume that would significantly affect ASM's impact and evaluability. We recognize there are underlying reasons why certain practices have yet to adopt CEHRT and that these practices currently not on CEHRT may share certain characteristics, such as smaller practice sizes with 15 or fewer clinicians, as defined at § 414.1305. To support these practices, we propose additional policies and flexibilities in ASM, such as the complex patient scoring payment adjustment described in section III.C.2.e.(3) of this proposed rule and the small practice scoring adjustment described in section III.C.2.e.(4) of this proposed rule, with the goal of not inadvertently penalizing these practices, particularly those who disproportionally care for populations with higher medical complexity and social risk. We also considered the alternative of requiring CEHRT but not requiring CEHRT-related attestations and requirements mentioned earlier, such as the Security Risk Assessment and SAFER Guides measures. We decided to include them given they help ensure safer and more meaningful use of CEHRT amongst ASM participants. Because they have been a consistent part of MIPS reporting in the past, ASM participants are likely familiar with these attestations and measures, which could help reduce burden.

We also considered the alternative of not requiring CEHRT to achieve a Promoting Interoperability ASM performance category score greater than zero. However, we were concerned this would deviate from existing MIPS policy and may disincentivize CEHRT adoption among ASM participants. Furthermore, requiring CEHRT to achieve a Promoting Interoperability category score underscores the role CEHRT plays in providing foundational IT capabilities to enable the reporting of quality data and inclusion of additional IT functionality, such as e-prescribing and health information exchange (HIE), which is captured in ASM's Promoting Interoperability measures. CEHRT use plays an important role in helping ASM participants improve and transform care for Medicare beneficiaries with chronic conditions, whether through electronic clinical decision support, physician order entry or exchanging electronic health information with other clinicians or health care settings.

Lastly, we considered inclusion of The Actions to Limit or Restrict Compatibility or Interoperability of CEHRT attestation in ASM as it would help ensure that ASM participants are acting in good faith when implementing and using CEHRT to exchange electronic health information, and not knowingly and willfully taking action to limit or restrict the compatibility or interoperability of CEHRT.

We request comments on our proposals to require that ASM participants use CEHRT to receive a score for the ASM Promoting Interoperability performance category. We also seek comments on the definition of meaningful EHR user and other alternatives discussed in this section of this proposed rule that would be required for ASM participants to achieve a Promoting Interoperability ASM performance category score greater than zero; this includes allowing for a CEHRT-related opt-out, not requiring CEHRT, and requiring the Actions to Limit or Restrict Compatibility or Interoperability of CEHRT attestation.

(ii) Promoting Interoperability Objectives and Measures

To receive a score for the ASM Promoting Interoperability performance category, clinicians must complete the relevant attestations and measures related to CEHRT and report Promoting Interoperability objectives and measures. Our Promoting Interoperability objectives and measures align with model goals and objectives and measures used in other CMS programs, including MIPS. We propose at § 512.740(b)(2) that an ASM participant must report on objectives and associated MIPS measures specified by CMS to assess performance in the Promoting Interoperability ASM performance category.

We propose at § 512.740(b)(2) that an ASM participant must fulfill the following requirements to earn an ASM performance category score for the Promoting Interoperability performance category: For each measure, as applicable, ASM participants would report the numerator (of at least one) and denominator, or yes/no statement or an exclusion for each measure that includes an option for an exclusion. We would require ASM participants to report all Promoting Interoperability

[230] Security Risk Analysis: *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2025-MIPS-Promoting%20Interoperability-Measure-Security-Risk-Analysis.pdf.*

[231] SAFER Guides. *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2025-MIPS-Promoting-Interoperability-Measure-High-Priority-Practices-Guide-of-SAFER-Guides.pdf.*

measures at the TIN/NPI level, which is consistent with the methodology used to identify eligible ASM participants, as described in section III.C.2.c.(3)(a)(i) of this proposed rule. We considered allowing for TIN-level reporting for Promoting Interoperability measures but decided to prioritize maintaining individual accountability and robust comparisons among ASM heart failure participants or ASM low back pain participants. We propose at §§ 512.740(b)(2)(i) through (iv) that ASM participants must attest to the objectives and associated measures for the ASM performance year. The Promoting Interoperability measures support the following objectives: Electronic Prescribing, HIE, Provider to Patient Exchange, and Public Health and Clinical Data Exchange, as shown in Table 41. The objectives encourage leveraging the electronic exchange of health information, with a focus on the safety of prescribing medications, communication between clinicians, patient access to their health information and reporting essential health data to public health agencies.

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TABLE 41: PROPOSED PROMOTING INTEROPERABILITY MEASURES

Objectives	Measures		Available Points (based on performance)	Redistribution if exclusion is claimed
e-Prescribing	e-Prescribing		1-10 points	10 points to HIE objective
	Query of PDMP		10 points	10 points to the e-Prescribing measure
Health Information Exchange (HIE)	Option 1	Support Electronic Referral Loops by Sending Health Information	1-15 points	15 points to Provide Patients Electronic Access to Their Health Information measure
		Support Electronic Referral Loops by Receiving and Reconciling Health Information	1-15 points	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	Option 2	HIE Bi-Directional Exchange	30 points	No exclusion
	Option 3	Enabling Exchange under TECFA	30 points	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information		1-25 points	No exclusion
Public Health and Clinical Data Exchange	Report to the following public health or clinical data registries: 1. Immunization Registry Reporting 2. Electronic Case Reporting		25 points for the objective	25 points to the Provide Patients Electronic Access to their Health Information measure if an exclusion is claimed for both measures.
	Option to report one of the following public health agency or clinical data registry measures: • Public Health Registry Reporting, OR • Clinical Data Registry Reporting, OR • Syndromic Surveillance Reporting		No bonus points	Not applicable

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As discussed earlier in this section of this proposed rule, ASM participants would be required to submit collected data for the required measures in each objective (unless an applicable exclusion is claimed) for the same 180 continuous days (or more) during the calendar year. Given these measures have remained consistent, required measures in MIPS, as stated at § 414.1375(b)(2), they are likely familiar with the measure specifications and implemented by many MIPS clinicians, which represents a substantial portion of potential ASM participants. We believe these measures align with the goals of ASM and reflect meaningful use of CEHRT. Electronic prescribing and provider to patient exchange, for example, through a patient portal, support patient-centered care and

improve communication between patients and providers. Interoperability is needed for effective collaboration between specialists and PCPs (aligning with the goals and activities of ASM's improvement activities), comprehensive care coordination, and seamless transitions of care.

Of the measures in the Public Health and Clinical Data Exchange category in MIPS, we would include the required measures only (Immunization Registry Reporting and Electronic Case Reporting) in ASM as they provide critical information to the mission and operations of our public health agencies. The other measures in this category (Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting) would remain optional in ASM. Given these measures have been a stable part of the MIPS Promoting Interoperability measure set, keeping them optional allows for ease of reporting for ASM participants who may already have developed workflows and infrastructure to capture this data.

(iii) Adding, Removing, and Modifying Measures

We propose to avoid making significant changes to these measure sets over the period of model; however, we may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. Note, because the measures currently proposed are all part of MIPS, any updates CMS applies to the measures within MIPS would be incorporated into the Promoting Interoperability ASM measure sets accordingly. Alternatively, we considered adopting the MIPS Promoting Interoperability measures, but requiring notice and comment rulemaking before adopting any modifications made to the measures' specifications specified by CMS through rulemaking for MIPS.

We seek public comments on these proposals on Promoting Interoperability measures and objectives and proposed alternative for adopting modifications made to the MIPS Promoting Interoperability measure specifications specified by CMS through rulemaking.

(iv) Supporting Use of CEHRT

ASM aims to support the electronic exchange of health information using CEHRT to improve patient care and coordination of care. We propose at § 512.740(b)(4) requirements to support the use of CEHRT.

- *Supporting the use and performance of CEHRT.* We propose at § 512.740(b)(4)(i)(A)(1) and (2) that the ASM participant support use of CEHRT by providing acknowledgement of the requirement to cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and if requested, cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field. Furthermore, we propose at § 512.740(b)(4)(i)(B) that an ASM participant has the option to attest to the following objectives and measures: at § 512.740(b)(4)(i)(B)(1) that the ASM participant acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and at § 512.740(b)(4)(i)(B)(2) if requested, that the ASM participant cooperate in good faith with ONC–ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field. Proposals to support providers with the performance of CEHRT aligns with requirements of the MIPS program as finalized at § 414.1375(b)(3)(i) through 414.1375(b)(3)(i)(B)(2).

We seek comments on our policies supporting the use and performance of CEHRT.

(d) Alternatives Considered for the Promoting Interoperability Reporting Requirements

We considered alternatives for the Promoting Interoperability reporting requirements. Our proposals mostly align with reporting requirements for the Promoting Interoperability performance category with the MIPS program for multiple reasons. Aligning with MIPS Promoting Interoperability objectives and measures where appropriate promotes standardization across CMS and its programs. Measure alignment can also reduce confusion, burden, and operational complexity for ASM participants by limiting the need for ASM participants to implement different specifications for potentially similar or related measures. Furthermore, the MIPS Promoting Interoperability measure set has been stable for several years and has been successfully reported in MIPS by most of its participants. Therefore, we do not believe it would be an undue burden for ASM participants to continue reporting these measures, particularly given they support the goals of ASM.

In our first alternative, we considered requiring reporting for CEHRT attestation, the ONC Direct Review Attestation, the Security Risk Assessment Measure, and the Safety Assurance Factors for EHR Resilience (SAFER) Guides Measure; each of these items is required in MIPS to get a Promoting Interoperability performance category score greater than zero. This option would not require specific reporting of Promoting Interoperability measures.

We also considered a second alternative that would require the attestations in the first alternative as well as reporting one of the Health Information Exchange options. We believe this option would emphasize the importance of health information exchange to the ASM.

A third alternative we considered was to adopt, by reference, the provisions of MIPS for the PI category, including both the measures and scoring policies. We also considered deferring the PI category measures within ASM to the PI category within MIPS such that the ASM would automatically update to align with MIPS for each future ASM performance year. Aligning with the PI category within MIPS would reduce complexity for ASM participants, especially those who have been participating in MIPS. While we believe this would limit confusion and align objectives across CMS, we decided that this could introduce risk to ASM insofar changes to the PI category could be introduced in MIPS that may not align with ASM's goals and priorities; in these cases, ASM could consider not adopting or delaying adoption of these changes. We believe that maintaining the PI category in ASM through rulemaking would be the better approach; however, we invite comment on the merits of ASM deferring measure selection and scoring to the MIPS PI category.

A fourth alternative would be to develop new Promoting Interoperability measures specific to ASM. While new measures could potentially more meaningfully capture the use of health IT in patient care, we were concerned about the feasibility of new measure development and the operational challenges that would be imposed on ASM participants and their EHR vendors to implement these new measures.

We seek comments on our proposals on Promoting Interoperability measures. We also seek comments on alternatives to reporting the full set of Promoting Interoperability performance category measures. We also seek comment on the alternative considered to adopt the PI category in MIPS in its entirety, in addition to the applicable scoring methods, for each applicable ASM performance year, including any ongoing updates to the MIPS PI category over the course of the model.

(e) Promoting Interoperability ASM Performance Category Scoring

We propose at § 512.740(c)(1) an ASM participant earns a score for each measure by fulfilling the reporting requirements specified at § 512.740(b) and if an exclusion, under the measure's specifications as maintained and published by MIPS, is reported for a measure, the points available for that measure are redistributed to another measure. We propose at § 512.740(c)(1)(i) maintaining the score amounts and applicable redistribution scoring policies for each required measure as set forth in the MIPS measure specifications. We refer readers to Table 41 for the scores assigned to each measure as defined in the MIPS measure specifications. We considered the alternative of developing an ASM-specific scoring system that assigns different scores to each Promoting Interoperability measure. However, we were concerned this would deviate from MIPS, which is likely already familiar to ASM participants. Furthermore, the existing scoring in MIPS already reflects ASM's priorities, for example, with more measure achievement points assigned to the Health Information Exchange category compared to the others.

As stated earlier and consistent with MIPS, the optional Public Health and Clinical Data Exchange measures (Public Health Registry Reporting, Clinical Data Registry Reporting, or Syndromic Surveillance Reporting) in ASM would remain optional in ASM. Furthermore, we are not adopting the MIPS scoring policy of assigning 5 bonus points for submitting a ''yes'' response for any of the optional Public Health and Clinical Data Exchange measures given they may be less relevant to the care provided to Medicare beneficiaries by ASM participant, for example, engaging with a public health agency to submit syndromic surveillance data from an urgent care setting. In addition, bonus points may signal greater importance of these measures over other Promoting Interoperability measures that more directly support ASM's goals, such as interoperability to support primary and specialty care integration. We continue to capture essential public health reporting activities on immunizations and reportable conditions in the two required Public Health and Clinical Data Exchange Promoting Interoperability measures.

We propose at § 512.740(c)(2) that unless otherwise specified by CMS, provided an ASM participant meets the CEHRT requirements as described in section III.C.2.d.(5).(b), CMS sums the scores for each of the required Promoting Interoperability measures described at § 512.740(b) and divides this sum by the total number of available Promoting Interoperability points to determine the ASM Promoting Interoperability performance category score. The ASM Promoting Interoperability performance category score cannot exceed 100 percent. If an ASM participant does not demonstrate meaningful CEHRT use as described in section III.C.2.d.5.(b) they would receive a zero for their Promoting Interoperability ASM performance category score. The Promoting Interoperability ASM performance category score would be used as a Promoting Interoperability performance category scoring adjustment to the final score specified under § 512.745(a)(1)(iv).

We considered automatically applying a score of zero for an ASM participant's Promoting Interoperability performance score for any ASM participant who did not meet achieve full points on the Promoting Interoperability performance category, however, we recognize it is important to acknowledge and credit the achieved points on the individual measures. Therefore, we would leverage the Promoting Interoperability performance category score for the Promoting Interoperability performance category scoring adjustments to the ASM final score, as discussed in section III.C.2.e.(1). of this proposed rule. The concepts represented in the Promoting Interoperability requirements support ASM participants in improving value, by improving patient care while maintaining or lowering the cost of care.

We are not proposing any exceptions for the Promoting Interoperability ASM performance category requirements. CMS has established automatic reweighting criteria of the Promoting Interoperability category in MIPS at § 414.1380(c)(2)(i)(C)(9) for certain MIPS eligible clinicians, such as hospital-based clinicians and Ambulatory Surgical Center-based clinicians, and for clinicians in small practices as defined in § 414.1305. The MIPS reweighting policy generally excludes the Promoting Interoperability performance category from the MIPS final score if the applicable clinician or group practice does not submit Promoting Interoperability data. Due to ASM's participant selection criteria (see section III.C.2.c.(3). of this proposed rule) many ASM participants, except for those in small practices with 15 or fewer clinicians, would not qualify for this automatic reweighting criterion if they were to be considered eligible clinicians under MIPS. For ASM participants in small practices or solo practitioner ASM participants, we are proposing to adjust final scores as described in section III.C.2.e.(4). of this proposed rule. We believe the potential confusion and complexity to develop and implement an exclusion policy for the Promoting Interoperability ASM performance category would outweigh any potential benefits it would have for a likely small number of participants.

Lastly, we are proposing an Extreme and Uncontrollable Circumstances policy at § 512.780 and discussed in section III.C.2.i. of this proposed rule, but we are not proposing to include a Promoting Interoperability-specific hardship application in ASM. Data analysis of 2023 data submitted by clinicians who participated in MIPS that would have met the ASM participant selection criteria showed that less than 1 percent of those clinicians submitted a Promoting Interoperability -specific hardship application. The operational lift and resources needed to develop and maintain a hardship application for ASM likely outweigh the potential benefit only a few practices may receive.

We seek comments on these proposals and discussed alternatives to score the ASM Promoting Interoperability performance category.

e. Proposed Final Score Methodology

In this section, we propose a scoring methodology for assessing the total performance of each ASM participant (referred to as a ''final score'') that allows for accountability and alignment for performance within each ASM cohort. Specifically, we propose to define at § 512.705 ''final score'' to

mean a composite assessment (using a scoring scale of zero to 100 points) for each ASM participant for an ASM performance year determined using the methodology for assessing the total performance of an ASM participant according to performance standards for applicable measures and activities for each ASM performance category as described in § 512.745.

The methodology discussed in this section would calculate a final score based on the quality and cost ASM performance categories scores for each ASM participant while considering negative scoring adjustments for the improvement activities and Promoting Interoperability ASM performance categories. Additional points would be added to the final score for ASM participants that address complex care and ASM participants that are part of small practices. Later in this section of the proposed rule, we propose specific data submission requirements for ASM participants to receive a final score. ASM participants that do not meet these minimum data submission requirements would receive a final score of zero, which would lead to the maximum negative payment adjustment applicable for the corresponding ASM payment year. We also propose that ASM participants who meet the data submission requirements to receive a final score but cannot be measured on quality or cost performance would not receive a final score and would therefore receive a neutral payment adjustment.

Specifically, we propose at § 512.745(a) to calculate a final score of zero to 100 points using the formula we propose in section III.C.2.e.(5). of this proposed rule and specified at § 512.745(a)(5) for each ASM participant that meets the requirements to receive a final score as proposed in section III.C.2.e.(2) of this proposed rule and specified at § 512.745(a)(2). We propose policies to determine scores for the ASM performance categories in sections III.C.2.d.(2). through III.C.2.d.(5). of this proposed rule. ASM performance category scores reflect the assessment of each ASM participant's performance on the applicable measures and activities for an ASM performance category for its applicable performance period based on the performance standards for those measures and activities.

We would use the final score to determine an ASM payment adjustment factor for the ASM participant for the applicable ASM payment year as discussed in section III.C.2.f. of this proposed rule.

(1) ASM Performance Category Weights and Scoring Adjustments

To create a final score from zero to 100 based on the individual ASM performance category scores, we propose at § 512.745(a)(1)(i) through (iv) to assign an ASM performance category weight of 50 percent to each of the quality and cost ASM performance categories and to apply adjustments to the final score based on scores in the improvement activities and Promoting Interoperability ASM performance categories. Accordingly, we propose that the improvement activities and Promoting Interoperability ASM performance categories would not have a performance category weight but would have separately applied scoring adjustments that are potentially applied to the final score. The proposed weights for the quality and cost ASM performance categories, as well as the improvement activities and Promoting Interoperability ASM performance category scoring adjustments are described in Table 42.

TABLE 42: ASM PERFORMANCE CATEGORY SCORING WEIGHTS AND ADJUSTMENTS BY ASM PERFORMANCE CATEGORY

ASM Performance Category	Weight or Scoring Adjustment in Final Score
Quality	50 percent weight
Cost	50 percent weight
Improvement Activity	Scoring adjustment of zero, -10, or -20 points
Promoting Interoperability	Scoring adjustment of zero to -10 points

We are proposing to only add weights to the quality and cost ASM performance categories for the final score and to not add weights to the improvement activities and Promoting Interoperability ASM performance categories to broaden the distribution of final scores. Based on historical MIPS performance in the improvement activities and Promoting Interoperability performance categories, we believe ASM participants would be likely to achieve higher ASM performance category scores in these two performance categories. One of the stated goals of ASM is to increase two-sided risk and create payment adjustments of a higher magnitude for ASM participants to incentivize performance improvements. If final scores were clustered around a small range of performance scores, differentiating performance and operationalizing a wider range of payment adjustments could prove difficult.

We are also proposing to weight the cost and quality ASM performance category scores at 50 percent each because those weights align with ASM's goal, as described in sections III.C.2.d.(2). and III.C.2.d.(3). of this proposed rule, of decreasing the cost of care for beneficiaries with ASM's targeted chronic conditions and improving quality care through a focused measure set relevant to ASM's clinical specialties and targeted chronic conditions. To drive cost and quality improvement as described in sections III.C.2.d.(2). and III.C.2.d.(3). of this proposed rule, we believe that weighting cost and quality ASM performance category scores at 50 percent creates the necessary incentives to lower chronic condition cost of care while improving quality metrics.

We propose at §§ 512.745(a)(1)(iii) and 512.745(a)(1)(iv) to introduce improvement activities and Promoting Interoperability scoring adjustments to the ASM participant's final score dependent on the performance in the improvement activities and Promoting Interoperability ASM performance categories. We propose at § 512.745(a)(1)(iii)(A) that ASM participants that achieve a 100 percent score for the improvement activities ASM performance category would not receive an improvement activities ASM performance category scoring adjustment to their final scores. We propose at § 512.745(a)(1)(iii)(B) that ASM participants that receive a 50 percent improvement activities ASM performance category score (that is, an ASM participant that attested to meeting the requirements of one of the two proposed required improvement

activities) would receive an improvement activities ASM performance category scoring adjustment of negative 10 points to the final score specified at § 512.745(a). We propose at § 512.745(a)(1)(iii)(C) that ASM participants that receive a zero percent improvement activities ASM performance category score would receive an improvement activities ASM performance category scoring adjustment of negative 20 points to the final score specified at § 512.745(a). The maximum improvement activities ASM performance category scoring adjustment would be negative 20 points.

To determine the Promoting Interoperability performance category scoring adjustment, we propose at § 512.745(a)(1)(iv)(A) and (B) that we would multiply the Promoting Interoperability ASM performance category score by 100 then subtract that product from 100 and divide by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10 points. The maximum Promoting Interoperability ASM performance category scoring adjustment would be negative 10 points. For example, if an ASM participant's Promoting Interoperability ASM performance category score was 73 percent, we would multiply 73 percent by 100, subtract 73 from 100 and divide the score by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10, resulting in a negative Promoting Interoperability ASM performance category scoring adjustment of 2.7 points.

We considered weighting all the ASM performance category scores to determine a final score instead of proposing the scoring adjustments for the improvement activities and Promoting Interoperability ASM performance category scores. Under this alternative, we considered the following ASM performance category weights to calculate the final score when there is no reweighting: (1) quality 30 percent; (2) cost 30 percent; (3) improvement activities 25 percent, and (4) Promoting Interoperability 15 percent. For similar reasons discussed earlier in this section of this proposed rule, we believe that increasing the weight on the improvement activities and decreasing the Promoting Interoperability ASM performance category weights relative to performance category weights in MVPs as defined at § 414.1365(e)(1) would increase the incentive to achieve the desired aims of improved primary care and specialty care integration under ASM. We believe that the improvement activities would be important to meet ASM's goal of better integrating specialty and primary care clinicians as described in section III.C.2.d.(4). of this proposed rule. Ultimately, we believe that the proposed ASM performance category weights and scoring adjustments, as discussed earlier in this section of this proposed rule, would overcome the potential challenges in determining meaningful payment adjustments if final scores were clustered around a small range of performance scores.

We also considered using the same ASM performance category weights used by the Quality Payment Program to score performance categories in MVPs as defined at § 414.1365(e)(1) but without the potential for reweighting as defined at § 414.1365(e)(2) (89 FR 98345). As defined at § 414.1365(e)(1), MVPs use the following performance category weights to calculate the final score when there is no reweighting: (1) quality 30 percent; (2) cost 30 percent; (3) improvement activities 15 percent; and (4) Promoting Interoperability 25 percent. We believe that the improvement activities ASM performance category's goal of integrating specialty managed care with primary care specialists is central to ASM's larger goal. Therefore, a higher weight should be given to the improvement activities ASM performance category over the Promoting Interoperability ASM performance category.

We believe weighting the quality and cost performance categories at 50 percent more accurately assigns points in support of ASM's goals. With regards to the negative scoring adjustments, the improvement activities ASM performance category's goal of integrating specialty managed care with primary care specialists is central to ASM's larger goal. Therefore, a higher number of potential negative scoring adjustment points should be given to ASM participants that do not meet requirements of the improvement activities ASM performance category over the Promoting Interoperability ASM performance category.

We seek comments on our proposed ASM performance category weights and scoring adjustments as proposed at § 512.745(a)(1) and the alternative ASM performance category weights we considered in this proposed rule.

(2) Requirements To Receive a Final Score

(a) Determining a Final Score When an ASM Participant Meets or Does Not Meet Minimum Data Submission Requirements

We propose at § 512.745(a)(2) that we would determine whether an ASM participant is eligible to receive a final score for the applicable ASM performance year depending on the data submitted by the ASM participant. We propose at § 512.745(a)(2)(i) that ASM participants who meet the data submission requirement for the quality ASM performance category as proposed at § 512.725(a)(1)(i) and receive quality and cost ASM performance category scores would receive a final score greater than zero but not exceeding 100 for the applicable ASM performance year. These ASM participants would receive a payment adjustment based on the methodology proposed in section III.C.2.f of this proposed rule. We propose at § 512.745(a)(2)(ii) that ASM participants who do not meet the data submission requirement for the quality ASM performance category as proposed at § 512.725(a)(1)(i) would receive a final score of zero for the applicable ASM performance year. As discussed in section III.C.2.f of this proposed rule, these ASM participants would be subject to the maximum negative payment adjustment for the applicable ASM payment year. We also note that an ASM participant's final score may also be affected if the ASM participant is affected by an eligible extreme and uncontrollable circumstance during an ASM performance year as discussed in section III.C.2.i of this proposed rule. We refer readers to section III.C.2.e.(2).(b) later in this section of this proposed rule for proposals related to final scores when ASM participants meet the quality ASM performance category data submission requirements but do not receive a quality or cost ASM performance category score. We also refer readers to Table 43 later in this section of this proposed rule for a summary of the proposed final score policies and their impact on payment adjustments.

As we propose ASM to be a mandatory model, we believe that we must set a minimum data submission requirement for an ASM participant to meet or otherwise be subject to the maximum negative payment adjustment as discussed in section III.C.2.f of this proposed rule. We believe that our proposed minimum data submission requirement is reasonable because it requires that an ASM participant reports at least one non-administrative claims-

based quality measure that also meets the data completeness requirement. Ultimately, this requirement would mean that the ASM participant is held accountable on the quality ASM performance category. Since we do not require ASM participants to submit data for the cost ASM performance category because we directly calculate the EBCMs, this proposed minimum data submission requirement would allow us to hold ASM participants accountable for quality and cost performance except in the case the ASM participant does not meet the case minimums for the quality and cost ASM performance category measures as discussed later in section III.C.2.e.(2).(b) of this proposed rule.

We seek comments on our proposed requirements at § 512.745(a)(2)(i) to calculate a final score for ASM participants and our proposal at § 512.745(a)(2)(ii) that an ASM participant who does not meet these requirements would receive a final score of zero for the applicable ASM performance year.

(b) Not Determining a Final Score When an ASM Participant Cannot Be Scored on the Quality or Cost ASM Performance Category

At § 512.745(a)(2)(iii), we propose that ASM participants who meet the data submission requirement for the quality ASM performance category as proposed at § 512.725(a)(1)(i) but do not receive a quality ASM performance category or a cost ASM performance category score would not receive a final score for the applicable ASM performance year. As discussed in section III.C.2.f.(4) of this proposed rule, these ASM participants would not receive payment adjustments in the corresponding ASM payment year. That is, only ASM participants who meet the requirements to receive a final score proposed earlier in this section of this proposed rule and receive a quality or cost ASM performance category score would receive a final score for the applicable ASM performance year. As proposed in section III.C.2.f.(4) of this proposed rule, ASM participants that receive a final score greater or equal to zero and not exceeding 100 would receive an ASM payment adjustment factor, defined in section III.C.2.f of this proposed rule, based on that final score for the applicable ASM payment year; otherwise, we propose that the ASM participant would not receive a final score and would receive no payment adjustments for the applicable ASM payment year. We also refer readers to section III.C.2.i of this proposed rule for how the proposed extreme and uncontrollable circumstance policy influences an ASM participant's final score if an ASM participant has been deemed to be affected by an eligible circumstance.

We believe that it is appropriate to hold ASM participants accountable for quality and cost for the purpose of determining payment adjustments. We recognize that there may be instances where an ASM participant meets the minimum data submission requirements for the ASM performance category to receive a final score described earlier in this section of this proposed rule but does not meet the case minimums for any required quality measure as discussed in section III.C.2.d.(2).(h) of this proposed rule or does not meet the case minimum for the required EBCM as discussed in section III.C.2.d.(3).(g) of this proposed rule. An ASM participant who does not receive a final score would receive a no payment adjustment (that is, neutral payment adjustment), meaning that they would not receive an upward or downward payment adjustment to their Medicare Part B payments for covered professional services for the applicable payment year because of participation in ASM. We believe that not determining a final score for the ASM participant and not adjusting payments during the applicable ASM payment year ensures that the ASM participant would not be unfairly penalized. We also believe that this proposal avoids complex reweighing policies. Reweighting policies would potentially mean that each final score represents a different mix of measures from different ASM performance categories. For example, one ASM participant could have a final score comprised of a cost ASM performance category score with improvement activities and Promoting Interoperability ASM performance category scoring adjustments whereas another could have a final score comprised of quality and cost ASM performance category scores. We believe that ensuring that all ASM participants' final scores reflect quality and cost performance is the most appropriate for determining payment adjustments that incentivize the care improvement and transformation that we seek to achieve through ASM.

We considered requiring that an ASM participant would only receive a final score if we could score them on all four proposed ASM performance categories as discussed in section III.C.2.d. of this proposed rule. We believed, however, that such a requirement would potentially be burdensome and not as well aligned with our intention to hold all ASM participants accountable for quality and cost performance at a minimum.

Table 43 summarizes the proposed requirements to receive a final score and the resulting impact on payment adjustments discussed in this section and in section III.C.2.f of this proposed rule.

TABLE 43: PROPOSED FINAL SCORE POLICIES AND RESULTING PAYMENT ADJUSTMENTS

ASM Participant Meets Quality ASM Performance Category Data Submission Requirement?	ASM Participant Receives a Quality ASM Performance Category Score?	ASM Participant Receives a Cost ASM Performance Category Score?	Final Score	Payment Adjustment
Yes	Yes	Yes	Greater than 0 and not exceeding 100	Positive, neutral, or negative adjustment depending on final score
Yes	No	Yes	None	None (that is, neutral)
Yes	Yes	No	None	None (that is, neutral)
Yes	No	No	None	None (that is, neutral)
No	No	Yes	0	Negative adjustment equal to the applicable ASM risk level
No	No	No	0	Negative adjustment equal to the applicable ASM risk level

We seek comments on our proposal at § 512.745(a)(2)(iii) that ASM participants that we cannot score on the quality or cost ASM performance category would not receive a final score for an ASM performance year. We also seek comments on the alternative of requiring data submission for all four ASM performance categories that we considered.

(3) Complex Patient Scoring Adjustment

We propose at § 512.745(a)(3) to apply a complex patient scoring adjustment to ASM participants' final scores for eligible ASM participants as described later in this section of this proposed rule. We propose to use two risk indicators, Hierarchical Condition Category (HCC) risk scores and the proportion of patients with dual eligible status, ''dual eligible proportion,'' to calculate the complex patient scoring adjustment to ASM participants' final scores. For the purposes of ASM, we propose at § 512.705 that ''risk indicator'' refers to Hierarchical Condition Category (HCC) risk scores under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act or the proportion of beneficiaries with dual eligible status used in calculating the complex patient scoring adjustment as defined at § 512.745(a)(3).

Social and medical risk factors, such as income and co-occurring chronic conditions, play a major role in health status and, accordingly, the types of services and procedures furnished to a beneficiary. Physicians may face unique challenges delivering care to those with more ''patient complexity,'' a term used to describe and account for a combination of factors that impact beneficiaries' health outcomes. In ASM, our aim is to shift the focus away from volume and towards direct accountability for the cost and quality of health care services delivered. At the same time, by introducing an assessment of performance among physicians with similar clinical profiles but who may have different caseloads of complex patients, we seek to ensure that the care furnished by ASM participants is assessed fairly to espouse predictability and sustainability. We believe that inclusion of a complex patient scoring adjustment in the determination of final scores would help to achieve these objectives.

The Quality Payment Program calculates a complex patient bonus and adds it to the MIPS final score for qualifying MIPS eligible clinicians based on their caseload of complex patients using two well-established risk indicators within the Medicare program: HCC risk scores and dual-eligible proportion under § 414.1380(c)(3). The CY 2018 Quality Payment Program final rule established a complex patient bonus to be added to the final score for the CY 2020 MIPS payment year (82 FR 53771 through 537756) as required by MACRA. The purpose of the policy was to address the impact patient complexity may have on MIPS scoring and mitigate discrepancies without masking performance. Subsequent rulemaking continued using the complex patient bonus and modified the formula based on several factors including stakeholder feedback, updated analysis, and implications from the HHS Assistant Secretary for Planning and Evaluation (ASPE) reports to Congress (86 FR 65510 through 65519).

We considered, but are not proposing, adopting an approach in which quality performance is risk adjusted for complex patients. We believe that providers have substantial control over the health care encounter and the outcomes assessed after the encounter. Thus, we decided that adjustments made at the quality measure or quality ASM performance category level would undermine our core aim to promote direct accountability and high-quality outcomes for all beneficiaries. Further, ASPE's second report released in June 2020, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, provides recommendations for addressing risk factors in Medicare's value-based payment programs, including discouraging risk adjustments on measures that assess the process and outcome of care given in the care setting.[232] The report reasoned that adjusting quality measures may have a negative impact on transparency for consumers and may inadvertently lower the standard of care. Instead, the report suggests including additional payments or bonuses for practices with a greater share of dual eligible and high-risk

[232] *https://aspe.hhs.gov/sites/default/files/private/pdf/263676/Social-Risk-in-Medicare%25E2%2580%2599s-VBP-2nd-Report-Executive-Summary.pdf.*

patients is more appropriate as it recognizes that providing excellent care for complex beneficiaries may require more physician services, resources, and capacity.[233]

Since the goal of the complex patient scoring adjustment policy in ASM is: (1) to protect access to care for complex patients and provide them with excellent whole-person care; and (2) to avoid placing ASM participants who care for complex patients at a potential disadvantage, we believe applying this complex patient scoring adjustment to the final score to determine payment adjustments is appropriate because caring for complex patients can affect all aspects of a practice, not just success in specific ASM performance categories. However, we recognize the importance of holding providers accountable for overall results, regardless of social and medical risk, and would want ASM participants to know the contribution of the complex patient scoring adjustment, if applicable, to their final score. Therefore, an ASM performance report, as discussed later in this section of this proposed rule, would include an ASM participant's complex patient scoring adjustment, if applicable, in addition to their final scores to ensure transparency in final score calculations.

We propose at § 512.745(a)(3)(i) that ASM participants who have at least one risk indicator (HCC risk scores and dual proportion) that is equal to or greater than the reference median for the risk indicator, described later in this section, for an applicable ASM performance year would have the complex patient scoring adjustment added to their final score for a given ASM performance year. The complex patient scoring adjustment would only be provided if the ASM participant meets the requirements to receive a final score greater than zero proposed at § 512.745(a)(2)(i) and discussed in section III.C.2.e.(2). of this proposed rule. We note that the proposed complex patient scoring adjustment calculation methodology is similar to MIPS' complex patient bonus. However, we propose limited methodological adjustments to better align the scoring adjustment with ASM's scoring approach.

To determine whether an ASM participant would qualify for the complex patient scoring adjustment, we propose to calculate a reference median for each risk indicator (HCC risk score and dual proportion) for each ASM cohort and for each ASM performance year. We propose to calculate the reference median of the ASM cohort's HCC risk scores and dual proportions using applicable data from 1 calendar year prior to the start of the applicable ASM performance year. We would only use applicable data from ASM participants that meet the data submission requirements for the quality ASM performance category for the applicable ASM performance year as described at § 512.725(a)(1)(i). For example, we would calculate the reference medians for the 2027 ASM performance year using data from the 2026 calendar year. We would then calculate each risk indicator (HCC risk score and dual proportion) for each ASM participant using data from the current ASM performance year (in this example, the 2027 ASM performance year). ASM participants who have at least one calculated risk indicator for the ASM performance year that is equal to or greater than the reference median risk indicator calculated for their applicable ASM cohort would be eligible to receive the complex patient scoring adjustment. ASM participants that do not have data available to calculate either risk indicator score for an applicable ASM performance year would not be eligible to have the complex patient scoring adjustment added to their final score.

We also propose to determine the reference median of each risk indicator separately for each ASM cohort to align with our proposed approach to make separate performance comparisons within each of these participant cohorts. We considered determining the reference median for each risk indicator using data from data from the concurrent ASM performance year but were concerned that Medicare claims runout periods would not provide complete data to calculate these medians within an ASM performance year. This approach would mirror the method that MIPS uses in calculating the complex patient bonus under § 414.1380(c)(3) with adaptations to align with the overall performance comparison approach of ASM. We also considered not requiring that an ASM participant have a median or higher value for at least one of the two risk indicators to qualify for the complex patient scoring adjustment. While this alternative would expand the number of ASM participants that would qualify for the complex patient scoring adjustment for an ASM performance, we believe targeting the complex patient scoring adjustments to ASM participants treating a higher caseload of highly complex patients would be more appropriate. We also considered using the mean, instead of the proposed median of the risk indicator as the cutoff point but believe it could decrease the percentage of ASM participants that would receive the complex patient scoring adjustment like what was observed by the Quality Payment Program in exploratory analyses for the MIPS complex patient bonus methodology (86 FR 65110).

We propose at § 512.745(a)(3)(ii)(C), like in MIPS, to determine a standardized score for each risk indicator based on the mean and standard deviation of the raw risk indicator score to provide a standardized measurement of the distance between each risk score and the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. We propose to use the mean and standard deviation from 1 calendar year prior to the ASM performance year using applicable data from ASM participants identified for that ASM performance year. Standardization allows us to determine how far each risk indicator score is from the mean. For example, the mean and standard deviations for the 2027 ASM performance year would be determined based on data from CY 2026 for ASM participants identified for the 2027 ASM performance year, which is a similar methodology to our proposed methodology to calculate the risk indicator reference medians described earlier in this section of this proposed rule.

We propose at § 512.745(a)(3)(ii)(A) to calculate the social complex patient scoring adjustment component as follows:

Medically complex patient scoring adjustment component = 1.5 + 4*associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by an ASM participant;

We propose at § 512.745(a)(3)(ii)(B) to calculate the medical complex patient scoring adjustment component as follows:

Social complex patient scoring adjustment component = 1.5 + 4* associated dual proportion standardized score.

We propose § 512.745(a)(3)(ii)(C) to add the components together to calculate one overall complex patient scoring adjustment.

[233] Johnston KJ, Joynt Maddox KE. The Role Of Social, Cognitive, and Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Aff (Millwood).* 2019;38(4):569–576. doi:10.1377/hlthaff.2018.05032. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05032.*

We propose at § 512.745(a)(3)(iii) that ASM participants with an HCC risk score or dual-eligible proportion above their respective medians, as calculated earlier in this section, would receive a complex patient scoring adjustment that cannot exceed 10 points and cannot be below zero points. We considered a complex scoring patient adjustment that could exceed 10 points and a complex scoring adjustment with a maximum point value less than 10 points but not below zero points. However, we believe that aligning the proposed complex patient scoring adjustment maximum point value with the MIPS complex patient bonus maximum point value would reduce confusion across ASM participant who would have previously participated in MIPS.

We believe the proposed formula compensates for a potential difference in payment related to HCC risk scores and dual proportion since MIPS uses the same approach in calculating the MIPS complex patient bonus defined at § 414.1380(c)(3) (86 FR 65510 through 65519). We believe this methodology and formula are strongly supported by data and analyses explained in the CY 2022 PFS proposed rule (86 FR 65510 through 65519). Furthermore, dual enrollees tend to have lower income, a greater prevalence of mental health conditions, somatic chronic conditions, and significantly higher annual costs of care than their nondual counterparts.[234] Thus, we believe that a complex patient scoring adjustment based on HCC risk scores and dual proportions, as is done in MIPS, would not only reduce inappropriate penalties among ASM participants that disproportionately care for dual eligible, high-risk populations but would also reduce inappropriate payments for ASM participants that care for less complex populations.

We seek comments on the proposed inclusion of the complex patient scoring adjustment in final scores and the proposed methodology for calculating the complex patient scoring adjustment. We also seek comments on our alternatives considered related to calculating the reference median based on data from the concurrent ASM performance year and using a reference mean instead of a reference median. We also seek comment on the alternative of not requiring ASM participants to have at least one risk indicator that is equal to or greater than the reference median to receive the complex patient scoring adjustment.

(4) Small Practice Scoring Adjustment

We propose at § 512.745(a)(4) that an ASM participant would be eligible to receive a small practice scoring adjustment in the calculation of their final score. We propose at § 512.705 to define a ''small practice'' as a practice consisting of 15 or fewer clinicians at the time we identify ASM participants for an ASM performance year as described at § 512.710(g). We propose at § 512.705 to define a ''solo practitioner'' as a practice consisting of 1 clinician at the time we identify ASM participants for an ASM performance year as described at § 512.710(g). Our proposed definitions for small practice and solo practitioner align with MIPS' small practice definition at § 414.1305.

We propose at § 512.745(a)(4)(i) to add 10 points to the final score of an ASM participant who: (1) is in a small practice as defined at § 512.705; (2) is not a solo practitioner as defined at § 512.705; and (3) and meets the requirement to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year. We propose at § 512.745(a)(4)(ii) to add 15 points to the final score of an ASM participant who is a solo practitioner as defined at § 512.705 and meets the requirement to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year.

We believe that it is necessary to support ASM participants against the potential challenges that they face in participation in Innovation Center models and other CMS value-based payment programs, like the Quality Payment Program. Participants in MIPS have provided feedback that many small practices and solo practitioners face challenges in their ability to participate in MIPS, including the costs to implement and maintain CEHRT, staff and training costs, and limited staff capacity to manage the complexity of the program (89 FR 98452). MIPS has several policies that aim to support small and solo practices, including scoring and reweighting policies as defined at § 414.1380. We considered adopting some of these policies for the purposes of ASM given our use of the MVPs as a framework for this model. However, our goal in designing a scoring policy for ASM was to increase incentives for participation and to reduce the complexity of reweighting policies based on the characteristics of an ASM participant or the context in which they practice.

We analyzed historical MIPS final score performance among a pool of likely ASM participants for both heart failure and low back pain. We found that small practices, including solo practitioners, were more likely to receive lower final MIPS scores compared to MIPS eligible clinicians in larger practices (that is, TINs with more than 15 clinicians). We also found that solo practitioners were more likely to receive lower scores than MIPS eligible clinicians in small practices (that is, practices with 2 to 15 clinicians in this situation). For these reasons, we believe that ASM participants in small practices would likely score lower than their counterparts in larger practices under ASM, with solo practitioners potentially scoring lower than other small practices. While we would not want to inadvertently skew the distribution of ASM participant final scores, we believe that it would be appropriate to support ASM participants in small practices to receive a final score adjustment.

We based the proposed magnitudes of the final scoring adjustments based on the distribution of MIPS final scores among likely ASM participants. We also considered small practice scoring adjustments that were lower and higher than the proposed 10 points for non-solo practitioner ASM participants in small practices and 15 points for solo practitioner ASM participants. However, we believe that the proposed magnitudes of the scoring adjustments would appropriately increase the applicable ASM participants' score and would be easily understood by ASM participants. We refer readers to section III.C.2.f.(4).(b). of this proposed rule for an alternative level of risk that we considered for ASM participants in small practices.

We believe that using a flat adjustment on the final score would be a clear and transparent method to support ASM participants to increase their score relative to other ASM participants so as to avoid potentially creating a barrier for them to achieve a net positive payment adjustment (see section III.C.2.f in this proposed rule for further discussion on our proposed payment methodology). Since we are not proposing to reweight ASM performance categories in the calculation of final scores as discussed earlier in this section of this proposed rule to simplify the data submission requirements and scoring policies, we believe that a flat adjustment would be a simple but effective mechanism to support ASM participants in small practices.

We considered but are not proposing a similar flat-point adjustment for ASM

[234] Johnston KJ, Joynt Maddox KE. The Role Of Social, Cognitive, and Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Aff (Millwood).* 2019;38(4):569–576. doi:10.1377/hlthaff.2018.05032. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05032.*

participants in rural areas as defined at § 512.705 (which aligns with the MIPS rural area definition at § 414.1305). We, however, found in our analysis of historical MIPS performance data among likely ASM participants that there was not a systematic difference in the performance data between likely ASM participants in rural and non-rural areas. While MIPS reduces the reporting requirements for the improvement activities performance category for MIPS eligible clinicians in rural areas as defined at § 414.1380(b)(3), the lack of a systematic difference in historical MIPS performance between likely ASM participants of rural and non-rural status led us to not propose a scoring adjustment for ASM participants in rural areas. Furthermore, we observed that a high proportion of likely ASM participants in small practices were in rural areas. Adding a rural scoring adjustment on top of the small practice scoring adjustments would potentially be duplicative and inappropriately skew the distribution of final scores.

We seek comments on our proposal at § 512.745 (a)(4)(i) to add 10 points to the final score of an ASM participant who is in a small practice, is not a solo practitioner, and meets the requirements to receive a final score greater than zero and not exceeding 100. We also seek comment on our proposal at § 512.745 (a)(4)(ii) to add 15 points to the final score of an ASM participant who is a solo practitioner and meets the requirements to receive a final score greater than zero and not exceeding 100. Finally, we seek comments on the alternative we considered of applying a similar flat-point adjustment for ASM participants in rural areas.

(5) Final Score Calculation

We propose at § 512.745(a)(5) the following formula to calculate the final score for each ASM participant that meets the minimum data submission requirements discussed in section III.C.2.e.(2).(a) of this proposed rule:

Final score = [(quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + Complex Patient scoring adjustment + Small Practice scoring adjustment.

NOTE: The final score cannot be below zero points or exceed 100 points

We believe that this proposed final score calculation appropriately utilizes the quality and cost ASM performance category scores as outlined in sections III.C.2.e of this proposed rule, weights the quality and cost ASM performance categories, and considers the inclusion of the negative improvement activities ASM performance category scoring adjustment, the negative Promoting Interoperability ASM performance category scoring adjustment, the positive complex patient payment adjustment, and positive small practice scoring adjustment.

For example, under the proposed final score calculation and the proposed weights for the quality and cost performance category, if an ASM participant has a quality performance category score of 80 percentage points [(40 measure achievement points out of 50 available measure achievement points)], a cost performance category score of 75 percentage points [(7.5 achievement points out of 10 available achievement points)], a negative improvement activity performance category scoring adjustment of −10 from successfully attesting to one improvement activity, a negative Promoting Interoperability ASM performance category scoring adjustment of −2.7 ((100 potential maximum Promoting Interoperability ASM performance category points − 73 Promoting Interoperability ASM performance category score)/ − 10), a complex patient scoring adjustment of 5.5, and a small practice scoring adjustment of 10 from being in a small practice, the final score would be as follows:

Final Score = [0.80 × 50 percent) + (0.75 × 50 percent)] × 100 + (− 10) + (− 2.7) + 5.5 + 10 = 80.3.

The ASM participant under the example conditions described above would have 77.5 points from the quality and cost ASM performance categories ([(0.80 × 50 percent) + (0.75 × 50 percent)] × 100), before the scoring adjustments are applied, and a final ASM score of 80.3 points

We seek comments on the proposed final score calculation formula.

(6) ASM Performance Report

We propose at § 512.745(b) to release an ASM participant's final score for each ASM performance year through an ''ASM performance report,'' which we propose to define at § 512.705 as the notification that CMS provides to the ASM participant for each ASM performance year, which contains the information specified at § 512.745(b). We propose at § 512.745(b)(1) through (7) that the ASM performance report would, at minimum, provide each ASM participant: (1) individual measure-level scores for each of the measures required under each ASM performance category; (2) ASM performance category-level scores; (3) complex patient scoring adjustment, as applicable; (4) small practice or solo practitioner scoring adjustment, as applicable; (5) final score, and (6) the applicable ASM payment adjustment factor and (7) ASM payment multiplier for the applicable ASM payment year as discussed in section III.C.2.f of this proposed rule. As proposed, the ASM performance reports would not contain any protected health information or personally identifiable information of beneficiaries. Accordingly, we would share the ASM performance reports with ASM participants as a matter of course without following the attestation and data sharing agreement process for CMS sharing of beneficiary-identifiable information proposed in section III.C.2.j. of this proposed rule.

We believe that the proposed approach to releasing ASM participant data would be a transparent way to help the ASM participant understand their performance on each of the required measures, activities, attestations, how those individual scores roll up to an overall ASM performance category score, and then how each ASM performance category score rolls up into the final score. We believe that this ASM performance report would be complementary to the other proposed data sharing approaches discussed in section III.C.2.j. of this proposed rule.

We seek comments on our proposal at § 512.745(b) to provide ASM participants with an ASM performance report for each ASM performance year. We also seek comments on the proposed components of the ASM performance report.

f. Proposed ASM Payment Approach

(1) Payment Approach

In this section, we discuss our proposed payment methodology to use an ASM participant's final score to determine net positive, neutral, or negative payment adjustments to an ASM participant's future Medicare Part B payments for an applicable ASM payment year.

ASM would test whether payment adjustments to ASM participants' future Part B FFS payments would preserve or improve the quality of care for beneficiaries with ASM's targeted chronic conditions receiving service from ASM participants while reducing program expenditures. Determining payment adjustments based on an ASM participant's performance across the ASM performance categories relative to other specialists furnishing services

related to each of ASM's targeted chronic conditions would directly incentivize performance improvement through financial incentives. We believe the proposed individualized payment adjustments under ASM would be reflective of the range of performance of specialists caring for beneficiaries with ASM targeted chronic conditions. As discussed in section III.C.1. of this proposed rule, we believe that the risk of a potential negative payment adjustment coupled with the incentive of a potential positive payment adjustment would incentivize the quality improvement and reduced low-value care spending that we aim to achieve through ASM. This type of risk arrangement would reward high performance and encourage ASM participants to improve the quality of care that they furnish to Medicare beneficiaries with ASM's targeted chronic conditions. Further, we believe that this type of incentive payment approach aligns with existing value-based purchasing programs, such as the Quality Payment Program, in which ASM participants may have previously participated, and through which they may have received payment adjustment on future Medicare Part B payments based on their performance in MIPS.

We believe our proposed payment methodology for an ASM participant to receive a positive, neutral, or negative payment adjustment based on their performance would be a strong incentive to promote performance improvement and achieve ASM's objectives.

(2) Payment Methodology Overview

We propose at § 512.750 a payment methodology for ASM where we would distribute, based on performance and in the form of scaled payment adjustments, a portion of the Medicare Part B payments paid to ASM participants for covered professional services during an ASM performance year, which would result in net positive, neutral, or negative payment adjustments during an ASM payment year. Accordingly, we propose to define at § 512.705 an ''ASM incentive pool'' that would be a fixed percentage of the total amount of Medicare Part B covered professional service claims paid to ASM participants with final scores within an ASM cohort during an ASM performance year that would be distributed in in the form of scaled payment adjustments during an ASM payment year. We would calculate an ASM incentive pool for each ASM cohort for each ASM payment year as described at § 512.750(c)(1)(iii). The ASM incentive pool would be the total amount of funds that we would use to calculate scaled payment adjustments for an ASM payment year. We propose to separately calculate an ASM incentive pool for each ASM cohort. For example, we would calculate a separate ASM incentive pool for the ASM heart failure cohort and ASM low back pain cohort. As discussed later in this section of this proposed rule, we would not prospectively withhold a portion of Part B payments for covered professional services during an ASM performance year to create the ASM incentive pools but would instead create virtual incentive pools based on actual spending during the ASM performance year.

We also propose to define at § 512.705 an ''ASM payment adjustment factor'' as a percent value based on an ASM's participant's final score as described at § 512.750(c)(1) that we use in calculating adjustments to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year. Based on their performance, an ASM participant could earn an ASM payment adjustment factor percentage that is less than, equal to, or more than the percentage of their Medicare Part B payments used to calculate the ASM incentive pool, leading to a net negative, neutral, or positive net payment adjustment. Similar to our proposal to calculate separate ASM incentive pools for each ASM cohort, we would determine ASM payment adjustment factors separately for each ASM cohort as described later in this section of this proposed rule. We also propose to define at § 512.705 an ''ASM payment multiplier'' as the numerical value equal to 1 plus the ASM payment adjustment factor determined for the ASM participant for an applicable ASM payment year as described at § 512.750(c).

As proposed at § 512.750(a), to adjust payments, the amount otherwise paid under Medicare Part B for covered professional services furnished by an ASM participant during an ASM payment year would be multiplied by the ASM participant's ASM payment multiplier unless that ASM participant receives no payment adjustment (that is, a neutral payment adjustment) as described at § 512.750(d) because they do not receive a final score for the corresponding ASM performance year. We refer readers to § 512.745(a)(2) and section III.C.2.e.(2). of this proposed rule for proposals related to final scores. We also refer readers to section III.C.2.f. of this proposed rule and § 512.750(f) for further proposals on how payment adjustments are applied in the case the ASM participant bills during an ASM payment year under a different TIN than the TIN we used to identify them as an ASM participant for the corresponding ASM performance year.

The proposed payment methodology is similar in design to existing incentive payment structures in CMS value-based programs, such as the Hospital Valued-Based Purchasing Program (Hospital VBP Program) [235] and the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP Program).[236]

- The Hospital VBP Program rewards acute care hospitals with incentive payments based on the quality of care they provide, rather than just the quantity of services they provide. The statutory requirements of the Hospital VBP Program are set forth in Section 1886(o) of the Social Security Act. The program uses selected measures that were first specified under the Hospital Inpatient Quality Reporting Program as established by section 1886(o)(2)(A) of the Act and defined at § 412.164(a).[237] A fixed percentage withhold of base operating Diagnosis-Related Group (DRG) payments for each discharge during an applicable fiscal year determines the amount of money that can be redistributed to participating hospitals through value-based incentive payments based on a participating hospital's total performance score. A hospital may earn back a value-based incentive payment percentage that is less than, equal to, or more than the applicable reduction for that program year (88 FR 59063 through 59108).

- Section 215 of the Protecting Access to Medicare Act of 2014 and subsequent additions of sections 1888(g) and (h) of the Act established the SNF VBP Program.[238] Then, section 111 of the Consolidated Appropriations Act, 2021 amended section 1888(h) of the Act to allow the Secretary to apply up to 9 additional measures to the SNF VBP Program.[239] The SNF VBP Program requires CMS to evaluate SNFs based on their performance on multiple measures, including improvement and achievement, provide quarterly performance reports to SNFs, and calculate incentive payments for SNFs based on their performance (88 FR

[235] *https://www.cms.gov/medicare/quality/initiativeshospital-quality-initiative/hospital-value-based-purchasing.*

[236] *https://www.cms.gov/medicare/quality/nursing-home-improvement/value-based-purchasing.*

[237] *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing.*

[238] 42 U.S.C. 1395yy(h).

[239] 42 U.S.C. 1395yy(h).

53276 through 53304).[240] To determine and fund the statutorily required incentive payments, CMS withholds 2 percent of SNFs' Medicare FFS Part A payments to fund the SNF VBP Program. CMS then redistributes 60 percent of this total withhold to SNFs as incentive payments, which CMS applies prospectively to all Medicare FFS Part A claims paid under the SNF Prospective Payment System (PPS) for the applicable program year (82 FR 36619 through 36621).

Our proposed payment methodology differs from the Hospital VBP Program and the SNF VBP Program in that we are not proposing a prospective withhold of ASM participants' Medicare Part B payments during an ASM performance year. Instead, we are proposing to determine a virtual ASM incentive pool as a fixed percentage of ASM participants' Medicare Part B covered professional service payments during the ASM performance year. We would then distribute this virtual incentive pool through scaled payment adjustments on ASM participants' future Medicare Part B payments during an ASM payment year. The size of each ASM incentive pool and the distribution of final scores within each ASM cohort would together influence the possible magnitude of the scaled payment adjustments and the distribution of net negative, neutral, and positive payment adjustments. As discussed earlier and later in this section of this proposed rule, we propose to calculate ASM incentive pools, ASM payment adjustment factors, and ASM payment multipliers separately for each ASM cohort. The higher an ASM participant's final score, the greater the likelihood that they would receive a positive payment adjustment. Under this proposed methodology, the ASM participant's performance during an ASM performance year would not have an immediate financial impact but would result in a future net payment adjustment determined by the ASM participant's performance relative to other ASM participants. We believe that this proposed payment methodology would allow ASM to create net positive, neutral, and negative payment adjustments based on the annual distribution of final scores in each ASM cohort.

We also recognize that MIPS, under the Quality Payment Program, uses a value-based purchasing approach but determines payment adjustments based on performance relative to a performance threshold. In accordance with section 1848(q)(6) of the Act and § 414.1405(b), MIPS compares each MIPS eligible clinician's final score against the performance threshold established for that MIPS payment year and against the other MIPS eligible clinicians in a single comparison pool to determine whether each MIPS eligible clinician will receive a positive, negative, or neutral payment adjustment. As defined at § 414.1405, scores equal to the defined performance threshold receive a neutral (zero percent) payment adjustment. Scores falling below one-quarter of the performance threshold receive a negative adjustment of minus 9 percent, while scores between one-quarter of the performance threshold and the performance threshold receive a negative payment adjustment less than zero percent and up to minus 9 percent based on a linear sliding scale. Scores above the performance threshold can receive positive payment adjustments greater than zero percent and up to positive 9 percent based on a linear sliding scale. Depending on the range of scores within a given MIPS performance period, a scaling factor (ranging from zero to 3 is applied to the positive adjustments to retain budget neutrality.

We considered, but decided not to propose, a payment methodology that includes a performance threshold like MIPS uses to determine ASM payment adjustment factors. To determine a MIPS payment adjustment factor for each MIPS eligible clinician for a MIPS performance period, CMS compares the MIPS eligible clinician's final score for the given year to the performance threshold CMS established for that same year in accordance with Section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that CMS compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years. For each CY performance period/MIPS payment year, CMS has finalized a performance threshold based on the mean final score of all MIPS eligible clinicians from a previous MIPS performance period, as set forth in § 414.1405(b)(4) through (10). CMS establishes the performance threshold via rulemaking prior to the beginning of each MIPS performance period.

Adopting a similar performance threshold and payment adjustment approach for ASM would introduce several operational complexities. First, given the proposed separate comparison of final scores and separate calculation of ASM payment adjustment factors and ASM payment multipliers for each ASM cohort, we would need to determine a performance threshold for each ASM cohort for each ASM performance year. Because ASM is a new Innovation Center model, we would need to set a prospective performance threshold for the first ASM performance year without historical data on final scores. This lack of historical data could present challenges in calibrating the performance threshold to actual performance within the first ASM performance year. Second, we believe that a payment methodology that leverages a prospective performance threshold would limit the magnitude of ASM's negative and positive payment adjustments and, ultimately, the model's incentives to improve performance compared to our proposal to scale the payment adjustments distributed to ASM participants to equal the amount of an ASM incentive pool. For example, if a larger proportion of participants score above the performance threshold relative to the proportion of participants who score below the performance threshold, then the positive payment adjustments for those participants scoring above the performance threshold may be smaller in magnitude due to there being fewer negative adjustments from participants scoring below the performance threshold that can be distributed in positive payment adjustments.

We seek comment on our overall payment approach for ASM, which would include an ASM incentive pool that is distributed in the form of scaled payment adjustments to ASM participants' future Medicare Part B payments based on their performance. We also seek comments on the alternative approach we considered that would use a performance threshold similar to MIPS in our payment methodology.

In the following sections, we propose and seek comments on our proposed policies to (1) compare performance across ASM participants within each ASM cohort and (2) calculate ASM payment adjustment factors and ASM payment multipliers, including how we propose to calculate the ASM incentive pools.

(3) Comparison of ASM Participant Performance

We propose at § 512.750(b) to separately compare the final scores of ASM participants in each ASM cohort to determine the payment adjustments

[240] *https://www.cms.gov/medicare/quality/nursing-home-improvement/value-based-purchasing.*

for each ASM participant. We believe that the ASM participant eligibility criteria appropriately identify specialists that can be held accountable for cost, quality, and practice improvement for specific chronic conditions. Accordingly, we believe that separately comparing ASM participants' final scores for each of the ASM targeted chronic conditions would provide more meaningful performance comparisons. Since each ASM cohort would be compared on the same set of requirements reported at the same TIN/NPI level (that is, the level at which an ASM participant is identified), the proposed performance comparison approach would allow for better differentiation in performance upon which to determine the payment adjustments.

Currently, under MIPS, performance measurement and the subsequent payment adjustment are based on a range of measures voluntarily reported by clinicians, each of whom receives a final score based on the submitted measures. A MIPS eligible clinician's performance is assessed against a pool of all clinicians, regardless of specialty type or the services they provide. In accordance with section 1848(q)(6) of the Act and § 414.1405(b), CMS compares each MIPS eligible clinician's final score against the performance threshold established for that MIPS payment year and against one another in a single comparison pool to determine whether each MIPS eligible clinician will receive a positive, negative, or neutral payment adjustment. CMS calculates MIPS payment adjustment factors in accordance with regulations at § 414.1405 (89 FR 61985). In ASM, we wish to test whether a more targeted approach where clinicians are evaluated: (1) on a set of relevant performance measures they are required to report; and (2) among clinicians furnishing similar sets of services, would produce final scores and subsequent payment adjustments that are more reflective of clinician performance. We believe our proposed approach to separately compare ASM heart failure participants against other ASM heart failure participants and ASM low back pain participants against other ASM low back pain participants supports and incentivizes accountable care by creating more meaningful payment adjustments that differentiate and reflect ASM participant performance related to the chronic condition for which we believe the ASM participant should be accountable.

We considered not separating ASM participants in each ASM cohort when comparing final scores to determine ASM payment adjustment factors and ASM payment multipliers, and instead, comparing the final scores of all ASM participants together. This approach would potentially be administratively easier to operationalize and would align with the current practice of comparison under MIPS, including MVPs, as defined at § 414.1405. It would also potentially lead to a more varied distribution of final scores that would translate into a more varied distribution of payment adjustment, which could be helpful in creating the desired payment incentives. However, we believe that comparing performance within each ASM cohort is more appropriate in meeting our aim to test whether like-to-like performance comparisons based on a clinically relevant measure set and the resulting payment incentives achieve ASM's objectives of increasing accountability for specialty care related to ASM targeted chronic conditions.

We also believe that comparing performance using a continuous distribution of final scores would result in more meaningful incentives for ASM participants because payment adjustments would be determined on relative performance across ASM participants instead of relative to a prospectively determined performance threshold. This approach also more closely mirrors the general market for goods and services, which does not provide an upfront guarantee of a certain market share or profit margin based on a predetermined threshold of performance. Rather, ASM participants would compete to provide the highest quality, most efficient care to ASM beneficiaries, and the top performers would receive positive payment adjustments—in the same way that competitive markets reward top performers with profits.

We seek comments on our proposal at § 512.750(b) to determine ASM payment adjustment factors and ASM payment multipliers by comparing final scores separately among each ASM cohort. We also seek comment on the alternative we considered of comparing final scores of all ASM participants together, like the MIPS approach for comparing performance scores.

(4) Calculation of ASM Payment Adjustment Factors and ASM Payment Multipliers

In this section, we first provide an overview of the proposed process to calculate ASM payment adjustment factors and ASM payment multipliers. We then break down each part of the calculation process and discuss our proposals and alternatives considered. As part of this process, we discuss the calculation of the ASM incentive pool using the ''ASM risk level,'' which we propose to define at § 512.705 as the magnitude of the maximum positive or negative net payment adjustment percentage to which an ASM participant would be subject during an ASM payment year as described at § 512.750(c)(1)(i), and the ''ASM redistribution percentage,'' which we propose to define at § 512.705 as a percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that CMS distributes in the form of payment adjustments to ASM participants during an ASM payment year as described at § 512.750(c)(1)(iii).

We then discuss our proposals on how we would convert final scores into ASM payment adjustment factors and ASM payment multipliers based on the ASM incentive pool and our proposed ''exchange function,'' which we propose to define at § 512.705 as the function used to translate an ASM participant's final score into an ASM payment adjustment factor as described at proposed § 512.750(c)(1)(ii). We also propose to define at § 512.705 a ''scaling factor'' as a numerical value calculated by CMS to ensure that the total estimated payment adjustments in an ASM payment year are equal to an ASM incentive pool for an applicable ASM payment year as described at § 512.750(c)(1)(iv).

Finally, we discuss how these ASM payment multipliers would be applied to future Medicare Part B claims for covered professional services during an ASM payment year.

(a) Overview of ASM Payment Adjustment Factor and Payment Multiplier Calculation Process

We propose at § 512.750(c) to use the following process to calculate ASM payment adjustment factors and ASM payment multipliers for each ASM payment year for ASM participants with final scores for the corresponding ASM performance year. We refer readers to Table 43 in section III.C.2.e.(2). of this proposed rule for a summary of how an ASM participant's final score influences their payment adjustment.

Calculation of ASM Incentive Pool

- *Step 1.* Calculate total Medicare Part B payments for covered professional services made to ASM participants with final scores in each ASM cohort during an ASM performance year.
- *Step 2.* Multiply the total calculated in Step 1 by the ASM risk level for each ASM payment year proposed at

§ 512.750(c)(1)(i) and discussed in section III.C.2.f.(4).(b).(i). of this proposed rule.

• *Step 3.* Multiply the amount calculated in Step 2 by the ASM redistribution percentage proposed at § 512.750(c)(1)(iii) and discussed in section III.C.2.f.(4).(b).(ii) of this proposed rule to determine the total ASM incentive pool amount available for payment adjustment for each ASM cohort.

Calculation of ASM Payment Adjustment Factor

• *Step 4.* Convert each ASM participant's final score into a transformed numerical final score by using the exchange function proposed at § 512.750(c)(1)(ii) and described in section III.C.2.f.(4).(c). of this proposed rule.

• *Step 5.* Calculate a scaling factor as proposed at § 512.750(c)(1)(iv) to ensure that the sum of applied ASM payment adjustment factors would equal the ASM incentive pool for each ASM cohort. The scaling factor is calculated by dividing the total amount in the ASM incentive pool (calculated in Step 3) by the sum of all ASM participant's transformed final scores (calculated in Step 4) multiplied by their respective total Medicare Part B covered professional services payments and the ASM risk level.

• *Step 6A.* For ASM participants that receive a final score greater than zero as described at § 512.745(2)(i), calculate an ASM payment adjustment factor for each ASM participant within each ASM cohort by multiplying the ASM risk level, the ASM participant's transformed final score (calculated in Step 4), and the scaling factor (calculated in Step 5), and then subtracting the ASM risk level from this product as described at § 512.750(c)(1)(i):

ASM payment adjustment factor = (ASM risk level × transformed final score × scaling factor) − ASM risk level

• *Step 6B.* For ASM participants that receive a final score of zero as described at § 512.745(2)(ii), calculate the ASM payment adjustment factor for each ASM participant equal to the negative of the applicable ASM risk level as described at § 512.750(c)(1)(i).

Calculation of ASM Payment Multiplier

• *Step 7.* Calculate the ASM payment multiplier for each ASM participant by using the following formula as described § 512.750(c):

ASM payment multiplier = 1 + ASM payment adjustment factor

Under this proposed calculation process, an ASM payment adjustment factor could be negative (meaning net negative payment adjustments), zero (meaning neutral or no payment adjustments), or positive (meaning net positive payment adjustments). Accordingly, an ASM payment multiplier above 1 would result in net positive payment adjustments; an ASM payment multiplier of 1 would result in no (that is, neutral) payment adjustments, and an ASM payment multiplier less than 1 would result in a net negative payment adjustment.

We propose at § 512.750(d) that ASM participants that do not receive a final score as discussed in section III.C.2.e.(2).(b). of this proposed rule would receive an ASM payment adjustment factor of zero and an ASM payment multiplier of 1 (that is, a neutral payment adjustment) for the applicable ASM payment year.

To illustrate how this process would work, we provide the following example of how we would calculate the ASM payment adjustment factor and ASM payment multiplier for individual ASM participants who received a final score greater than zero. In this example, we assume an ASM risk level of 9 percent and an ASM redistribution percentage of 85 percent.

• *Step 1.* We determine that all ASM participants with final scores in the example ASM cohort had a total of $1 billion in Medicare Part B covered professional service payments during the ASM performance year.

• *Steps 2 and 3.* We multiply the $1 billion calculated in Step 1 by the 9 percent ASM risk level and the 85 percent ASM redistribution percentage to determine an ASM incentive pool of $76.5 million for this example.

• *Step 4.* An ASM participant, in this example, received a final score of 80 points and the median score for the example ASM cohort was 50 points. When transformed under the exchange function, this final score would result in a transformed final score of 0.95.

• *Step 5.* We calculate a scaling factor of 1.5 applicable for all ASM participants in this example ASM cohort to ensure that the amount in the ASM incentive pool would be distributed in the form of scaled payment adjustments. The numerator of the scaling factor would be the $76.5 million in the ASM incentive pool (calculated in Steps 2 and 3) and the denominator would be calculated as $51 million based on the sum of all ASM participant's transformed final scores multiplied by their respective total Medicare Part B covered professional services payments and the 9 percent ASM risk level: ($76.5 million/$51 million = 1.5).

• *Step 6A.* The ASM payment adjustment factor, in this example, would be calculated as: [ASM risk level (9 percent) × transformed final score (0.95) × scaling factor (1.5)] − ASM risk level (9 percent) = 0.0385

• *Step 7.* The resulting ASM payment multiplier, in this example, would be calculated as: 1 + ASM payment adjustment factor (0.0385) = 1.0385. The value of this ASM payment multiplier would mean that the example ASM participant would receive a positive adjustment of 3.85 percent on all Medicare Part B covered professional service payments during the corresponding ASM payment year. We note that the parameters of the previous calculation are fictitious and may look entirely different when calculating the ASM payment adjustment factors and ASM payment multipliers for the model, depending on the distribution of final scores, the magnitude of Medicare Part B covered professional service payments associated with ASM participants, the size of ASM incentive pool, among other factors.

As discussed earlier in this section of this proposed rule, we are not proposing to use a performance threshold to determine a cutoff between positive and negative ASM payment adjustment factors and resulting ASM payment multipliers. We would, therefore, calculate ASM payment adjustment factors and resulting ASM payment multipliers based on the size of the ASM incentive pool and the distribution of final scores for a given ASM performance year using the proposed payment methodology described throughout this section of this proposed rule.

Our proposed process to calculate ASM payment adjustment factors and adjust an ASM participant's Medicare Part B payments using an ASM payment multiplier during an applicable ASM payment year as proposed at § 512.750 currently aligns with the processes and timelines by which the Quality Payment Program applies MIPS payment adjustments for each Medicare Part B claim made for covered professional services furnished by a MIPS eligible clinician as defined at § 414.1405(e). We believe that aligning the timeline and processes with the Quality Payment Program's application of MIPS payment adjustments would ensure operational consistency and minimize confusion. As discussed in section III.C.2.e.(6). of this proposed rule, we propose to provide an ASM participant with their ASM payment adjustment factor and ASM payment multiplier in the ASM

performance report provided to each ASM participant for the applicable ASM performance year.

We seek comment on our proposed process as described at § 512.750(c) to calculate the ASM payment adjustment factors and ASM payment multipliers, and how we would apply ASM payment multipliers to an ASM participant's Medicare Part B payment during an ASM payment year.

The following sections discuss our proposals and alternatives on how we propose to calculate an ASM incentive pool, including the proposed ASM risk level, ASM redistribution percentage, and our proposal for the exchange function.

(b) ASM Incentive Pool

As discussed earlier in this section of this proposed rule, we propose to calculate the ASM incentive pool for each ASM cohort based on two factors: (1) the ASM risk level as described at § 512.705(c)(1) (that is, the magnitude of the maximum positive or negative net payment adjustment percentage to which an ASM participant would be subject during an ASM payment year) and (2) the ASM redistribution percentage as described at § 512.750(c)(1)(iii) (that is, the percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that would be distributed in the form of payment adjustments to ASM participants during an ASM payment year). We discuss our proposals for the magnitude of ASM risk level and ASM redistribution percentage later in this section of this proposed rule. The total amount in an ASM incentive pool would directly determine the magnitude of ASM payment adjustment factors and resulting ASM payment multipliers that each ASM participant would receive during an ASM payment year.

We describe the step-by-step process of calculating the ASM incentive pool earlier in this section of this proposed rule. In summary, we propose at § 512.750(c)(1)(iii) to calculate an ASM incentive pool for each ASM cohort for applicable for each ASM payment year using the following formula:

$$\text{ASM Incentive Pool} = \text{ASM risk level} \times \text{ASM redistribution percentage} \times \Sigma \text{ASM participant Medicare Part B payments}$$

The proposed approach to calculating an ASM incentive pool aligns with the current approach that other CMS VBP programs use when calculating the total amount that can be distributed to program participants through payment adjustments. Both the SNF VBP Program (82 FR 36619 through 36621) and the Hospital VBP Program (88 FR 59063 through 59108) employ a similar calculation to determine the total amount that can be redistributed through payment adjustments for their respective program participants. We believe the proposed approach would determine an ASM incentive pool amount that would be appropriate to distribute through scaled payment adjustments, and that the proposed approach would align with the desired level of two-sided risk that we believe would incentivize behavioral change and increased accountability.

We seek comments on our proposed approach to calculate the ASM incentive pool for each ASM cohort.

(i) ASM Risk Level

As discussed earlier in this section of this proposed rule, we propose to use the annual ASM risk level to calculate the ASM incentive pool for each ASM cohort. We propose at § 512.750(c)(1)(i) to establish the ASM risk level that is the magnitude of the maximum downside or upside risk to which an ASM participant would be subject to during an ASM payment year. We propose at § 512.750(c)(1)(i)(A) through (E) the risk levels for each ASM payment year as summarized in Table 44.

TABLE 44: ASM RISK LEVELS

ASM Performance Year	ASM Payment Year	ASM Risk Level
2027	2029	9 percent
2028	2030	9 percent
2029	2031	10 percent
2030	2032	11 percent
2031	2033	12 percent

Our proposed ASM risk level of 9 percent for the 2029 ASM payment year (based on 2027 ASM performance year performance) and the 2030 ASM payment year (based on 2028 ASM performance year performance) aligns with the CY2024 applicable percent of 9 percent under MIPS, which is the maximum and minimum range of potential MIPS payment adjustment factor for a given MIPS payment year defined at § 414.1405(c) (88 FR 79378). Depending on the range of MIPS eligible clinicians' scores within a given MIPS performance period, a scaling factor (ranging from zero to 3) is applied to positive adjustments to retain budget neutrality as defined at § 414.1405(b)(3) (88 FR 79378), meaning that the maximum positive payment adjustment factor may be below or above the applicable percent. A MIPS eligible clinician with a score of zero receives a payment adjustment factor equal to the negative of the applicable percent as defined at defined at § 414.1405, meaning that all MIPS eligible clinicians are potentially subject to a maximum downside risk equivalent to the applicable percent. Based on our proposed ASM performance category and scoring approach that leverages the MVP measurement framework, we believe that starting and keeping the ASM risk level at 9 percent for the first two ASM payment years would be appropriate given its continued use within MIPS. We believe that gradually increasing the ASM risk level over time would provide an incentive for increased accountability that would be central to increasing accountability for longitudinal care management and improving the quality of care for beneficiaries with heart failure and low back pain.

We considered annual ASM risk levels higher and lower than what we propose for each ASM performance year. Higher ASM risk levels would mean that ASM participants with lower final scores would be subject to potentially higher negative payment adjustments, whereas lower ASM risk levels would mean that ASM participants with lower final scores would be subject to potentially lower negative payment adjustments. Calibrating the right level of risk is critical to ensure that ASM participants

would receive meaningful incentives to improve performance. We believe that starting with a level of downside risk already familiar to many ASM participants who previously participated in MIPS would be appropriate given that the application of ASM payment adjustment factors would be applied to Medicare Part B claims for covered professional services (as discussed earlier in this section of this proposed rule) in a similar fashion as MIPS as defined at § 414.1405(e).

While we propose at § 512.745(a)(4) a small practice scoring adjustment in an ASM participant's final score, we also considered whether to reduce the ASM risk level for ASM participants in small practices. Given the systematic differences in historical MIPS performance of likely ASM participants in small practices that we observed and discuss in section III.C.2.e.(4). of this proposed rule, reducing the ASM risk level for ASM participants in small practices would be one way to prevent them from being unfairly penalized in their payment adjustments. We were, however, concerned that decreasing the ASM risk level for ASM participants in small practices to be lower than the equivalent applicable percent in MIPS as defined at § 414.1405(c) would be a disincentive for ASM participants in small practices to submit the required data under ASM and would potentially limit the magnitude of any net positive payment adjustments. We, therefore, believe that the proposed small practice scoring adjustment is a simpler and more transparent adjustment for ASM participants in small practices.

We also considered a similar adjustment in ASM risk level for ASM participants in a rural location as an alternative to the rural practice scoring adjustment that we considered in section III.C.2.e.(4). of this proposed rule. For the same reasons discussed in section III.C.2.e.(4). of this proposed rule, we decided not to propose a scoring adjustment for ASM participants in rural areas.

We seek comments on our proposed ASM risk level for each ASM payment year as part of our payment approach. We also seek comment on the alternative risk levels we considered for each ASM payment year. Finally, we seek comment on the alternatives we considered related to a lower ASM risk level for ASM participants in small practices and in rural areas.

(ii) ASM Redistribution Percentage

As discussed earlier in this section of this proposed rule, we propose to set an ASM redistribution percentage that is the percentage of the Medicare Part B covered professional service payments to ASM participants during an ASM performance year multiplied by the applicable ASM risk level that would be distributed in the form of scaled payment adjustments to ASM participants during an ASM payment year. As discussed earlier, we propose to define this total amount available for distribution as the ASM incentive pool. We propose at § 512.750(c)(1)(iii) an ASM redistribution percentage of 85 percent beginning with the 2029 ASM payment year. Under this proposed ASM redistribution percentage, 85 percent of the Medicare Part B covered professional service payments to ASM participants during an ASM performance year multiplied by the applicable ASM risk level (that is, the value of the ASM incentive pool) would be distributed to ASM participants in the form of scaled payment adjustments. The other 15 percent of the Medicare Part B payments multiplied by the ASM risk level would be retained in the Medicare Trust Fund. To illustrate the scale of the net payment adjustments under these proposed policies, the proposed ASM redistribution percentage of 85 percent and an ASM risk level of 9 percent would lead to an estimated net 7.65 percent (that is, 85 percent multiplied by 9 percent) of the Medicare Part B covered professional service payments distributed in the form of payment adjustments to ASM participants and an estimated 1.35 percent (that is, 15 percent multiplied by 9 percent) retained by Medicare We refer readers to the regulatory impact analysis in section VII of this proposed rule for further discussion on the estimated impacts of these payment adjustments.

As with our proposed exchange function discussed later in this section of this proposed rule, we view the important factors when specifying a ASM redistribution percentage to be—(1) the number of ASM participants that receive a positive payment adjustment; (2) the marginal incentives for all ASM participants to make broad-based care quality improvements and reduce low-value care,; and (3) the ability for ASM to demonstrate savings over the ASM test period. We intend for the proposed ASM redistribution percentage to appropriately balance these factors.

We analyzed the distribution of ASM payment adjustment factors using simulated final scores data, focusing on the full range of available ASM payment adjustment factors using a sample of likely ASM participants. We found that an 85 percent ASM redistribution percentage would achieve an appropriate distribution of the number of ASM participants that would receive positive and negative payment adjustments under the different exchange functions that we considered, as discussed later in this section of this proposed rule. We also found that an 85 percent ASM redistribution percentage under the proposed exchange function would achieve the desired magnitude of positive and negative ASM payment adjustment factors under the ASM risk level proposed for the 2027 ASM performance year.

We considered ASM redistribution percentages as high as 100 percent and as low as 60 percent. An ASM redistribution percentage of 100 percent would mean that the entirety of Medicare Part B covered professional service payments multiplied by the applicable ASM risk level would be distributed through ASM payment adjustment factors to ASM participants. We believe that ensuring a particular level of net savings through an ASM redistribution percentage less than 100 percent would help guarantee a particular level of Medicare Part B savings that would contribute to the net savings in total cost of care from provider behavioral effects that we hypothesize would occur as part of ASM as described in section III.C.1.(b). of this proposed rule.

We refer readers to the regulatory impact analysis in section VII. of this proposed rule for further discussion on the scale of ASM and its estimated financial impacts. We considered an ASM redistribution percentage as low as 60 percent because it would increase the potential for higher net savings on Medicare Part B payments and mirrors a similar rate used by SNF VBP Program (82 FR 36619 through 36621). In analyses, however, we found decreasing the ASM redistribution percentages below what we are proposing (for example, to 60 percent or 75 percent) would result in an unfavorable distribution of negative and positive ASM payment adjustment factors that would not create the desired set of payment incentives to achieve ASM's goals.

We seek comments on our proposed ASM redistribution percentage and alternatives considered.

(c) Exchange Function

An exchange function translates a participant's final score into a payment adjustment. The type of exchange function used can influence: (1) how many participants receive positive, neutral, or negative payment adjustments; and (2) the size, or magnitude, of the payment adjustment percentage that corresponds to a given

performance score. The choice of an exchange function ultimately contributes to creating an optimal set of incentives by setting the distribution and size of payment adjustments.

We propose at § 512.750(c)(1)(ii) to use a logistic exchange function to translate final scores into ASM payment adjustment factors that would distribute each ASM incentive pool to their respective ASM participants through ASM payment adjustment factors that result in net negative, neutral, or positive payment adjustments.

In our view, important factors when adopting an exchange function include: (1) the percentage of ASM participants that would receive positive payment adjustments compared to those that would receive negative payment adjustments and (2) the magnitude of the maximum positive and negative net payment adjustment. We believe that ASM would be most effective at encouraging ASM participants to improve the quality of care that they provide to Medicare beneficiaries if ASM participants can earn positive adjustments through high performance across ASM's performance categories but also face some level of downside risk through possible negative payment adjustments. We also believe that the magnitude of negative and positive adjustments must create a strong incentive for improving care related to ASM's targeted chronic conditions. The choice of an exchange function, and the specific parameters of the chosen exchange function, can create different distributions of ASM payment adjustment factors, ASM payment multipliers, and net payment adjustments based on the final scores of ASM participants in each ASM cohort.

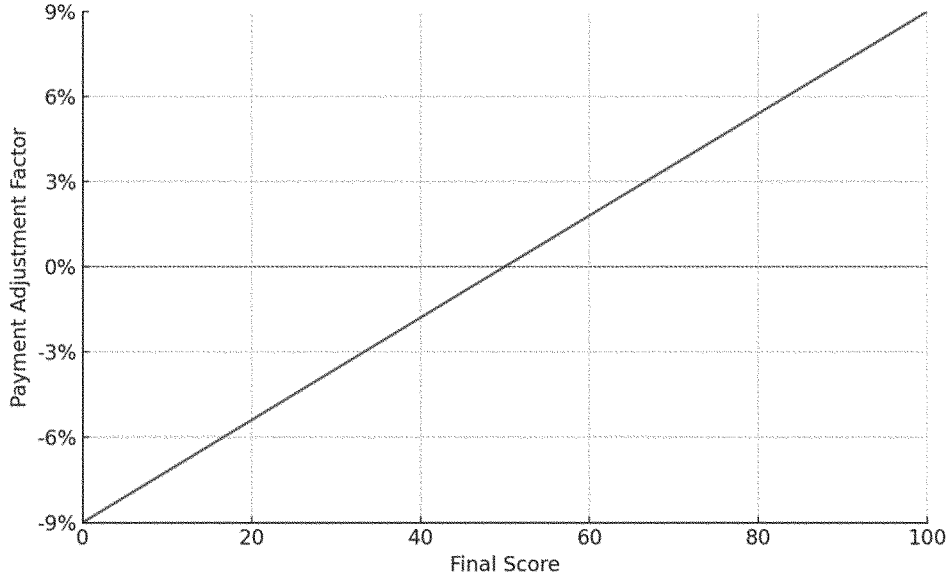
In the Quality Payment Program, CMS uses a linear exchange function to translate MIPS eligible clinicians' final scores into MIPS payment adjustment factors relative to an annually determined performance threshold so that the program is budget neutral (89 FR 62199). Under the Hospital VBP Program, CMS uses a linear exchange function to translate a hospital's Total Performance Score into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY (76 FR 26531 through 26534). We refer readers to the Hospital VBP Program Final Rule (76 FR 26531 through 26534) for detailed discussion of the Hospital VBP Program's exchange function, as well as responses to public comments on this issue. Under the SNF VBP Program, CMS uses a logistic function to translate a SNF's performance score into an incentive payment multiplier (82 FR 36616 through 36619). The SNF VBP Program also considered a cube exchange function during its notice-and-comment rulemaking related to the SNF VBP Program exchange function (82 FR 36616 through 36619). We refer readers to the SNF VBP Program final rule (82 FR 36616 through 36619) for detailed discussion on the SNF VBP Program's exchange function and responses to public comments on this issue.

Using the exchange functions that other Medicare VBP programs use or considered using while determining their payment methodology, we considered three exchange functions for use in ASM's payment methodology: (1) linear, (2) logistic, and (3) cube. The equations and graphs of the proposed exchange functions displayed in the remainder of this section of this proposed rule are illustrative. We note that the actual exchange functions' forms and slopes would vary depending on the distributions of final scores and wish to emphasize that we present these representations solely for the reader's clarity as we discuss our exchange function policy.

The linear function is a simple, steadily increasing function ranging from zero to one hundred (Figure 2). A linear exchange function would provide ASM participants the same marginal incentive to continually improve performance of their final score. The linear exchange function we considered had the following formula, where x_i is an ASM participant's final score:

$$f(x_i) = \frac{x_i}{100}$$

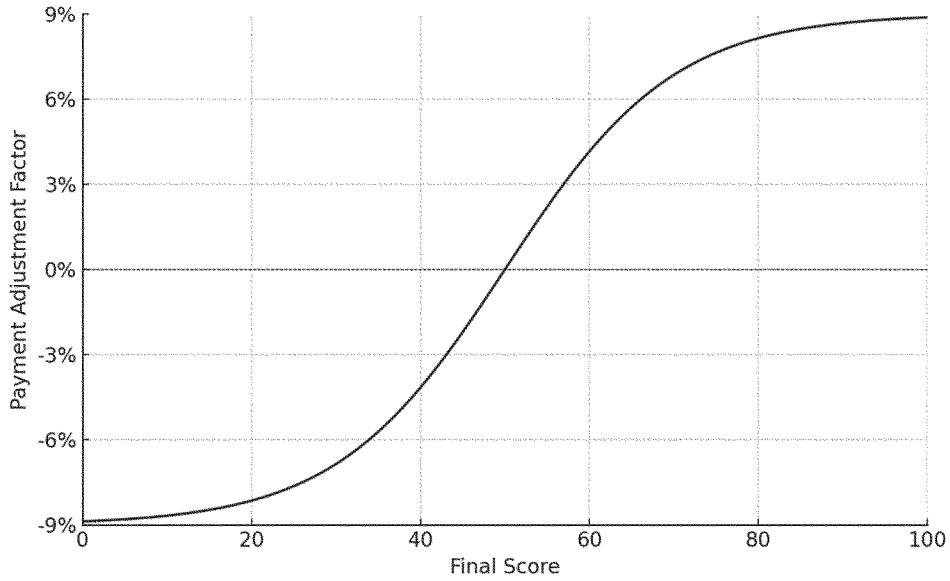
FIGURE 2: Illustrative Linear Exchange Function



The logistic function is an S-shaped curve ranging between zero and one hundred with an inflection point at a specified midpoint (Figure 3). The S-shaped curve would mean that participants with scores within the bottom end of the distribution would receive similar payment adjustments and participants at the top end of the distribution would receive similar payment adjustments to one another. There would be more variation in the resulting payment adjustments for those participants with final scores in the middle of the distribution. The logistic exchange function we considered had the following formula, where x_i is an ASM participant's final score, x_0 represents the function's midpoint:

$$f(x_i) = \frac{1}{1 + e^{-0.1(x_i - x_0)}}$$

FIGURE 3: Illustrative Logistic Exchange Function

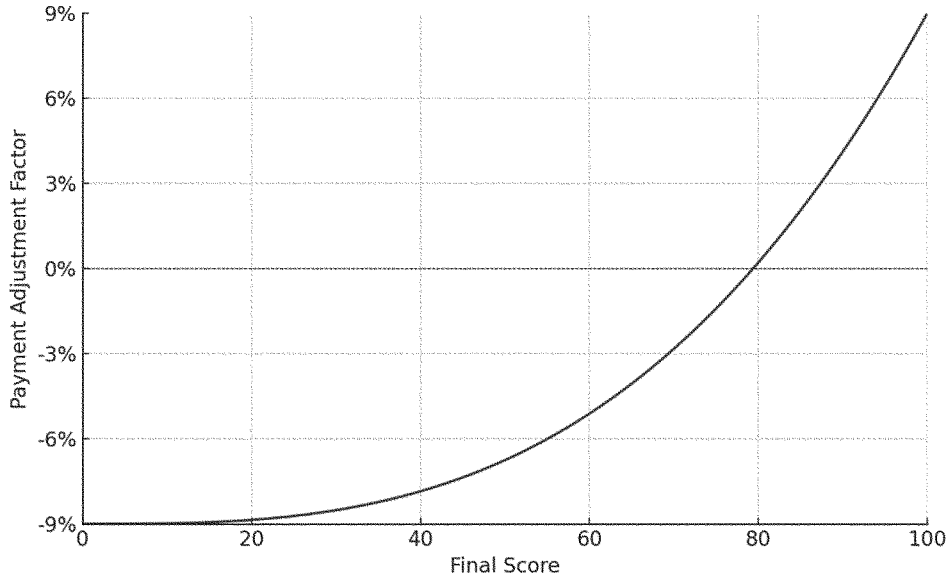


For the logistic exchange function, we considered values of the function's midpoint (that is, x_0 in the earlier formula) set at: (1) 50, which represents the midpoint between the zero to 100 point range that an ASM participant could achieve in their final score; (2) the annual median final score in the ASM performance year for each ASM cohort, and (3) the annual mean final score in the ASM performance year for each ASM cohort. The functional form of the logistic function when centered at 50 points would mean that those ASM participants with final scores within the top 25 percent and the bottom 25 percent of final scores would receive relatively similar ASM payment adjustment factors. However, setting the midpoint at the median or mean final score could help to achieve a more balanced distribution between ASM payment adjustment factors that result in net positive or net negative payment adjustments.

The cube function exponentially increases between zero and one hundred (Figure 4). The cube functions means that the incentive to improve performance increases more dramatically at the top end of the score distribution, meaning that a one-point difference in final score at the top end would result in a bigger difference in payment adjustment than the same one-point difference at the lower end of the final score distribution. The cube exchange function we considered had the following formula, where x_i is an ASM participant's final score:

$$f(x_i) = \left(\frac{x_i}{100}\right)^3$$

FIGURE 4: Illustrative Cubic Exchange Function



We analyzed these three exchange functions using simulated final score data. For the logistic exchange function, we used a midpoint of the median final score within each ASM cohort (see discussion on the logistic function's midpoint earlier in this section of this proposed rule). We simulated final scores by simulating each of the four ASM performance category scores using informed distributions for measures and the proposed scoring policies for each ASM performance category (see the regulatory impact analysis in section VII of this proposed rule for further information on our simulation methods). Our modeling ensures that the estimated ASM payment adjustment factors and ASM payment multipliers for each ASM cohort resulted in net payment adjustments that equaled the total ASM incentive pool for the applicable ASM cohort. We evaluated the distribution of ASM payment adjustments factors that resulted from each function (that is, the number and proportion of each ASM cohort that received net negative and positive payment adjustments). We also evaluated descriptive statistics (for example, mean, median, minimum, maximum) of the resulting ASM payment adjustment factors and ASM payment multipliers from each function. We also considered the distribution of ASM payment adjustment factors and ASM payment multipliers by specific ASM participant characteristics, such as small practices.

In our analysis, we found that linear and logistic exchange functions produced relatively similar distributions of ASM participants that would receive net positive payment adjustments, whereas more ASM participants would receive net positive payment adjustments under the cube function. Comparatively, the steadily increasing linear exchange function would mean that there would be a more even distribution of ASM payment adjustment factors across the distribution of final scores. Under the cube function, fewer ASM participants would receive net positive payment adjustments.

We found that setting the logistic function midpoint at the median or mean final score for each ASM cohort produced a maximum ASM payment adjustment factor that exceeded the maximum ASM payment adjustment factor under the linear exchange function (we refer readers to the discussion of the logistic function's midpoint earlier in this section of this proposed rule). That is, adjusting the logistic function midpoint to a value around the mean or median final score of each ASM cohort would increase the maximum net positive payment adjustment while producing a more even distribution between net positive and negative payment adjustments. The cube function produced the highest maximum ASM payment adjustment factor. All the exchange functions had the same maximum negative ASM payment adjustment factor because the ASM risk level would determine the maximum net negative payment adjustment.

When we compared the median ASM payment adjustment factor produced under each exchange function, we found that the logistic exchange function would produce the highest median net payment adjustment followed by the linear exchange function and then the cube exchange function. The cube exchange function would allow those ASM participants that achieve the highest final scores to achieve high ASM payment adjustment factors but would mean that ASM participants with final scores near the median final score would receive potentially lower ASM payment adjustment factors.

Based on the results of this analysis, we believe that the logistic exchange function would be best suited to achieving the appropriate distribution of ASM payment adjustment factors at the appropriate level of magnitude.

We recognize that using the same exchange function from other CMS programs would help stakeholders that use these programs' payment information across care settings better understand ASM's payment methodology. Both the Hospital VBP program and the Quality Payment

Program use some form of a linear exchange function in their payment methodologies. Three key program aspects that facilitate the use of a linear exchange function are a program's number of measures, measure weights, and correlation across program measures. These three aspects mean that there is less chance for a single required measure to skew scores into a non-normal distribution, meaning that it would be appropriate to use a linear exchange function for these programs (82 FR 36618). When first established, the SNF VBP Program relied on a single performance measure to determine performance scores. This approach meant that the distribution of performance scores could have been easily skewed, which could have resulted in an undesired distribution of incentive payments (82 FR 36618). The SNF VBP Program has since added up to 9 measures by which it can assess performance and has retained use of a logistic exchange function (88 FR 53276 through 53304). In our analysis, we found that simulated final scores among likely ASM participants could be skewed due to the potential directional correlation between measures across ASM's performance categories; for example, an ASM participant who performs well on one required quality measure may perform well across other quality measures. The potential for a skewed final score distribution and the use of a linear exchange function could result in an undesired distribution of ASM payment adjustment factors. For these reasons, we believe that the logistic exchange function would be more appropriate for the purposes of ASM's payment methodology.

We seek comments on our proposal to use a logistic exchange function with midpoint set at the median final score for each ASM cohort to translate final scores into ASM payment adjustment factors. We also seek comments on the alternative exchange functions and specifications of each exchange function we considered.

(d) Notification of ASM Payment Adjustment Factors and ASM Payment Adjustment Multipliers to ASM Participants

As discussed in section III.C.2.e.(6) of this proposed rule, we propose at § 512.750(e) to notify ASM participants of their ASM payment adjustment factor and ASM payment multiplier through the ASM performance report provided for each ASM performance year. As discussed earlier, we propose at § 512.750(a) that the amount otherwise paid under Medicare Part B for covered professional services furnished by an ASM participant during an ASM payment year would be multiplied by the ASM payment multiplier determined based on an ASM participant's performance during an ASM performance year.

As discussed earlier in this section of this proposed rule, our proposed process currently draws from the processes and timelines by which the Quality Payment Program applies MIPS payment adjustments for MIPS eligible clinician as defined at § 414.1405(e). Aligning the timeline and processes with the Quality Payment Program application of MIPS payment adjustments would ensure operational consistency and minimize confusion for ASM participants that have previously participated in MIPS.

Given the time separation between the ASM performance year and the ASM payment year, there may be situations when an ASM participant's TIN affiliation changes between the ASM performance year and the corresponding ASM payment year. We propose at § 512.750(f) that ASM payment adjustment factors and ASM payment multipliers would continue to apply to Medicare Part B covered professional services payments to ASM participants during an ASM payment year with adjustments made depending on how TIN affiliations change after an ASM performance year and the end of the corresponding ASM payment year. In Table 45, we provide several illustrative scenarios and how our proposed policies discussed in this section of this proposed rule would affect the application of ASM payment multipliers in each scenario.

During an ASM payment year, we propose at § 512.750(f)(1) that Medicare Part B professional service claims submitted by an NPI who is an ASM participant with a final score for an ASM performance year but under a TIN (1) that did not identify the NPI as an ASM participant for the applicable ASM performance year and (2) to which the NPI began assigning billing rights after the ASM performance year but before the end of the payment year would be adjusted using the ASM payment multiplier calculated for the ASM participant for the corresponding ASM performance year. For example, if an ASM participant identified by TIN-A/NPI bills Medicare under their original practice (TIN A) during an ASM performance year but begins billing Medicare Part B covered professional services claims under a new practice (TIN B) after the ASM performance year but before the end of the corresponding ASM payment year, then we would apply the ASM participant's ASM payment multiplier to Medicare Part B claims submitted by the NPI under the new practice (TIN-B/NPI). If the same ASM participant (TIN-A/NPI) from the above example also billed under TIN A during the same ASM payment year, we would adjust their Medicare Part B payments for covered professional services using the applicable ASM payment multiplier calculated for the ASM participant.

Our proposal means that we would not apply ASM payment multipliers to Medicare Part B claims submitted by TINs, other than the TIN identifying an ASM participant for an applicable ASM performance year and corresponding ASM payment year, to which the ASM participant assigned billing rights to before or during an ASM performance year. For example, if an ASM participant identified by TIN-A/NPI billed to TIN A and TIN B during the ASM performance year, then we would not apply the ASM payment multiplier to Medicare Part B claims submitted by the NPI under TIN-B during the corresponding ASM payment year. Our reasons for only applying ASM payment multipliers to Medicare Part B claims to TIN/NPIs combinations created after the end of the ASM performance year and before the end of the corresponding ASM payment year would be to prevent application of multiple payment adjustments on Medicare Part B claims, such as MIPS payment adjustments, during an ASM payment year. Building on the earlier example, in a given ASM performance year, an ASM participant (TIN-A/NPI) could be a MIPS eligible clinician under a different TIN/NPI combination (TIN-B/NPI) and receive a MIPS payment adjustment factor that would apply in the MIPS payment year that aligns with the corresponding ASM payment year. We would not want to interfere with the application of a MIPS payment adjustment factor to Medicare Part B claims billed under the TIN that identified the same NPI as a MIPS eligible clinician.

If we identify an NPI as ASM participants under multiple TINs and that NPI begins billing Medicare Part B claims under a new TIN (that is, neither of the original TINs) after the ASM performance year but before the end of the corresponding ASM payment year, then we propose at § 512.750(f)(2) to adjust Medicare Part B covered professional service payments submitted by the NPI under the new TIN using the highest of all ASM payment multipliers received for all TIN and NPI combinations that identified the NPI as multiple ASM participants for the corresponding ASM performance year. While we believe that there would

be few instances where a single NPI would be identified as multiple ASM participants, we believe this policy would appropriately track accountability to the NPI under a new TIN while reducing complexity by only applying on ASM payment adjustment multiplier.

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TABLE 45: APPLICATION OF PAYMENT ADJUSTMENTS DURING AN ASM PAYMENT YEAR

Scenario	Payment Adjustment
An ASM participant receives a final score under TIN A for an ASM performance year and bills under TIN A in the corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN A/NPI combination using the ASM payment multiplier received under the TIN A/NPI combination.
An ASM participant receives a final score under TIN A for an ASM performance year and begins billing under TIN B after the end of the ASM performance year but before the end of corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN B/NPI combination using the ASM payment multiplier received under the TIN A/NPI combination.
An ASM participant receives a final score under TIN A for an ASM performance year but bills under TIN B during the corresponding ASM payment year. The ASM participant billed under TIN B before or during the ASM performance year.	The ASM participant would not receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN B/NPI combination using the ASM payment multiplier received under the TIN A/NPI combination.
An NPI is considered an ASM participant and receives a final score under TIN A and TIN B for an ASM performance year and continues to bill under TIN A and TIN B in the corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN A/NPI combination using the ASM payment multiplier received under TIN A/NPI combination and payment adjustments under TIN B/NPI combination using the ASM payment multiplier received under the TIN B/NPI combination.
An NPI is considered an ASM participant and receives a final score under TIN A and TIN B for an ASM performance year but begins billing only under TIN C after the ASM performance year but before the end corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN C/NPI combination using the higher of all ASM payment multipliers received under TIN A/NPI or TIN B/NPI combinations.

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Our proposals would closely link the ASM participants' performance during an ASM performance year to the ASM payment multiplier. It would also ensure that ASM participants that qualify for net positive payment adjustments keep them, even if they change TINs by the start of the ASM performance year. For those who have a net negative payment adjustment, this proposal would also ensure ASM participants would remain accountable for their performance. As discussed earlier in this section of this proposed rule, our proposals would also prevent interference with the application of MIPS payment adjustment factors if the NPI identifying the ASM participant was a MIPS eligible clinician under a different TIN/NPI combination during the same ASM performance year/MIPS performance period.

We based our proposed approach on sub-regulatory guidance issued by the Quality Payment Program on how MIPS payment adjustment factors follow MIPS eligible clinicians if they change their TIN affiliation after a MIPS performance period (81 FR 77330, 85 FR 84917 through 84919, and 86 FR 65536).[241] Like MIPS, our proposal for ASM tracks accountability to the ASM participant regardless of their specific TIN affiliation at the time we would apply ASM payment multipliers to an ASM participant's Medicare Part B covered professional services payments during an ASM payment year.

We seek comments on our proposed approach to notify and apply ASM payment multipliers to Medicare Part B covered professional services payments during an ASM payment year. We also seek comment on how ASM payment multipliers would be applied to Medicare Part B covered professional services payments for ASM participants whose TIN affiliations change after an ASM performance year and before the end of a corresponding ASM payment year.

g. Proposed Timely Error Notice Process

We believe that it is necessary to have a process by which ASM participants may appeal the ASM performance report. However, the standard CMS claims appeals process submitted through a MAC would not lead to timely resolution of disputes for the purposes of ASM because MACs and other CMS officials would not have timely access to beneficiary attribution data. Therefore, we propose to waive the requirements of section 1869 of the Act specific to

[241] *https://qpp.cms.gov/resources/document/21ee9d76-a002-4f5d-b228-3a99b32aa7dc.*

claims appeals for purposes of testing ASM. The proposed ASM error notice process is specific to ASM and distinct from the standard CMS appeals procedures set forth under section 1869 of the Act. We note that ASM participants would still be subject to the same limitations on review as stipulated at § 512.170.

We propose at § 512.755(a) to permit ASM participants to submit a timely error notice regarding the calculations contained within the ASM performance report if the ASM participant believes an error occurred in calculations due to data quality or other issues, or if the ASM participant believes an error occurred in calculations due to misapplication of methodology. We propose at § 512.755(b) that if an ASM participant believes the ASM performance report contains a calculation error, then the ASM participant would be required to submit a timely error notice documenting the suspected calculation error within 30 calendar days of issuance of the ASM performance report. We also propose that CMS may specify different requirements for the form, manner, or deadline for submission of the error notice. If the ASM participant does not provide such timely error notice error in accordance with the timelines and processes specified by CMS, then we propose at § 512.755(b)(1) that the ASM performance report would be deemed final and the ASM participant would be precluded from later contesting those elements of the ASM performance report for that performance year. Additionally, we propose that only an ASM participant may submit a written timely error notice according to the provisions at proposed § 512.755(b)(2).

The proposed 30-day window to review and appeal CMS calculations aligns with the length of time we have finalized for submitting appeals in other mandatory Innovation Center models, such as TEAM and the Increasing Organ Transplant Access (IOTA) Model.

We acknowledge that the Quality Payment Program allows MIPS eligible clinicians to request a targeted review within 60 days of the closing of the data submission period. As explained in the 2016 Quality Payment Program Final Rule (81 FR 77353), section 1848(q)(13)(A) of the Act describes the required review process for MIPS as ''targeted'' and ''informal,'' and does not warrant a second level of review or appeals. Under MIPS, all decisions under the targeted review process are final.

We considered an appeal window that conforms with MIPS, however, a 60-day timeframe would not be appropriate for ASM, as it would not provide sufficient time to generate final ASM payment adjustment factors and ASM payment multipliers before the applicable ASM payment year begins, given the process outlined in § 512.190 of the Standard Provisions—which offers the ASM participant the opportunity to request two additional levels of appeal, including a final review by the CMS Administrator. If an ASM participant elects to go through all levels of appeal available to them, this would be a lengthy process that must conclude by December 1, when CMS must submit final payment adjustment factors to the MACs for the subsequent payment year. Therefore, because of the two additional levels of appeal, CMS is unable to offer ASM participants a lengthier period to review their initial calculations.

We propose at § 512.755(c) that if CMS receives a timely notice of a calculation error, we would issue an initial determination in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. We note that CMS would reserve the right to an extension of the time for providing its initial determination upon written notice to the ASM participant.

If an ASM participant disagrees with CMS' initial and wishes to dispute the results of the initial determination, under proposed § 512.755(d), the ASM participant or CMS may request a reconsideration of the initial determination by following the reconsideration review process described in the standard provisions at § 512.190.

We solicit comment on our proposed timely error notice process for ASM appeals at § 512.755 as well as alternatives considered.

h. Proposed Waivers of Medicare Program Requirements

(1) Background

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. We propose to waive ASM participants from MIPS reporting and payment adjustments. We also propose to waive certain telehealth restrictions to encourage greater flexibility with the use of telehealth services by ASM participants. We seek comment on these proposed waivers.

(2) MIPS Waiver

We believe it may be necessary and appropriate to provide flexibilities to clinicians participating in ASM. We propose at § 512.775 to use the Innovation Center's statutory authority under section 1115A(d)(1) of the Act to waive all ASM participants from participation in MIPS for any ASM performance year/ASM payment year in which they meet the ASM participant eligibility criteria, unless otherwise specified at proposed § 512.710(a)(2). Our previous and current efforts in testing models where participants are judged against the performance of their peers, such as the SNF VBP Program and the HVBP Program, are likely to incentivize substantial improvements in cost savings and efficiency. We are building off existing mechanisms for payment adjustments of Medicare Part B claims found in MIPS. To maximize the effectiveness of these payment adjustments, we propose to waive ASM participants from participation in MIPS. This waiver would ease administrative burden, as ASM participants would be required to only report ASM performance category measures. The waiver would also prevent possible double-payment adjustments by ensuring ASM participants report their performance measures and receive payment adjustments through ASM alone. The MIPS waiver would only be available to ASM participants for the year(s) for which they are measured for performance under the model (that is, the ASM performance year). For example, if a clinician meets eligibility criteria for the model in CY 2027 and is measured for performance under the model for that year, the MIPS waiver applies to CY 2027 and the clinician is not required to participate in MIPS and be measured for performance under MIPS for that year. Yet, for any subsequent year that that clinician does not meet ASM eligibility criteria and is not measured for performance under the model, the MIPS waiver does not apply. The clinician must participate in MIPS and be measured for performance under MIPS if determined to be a MIPS eligible clinician for the applicable MIPS performance period.

As described in section III.C.2.m of this proposed rule, we intend to promote as much longitudinal model overlap as possible and ensure maximum flexibility for ASM participants to join existing voluntary models, including Advanced APMs. Specialty care providers have been part of whole-person and primary care models, such as the Medicare Shared Savings Program, but the performance

measures in those programs are less relevant to specialty care. ASM takes the founding tenets for MVPs and goes further, allowing for like-to-like comparisons for all ASM participants by ensuring they are reporting on the same, clinically relevant measures.

For these reasons, we propose to seek a MIPS waiver at § 512.775(a) for all ASM participants regardless of whether they have achieved QP status through another Medicare model or program.

We seek comment on the proposed MIPS waiver for all ASM participants at § 512.775(a).

(3) Telehealth

(a) Background

We expect that the proposed ASM design features would lead to greater interest on the part of ASM participants caring for ASM beneficiaries in furnishing services to beneficiaries in their home or place of residence. ASM would create new incentives for comprehensive care management for beneficiaries, including early identification and intervention regarding changes in health status. Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. Under the longstanding statutory payment requirements, telehealth services must be furnished to a beneficiary located in one of the originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the geographic requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the Medicare Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all the following other requirements for payment: (1) the service must be furnished via an interactive telecommunications system, (2) the service must be furnished to an eligible telehealth individual, and (3) the individual receiving the services must be in an eligible originating site. For most telehealth services, this requires the beneficiary to be located at an originating site that is in certain, mostly rural, areas, and in a setting that is a health care facility.

During the COVID–19 PHE, CMS used emergency authority under section 1135(b)(8) of the Act to waive these requirements to allow beneficiaries to be located in an originating site in any geographic area and in any setting, including the home of the beneficiary. Congress has enacted several laws that temporarily extend these flexibilities beyond the PHE. Most recently, the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4) amended section 1834(m)(4)(C)(iii) of the Act to extend these originating site flexibilities through September 30, 2025. Absent Congressional action, beginning October 1, 2025, the statutory limitations that were in place for Medicare telehealth services prior to the COVID–19 PHE will retake effect for most telehealth services. These include geographic and location restrictions on where the services are provided.

When all these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS website at *https://www.cms.gov/medicare/coverage/telehealth/list-services.* Under section 1834(m)(4)(F)(ii) of the Act, we have an annual process to consider additions to and deletions from the list of telehealth services.

Some literature suggests certain beneficial telehealth technologies, which enable health care providers to deliver care to patients in locations remote from providers, are being increasingly used to complement face-to-face patient-provider encounters to increase access to care, especially in rural or underserved areas.[242] In these cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We note that certain covered professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode-based payment models, such as TEAM and the Comprehensive Care for Joint Replacement Model (CJR) model, participants were permitted to use telehealth waivers that applied to two provisions:

- CMS waived the geographic site requirements under 1834(m)(4)(C)(i)(I) through (III) of the Act which allowed telehealth services to be furnished to eligible telehealth individuals when they are located at an originating site at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements.
- CMS waived the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act which allowed the eligible telehealth individual to not be in an originating site when the otherwise eligible individual is receiving telehealth services in their home or place of residence.

These telehealth waivers allowed providers and suppliers furnishing services to ASM beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and allowed the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe similar telehealth waivers would be essential to maximize the opportunity to improve the quality of care and efficiency for ASM.

(b) Telehealth Waivers

Specifically, like the telehealth waivers in TEAM and the CJR model, we propose at § 512.775(b) to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiving of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim that is not excluded from the proposed episode (see section III.C.2.c.(3).(b). of this

[242] Azizi Z, Broadwin C, Islam S, et al. Digital Health Interventions for Heart Failure Management in Underserved Rural Areas of the United States: A Systematic Review of Randomized Trials. *J Am Heart Assoc.* 2024;13(2):e030956. doi:10.1161/JAHA.123.030956.

proposed rule) could be furnished to an ASM beneficiary, regardless of the beneficiary's geographic location. Under ASM, this waiver would support care coordination and increasing timely access to high quality care for all ASM beneficiaries, regardless of geography. Additionally, we propose waiving the originating site requirements of sections 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we propose at § 512.775(b)(2) to waive the requirement only when telehealth services are being furnished in the ASM beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services that is not excluded from the proposed episode definition (see section III.C.2.c.(3).(b). of this proposed rule) could be furnished to a ASM beneficiary in their home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are in that setting. Section 1834(m) of the Act provides for the conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. To create a mechanism to report E/M services accurately, TEAM and the CJR model used specific sets of HCPCS G-codes to describe the E/M services furnished to the model beneficiaries in their homes via telehealth. We considered whether establishing ASM-specific G-codes would serve a distinct purpose to the model. Upon review of existing G-codes for services provided via telehealth, we identified concerns with administrative burden and duplicative codes. Thus, we propose to allow ASM participants to bill established G-codes.[243]

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home). Finally, ASM participants furnishing a telehealth service to an ASM beneficiary in his or her home or place of residence would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished under the telehealth waivers only during the episode.

We plan to monitor patterns of utilization of telehealth services under ASM to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with ASM participants.

We seek comments on the proposed waivers with respect to telehealth services at § 512.775(b).

i. Proposed Extreme and Uncontrollable Circumstances (EUC) Policy

Events may occur outside the purview and control of the ASM participant that may affect their performance in the model. We propose at § 512.780 to apply a variation of the EUC policy for MIPS eligible clinicians (83 FR 60081), but with notable differences around scoring. Currently, MIPS has three mechanisms to adjust scoring MIPS performance categories due to external circumstances that may impact a MIPS eligible clinician's ability to report during a given performance year: (1) the MIPS automatic EUC policy; [244] (2) the MIPS EUC Exception; and (3) the MIPS Promoting Interoperability Performance Category Hardship Exception.[245] The latter two require affected MIPS eligible clinicians to submit an application to MIPS for consideration before being granted the exception. The MIPS Automatic EUC Policy, however, grants the exception to any MIPS eligible clinician located in a CMS-designated region affected by EUC, such as a Federal Emergency Management Agency (FEMA)-designated major disaster or an HHS-determined public health emergency. The exception eliminates the need for an application to request reweighting one or more MIPS performance categories.

We propose to adopt at § 512.780 a modified version of the MIPS Automatic EUC Policy. We would use the same triggering events from the MIPS Automatic EUC Policy, such as federal disaster and/or public health emergency declarations, as the basis for determining whether an ASM participant may be automatically exempted from submitting ASM performance category data for an ASM performance year during which they were impacted by the EUC. If the ASM participant's CBSA or metropolitan division that we use to determine ASM participant eligibility (as described at § 512.710(e)(5)) is within an area identified by CMS, under § 414.1380(c)(2)(i)(A)(8), as having been affected by extreme and uncontrollable circumstances,, then the ASM participant would be exempted from the requirement to submit ASM performance category data, as described at proposed § 512.720. We propose at § 512.780(c)(1) that ASM participants who qualify for the exemption and do not submit ASM performance category data that meet the requirements at § 512.720 would not receive a final score and would receive an ASM payment adjustment factor that results in a neutral payment adjustment for the applicable ASM payment year. We propose at § 512.780(c)(2) that ASM participants who qualify for the exemption but still submit ASM performance category data that meet the requirements at § 512.720 would be scored according to the methodology described at proposed § 512.745. We also considered using claims data to determine whether an ASM participant furnishes services in a Federal disaster area or in an area in which HHS has declared a public health emergency. However, we believe that using the same methodology to determine whether a clinician furnishes services in a mandatory geographic area as part of the ASM participant eligibility criteria would ensure consistency across geographic determinations used for EUC-related exemptions.

Furthermore, we recognize the external impact of circumstances outside of the ASM participants' control, such as large-scale cyberattacks

[243] *https://www.cms.gov/medicare/coverage/telehealth/list-services.*

[244] *https://qpp.cms.gov/resources/document/3579730b-0891-4491-b880-eb21da631b15.*

[245] *https://qpp.cms.gov/mips/exception-applications.*

and other emergencies outside of those identified in the previous paragraphs. We propose at § 512.780(b)(1) and (2) to allow CMS to determine, based on information known to the agency prior to the beginning of the relevant ASM payment year, that data for an ASM participant are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents, including third-party intermediaries. We propose to notify ASM participants of CMS' decision on the existence of circumstances as proposed at § 512.780(b)(1) and the impact of these circumstances upon scoring methodology for affected ASM participants. We also propose to grant CMS discretion in the form and manner of the notice to ASM participants.

We considered adopting an application-based process for EUC exceptions like the MIPS provisions described at § 414.1380(c)(6). However, we believe that any hardships outside of those contemplated at proposed § 512.780(a) and (b) that renders an ASM participant unable to report on ASM performance categories for quality, improvement activities, or Promoting Interoperability, would likely result in the ASM participant being unable to bill claims for that ASM performance year as well. Accordingly, we believe that ASM participants in these circumstances would likely not meet the case minimums for quality and cost measures in their respective ASM performance categories (as proposed at §§ 512.725(g) and 512.730(d)) and would, therefore, be subject to a neutral payment adjustment for the applicable ASM payment year. For example, if the ASM participant does not have 20 EBCM episodes identified in claims data for the impacted ASM performance year, then the ASM participant would not receive a final score and would be subject to an automatic neutral payment adjustment. However, in this scenario, since CMS is unable to determine whether the ASM participant meets the 20 EBCM episodes for the given ASM performance year until all claims for that ASM performance year have been completed, the ASM participant is encouraged to submit as much data as they are able to for all other ASM performance measures.

We considered whether an ASM participant affected by the circumstances at proposed § 512.780(a) or (b) who chooses to report ASM performance category data would be subject to a lower risk level as described at § 512.745(a)(3). Applying a differential risk level for some ASM participants could skew the calculation of ASM payment adjustment factors for all ASM participants depending on how many ASM participants are impacted by the identified circumstances. Instead of adjusting the ASM participant's risk level, we believe it would be preferable for ASM participants not to receive a final score, which would result in an automatic neutral payment adjustment.

We seek comments on the proposed provisions at § 512.780, as well as the alternatives that we considered.

j. Proposed Data Sharing

Under this proposed model, we aim to incentivize ASM participants to engage in care redesign efforts to improve quality of care and reduce Medicare FFS spending for ASM beneficiaries. We expect ASM participants to work toward independently tracking their own data through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of health care items and services. However, we are proposing certain data sharing requirements in § 512.760 to assist ASM participants in this process and in meeting the model objectives.

We propose at § 512.760(d) to provide certain aggregate data that has been de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 CFR 164.514(b), for the purposes of helping ASM participants understand their progress towards improving upon the model's performance metrics. Any aggregate data provided in advance of an ASM performance report for an ASM performance year would not be a guarantee of the ASM participant's final score or ASM payment adjustment factor.

Additionally, as with other mandatory Innovation Center models such as TEAM and IOTA, we propose to provide certain beneficiary-identifiable data to ASM participants regarding the ASM beneficiaries under their care, upon request and execution of a data sharing agreement. We anticipate that ASM participants would use this data to assess their treatment patterns and overall care plans and to identify room for improvement under the model or conducting other ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 165.501. Specifically, subject to the limitations discussed in this proposed rule, and in accordance with applicable law, including the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164), we propose at § 512.760(b) that CMS may offer an ASM participant an opportunity to request certain Medicare beneficiary-identifiable data. We propose that CMS would share this beneficiary identifiable data with ASM participants on the condition that the ASM participants and other individuals or entities performing functions or services related to the ASM participant's activities observe all relevant statutory and regulatory provisions regarding: (1) the appropriate use of data; and (2) the confidentiality and privacy of individually identifiable health information, and comply with the terms of the data sharing agreement proposed at § 512.760(e).

Moreover, we recognize that an individual clinician generally may not be a covered entity. However, the participant clinicians are likely part of a covered entity and therefore are subject to the HIPAA Rules.

We propose at § 512.760(f) that ASM participants must allow Medicare beneficiaries to request restrictions on sharing data, consistent with 45 CFR 164.522(a). We also propose at § 512.760(b)(4) that, for the beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with an ASM participant.

We request comment and feedback on our proposed policies at § 512.760(a) to make certain beneficiary-identifiable data available to ASM participants upon execution of an ASM data sharing agreement.

(1) Data Provided to ASM Participants

(a) Legal Authority To Share Beneficiary-Identifiable Data and Applicability to Proposed ASM Data Sharing Processes

We believe that an ASM participant may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating its performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 164.501.

We recognize there are sensitivities surrounding the disclosure of beneficiaries' individually identifiable health information, and that several laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure

of information collected under the Act without consent unless a law (statute or regulation) permits the disclosure. Here, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS to ASM participants so they can carry out ''health care operations'' that fall within the first and second paragraphs of the definition of the term as defined at 45 CFR 164.501. In this proposed rule, we propose to make ASM participants accountable for quality and cost outcomes during an applicable ASM performance year. We believe it is necessary for the purposes of this model to offer ASM participants the ability to request certain raw beneficiary-identifiable Medicare claims data that CMS used to determine ASM participant eligibility for an applicable ASM performance year, as well as for the beneficiaries who trigger an EBCM episode with the ASM participant during the applicable ASM performance year. ASM participants would only receive data for the ASM beneficiaries who are their patients. We believe these data would constitute the minimum information necessary to enable ASM participants to understand care spending patterns, appropriately coordinate care, and target care strategies toward ASM beneficiaries.

Under the HIPAA Privacy Rule, covered entities (defined in 45 CFR 160.103 as health plans, health care providers that conduct certain transactions electronically, and health care clearinghouses) may only use or disclose protected health information (PHI), a subset of individually identifiable health information I, as permitted or required by the HIPAA Privacy Rule, without the individual's authorization. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the use or disclosure of PHI without an individual's authorization. ASM participants are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they electronically transmit any health information in connection with one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. ASM participants are clinicians who are either covered entities themselves, or they are part of a covered entity. We believe that the proposed disclosure of beneficiary-identifiable data under the ASM model would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operation's purposes if both covered entities have or had a relationship with the subject of the PHI being requested, the PHI pertains to such relationship, and the PHI disclosure is for a ''health care operations'' purpose listed within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination.'' The second paragraph of the definition of health care operations includes ''evaluating practitioner and provider performance'' (45 CFR 164.501).

We propose at § 512.760 that, subject to having an ASM data sharing agreement in place, an ASM participant may request from CMS certain beneficiary-identifiable claims for ASM beneficiaries under their care. Under the ASM data sharing agreement, we propose at § 512.760(b)(5)(i) and (ii) to allow CMS to share data with an ASM participant which includes unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data used to determine ASM participant eligibility for an applicable ASM performance year, as well as unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data for ASM beneficiaries who trigger an episode with the ASM participant during the applicable ASM performance year. ASM participants would use the data on their patients to evaluate the performance of the ASM participant and other providers and suppliers, such as clinicians with whom the ASM participant may have entered into a collaborative care arrangement, that furnished services to the patient, conducts quality assessment and improvement activities, and conducts population-based activities relating to improved health for their patients. When done by or on behalf of an ASM participant that is a covered entity, these data uses would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. This encompasses the anticipated uses of the beneficiary-identifiable data by an ASM participant so that such uses would be permissible under the HIPAA Privacy Rule. Moreover, done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501, thus encompassing the anticipated uses of the beneficiary-identifiable data by an ASM participant and that such uses would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities or business associates must make ''reasonable efforts to limit'' the PHI that is used, disclosed, or requested to the ''minimum necessary'' to accomplish the intended purpose of the use, disclosure, or request (45 CFR 164.502(b)). Thus, ASM participants must limit their beneficiary-identifiable data requests to the minimum necessary, as selected from the proposed data elements identified at § 512.760(c), to accomplish the intended purpose of the use, disclosure, or request. The proposed minimum necessary data elements include, but are not limited to:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Sex.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax identification number.
- National provider identifier.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when Federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. For the proposed ASM model, we believe that the proposed data disclosures are compatible with the purposes for which the data discussed in this rule was collected, and, thus, would not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records ''routine use'' is in place prior to making any disclosures. The systems of records from which CMS would share data are the Medicare Integrated Data Repository (IDR), the Common Working File, Medicare Provider Enrollment, Chain, and Ownership System (PECOS), the Enrollment Database (EDB), and the Part D Event (PDE) File. We believe that the proposed data disclosures are compatible with the purposes for which the data discussed in the proposed rule were collected and may be disclosed in accordance with the routine uses applicable to those records.

We propose at § 512.760 that we would share the ASM beneficiary-identifiable lists and data with ASM participants who have submitted a formal request for the data. Under our proposal, the request must be submitted on at least an annual basis in a manner and form specified by CMS. The request also would need to identify the data being requested and include an attestation that (1) the ASM participant is requesting this beneficiary-identifiable data as a HIPAA covered entity, or as part of a HIPAA covered entity, and (2) the ASM participant's request reflects the minimum data necessary for the ASM participant to conduct activities that are described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501. In addition, ASM participants who request this data must have a valid and signed ASM data sharing agreement in place, as described in more detail later in this section of this proposed rule. We propose at § 512.760(b) that we would make available beneficiary-identifiable data for ASM participants to request for purposes of conducting activities described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries. We believe that access to beneficiary-identifiable claims data would improve care coordination between ASM participants and other health care providers.

We also propose at § 512.760(b)(2)(ii) that ASM participants limit the request for beneficiary-identifiable claims data to Medicare beneficiaries who have been seen by ASM participants for an ASM targeted chronic condition, and who did not request to restrict sharing their claims data with the ASM participant, as proposed at § 512.760(f)(1). Finally, we propose that CMS would share beneficiary identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's activities, comply with all applicable laws governing the use of data and the privacy and security of individually identifiable health information and the terms of the ASM data sharing agreement proposed at § 512.760(e)(1).

(b) Medicare Beneficiary Opportunity To Request Restrictions on Data Sharing

We propose at § 512.760(f)(1) that ASM beneficiaries would be notified about the opportunity to request restrictions on sharing claims data with an ASM participant, in accordance with 45 CFR 164.522. Recognizing the administrative burden associated with such restrictions, however, we note that under 45 CFR 164.522(a)(1)(iii), covered entities are not required to agree to such a restriction unless the request fulfills the conditions set forth at 45 CFR 164.522(a)(1)(vi). Furthermore, we propose that Medicare beneficiaries may not decline to have the aggregate, de-identified data proposed in § 512.760(d) shared with ASM participants. We also note that, in accordance with 42 U.S.C. 290dd–2 and its implementing regulations at 42 CFR part 2, we do not share beneficiary identifiable claims data relating to the diagnosis and treatment of substance use disorders under this model.

We recognize this policy is distinct from the data sharing policy in IOTA and other voluntary Innovation Center models. We considered aligning the data sharing provisions with IOTA but decided to align with HIPAA requested data restriction provisions because they are less administratively burdensome on providers. We request comment and feedback on our proposed policies at § 512.760(f) to enable ASM beneficiaries to request restrictions on data sharing with their treating ASM participant. We also request comment and feedback on whether ASM should align its data sharing policies with existing Innovation Center models or retain its existing proposed structure, which is based on HIPAA requirements at 45 CFR 164.522.

(c) Aggregated Data Sharing

We propose at § 512.760(d) to deliver certain aggregate data that has been de-identified in accordance with the HIPAA Privacy Rule, 45 CFR 164.514(b), for the purposes of helping ASM participants understand their progress towards improving upon the model's performance metrics. Such aggregated, de-identified data could include, when available, claims-based cost, utilization, and quality data. Cost and utilization data could include fields such as average Medicare FFS (Part A and Part B) expenditure per beneficiary, the top diagnosis codes for beneficiaries the ASM participant is seeing, or hospital admission and readmission rates. Quality data could include preliminary measure rates for the claims-based measures in each ASM measure set. The data would support ASM participants in analyzing care provided to their Medicare patients and their efforts to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. We are considering providing these two forms of performance feedback at regular intervals, allowing insights into trends that could result in improved model performance and beneficiary care. We seek comments on the elements, cadence, and format of this claims-based performance aggregated data and how it could be most beneficial to ASM participants in improving quality and reducing costs.

Any aggregate data provided in advance of an ASM performance report for an ASM performance year would not be a guarantee of the ASM participant's final score or ASM payment adjustment factor. Since this data would be de-identified according to the HIPAA Privacy Rule requirements and would not contain any protected health information (PHI) or personally identifiable information (PII), this aggregate data would be provided to ASM participants regardless of whether they have executed an ASM data sharing agreement with CMS.

(2) ASM Data Sharing Agreement

(a) General Requirement for Beneficiary-Identifiable Data

We propose at § 512.760(e)(1) that if an ASM participant wishes to retrieve ASM beneficiary-identifiable data, the ASM participant would be required to

complete, sign, and submit—and thereby agree to the terms of—an ASM data sharing agreement with CMS on at least an annual basis. We propose to define the ''ASM data sharing agreement'' as an agreement between the ASM participant and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the ASM participant under proposed § 512.760(e). We propose that under the ASM data sharing agreement, the ASM participant would be required to comply with the limitations on the use and disclosure of PHI imposed by the HIPAA Privacy Rule, the applicable ASM data sharing agreement, and the statutory and regulatory requirements of ASM. We also propose that the ASM data sharing agreement would include certain protections and limitations on the ASM participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. We propose at § 512.760(g) that a designated data custodian would be the individual(s) that an ASM participant would identify as responsible for ensuring compliance with all privacy and security requirements, including all applicable laws and terms of the ASM data sharing agreement, and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

We believe it is important for the ASM participant to first complete and submit a signed ASM data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the ASM participant. As noted previously in this section of the proposed rule, there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ASM participants would be further protected in an appropriate fashion.

We seek public comment on our proposal at § 512.760(e) to require that the ASM participant agree to comply with all applicable laws and terms of the ASM data sharing agreement as a condition of retrieving beneficiary-identifiable data, and on our proposal that the ASM participant would need to submit the signed ASM data sharing agreement at least annually if the ASM participant wishes to retrieve the beneficiary-identifiable data.

(b) Content of the ASM Data Sharing Agreement

We recognize that ASM participants may already be required to comply with the HIPAA Privacy Security, and Breach Notification Rules ''(HIPAA Rules'') as covered entities themselves, or as employees or owners of HIPAA covered entities. However, since ASM participation is at the TIN–NPI level, we recognize that the TINs to which the ASM participants belong may be the covered entities, rather than the ASM participants themselves. Thus, we included language allowing ASM data sharing agreements to be executed between CMS and ASM participants or the covered entities that conduct HIPAA standard transactions on behalf of the ASM participants. We also propose at §§ 512.760(e)(1)(i) through (v) to impose CMS-specific requirements within the ASM data sharing agreement to reinforce the Innovation Center's specific expectations and consequences for misuse, which is intended to protect the privacy and security CMS' beneficiary-identifiable data in the hands of ASM participants and any downstream recipients. We propose that under the ASM data sharing agreement, ASM participants would agree to certain terms, including:

- Complying with the requirements for use and disclosure of this ASM beneficiary-identifiable data that are imposed on covered entities, as defined by 45 CFR 160.103, by the regulations at 45 CFR part 160 and part 164, subparts A and E, including but not limited to ensuring the data will not be used for purposes outside of conducting health care operations as defined at 45 CFR 164.501 and as permitted by 45 CFR 164.506(c)(4) on behalf of their ASM beneficiaries
- Complying with privacy, security, breach notification, and data retention requirements specified by CMS in the ASM data sharing agreement if CMS deems such requirements necessary to safeguard beneficiary data, in addition to applicable law, such as the HIPAA Privacy, Security, and Breach Notification Rules
- Contractually binding any and each downstream recipient of the ASM beneficiary-identifiable data, such as persons or entities performing functions or services related to the ASM participant's data sharing activities including those that meet the definition of a business associate as defined at 45 CFR 160.103 and non-ASM participant parties to collaborative care arrangements described at § 512.771, to the same terms and conditions to which the ASM participant is itself bound in its ASM data sharing agreement with CMS as a condition of the business associate's receipt of the ASM beneficiary-identifiable data obtained by the ASM participant
- Acknowledging that if the ASM participant or any downstream recipient misuses or discloses the ASM beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the ASM data sharing agreement, CMS may do any or all of the following: deem the ASM participant ineligible to obtain ASM beneficiary-identifiable data for any amount of time, or subject the ASM participant to additional sanctions and penalties available under applicable law.
- An ASM participant must comply with all applicable laws and the terms of the ASM data sharing agreement to obtain ASM beneficiary-identifiable data.

We propose at § 512.760(e)(2) that CMS would share beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including business associates of the ASM participant as defined at 45 CFR 160.103 and non-ASM participant parties to collaborative care arrangements described at § 512.771, comply with all relevant laws governing the use of data and the privacy and security of individually identifiable health information and the proposed terms of the ASM data sharing agreement.

We believe that these proposed terms for sharing beneficiary-identifiable data with ASM participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ASM participants would be further protected by the ASM participant, and any business associates of the ASM participant as defined at 45 CFR 160.103 and non-ASM participant parties to collaborative care arrangements described at § 512.771, in an appropriate fashion. We have these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards for data storage and transmission; limitations on further use and disclosure of the data; procedures

for responding to data incidents and breaches; and data destruction and retention. These provisions would be in addition to any restrictions imposed by applicable law, such as the HIPAA Rules. These ASM data sharing agreement provisions would not prohibit the ASM participant from making any disclosures of the data otherwise required by law.

We solicit public comments on this proposal at § 512.760(e) to impose certain requirements in the ASM data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

k. Proposed ASM Beneficiary Incentives, Collaborative Care Arrangements, and Applicability of CMS-Sponsored Model Safe Harbor at § 1001.952(ii)

(1) ASM Beneficiary Incentives

As part of CMS' commitment to empower patients to actively participate and be accountable for quality and whole health outcomes, we invite ASM participants to think outside the box with regards to physical and lifestyle factors that contribute to the ASM's targeted chronic conditions. We propose at § 512.770(a)(1) through (8) to allow ASM participants the option of providing in-kind patient engagement incentives, so long as the following criteria are met:

- The incentive must be provided directly by the ASM participant or by an agent of the ASM participant under the ASM participant's direction and control to an ASM beneficiary who is an established patient of the ASM participant.
- The ASM participant must be solely responsible for any costs associated with the provision of the incentive, including but not limited to, the retail value of the item or services offered as the ASM beneficiary incentive.
- The item or service provided must be reasonably connected to medical care provided by the ASM participant to an ASM beneficiary for an ASM targeted chronic condition.
- The item or service must be a preventive care item or service or an item or service that advances a clinical goal for an ASM beneficiary by engaging the ASM beneficiary in better managing an ASM targeted chronic condition. ASM's clinical goals are centered around promoting preventive care through improved management of ASM targeted chronic conditions; empowering patients to actively participate and be accountable for quality and whole health outcomes; and facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.
- The item or service must not be tied to the receipt of items or services outside the services furnished by the ASM participant to the ASM beneficiary.
- The item or service must not be tied to the receipt of items or services from a particular provider or supplier.
- The availability of the items or services must not be advertised or promoted, except that an ASM beneficiary may be made aware of the availability of the items or services at the time the ASM beneficiary could reasonably benefit from them.
- The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.
- The totality of items or services, including technology as described at paragraph (b) of this section, provided to an ASM beneficiary may not exceed $1,000 in retail value for any one ASM beneficiary.

We envision this could take the form of remote patient monitoring devices such as blood pressure monitors or scales with or without the capability to send data to their providers, vouchers for healthier food options or meal planning, and promotions for regular physical activity such as gym memberships or classes. These are, however, just examples and are not inclusive of all options available to ASM participants who offer beneficiary incentives. To safeguard against potential fraud, waste, and abuse, however, we propose to require limits on the retail value of offered items or services, when offered items must be retrieved from the ASM beneficiary, and when an ASM beneficiary becomes eligible for ASM beneficiary incentives. Specifically, due to multi-use nature of technological items and devices, we propose at § 512.770(b)(1) and (2) the following stipulations for technology that is provided to ASM beneficiaries:

- Items or services involving technology provided to a ASM beneficiary must be the minimum necessary to advance a clinical goal of the model as proposed at § 512.770(b), which are: promoting preventive care through improved management of ASM targeted chronic conditions; empowering patients to actively participate and be accountable for quality and whole health outcomes; and facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.
- Items of technology exceeding $75 in retail value must remain the property of the ASM participant. However, upon the end of their care relationship with the ASM participant, that technology must be retrieved from the ASM beneficiary with documentation of the ultimate date of retrieval. The ASM participant must document all retrieval attempts. In cases when the item of technology is not able to be retrieved, the ASM participant must determine why the item was not retrievable. If it was determined that the item was misappropriated, then the ASM participant must take steps to prevent future beneficiary incentives for that ASM beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement. If the provided technology breaks or is otherwise rendered unusable for its intended purposes, the technology must be retrieved from the ASM beneficiary with documentation of the ultimate date of retrieval. The ASM participant may replace the unusable unit with the same or similar technology, to the extent practicable, that meets the original requirements for the technology.
- In addition to the requirements on audits and record retention at § 512.135, we propose at § 512.770(c)(1) through (4) that ASM participants who wish to offer ASM beneficiary incentives must also ensure documentation of the incentives distributed according to the following requirements:
- ASM participants must maintain documentation of items and services furnished as beneficiary incentives that exceed $75 in retail value.
- The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the date the incentive is provided and the identity of the ASM beneficiary to whom the item or service was provided.
- The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable.
- The ASM participant must retain and provide access to the required documentation.

We seek comment on the proposed parameters at § 512.770 for allowed ASM beneficiary incentives, especially regarding the practicality and feasibility

of the requirements around items of technology.

(2) Collaborative Care Arrangements

To support the goals of ASM, we propose to encourage ASM participants to enter into collaborative care arrangements with primary care practices to further the ASM participant's performance in the improvement activities ASM performance category or advance the clinical goals of ASM.

To allow ASM participants greater flexibility when negotiating collaborative care arrangements, we propose at § 512.771(a) to make the CMS-sponsored model arrangements safe harbor at 42 CFR 1001.952(ii)(1) available to ASM participants when establishing collaborative care arrangements so long as they comply with the requirements of that safe harbor and proposed § 512.771. We propose at § 512.771(a) to require all collaborative care arrangements to:

- Be in writing, signed by both parties, and containing the effective date of the collaborative care arrangement.
- Be exclusively between the ASM participant and the primary care practice with whom the ASM participant shares at least one established patient who is an ASM beneficiary,
- The arrangement must be entered into for the purpose of furthering the ASM participant's improvement activities or advancing at least one of ASM's three clinical goals proposed at § 512.771(b), which are: promoting preventive care through improved management of ASM targeted chronic conditions; empowering patients to actively participate and be accountable for quality and whole health outcomes; and facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.
- Participation in a collaborative care arrangement must be voluntary and without penalty for nonparticipation.
- Both parties to the collaborative care arrangement must comply with all applicable statutes, regulations, and guidance, including without limitation: federal criminal laws; the False Claims Act (31 U.S.C. 3729 *et seq.*); the anti-kickback statute (42 U.S.C 1320a–7b(b)); the civil monetary penalties law (42 U.S.C. 1320a–7a); and the physician self-referral law (42 U.S.C. 1395nn).
- The opportunity to enter into a collaborative care arrangement, and the amount of any payment or other remuneration under a collaborative care arrangement, must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the collaborative care arrangement or any other person.
- Any payment or other remuneration between the parties set forth in a collaborative care arrangement must not exceed fair market value and must be determined in accordance with a methodology that is solely based on the purposes identified at paragraphs (b)(2)(i) and (b)(2)(ii) of this section.
- Any payment or other remuneration set forth in the collaborative care arrangement must be solely between the parties to the arrangements. Any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.
- Both parties to the collaborative care arrangement must retain the ability to make decisions in the best interests of the ASM beneficiary, including the selection of clinicians, devices, supplies, and treatments.
- The collaborative care arrangement must not induce any party to reduce or limit medically necessary services to any Medicare beneficiary, or reward the provision of items and services that are medically unnecessary.
- ASM participants must maintain contemporaneous documentation, in accordance with § 512.135, regarding all collaborative care arrangements to which they are a party.
- The collaborative care arrangement must stipulate that any non-ASM participant party is considered a downstream recipient for CMS data sharing purposes, and must require the non-ASM participant party to comply with applicable data sharing requirements at proposed § 512.760.
- Any non-ASM participant party to a collaborative care arrangement shall be a downstream participant subject to the standard provisions for Innovation Center models specified in subpart A of this part 512.

As currently defined, a collaborative care arrangement is exclusively between an ASM participant and a primary care practice. We considered expanding this definition to allow multiple ASM participants in the same TIN to enter into a collaborative care arrangement with a primary care practice. We are concerned about the burden that may be introduced by having each ASM participant enter these arrangements individually, however, elevating the arrangement to the TIN level opens risks related to other elements of collaborative care arrangement, such as remuneration. We welcome comments on our collaborative care arrangement definition and how to address the burden it may impose on ASM participants and partnered primary care practices. We also welcome comments on the types of services and remuneration that ASM participants may contemplate in their collaborative care arrangements to meet improvement activity specifications or advancing at least one of ASM's three clinical goals as proposed at § 512.771(b).

We welcome comments on these proposals at §§ 512.771(a) and (b).

(3) Application of the CMS-Sponsored Model Arrangements and Patient Incentives Safe Harbor to ASM Beneficiary Incentives and Collaborative Care Arrangements

Consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to ASM and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this proposed rule, ASM participants must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued under section 1115A(d)(1) of the Act specifically for ASM.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2)) is available to protect remuneration exchanged under certain collaborative care arrangements and patient incentives that may be permitted under the final rule, if issued. Specifically, we propose at §§ 512.765(a) and (b) that the CMS-sponsored models safe harbor would be available to protect collaborative care arrangements and ASM beneficiary incentives so long as they meet specified requirements at proposed §§ 512.770 and 512.771 under the model and the requirements of the safe harbor at § 1001.952(ii).

We considered not allowing use of the respective safe harbor provisions for ASM participants who enter into collaborative care arrangements or who wish to provide beneficiary incentives. However, we determined that use of the safe harbor would encourage the goals of the model. We believe that a

successful model requires integration and coordination among ASM participants and other health care providers and suppliers. We believe the use of the respective safe harbor provisions available for collaborative care arrangements and beneficiary incentives would encourage and improve beneficiary experience of care and coordination of care among providers and suppliers. We also believe these safe harbor provisions offer flexibility for innovation and customization of the patient care experience. Use of the respective safe harbor provisions for collaborative care arrangements and beneficiary incentives allow for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

Thus, we propose at § 512.765 making the CMS-sponsored model arrangements at §§ 1001.952(ii)(1) and 1001.952(ii)(2) available for ASM participants to foster stronger connections with primary care providers in their communities and to promote a more holistic approach to ASM beneficiary care outcomes, so long as they comply with the proposed requirements at §§ 512.770 and 512.771. We seek public comments on this proposal.

l. Proposed Evaluation Approach

(1) Background

As proposed, ASM is designed to incentivize specialist providers to engage in accountable care and aims to improve quality of care while lowering spending. An evaluation of ASM would be required in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center (84 FR 34533). All Innovation Center models are rigorously evaluated on their ability to improve quality of care and reduce costs. Additionally, we routinely monitor Innovation Center models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. Outlined later in this section are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed ASM.

(2) Design and Evaluation Methods

We propose an evaluation methodology for ASM that would be consistent with the standard Innovation Center evaluation approaches that we have taken in other models, such as TEAM and CJR. Specifically, the evaluation design and methodology for ASM would be designed to allow for a comparison of historic patterns of care among ASM participants to any changes made in these patterns in response to ASM. The overall design would include a comparison of ASM participants with comparable specialist providers not participating in ASM to help us discern simultaneous and competing providers and market level forces that could influence our findings.

Our proposed evaluation methodology for this model builds upon our proposal to use CBSAs and metropolitan divisions as the geographic unit of selection for participation in the model based on a stratified random assignment as described in section III.C.2.c.(4) of this proposed rule. Under this approach, researchers evaluate the effects of the model on outcomes of interest by directly comparing CBSAs and metropolitan divisions that are randomly selected to participate in the model to a comparison group of CBSAs and metropolitan divisions that were not randomly selected for the model but could have been. Randomized evaluation designs of this kind are widely considered the ''gold standard'' for social science and medical research because they ensure that the systematic differences are reduced between units that do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. With these methods, we would be able to examine the experience of the ASM participants over time relative to those in the comparison group controlling for as many of the relevant confounding factors as is possible. The evaluation would also include rigorous qualitative analyses to understand the contextual factors influencing the implementation and impact of ASM and the evolving nature of care delivery transformation.

In our proposed evaluation methodology, we plan to account for the impact of ASM at the geographic unit level, the TIN/NPI level, and the beneficiary level. We would also consider various statistical methods to address factors that could confound or bias our results. We would also account for clustering of beneficiaries within TINs and markets. Accounting for clustering ensures that we do not overstate our effective sample size by failing to account for the fact that the performance of participants in a market may not be fully independent of one another. Accounting for clustering may also improve statistical precision and allow us to better examine how patterns of performance vary across TINs and markets. Thus, in our analysis, if a large TIN consistently has poor performance, clustering would allow us to detect improved performance in the other, smaller TINs in a market rather than place too much weight on the results of one TIN and potentially lead to biased estimates and mistaken inferences.

Finally, we plan to use various statistical techniques to examine the effects of the ASM while also accounting for the effects of other ongoing interventions such as the Medicare Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding ASM in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

(3) Data Collection Methods

As part of our proposed evaluation methodology, we propose to consider multiple sources of data to evaluate the effects of ASM. We expect to base much of our quantitative analyses on secondary data sources including Medicare FFS claims. The beneficiary claims data would provide information such as utilization and expenditures in total and by type of provider and service. In conjunction with the secondary data sources mentioned previously, we would consider a CMS-administered survey, guided interviews, and focus groups of beneficiaries who experienced a heart failure or low back pain episode during the ASM test period. This survey would be administered to ASM beneficiaries who were in an episode or similar patients selected as part of a control group. The primary focus of this survey would be to obtain information on the ASM beneficiary's experience in episodes relative to usual care. We are also considering a survey administered by CMS to ASM participants. These surveys would provide insight into providers' experience under the model and further information on the care redesign strategies undertaken by health care providers.

In addition, we would consider site visits and focus groups with selected active ASM participants. We believe that these qualitative methods would

provide contextual information that would help us better understand the dynamics and interactions occurring between ASM participants and other providers. For example, these data would help us better understand ASM participants' plans for engagement with PCPs in accountable care arrangements, as well as how those plans were implemented and what they achieved. Additionally, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to capture variations in implementation as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

We are considering primary data collection efforts with providers and beneficiaries within the comparison group. The systematic data collection from comparison group providers would allow for parsing out changes in standard of care from the ASM impact. Additionally, primary data collection with beneficiaries who received care at comparison group providers would provide critical information about the impact of the model on self-reported health status, experience of care and overall satisfaction.

(4) Key Evaluation Research Questions

Our evaluation would assess the impact of ASM on the dual aims of improved care quality and reduced costs. The evaluation would include assessments of Medicare expenditures, utilization, quality outcomes, and patient experience of care. Our key evaluation questions would include, but are not limited to, the following:

- Payment. Is there a reduction in Medicare expenditures in absolute terms? By subcategories including major cost drivers for heart failure and low back pain episodes? Does ASM reduce variations in expenditures that are not attributable to differences in health status? Did ASM result in net savings to the Medicare program, after accounting for any payment adjustments made under the model?
- Utilization. Are there changes in Medicare utilization patterns overall and for specific types of services including services identified as ''low value''? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes, and general clinical judgment of appropriate care?
- Quality of care. What impact did the model have on quality of care for beneficiaries? Did the incidence of relevant clinical outcomes such as hospital admissions remain constant or decrease? Were there changes in beneficiary outcomes under the model compared to appropriate comparison groups?
- Beneficiary experience. What impact did the model have on beneficiary experience overall and for beneficiary subgroups? Did the model have an impact on beneficiaries' engagement in their health care decisions?
- Care delivery transformation. How has provider behavior in the mandatory geographic areas changed under the model? Is there evidence of broader market-level changes? Are provider relationships changing over the course of the model? Is the model facilitating continuity of care between specialty and PCPs? Is there evidence that the participants' changes in care delivery that were made in the response to the model will be sustained?
- Unintended outcomes. Did ASM result in any unintended consequences, including adverse selection of patients, access problems, cost shifting, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? If so, how, to what extent, and for which beneficiaries or providers?

(5) Evaluation Period and Anticipated Reports

As discussed in section III.C.2.b. of this proposed rule, we propose that the ASM test period would be 7 years that includes both ASM performance years and ASM payment years. The evaluation period would encompass the ASM test period. We would plan to evaluate ASM on an annual basis. However, we recognize that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while we intend to conduct periodic summaries to offer useful insight during the model test, a final analysis after the end of the 7-year ASM test period would be important for ultimately synthesizing and validating results.

We seek public comments on our proposed design, evaluation, data collection methods, and research questions.

m. Proposed Overlap With Other Models Tested Under Section 1115A and CMS Programs

We propose to permit ASM to overlap with other CMS Innovation Center models and CMS programs, with the exception of MIPS, from which ASM participants would be excluded from reporting and participation, as proposed in section III.C.2.h.(2) of this proposed rule.

We intentionally designed ASM to apply to Medicare FFS beneficiaries that are assigned, aligned, or attributed to other CMS Innovation Center models, such as existing or forthcoming population-based total cost of care models, or CMS programs, such as the Medicare Shared Savings Program, while ensuring compatibility and alignment towards improving care and reducing spending. The ASM payment methodology allows for overlaps between ASM and other Innovation Center models or CMS programs by avoiding shared savings payments to participants in more than one shared savings model, as barred by statute in 42 USC 1395jjj(b)(4)(A).

Overlapping incentives are key to aligning incentives across the care team because clinicians are more likely to change their behavior or engage in care transformation when the incentives directly affect them.[246] Because specialists drive the majority of spending within Original Medicare, increasing specialist awareness of their participation in ACOs and better engaging them in care transformation is key.[247] [248] Given this objective, ASM would apply to all clinicians meeting the ASM participant eligibility criteria, regardless of whether the clinician is excused from reporting to MIPS due to Advanced APM participation or if the clinician is exempt from reporting MIPS due to eligibility requirements. One reason that we propose to include this broad selection of clinicians as part of ASM is to encourage more specialist engagement with ACOs. The benefits of driving further specialist engagement in value-based care outweigh the additional burdens, especially given the specialists' patient panels make up a smaller portion of ACO-assigned beneficiaries relative to primary care.[249]

[246] Leao DLL, Cremers HP, van Veghel D, Pavlova M, Groot W. The Impact of Value-Based Payment Models for Networks of Care and Transmural Care: A Systematic Literature Review. Appl Health Econ Health Policy. 2023 May;21(3):441–466. doi: 10.1007/s40258–023–00790–z.

[247] Markovitz AA, Ryan AM, Peterson TA, Rozier MD, Ayanian JZ, Hollingsworth JM. ACO Awareness and Perceptions Among Specialists Versus Primary Care Physicians: a Survey of a Large Medicare Shared Savings Program. J Gen Intern Med. 2022 Feb;37(2):492–494.

[248] Lewis, Valerie A.; Schoenherr, Karen; Fraze, Taressa; Cunningham, Aleen. Clinical coordination in accountable care organizations: A qualitative study. Health Care Management Review 44(2):p 127–136, ⁴⁄₆ 2019.

[249] Barnett ML, McWilliams JM. Changes in specialty care use and leakage in Medicare accountable care organizations. Am J Manag Care. 2018 May 1;24(5):e141–e149.

Furthermore, for any clinician who achieves Qualifying APM Participant (QP) status in an Advanced Alternative Payment Model, the QP is waived from reporting and participating in MIPS (81 FR 77062). In addition, participation in MIPS is optional for those Advanced APM participants who are partial QP (81 FR 77014). ASM, however, was designed to purposely overlap with Advanced APMs and ACOs to increase engagement of specialists, regardless of organizational structure. And for specialists participating in an ACO, ASM intends to capture Medicare FFS beneficiaries across the entire specialist practice rather than only the subset of beneficiaries assigned to the ACO. This expands the impact of incentives beyond those beneficiaries assigned to the ACO to the specialist's full panel of beneficiaries who are treated for each relevant condition. This ensures that ACOs are enabled by a landscape of specialists, whether participating in an ACO model or not, who are more likely to cooperate in care transformation to achieve their shared goals.

For these reasons, we propose to allow overlaps between ASM and other Innovation Center models and CMS programs. We propose that this model would apply to all clinicians meeting the eligibility criteria, regardless of whether the clinician is exempt from MIPS reporting during ASM's performance year due to QP status or Partial QP status as a result of meeting the thresholds for payments or patients tied to participation in an Advanced APM. We seek comment on the proposal to permit overlap between ASM and other Innovation Center and CMS programs.

n. Application of Standard Provisions for Mandatory Innovation Center Models

ASM meets the criteria for application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A). Unless otherwise specified, all ASM participants and ASM beneficiaries would be subject to the provisions at §§ 512.100 through 512.190, which address the following areas:

- Beneficiary Protections.
- Cooperation in Model Evaluation and Monitoring.
- Audits and Record Retention.
- Rights in Data and Intellectual Property.
- Monitoring and Compliance.
- Remedial Action.
- Innovation Center Model Termination by CMS.
- Limitations on Review.
- Miscellaneous Provisions on Bankruptcy and Other Notifications.
- Reconsideration Review Process.

We recognize the standard provisions were not intended to encompass all the terms and conditions that would apply to each Innovation Center model, because each model embodies unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that would continue to be included in each model's governing documentation. Thus, we seek public comment on whether ASM should set forth model-specific provisions related to any of the provisions identified above.

E. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model (hereafter, ''MDPP'' or ''MDPP expanded model'') is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012–2016).[250] The DPP model test successfully met statutory criteria for model expansion,[251] demonstrating 5 percent weight loss from their starting weight by participants (a key metric of the program's success) along with statistically significant reductions in Medicare spending, emergency department (ED) visits, and inpatient stays.[252] The MDPP expanded model was implemented through the rulemaking process in two phases, in the CY 2017 PFS (81 FR 80459 through 80483) and CY 2018 PFS final rules (82 FR 53234 through 53339).

MDPP was established in 2017 as an ''additional preventive service,'' [253] covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model tested by The CMS Innovation Center), CMS created a new MDPP supplier type through rulemaking in the CY 2017 PFS final rule (81 FR 80471), in addition to requiring organizations that wish to participate in MDPP to enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 intensive sessions furnished over 12 months, which consists of 16 core sessions delivered weekly over 6 months followed by core maintenance sessions delivered monthly in the following 6 months. MDPP sessions are delivered by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction. All sessions must adhere to a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum [254] and must be 1 hour in length. The primary goal of the MDPP expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss from the first core session (81 FR 80465).

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP on April 1, 2018 (82 FR 53237). As of March 2025, there were 331 approved MDPP suppliers.[255] The most recent MDPP evaluation report reflected that between April 2018 and September 2024, approximately 9,015 beneficiaries have participated in MDPP. Of these, 4,396 were Medicare FFS beneficiaries and 4,650 were MA beneficiaries.[256]

[250] The Health Care Innovation Awards funds awards to organizations that implemented the most compelling new ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid and Children's Health Insurance Program (CHIP), particularly those with the highest health care needs. The CMS Innovation Center announced the first batch of awardees for the Health Care Innovation Awards on May 8, 2012, and the second (final) batch on June 15, 2012. For more, see *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[251] Paul Spitalnic. Certification of Medicare Diabetes Prevention Program. Mar. 14, 2016.*https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.*

[252] Rojas Smith. L., Amico, P., Hoerger, T.J., Jacobs, S., Payne. J., & Renaud, J.: Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report Addendum—August 2017 *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf* (pp. 858–914).

[253] 42 CFR 410.64—*Additional preventive services.*

[254] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

[255] Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Unpublished data.

[256] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/*2025/*mdpp*-finalevalrpt.

Through the Diabetes Prevention Recognition Program (DPRP), CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards,[257] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test,[258] the CDC's National DPP,[259] and DPRP Standards,[260] please refer to the CY 2017 (81 FR 80471) and CY 2018 PFS (82 FR 52976) final rules and related websites.

The Public Health Emergency (PHE) for COVID–19 prompted changes to allow live, virtual delivery via distance learning for MDPP, among other changes (85 FR 84830 through 84841). Changes to MDPP in the CY 2024 PFS final rule (88 FR 78818) included a simplified payment structure to allow for FFS payments for beneficiary attendance while retaining the performance-based payments for diabetes risk reduction (that is, weight loss). Beginning January 1, 2024, payments are made to an MDPP supplier if an MDPP beneficiary attends any core session in the first 6 months or core maintenance session in the second 6 months, allowing payment for up to 22 sessions in a 12-month timeframe. The CY 2024 PFS final rule also extended certain PHE flexibilities, including the option to deliver some or all MDPP sessions via distance learning and for beneficiaries to virtually self-report weight for MDPP distance learning sessions, until December 31, 2027 (88 FR 79241).

CDC released the 2024 DPRP Standards [261] to replace the 2021 DPRP Standards in June 2024. The CY 2025 PFS final rule (89 FR 97710) made conforming changes to align with the 2024 CDC DPRP Standards and further clarify regulatory language pertaining to program delivery and claim submission by adding new MDPP terms for ''in-person with a distance learning component'' and ''combination with an online component.'' The CY 2025 PFS final rule also updated self-reporting weight requirements for an MDPP distance learning session by providing beneficiaries with a new option to self-report their weight using two photos for distance learning sessions. In addition, the CY 2025 PFS final rule added a HCPCS modifier for reporting a make-up session on the same day as a regularly scheduled MDPP session, and bridge payments were removed from MDPP's FFS payment structure.

While the CY 2024 and CY 2025 PFS final rules included changes to MDPP, which included enhancements that simplified payment structure and extended the ability for MDPP suppliers to deliver some or all MDPP sessions via distance learning, additional changes to MDPP through the CY 2026 PFS proposed rule are necessary to increase uptake of MDPP. Participation in MDPP has been low, with less than 1 percent of eligible beneficiaries participating in the program. While an estimated 9.3 million Medicare FFS beneficiaries are potentially eligible for the program (that is, have a prediabetes diagnosis but not a diabetes diagnosis in claims), fewer than 5,000 Medicare FFS beneficiaries have participated in MDPP during the first 6 years of the program. Increasing the uptake of MDPP among both suppliers and beneficiaries is necessary to increase the impact and success of the program.

In this proposed rule, we are proposing several changes which are aimed towards increasing the uptake of this important prevention-focused program while empowering beneficiaries and promoting further alignment between MDPP and the CDC DPRP Standards. Specifically, we are proposing changes to 42 CFR 410.79(b) to add definitions for the following terms: Live Coach interaction, Online delivery period, and Online session while modifying the definition of ''Online.'' We also propose changes to the expanded model by amending § 410.79(c)(1)(ii) and (e)(3)(iii)(C) to address operational questions and barriers related to weight collection requirements. We also propose to extend flexibilities allowed during the PHE for COVID–19 through December 31, 2029 by modifying the definition of extended flexibilities period in § 410.79(b). Finally, we are proposing to test the inclusion of an asynchronous delivery modality by modifying § 410.79 by revising paragraph (b) adding paragraph (f) and amending § 424.205(c)(10), (f)(2)(i), and (f)(5), which will allow MDPP suppliers to deliver the Set of MDPP services Online through December 31, 2029, clarify that MDPP suppliers are not required to maintain in-person delivery capability through December 31, 2029, and introduce a new G-code and payment for Online sessions. These changes are expected to expand beneficiary access to MDPP, reduce barriers to participation, improve MDPP session attendance and retention, and promote safety.

1. Changes to § 410.79(b)

The 2024 CDC DPRP Standards include the following delivery modes with definitions: ''In-person,'' ''Distance learning (live),'' ''In-person with a distance learning component,'' ''Online (non-live),'' and ''Combination with an online component.'' [262] These delivery modes also serve as organization codes for CDC DPRP recognition. As indicated in § 410.79(b), distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

The CY 2024 PFS final rule introduced and defined ''distance learning'' for MDPP and provided a definition for ''online delivery'' (88 FR 79243). The CY 2025 PFS final rule modified the definition for ''online delivery'' at § 410.79(b), to align with the 2024 CDC DPRP Standards [263] by revising the term from ''online delivery'' to ''online'' to align with both the MDPP ''distance learning'' term and CDC DPRP ''online (non-live)'' term (89 FR 98045). We also finalized the definition for the MDPP ''Online'' delivery mode to provide that sessions that are delivered one hundred percent (100 percent) through the internet via smartphone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach

[257] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[258] Health Care Innovation Awards. *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[259] *https://www.cdc.gov/diabetes/prevention/index.html.*

[260] *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[261] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[262] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[263] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for Online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. E-mails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant, whereby both parties engage in the interaction. Chat bots and AI forums do not count as live Coach interaction. This modified definition added the term ''non-live'' and further clarified that Chat bots and AI forums do not constitute live interaction.

We propose to amend § 410.79(b) by adding definitions for Live Coach Interaction and Online session while modifying the definition for Online as defined at § 410.79(b) to clarify the Online delivery modality and remove requirements in the Online definition that will be outlined at § 410.79(f). We also propose adding the definition of Online delivery period, which refers to the 4-year period (January 1, 2026 to December 31, 2029) to test the inclusion of the Online delivery modality, described at § 410.79(f), to apply. During this time, MDPP suppliers may deliver the Set of MDPP services Online.

We propose to amend § 410.79(b) by adding definitions for ''Live Coach Interaction'' and ''Online Session'' while modifying the definition for Online as defined at § 410.79(b) to clarify the ''Online'' delivery modality and remove requirements in the Online definition that will be outlined at § 410.79(f). We also propose adding the definition of Online Delivery Period, which refers to the 4-year period (January 1, 2026 to December 31, 2029) to test the inclusion of the Online delivery modality, described at § 410.79(f), to apply. During this time, MDPP suppliers may deliver the Set of MDPP services Online.

The CY 2024 PFS final rule extended certain PHE flexibilities finalized in the CY 2021 PFS final rule, including the option to deliver some or all MDPP sessions via distance learning and for beneficiaries to virtually self-report weight for MDPP distance learning sessions, until December 31, 2027 (88 FR 79241). In the CY 2024 PFS, we finalized that during the Extended flexibilities period, MDPP suppliers may provide virtual services as long as they are provided in a manner consistent with the CDC DPRP standards for distance learning. The extension of these flexibilities allowed beneficiaries to obtain the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning for a proposed period of 4 years. The Extended flexibilities definition refers to § 410.79(e)(3)(iii) and (iv), and the extended flexibilities period described at § 410.79(b) refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

Prior to the PHE for COVID–19, MDPP suppliers delivered the program predominantly in-person. Delivery modes have shifted over time, with an increasing number of beneficiaries participating through the virtual delivery option. The most recent evaluation report indicates that from April 2018 through March 2024, 59 percent of MDPP beneficiaries predominantly attended the program in person, 7.5 percent of MDPP beneficiaries attended the program through a mix of in-person and virtual sessions, and 33.5 percent predominantly attended the program virtually.[264] Among beneficiaries who participate in MDPP via distance learning or in-person with a distance learning component (hybrid), most expressed their satisfaction by citing the flexibility the choices provided when faced with challenges such as inclement weather or travel restrictions that made in-person participation difficult.[265]

We are also proposing to extend flexibilities allowed during the PHE for COVID–19 through December 31, 2029 by revising the dates included in the definition for ''extended flexibilities period'' a § 410.79(b). We propose extending this flexibility to promote continued access to MDPP for beneficiaries. In particular, beneficiaries in geographic areas with a limited number of in-person MDPP suppliers or other areas (for example, rural) where travel to an in-person session may be challenging and may be further exacerbated under certain circumstances; for example, during inclement weather.

This proposed change will ensure that all delivery modalities for MDPP are available during the same period of time (that is, through December 31, 2029) creating greater alignment, reducing potential confusion amongst beneficiaries and suppliers, and streamlining the program. Additionally, the proposed change provides MDPP suppliers with a variety of modes in which to deliver the program and facilitates consistency across delivery modalities adhering to this same timeframe.

We are proposing to amend § 410.79(b) and seek comments on these proposals.

2. Proposed Changes to § 410.79 (c)(1)(ii) and (e)(3)(iii)(C)

Our policies for obtaining weight measurements for baseline weight and performance-based weight loss achievement goals are described at § 410.79(c)(1)(ii), and for the MDPP expanded model emergency policy, summarized at § 410.79(e)(3)(iii). Currently, these policies permit weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be taken in person by an MDPP supplier during an MDPP session, or via digital technology during the Extended flexibilities period. Specifically, these policies permit an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) in-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations; (2) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (3) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary (89 FR 98046).

The CY 2025 PFS policies regarding beneficiary weight self-reported measurements and virtual weight collection (89 FR 98045) provided additional flexibilities for beneficiaries to self-report their weights by providing one or 2 (two) date-stamped photo(s) or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo(s) or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit one photo, this photo must show the beneficiary's weight on the scale with the beneficiary visible in their home. If choosing to submit two (2) photos, one photo must show the beneficiary's weight on the digital scale, and a second photo must show the beneficiary visible in their home.

Overall, commenters on the proposed MDPP Extended flexibilities in the CY 2024 PFS and CY 2025 PFS rules were very supportive of CMS continuing to

[264] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.*

[265] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.*

allow virtual weight collection (88 FR 79240 through 79256, 89 FR 98046). However, we received several comments regarding barriers to virtual weight collection experienced by MDPP suppliers and beneficiaries. This problem has become even more relevant as suppliers continue to expand distance learning to help reach beneficiaries in rural and underserved areas, sometimes across state lines.

For example, several commenters reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. The current weight collection requirements discourage individuals with mobility concerns from participating in MDPP due to risk of injury while self-reporting weight from home. Beneficiaries with mobility concerns may need to obtain weight at a medical office using a special scale (for example, wheelchair scale). Currently, beneficiaries do not have the option to submit medical record data as proof of weight, contributing to participant burden. Additionally, we have received feedback from suppliers stating that the requirement that beneficiaries must self-report weight by providing date-stamped photo(s) or video which must show the beneficiary's weight on the digital scale and the visible in their home is restrictive.

We acknowledge in our responses to these comments that some MDPP beneficiaries may lack the technology or capacity to provide a date-stamped photograph to document their body weight measurements. We previously stated that in situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in person (88 FR 79249). However, this may not be a practical option for beneficiaries who have chosen distance learning based on not living within driving distance from an MDPP supplier location, lack access to transportation, or are participating from a location outside of their home or an in-person delivery site.

Therefore, we propose revising § 410.79(c)(1)(ii) to allow for weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record within 2 days of the completion of the MDPP session. Currently, beneficiaries must weigh in during their in-person MDPP session or self-report weight measurements on the date associated with the billable MDPP session. We anticipate that suppliers and beneficiaries will appreciate the expanded flexibilities surrounding weight collection for MDPP as current requirements limit the ability of a beneficiary to report their weight from locations outside of an in-person delivery site or their home and prevent beneficiaries from submitting weight measurements documented in a medical record. We expect these additional flexibilities to empower beneficiaries, improve MDPP beneficiary engagement, session attendance, retention, and program completion. We considered alternative timeframes ranging from 3 to 5 days for this proposed change. We believe a 2-day documentation window prevents significant overlap between session documentation periods, considering core sessions occur weekly. We believe a shorter timeframe would be overly restrictive for suppliers and beneficiaries. We solicit public comments on this proposed timeframe and welcome feedback on whether the two (2) day documentation window is appropriate, or if alternative timeframes would better serve MDPP suppliers and MDPP beneficiaries while maintaining program integrity.

Additionally, we propose revising § 410.79(e)(3)(iii)(C) to allow beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site. Examples of a reasonable location outside of an in-person delivery site include, but are not limited to fitness centers, medical facilities, and temporary abodes (for example, travel accommodations or a family member's home). Currently, beneficiaries must submit photo(s) or video documenting their weight on a digital scale from their home, which limits their ability to submit required weight measurements when on vacation or away from their home. We are continuing to require the date-stamp on photo(s) to ensure program integrity in the virtual setting.

We propose amending § 410.79(c)(1)(ii) and (e)(3)(iii)(C). We are soliciting comments on these proposals.

3. Proposed Changes to § 410.79 by Adding Paragraph (f) and Amending § 424.205(c)(10), (f)(2)(i), and (f)(5)

In the CY 2018 PFS final rule, we stated our intention to align MDPP with CDC DPRP Standards whenever possible (82 FR 53245). The CDC DPRP Standards have included virtual, online modalities and approaches since 2015.[266] MDPP has included in-person delivery of the Set of MDPP Services since it began serving beneficiaries in 2018. The MDPP expanded model emergency policy (85 FR 84831) broadened the delivery of the Set of MDPP services through synchronous distance learning to provide greater flexibility during the PHE for COVID–19, and later extended distance learning, and other related flexibilities through December 31, 2027, as part of the CY 2024 PFS final rule (82 FR 53249).

In the CY 2021 PFS final rule, we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by MDPP suppliers who offered in-person services (85 FR 84830) and maintained CDC DPRP ''in-person'' recognition (85 FR 84830 and 84831). In the CY 2024 PFS final rule, we extended flexibilities allowed during the PHE for COVID–19 for 4 years, or through December 31, 2027 (88 FR 79241). We also confirmed that suppliers who exclusively delivered MDPP services virtually via distance learning without maintaining in-person delivery capability were not permitted to furnish the Set of MDPP services because MDPP beneficiaries may elect to return to in-person services, and MDPP suppliers need to be able to accommodate their request (88 FR 79248).

The CY 2025 PFS final rule confirmed that only MDPP ''in-person,'' ''distance learning,'' and ''in-person with a distance learning component'' delivery modes are acceptable delivery modalities for MDPP during the Extended flexibilities period, as finalized in the CY 2024 PFS final rule (88 FR 79241). The CY 2025 PFS final rule did not include ''online'' nor ''combination with an online component'' as accepted delivery modalities for MDPP. For the MDPP Extended flexibilities period, we finalized in the CY 2024 PFS final rule to limit virtual delivery to the CDC DPRP definition of ''distance learning'' (88 FR 79243). We stated that the MDPP Extended flexibilities do not include online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''Online'' modality, including virtual make-up sessions (88 FR 79244). The 2024 CDC DPRP Standards allow for National DPP make-up sessions to be furnished using any delivery mode, including online.[267]

[266] 2015 CDC DPRP Standards: *https://stacks.cdc.gov/view/cdc/44247.*

[267] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://*

The MDPP expanded model was certified as a primarily in-person program. Virtual-only providers include those that deliver the National DPP services solely by distance learning or online delivery. Although ''telehealth'' is included in CDC's definition of distance learning, CMS stated in the CY 2017 PFS final rule (82 FR 53235) that the Set of MDPP services delivered via a telecommunications system, or other remote technologies do not qualify as telehealth services. Additionally, we have stated that through utilizing distance learning, participants may still interact with their Coach and other participants in their cohort in real-time, allowing for relationship building and peer support, unlike the Online modality which is delivered asynchronously (88 FR 79244).

We have responded to previous public comments requesting that CMS allow asynchronous delivery of MDPP and virtual-only providers to offer MDPP in previous rules (85 FR 84831, 89 FR 98045). Commenters have expressed that the exclusion of an asynchronous delivery modality is misaligned with the CDC DPRP Standards, which permit ''online'' asynchronous participation. Suppliers have commented that the exclusion of asynchronous modality significantly limits program participation. Advocacy group members pursued legislation that would require CMS to open the MDPP to suppliers of asynchronous ''online'' MDPP programs through the PREVENT DIABETES Act [H.R. 7856] [268] in April 2024. Although this bill was not enacted into law, suppliers continue to encourage CMS to meet the demand for asynchronous delivery of MDPP. After the PHE went into effect in March 2020, more than 90 percent of all MDPP sessions were delivered virtually via Distance learning. To date, average weight loss for MDPP beneficiaries is 4.9 percent of starting body weight. Among beneficiaries that attend their sessions primarily in person, the average weight loss was 4.6 percent, compared with an average weight loss of 5.3 percent among those that attend sessions virtually via Distance learning.[269]

We propose adding paragraph (f) to 45 CFR 170.79 to test the addition of coverage of an Online delivery modality during the Online delivery period (until December 31, 2029). Consistent with the 2024 CDC DPRP Standards, organizations are required to submit a separate application for each delivery mode used to the CDC. This will result in a separate organization code (orgcode) for each delivery mode. Therefore, organizations are required to obtain an online organization code from CDC prior to delivering Online sessions for MDPP.

As referenced above, The MDPP expanded model was certified as a primarily in-person program, and CMS previously opposed inclusion of an asynchronous delivery modality for MDPP for various reasons. We consider the proposed change to include the Online, asynchronous delivery modality as an MDPP delivery modality as a test during the Online delivery period permitted under the PHE. To evaluate the efficacy of Online delivery during the Online delivery period, beneficiary outcomes from asynchronous (that is, Online) will be evaluated to determine if this delivery modality reduces costs and improves quality. We continuously monitor MDPP trends and believe that the inclusion of Online delivery during the Online delivery period will build upon previous changes to introduce distance learning during the PHE for COVID–19 (85 FR 84830 through 84841) and respond to innovations in health care delivery and the increased provision of services outside of in-office settings. In addition, we anticipate that the inclusion of the Online delivery modality will promote beneficiary access to services, remove the barrier of beneficiaries having to wait for a cohort to start due to the on-demand nature of this proposed modality, build on the inclusion of the distance learning delivery modality, and align with the CMS Innovation Center Strategy to Make America Healthy Again by promoting evidence-based prevention, empowering people to achieve their health goals, and driving choice and competition for people.[270] In the CY 2024 PFS, CMS reminded MDPP suppliers that they are required to maintain capacity to deliver the MDPP set of services in-person [271] however, we are proposing under paragraph (f)(2) of 42 CFR 410.79 to explicitly not require MDPP suppliers to maintain in-person delivery capability during the Online delivery period. This will allow for distance learning and online-only organizations to enroll in Medicare as an MDPP supplier and streamline the process to allow for Online delivery of the Set of MDPP services. In hopes of further increasing program participation among suppliers and beneficiaries and promoting alignment between MDPP and the 2024 CDC DPRP Standards, we propose adding coverage of the delivery of the Set of MDPP services using the Online modality during the Online delivery period to test if outcomes, for MDPP beneficiaries, including weight loss, are similar to the in-person and distance learning delivery modalities.

Additionally, under § 410.79 (f)(2)(i), we propose that Online sessions must be furnished in a manner consistent with the DPRP Standards regarding program format, coach interaction, and program intensity and duration to qualify for payment. Online sessions must be delivered one hundred percent (100 percent) through the internet via smartphone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence ([AI]) Coach teaching the content. We propose at § 410.79 (f)(2)(i)(A) that Live Coach interaction must occur between MDPP beneficiaries and Coaches during the weeks when the beneficiary has engaged with content to qualify for payment. MDPP suppliers may not use AI or Machine Learning (ML) to replace Live Coach interaction.

Additionally, we propose that weight collection procedures referenced in the MDPP expanded model emergency policy at § 410.79(e)(3)(iii)(C) as well as the proposed (c)(1)(ii) apply during the online delivery period for MDPP services, as defined at § 410.79 (b). Beneficiaries must submit weight measurements on the date on which the online session is completed. We also propose at § 410.79 (f)(2)(i)(B) that MDPP suppliers must ensure safeguards are in place to ensure the accuracy of beneficiary weight measurements. These safeguards may include but are not limited to quality controls, diagnostic testing of hardware and/or software, and monitoring of trends (for example, rapid beneficiary weight loss within a short timeframe), are in place to ensure the accuracy of beneficiary weight

nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.

[268] H.R. 7856 (118th): PREVENT DIABETES Act, *https://www.govtrack.us/congress/bills/118/hr7856/text.*

[269] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.*

[270] CMS Innovation Center Strategy to Make America Healthy Again *https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again,*

[271] Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (88 FR 79249), Thursday November 16, 2023. *https://www.federalregister.gov/documents/2023/11/16/2023–24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other#page-79249*

measurements. For example, if organizations choose to use a website or mobile application to deliver the Set of MDPP services Online, integrations with hardware such as smart/Bluetooth™ scales may be used to collect beneficiary weight measurements. Scales may be set up to automatically transmit weight measurements directly to the MDPP supplier and MDPP suppliers may opt to perform data validation checks and flag suspicious entries or ensure necessary firmware updates are deployed to ensure the accuracy and/or security of such scales. As described in at § 410.79 (f)(2)(i)(B), MDPP suppliers delivering the Set of MDPP services must ensure necessary technological safeguards to ensure the accuracy of weight collected through Bluetooth™ scales, transmitted through an application, or utilizing any other means that do not involve direct Coach interaction or coach review of photos/video. For instance, CMS expects organizations to ensure safeguards to avoid fraud, waste, and abuse (including but not limited to hardware or software errors and data manipulation) and organizations may be subject to audits to ensure compliance.

While CDC DPRP Standards define ''combination with an online component'' as a yearlong National Diabetes Prevention Program Lifestyle Change Program (National DPP LCP) delivered as a combination of online (non-live) with in-person and/or distance learning, we are proposing that MDPP suppliers deliver MDPP via in-person, distance learning, in-person with a distance learning component, or Online modalities. While MDPP suppliers may offer synchronous and asynchronous modalities, they may not intermingle asynchronous (for example, Online) and synchronous (that is, In-Person, In-person with a distance learning component, and Distance learning) delivery modalities for individual beneficiaries. The Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component) or fully asynchronously (that is, Online). To evaluate the efficacy of the Online delivery modality during the Online Delivery Period, beneficiary outcomes from synchronous (that is, In-person, distance learning, or In-person with a distance learning component) delivery of the Set of MDPP services must be compared to beneficiary outcomes from asynchronous (that is, Online), therefore, these modalities must be delivered separately for individual beneficiaries in order to evaluate whether Online results, including weight loss, are similar to in-person and distance learning delivery modalities.

If organizations choose to provide the Set of MDPP services Online, we propose that organizations must adhere to requirements consistent with CDC DPRP Standards regarding program format, coach interaction, and program intensity and duration to qualify for payment, as described at § 410.79 (f)(2)(i).[272] Specifically, we propose during the Online delivery period at § 410.79(f)(2)(i)(D) that organizations must ensure that participants enrolled in self-paced programs engage with the content through use of one or more of the following: documented completion of videos/presentations and other learning modules in the application; knowledge checks (multiple choice or short answer); participant contributions to group discussions on a community board; and participant responses to the Coach via email, text message, or in-app messaging.

Though the 2024 CDC DPRP Standards indicate live lifestyle coach interaction is required for Online delivery and should be offered to each participant during weeks when the participants have engaged with program content, we propose that live coach interaction must occur between the Coach and MDPP beneficiary as part of each session for the MDPP supplier to receive payment for that session at § 410.79(f)(2)(i)(A). Consistent with the CDC DPRP Standards, E-mails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication (that is, organizations may not simply send out an announcement via text or e-mail and count that as live coach interaction; the participant must have the ability to respond to and get support from the live coach) and both parties engage in some sort of communication. In alignment with CDC DPRP Standards, we are proposing that Coaches be required to track beneficiary engagement and completion of Online modules. Additionally, proactive outreach by the Coach may be used to encourage session completion and reporting of weight. To promote consistency with the 2024 CDC DPRP Standards and to ensure that beneficiaries receive Live Coach interaction across delivery modalities, we are proposing that MDPP Suppliers may not require that beneficiaries initiate Coach interactions and MDPP Suppliers may not use AI or Machine Learning (ML) to replace live coaching, as described at § 410.79(f)(2)(i)(A).

We also propose to amend § 424.205(c)(10) to allow the minimum number of required MDPP core sessions and core maintenance sessions to be delivered Online during the Online delivery period.

At § 424.205(c)(10)(i), we propose to require 16 in-person, distance learning, or online core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session. Next, at § 424.205(c)(10)(ii), we propose to require one in-person, distance learning, or online core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

We also propose to amend § 424.205(f)(2)(i) to include the online modality among acceptable session types for session documentation. We are proposing in § 424.205(f)(5)(i) through (iv) to incorporate changes necessary for other proposed changes, including the addition of references directly to § 410.79(c)(1)(ii), and removal of references to ''in person'' in regard to how weight loss must be measured. These proposed changes provide greater clarity regarding the MDPP supplier's records in regard to claim submission for weight loss and are aligned with the proposed changes allowing for weight documented in a medical record.

We anticipate that beneficiaries will appreciate the option to participate in MDPP via the Online modality, which will expand beneficiary access to MDPP, reduce barriers to participation, and improve health outcomes. MDPP suppliers and advocacy groups will also appreciate inclusion of the Online modality, as these entities have commented that the exclusion of the online modality significantly limits program participation, particularly for beneficiaries living in areas without a nearby in-person MDPP delivery site (for example, rural areas) or access to transportation.

We propose to amend § 410.79(f) and § 424.205(c)(10), (f)(2)(i), and (f)(5). We are soliciting comments on these proposals.

4. Changes to § 414.84

MDPP, as defined at § 410.79(b), consists of up to 16 sessions offered during the core session period (Months 1 to 6) and 6 monthly maintenance sessions offered during the core

[272] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

maintenance session interval period (Months 7 to 12), (collectively the ''core services period''). While MDPP has an attendance-based fee-for-service payment structure as finalized in the CY 2024 PFS final rule (88 FR 79251), MDPP suppliers are also rewarded for successful outcomes for beneficiaries (weight loss), motivating them to not only retain participants, but also deliver a high-quality program that achieves better outcomes through performance-based payments. The fee-for-service payment structure finalized in the CY 2024 PFS final rule (88 FR 79251) added a distance learning HCPCS G-code, taking into consideration the Extended flexibilities.

We propose edits throughout § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text to update language to include all accepted MDPP delivery modes for performance goals in which beneficiaries achieve weight loss milestones. We also propose adding paragraph (c)(3) to indicate payment for Online delivery, including the inclusion of a new HCPCS G-code, G9871, for online delivery (Behavioral counseling for diabetes prevention, online, 60 minutes). Finally, we propose redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively and revising the redesignated paragraph (c)(4)(ii) to include a payment rate for a core session or core maintenance session furnished Online during the Online delivery period ($18). We seek comments on these proposals.

Table 46 displays the proposed CY 2026 MDPP payment structure for the set of MDPP services delivered Online.

TABLE 46: MEDICARE DIABETES PREVENTION PROGRAM (MDPP) EXPANDED MODEL CALENDAR YEAR PROPOSED (CY) 2026 ONLINE PAYMENT STRUCTURE

HCPCS G-Code	Payment Description*	CY 2026
G9871	Behavioral counseling for diabetes prevention, online, 60 minutes	$18
G9880	5 percent WL Achieved from baseline weight	$XXX
G9881	9 percent WL Achieved from baseline weight	$XX
G9888	Maintenance 5 percent WL from baseline in months 7-12	$X

Note: Medicare pays up to 22 sessions. Online sessions billed with code G9871cannot be combined with G9886 or G9887, in a 12-month period:
Months 1-6: one online session every week (up to 16)
Months 7-12: one online session every month (up to 6)
Months 7-12, once participant achieves 5% WL, suppliers delivering the set of MDPP services Online may submit Maintenance of 5% WL claim with attendance claim (G9888 + G9871). Medicare will pay for Maintenance 5% WL up to 6 times in months 7-12.

As indicated in Table 46, performance payments for 5 percent weight loss achieved from baseline weight (G9880) and 9 percent weight loss achieved from baseline weight (G9881) will remain the same regardless of delivery modality for MDPP. For each beneficiary, MDPP suppliers must either bill claims with G9886, G9887, a combination of G9886 and G9887, or G9871. The proposed G9871 for behavioral counseling for diabetes prevention, online, 60 minutes is for the set of MDPP services delivered Online, asynchronously. The existing G9886, behavioral counseling for diabetes prevention, in-person, group, 60 minutes, and G9887, behavioral counseling for diabetes prevention, distance learning, 60 minutes are delivered synchronously. Therefore, we are proposing that for each beneficiary, suppliers may not bill for the Set of MDPP services that were delivered through a combination of synchronous and asynchronous delivery modalities. Specifically, for MDPP beneficiaries, MDPP suppliers may not bill for Online Sessions as well as In-Person or Virtual Sessions during the Online delivery period. The Set of MDPP services must be delivered to individual beneficiaries as exclusively Online sessions (fully asynchronous) or exclusively In-person, distance learning, or In-person with a distance learning component sessions (fully synchronous). To evaluate the efficacy of Online delivery during the Online Delivery Period, beneficiary outcomes from synchronous (that is, In-person, Distance learning, or In-person with a distance learning component) delivery of the Set of MDPP services must be compared to beneficiary outcomes from asynchronous (that is, Online), therefore, these modalities must remain mutually exclusive for individual beneficiaries. While the 2024 CDC DPRP Standards define ''Combination with an online component'' as sessions that are delivered as a combination of online (non-live) with in-person or distance learning, this will not be an accepted delivery modality for MDPP while online delivery is being tested through December 31, 2029.

In summary, we are proposing to amend § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text; adding paragraph (c)(3); redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively; and revising the redesignated paragraph (c)(4)(ii). We are seeking comments on these proposals.

I. Medicare Prescription Drug Inflation Rebate Program

1. Background

a. Overview of the Medicare Prescription Drug Inflation Rebate Program

Sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A of the Social Security Act (the

Act) by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B.

Section 11102 of the IRA added section 1860D–14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period that began on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug, which is calculated as set forth in section 1860D–14B(b)(2) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1860D–14B(b)(3) of the Act. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. The definition of a Part D rebatable drug includes drugs approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act, drugs approved under an abbreviated new drug application under section 505(j) of the FD&C Act that meet certain sole source criteria described at sections 1860D–14B(g)(1)(C)(ii)(I) through (IV) of the Act, and biologicals licensed under section 351 of the Public Health Service Act, including biosimilars.

The IRA sets forth different parameters for determining rebates under the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. With respect to the rebates owed, for each calendar quarter beginning on or after January 1, 2023, the manufacturer of a Part B rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from CMS, to pay a rebate into the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount (calculated as set forth in section 1847A(i)(3)(C) of the Act) for an applicable calendar quarter. In contrast, for each 12-month applicable period beginning on or after October 1, 2022, the manufacturer of a Part D rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from CMS, to pay a rebate into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund if the amount of the AnMP (calculated as set forth in section 1860D–14B(b)(2) of the Act) exceeds the inflation-adjusted payment amount (calculated as set forth in section 1860D–14B(b)(3) of the Act). With respect to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, CMS must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, CMS has until September 30, 2025, to invoice manufacturers for rebates. In contrast, under section 1860D–14B(a) of the Act, CMS must report rebate amounts to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period, except that for the first two applicable periods (that is, October 1, 2022, to September 30, 2023, and October 1, 2023, to September 30, 2024), CMS has until December 31, 2025, to invoice manufacturers for Part D inflation rebates. Additionally, there are statutory differences in the inputs (that is, data sources) used to calculate the rebate amounts for Part B and Part D.

In the CY 2025 PFS final rule (89 FR 98228 through 98313), to implement sections 11101 and 11102 of the IRA, we codified these requirements and established other policies at parts 427 and 428 under title 42, chapter IV of the Code of Federal Regulations for Part B and Part D, respectively.

b. Summary of Proposed Policies for the Medicare Prescription Drug Inflation Rebate Program

We are proposing new policies for the Medicare Part B Drug Inflation Rebate Program as follows:

- Proposed § 427.302(c)(5) describes how CMS would identify the payment amount benchmark quarter if data needed to calculate the payment amount in the payment amount benchmark quarter are not available.
- Proposed § 427.302(d)(1)(i) describes CMS' method for calculating the payment amount in the payment amount benchmark quarter if a published payment limit is not available.
- Proposed § 427.302(d)(1)(ii) describes CMS' method for calculating the payment amount in the payment amount benchmark quarter if there is no published payment limit and neither positive Average Sale Price (ASP) nor positive Wholesale Acquisition Cost (WAC) data are available in the ASP Data Collection System.

We also are proposing new policies for the Medicare Part D Drug Inflation Rebate Program as follows:

- Proposed to use a claims-based methodology to implement § 428.203(b)(2), which provides that, for claims with dates of service on or after January 1, 2026, and with respect to an applicable period, CMS will exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program.
- Proposed to establish a 340B repository to receive voluntary submissions from 340B covered entities of certain data elements from Part D 340B claims.

2. Medicare Part B Drug Rebates for Single Source Drugs and Biological Products With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 427.20)

We propose to amend § 427.20 by removing the term ''Billing and payment code FDA approval or licensure date''. The term was not included in the CY 2025 PFS proposed rule. This term was intended to be used in the final rule at § 427.302(c), as evidenced by references to it in the final rule (89 FR 98244). Prior to publication of the final rule, however, we ultimately incorporated the definition text in place of the defined term, rendering the defined term inoperative, and we neglected to delete the unused term. To avoid any confusion arising from superfluous

regulatory text, we are proposing to remove the definition.

In the CY 2025 final rule (89 FR 98579), we codified the definition of manufacturer in § 427.20 to have the meaning set forth in section 1847A(c)(6)(A) of the Act. As articulated in the CY 2025 final rule (89 FR 98266), we will identify the manufacturer that is responsible for paying a rebate amount using the same approach used for reporting ASP and Medicaid Drug Rebate Program (MDRP) data. In this proposed rule, as a matter of operations, we are clarifying that CMS identifies the manufacturer with financial responsibility for the inflation rebate for a Part B rebatable drug by reviewing ASP data submissions for the current reporting period and the agency will also take into account, as applicable, manufacturer-identifying information in other CMS systems including MDRP.

b. Drugs Covered as Additional Preventive Services (DCAPS)

Medicare Part B covers ''additional preventive services,'' as defined under section 1861(ddd)(1) of the Act, that identify medical conditions or risk factors and that the Secretary determines are: (A) reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force; and (C) appropriate for individuals entitled to benefits under Part A or enrolled under Part B. Section 1861(ddd)(2) of the Act states that, in making determinations under section 1861(ddd)(1) of the Act, the Secretary shall use the process for making National Coverage Determinations (as defined in section 1869(f)(1)(B) of the Act) in the Medicare program. Section 1833(a)(1)(W)(ii) of the Act provides for the payment for additional preventive services, including drugs.

On September 30, 2024, CMS established coverage of certain drugs as an additional preventive service under section 1861(ddd)(1) of the Act for the first time.[273] Such drugs covered as additional preventive services are referred to DCAPS, and we will use the term ''DCAPS drug(s),'' for ease of the reader.

As described at § 410.152(o)(3), CMS will determine the payment limit for the applicable billing and payment code for a DCAPS drug by applying the ASP methodology if ASP data is available (89 FR 98225). If ASP data is not available, then the payment limit would be determined using National Average Drug Acquisition Cost (NADAC) prices for the drug. If ASP data and NADAC prices are not available, the payment limit would be calculated using the Federal Supply Schedule (FSS) prices for the drug. If ASP data, NADAC prices, and FSS prices are not available, the payment limit would be the invoice price determined by the Medicare Administrative Contractor.

In this proposed rule we are addressing whether DCAPS drugs are Part B rebatable drugs, as discussed in the CY 2025 PFS final rule (89 FR 98250). The current set of drugs covered as DCAPS drugs meets the definition of a Part B rebatable drug under section 1847A(i)(2) of the Act. Therefore, CMS intends to identify DCAPS drugs as Part B rebatable drugs as defined in section 1847A(i)(2) of the Act. Under this proposal, we would calculate rebates for DCAPS drugs in alignment with the methodology described in §§ 427.300 through 427.402. Manufacturers of DCAPS drugs would receive reports of rebate amounts subject to the process and timing described in §§ 427.500 through 427.505.

c. Billing Units That Are Packaged Into the Payment Amount for an Item or Service and Are Typically Not Separately Payable

Section 1847A(i)(3)(B)(ii)(II) of the Act requires that units ''that are packaged into the payment amount for an item or service and are not separately payable'' be excluded from the total number of units of a billing and payment code for a Part B rebatable drug. As stated in the CY 2025 final rule (89 FR 98247), we will remove billing units that are packaged into the payment amount for an item or service and are not separately payable. We codified this policy at § 427.303(b)(3). We have identified rare instances where claims for separate payment have been submitted for a Part B rebatable drug when such claims are reimbursable only as part of a bundled payment. CMS excludes units associated with such separately billed claims from the rebate calculation consistent with § 427.303(b)(3).

d. Identification of the Payment Amount Benchmark Quarter (§ 427.302(c))

We are proposing at § 427.302(c)(5) that if data needed to calculate the payment amount in the payment amount benchmark quarter as described in and determined under § 427.302(d)(1) are not available in the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, CMS will use the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code as the payment amount benchmark quarter. Without a payment amount in the payment amount benchmark quarter, we would not be able to calculate Part B inflation rebates for such billing and payment codes. We believe this approach will allow CMS to calculate a payment amount in the payment amount benchmark quarter, incorporating the two-quarter lag used to set payments in alignment with section 1847A of the Act. We are making this proposal to address identified instances as described in section III.E.2.e. of this proposed rule.

This proposal would require CMS to make technical edits to and to renumber regulations at § 427.302(c). Therefore, we propose conforming changes to § 427.302(c) and to redesignate § 427.302(c)(5) as § 427.302(c)(6).

e. Identification of the Payment Amount in the Payment Amount Benchmark Quarter (§ 427.302(d)(1))

Section 1847A(i)(3)(C) of the Act specifies use of the ''payment amount for the billing and payment code for such drug in the payment amount benchmark quarter'' (''payment amount in the payment amount benchmark quarter'') in the determination of the inflation-adjusted payment amount. As stated in the CY 2025 PFS final rule (89 FR 98244), to identify the payment amount in the payment amount benchmark quarter, we use the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter. If the published payment limit is not available for the applicable benchmark quarter, we stated we will use the lower of 106 percent of ASP or 106 percent of WAC. However, we have identified instances in which some or all NDCs in a billing and payment code have zero or negative ASP or WAC values. Using such data could result in a payment amount in the payment amount benchmark quarter that is zero, negative, or unreasonably low due to the inclusion of the zero or negative ASP or WAC values. In addition, when the published payment limit is not available, using 106 percent of ASP or 106 percent of WAC to calculate the payment amount in the payment amount benchmark quarter may not be appropriate in instances where the payment limit is based on a different amount, such as in the case of Part B rebatable drugs that are biosimilars for which the add-on amount reflects the

[273] See: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection, available at *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310.*

payment amount for the reference biological product (as set forth in section 1847A(b)(8) of the Act). For the purposes of calculating a payment amount under the statute, CMS finalized in the CY 2025 PFS final rule (89 FR 97981) that negative or zero manufacturer's ASP data are considered ''not available.'' We also note that the published payment limit for a drug with negative or zero ASP data reported after January 1, 2025, could be based on a positive amount that is carried forward from a previous quarter in accordance with § 414.904(i).

In this proposed rule, we are proposing to remove from § 427.302(d)(1) ''determined under section 1847A of the Act''. This text was inadvertently included in the PFS CY 2025 final rule (89 FR 98583) and needs to be removed because the statutory provision governing the payment amount in the payment amount benchmark quarter, section 1847A(i)(3)(C)(i) of the Act, does not limit that amount to payment amounts determined under section 1847A of the Act and because the payment limits for some Part B rebatable drugs are not determined under section 1847A of the Act.

Additionally, in this proposed rule, we are proposing to revise § 427.302(d)(1)(i) by removing ''If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS will use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC.'' We also are proposing to revise § 427.302(d)(1)(ii) by removing ''If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS will use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of this section, CMS will consider to be the payment amount for the payment amount benchmark quarter.'' If a published payment limit is not available for the applicable payment amount benchmark quarter, at § 427.302(d)(1)(i), we are proposing to calculate the payment amount in the payment amount benchmark quarter using positive ASP or positive WAC data reported by manufacturers to the ASP Data Collection System.[274] Additionally, at § 427.302(d)(1)(ii), if neither positive ASP nor positive WAC data are available in the ASP Data Collection System for the given quarter, we are proposing to use WAC data from other public sources for the given quarter to calculate the payment amount in the payment amount benchmark quarter. We believe these proposals would allow CMS to calculate a payment amount in the payment amount benchmark quarter that aligns with section 1847A of the Act, rather than strictly limiting this calculation to the lower of 106 percent of ASP or 106 percent of WAC as reported for a given drug, as previously stated in the CY 2025 PFS final rule, which may not align with CMS' policy for calculating payment limits under § 414.904. Under this proposed approach, we would also avoid calculating inappropriately large inflation rebate amounts for drugs that had zero or negative sales in their payment amount benchmark quarter.

f. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 427.500 Through 427.505)

Section 1847A(i)(1)(A) of the Act requires the Secretary to provide a report to each manufacturer of a Part B rebatable drug with the following information not later than 6 months after the end of an applicable calendar quarter: (1) the total number of billing units for each Part B rebatable drug; (2) the amount, if any, of the excess average sales price increase (the amount by which the specified amount exceeds the inflation-adjusted payment amount as calculated at § 427.302(g)) for an applicable calendar quarter; and (3) the rebate amount for the Part B rebatable drug. In compliance with section 1847A(i)(1)(B) of the Act, manufacturers of a Part B rebatable drug must provide a rebate for each Part B rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1847A(i)(1)(A) of the Act.

In accordance with §§ 427.504 and 427.505, CMS has established a standard method and process to issue Rebate Reports to manufacturers of Part B rebatable drugs and to accept manufacturer rebate payments. CMS has established an online portal, the ''Manufacturer Payment Portal'' (MPP),[275] administered by a CMS contractor, through which manufacturers will access their Rebate Reports, submit Suggestions of Error, as applicable, and pay rebate amounts due, as described in §§ 427.504 and 427.505. Manufacturers of Part B rebatable drugs should provide points of contact to view Preliminary Rebate Reports Rebate Reports, enter and modify banking information, and initiate payment of rebate amounts through the MPP.

i. Rebate Reports and Reconciliation (§ 427.501)

As stated in the CY 2025 PFS final rule (89 FR 98264), we codified a multi-step process to provide a manufacturer, as defined in § 427.20, with the rebate information specified in section 1847A(i)(1)(A) of the Act. Specifically, in the CY 2025 PFS final rule (89 FR 98264), CMS established the information that will be included in a Rebate Report at § 427.501, including the NDC(s) and billing and payment codes identified for the Part B rebatable drug, the total number of billing units, the applicable calendar quarter, and the rebate amount due, among other items specified in § 427.501. Consistent with the approach specified in section 80.3 of the Medicare Part B Drug Inflation Rebate Guidance, published December 14, 2023, we propose to add paragraph (c)(3) in § 427.501 to clarify that CMS would report the manufacturer's rebate amount due as a dollar amount that is rounded to the nearest cent. CMS did not specify an approach to reporting of the rebate amount in the CY 2025 PFS final rule and we believe it is necessary to provide this information to manufacturers to provide notice of CMS' approach to rounding of the rebate amount. The calculation steps specified in subpart D of part 427 will not include rounded values.

In the CY 2025 PFS final rule (89 FR 98578), to determine which data elements would be included when CMS reports the rebate amount to the manufacturer, we stated that we considered the statutory requirements outlined in section 1847A(i)(1)(A)(i) through (iii) of the Act to determine what information is necessary for manufacturers to review the accuracy of the rebate amount while also protecting proprietary information. As stated on page 98578 of the CY 2025 PFS final rule, CMS structured a two-step reporting process to first include a Preliminary Rebate Report to provide an initial notice to manufacturers regarding whether they may owe a rebate amount, followed by the Rebate Report. Further, we proposed and finalized additional data elements within the Preliminary Rebate Reports and the Rebate Reports not listed in statute based on input from public comments (for example, the applicable benchmark period, the rebate period CPI–U). CMS did not finalize additional elements suggested, such as claims-level data, after weighing whether any such additional information fulfilled CMS' statutory obligation and the potential benefits to

[274] Available at *https://portal.cms.gov/portal/*.

[275] See: *https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-onboarding-memo.pdf*.

manufacturers against the administrative burden additional reporting would impose on the agency and operational feasibility. The data elements set forth in § 427.501(b)(1) and (c)(1) satisfy these considerations.

In this proposed rule, CMS clarifies that certain data elements provided to manufacturers in Preliminary Rebate Reports, Rebate Reports, and reconciled reports of a rebate amount (which may each include the same elements, revised as applicable due to updates in the data), are provided to manufacturers of a Part B rebatable drug in a manner consistent with section 1927(b)(3)(D) and 1847A(f)(2)(D) of the Act. Section 1927(b)(3)(D) of the Act specifies that information disclosed by manufacturers or wholesalers under section 1927(b)(3) (submissions of drug product and pricing information under the National Drug Rebate Agreement (NDRA)) or under a Master Agreement with the Secretary of Veterans Affairs (other than WAC) ''is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except'' as otherwise allowed in section 1927(b)(2)(D)(i) through (vii) of the Act. Section 1927(b)(3)(D)(i) provides an exception to this confidentiality requirement ''as the Secretary determines to be necessary to carry out'' certain sections of the Act, including section 1847A of the Act (that is, the Part B Drug Inflation Rebate Program). Section 1847A(f)(2)(D) of the Act contains parallel confidentiality protections for ASP information reported by manufacturers and wholesalers, including a parallel exception for purposes of Part B rebate effectuation, and would apply to ASP data reported by entities that do not have a NDRA and that report ASP data outside the MDRP.

Specifically, CMS anticipates that most data included in Preliminary Rebate Reports, Rebate Reports, reconciled Preliminary Rebate Reports, and reconciled Rebate Reports will not implicate sections 1927(b)(3)(D) or 1847A(f)(2)(D) of the Act, as CMS anticipates that in most cases the party that will receive these reports will be the same party that reported the relevant information. However, CMS acknowledges that some situations may raise a possibility of disclosure by the Secretary of AMP or ASP information, or information derived therefrom, to a party besides the party that reported the information originally; such situations could implicate sections 1927(b)(3)(D) and/or section 1847A(f)(2)(D) of the Act. Such situations may include, but are not necessarily limited to: (1) transfer of a rebatable drug from one manufacturer to another manufacturer, such that the manufacturer identified in the Rebate Report differs from the manufacturer that originally reported certain benchmark pricing information (see also section III.E.2.a of this proposed rule regarding transfer of labeler codes); and (2) cases in which CMS displays a specified amount, the total HCPCS units, and the proportion of manufacturer-reported ASP units for reports associated with grouped HCPCS codes. In instances where the parties may be different, CMS emphasizes that the data included in a report of the rebate amount is based on CMS' independently performed calculations. Though these calculations rely on information disclosed by manufacturers as inputs, in most cases the data reported in a Preliminary Rebate Report and a Rebate Report (or a reconciled version of these reports) will not be identical to the information reported by manufacturers (for example, manufacturers report ASP data at the NDC–11 level, whereas the payment amount in the payment amount benchmark quarter reflects an aggregated, HCPCS-level value that was calculated using the NDC–11-level ASP data). Therefore, reporting such data elements to another manufacturer for purposes of the Part B Drug Inflation Rebate Program would not violate the confidentiality requirements in sections 1927 and 1847A of the Act.

Second, on page 98265 of the CY 2025 PFS final rule, CMS stated that the purpose of providing additional data elements not explicitly listed in section 1847A(i)(1)(A)(i) through (iii) of the Act (for example, the payment amount in the payment amount benchmark quarter, specified amounts, and certain unit data) is based on CMS' assessment of ''data elements that are necessary for a manufacturer to review the Preliminary Report and for a Suggestion of Error.'' Providing these data in the Preliminary Rebate Report (and corresponding subsequent reports) ensures that—(1) manufacturers will be able to submit a Suggestion of Error, thereby promoting accuracy in the implementation of the rebate program; and (2) manufacturers will have advanced notice of a potential rebate amount due. While section 1847A(i)(1)(A)(i) of the Act states that ''[T]he Secretary shall, for each part B rebatable drug, report to each manufacturer . . . information on the total number of units of the billing and payment code'' this level of information alone is not sufficient to support CMS' goal of providing enough information for a manufacturer to submit a Suggestion of Error, if necessary. For Part B rebatable drugs, it is necessary to provide the proportion of ASP-reported units in addition to providing the total HCPCS units (as required by statute) so that the manufacturer has sufficient information to understand the total rebate amount calculated. CMS acknowledges that by providing the proportion of ASP-reported units, a manufacturer could estimate the proportion of ASP-reported units for another drug(s) included in the same HCPCS code. However, CMS believes that providing this information is necessary to carry out the rebate program because it enables manufacturers to submit a potential Suggestion of Error, which promotes accuracy in the calculation of the rebate amount.

ii. Rebate Report for Applicable Calendar Quarters in CY 2023 and CY 2024 (§ 427.502)

As stated in the CY 2025 PFS final rule (89 FR 97710), we codified at § 427.502 the option afforded to CMS in section 1847A(i)(1)(C) of the Act to delay sending the information required by section 1847A(i)(1)(A) of the Act for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025. Specifically, per § 427.502, CMS will issue one report for the 4 applicable calendar quarters in CY 2023 and one report for the 4 applicable calendar quarters in CY 2024. Additionally, CMS will send a reconciled rebate amount for the four applicable calendar quarters in CY 2024 9 months after the Rebate Report, to allow for 12 months of claims run-out for each applicable calendar quarter. We stated in the CY 2025 PFS proposed rule (89 FR 61959) that this approach aligns claims and payment data run-out with the run-out used during a regular reconciliation cycle. However, CMS finalized the regulatory text specifying the time periods for regular reconciliation cycles at § 427.501(d) with text that provides CMS with operational flexibility as to the exact date the report with the reconciled rebate amount will be provided to each manufacturer of a Part B rebatable drug by including the word ''within'' prior to the specified date. We propose to amend § 427.502(c)(2)(ii) to add the word ''within'' prior to ''nine months'' to be consistent with the regulatory text and cadence for regular reconciliation cycles as well as to provide operational

flexibility on the timing of the release of the report with the reconciled rebate amount.

3. Medicare Part D Drug Rebates for Certain Drugs and Biologicals With Prices That Increase Faster Than the Rate of Inflation

a. Clarification Regarding the Payment Amount Benchmark Period for Certain Subsequently Approved Drugs

In the CY 2025 PFS final rule (89 FR 98280), CMS finalized policies to identify the payment amount benchmark period as set forth in § 428.202(c). At § 428.202(c)(2), we finalized that for a subsequently approved drug, the payment amount benchmark period is the first calendar year beginning after the drug's first marketed date. At § 428.202(c)(4), we finalized that, notwithstanding § 428.202(c)(2), for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in § 428.202(d)(3), the payment amount benchmark period is the first calendar year in which such NDC–9 has at least 1 quarter of AMP reported.

At § 428.202(c)(3), we specified that the payment amount benchmark period must be no earlier than calendar year 2021 for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in § 428.202(d)(3). At the time of development for rulemaking on the CY 2025 PFS, we did not believe it was necessary to clarify in § 428.202(c)(2) or (c)(4) that the payment amount benchmark period for a subsequently approved drug also must be no earlier than calendar year 2021, since a subsequently approved drug is by definition a Part D rebatable drug first approved or licensed by the FDA after October 1, 2021.

However, we have identified rare instances in which a subsequently approved drug's first marketed date precedes the FDA approval date reported under section 1927(b)(3)(A)(v) of the Act. It is therefore possible that a subsequently approved drug could have a first marketed date prior to 2020; in other words, the first calendar year beginning after the drug's first marketed date could precede 2021. The definition of the payment amount benchmark period at section 1860D–14B(g)(3) of the Act and the description of a subsequently approved drug at section 1860D–14B(b)(5)(A) of the Act suggest that a Part D rebatable drug should not have a payment amount benchmark period prior to 2021. As such, we propose to clarify in this rule that the payment amount benchmark period identified under § 428.202(c)(1) through (c)(5) for a Part D rebatable drug will be no earlier than 2021 in all instances. CMS also proposes to clarify that the payment amount benchmark period set forth in § 428.202(c)(3) or (c)(4) cannot precede the payment amount benchmark period set forth in § 428.202(c)(1) or (c)(2), as applicable, for a Part D rebatable drug.

b. Clarification Regarding Calculation of the Benchmark Period Manufacturer Price or AnMP in Instances of Quarters With Monthly Units but no Quarterly AMP

In the CY 2025 PFS Final Rule (89 FR 98287), CMS established policies for calculating the benchmark period manufacturer price and AnMP, as applicable, in situations in which certain data are missing but CMS still has sufficient data to complete the calculations. At § 428.202(g)(1), we finalized that if there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units.

In this proposed rule, we are clarifying that we are taking the same approach for the inverse scenario. That is, if there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act but has reported units under section 1927(b)(3)(A)(iv) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with AMP. In other words, when a manufacturer has not reported AMP for a quarter but has reported units for months in that quarter, CMS will not use the units from that quarter in the calculation of the benchmark period manufacturer price or AnMP, as applicable. To the extent that a manufacturer reports a quarterly AMP value of zero for a given quarter, CMS will not consider zero to be a valid value and will instead consider AMP to be missing for that quarter.[276]

CMS will monitor this approach and may modify our policy in the future. We also remind manufacturers of their reporting obligations under section 1927(b) of the Act and § 447.510 of this title and that failure to provide timely information required under those authorities may result in penalties as detailed in section 1927(b)(3)(C)(i) of the Act.

c. Exclusion of 340B Acquired Units From Part D Rebatable Drug Requirements (§ 428.203(b)(2))

Section 1860D–14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units will only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026.

As we stated in the CY 2025 PFS final rule (89 FR 98289), data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D–14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and we do not currently have access to this data through other means. We understand that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale, and that 340B covered entities (hereinafter ''covered entities'') typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based on claims information reported to CMS by the covered entity. For these reasons, in this rule we are proposing a claims-based methodology to exclude 340B units starting on

[276] See CMS instructions for reporting AMP when a zero or negative value occurs. For example: *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-038.pdf* and *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf.*

January 1, 2026. Additionally, we are proposing to establish a voluntary 340B repository for data from covered entities about 340B units that we anticipate will allow for CMS to identify 340B units at the claim-level in future applicable periods.

i. Summary of Policies Discussed in the CY 2025 PFS Final Rule

In the CY 2025 PFS proposed rule (89 FR 62245), to fulfill the statutory requirement to remove 340B units from rebate calculations beginning on January 1, 2026, we proposed at § 428.203(b)(2)(i) to exclude from the total number of units determined under § 428.203(a), units for which a manufacturer provided a discount under the 340B Program (''340B units''). At § 428.203(b)(2)(ii), we proposed to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. In the preamble discussion (89 FR 61969), we proposed a new policy in accordance with proposed § 428.203(b)(2) to remove units from the total number of units dispensed of a Part D rebatable drug for each applicable period based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. We proposed the percentage (hereinafter, ''estimation percentage'') to equal the total number of units purchased by covered entities under the 340B Program for an NDC–9, divided by the total units sold of that NDC–9.

We stated that the estimation policy is consistent with CMS' authority under sections 1860D–14B(b)(1)(B), 1102(a), and 1871(a)(1) of the Act, the latter of which provide the authority to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program. Because the statutory requirement to remove 340B units from rebate calculations does not begin until January 1, 2026, for the applicable year that begins on October 1, 2025, we proposed to apply the estimation percentage only to those units associated with claims with dates of service in the last 3 quarters of the applicable period (that is, January 1, 2026, through September 30, 2026).

To identify the numerator of the estimation percentage (that is, the total number of units purchased under the 340B Program for an NDC–9), we proposed to use data from the Health Resources and Services Administration's (HRSA) 340B Prime Vendor Program (PVP). To identify the denominator of the estimation percentage (that is, the total units sold of an NDC–9), we proposed to use existing manufacturer reporting under the MDRP of AMP unit sales. Specifically, we proposed to use the total number of AMP units that are used to calculate the monthly AMP and which manufacturers are required to report to CMS for each covered outpatient drug (COD) in accordance with section 1927(b)(3)(A)(iv) of the Act. We believed that using these AMP unit data to calculate an estimation percentage would be consistent with the use of these same data to calculate the AnMP at § 428.202(b) and the benchmark period manufacturer price at § 428.202(d).

In the CY 2025 PFS proposed and final rules, we acknowledged certain limitations with the proposed data sources. For instance, the numerator of the proposed estimation percentage (PVP data) represents 340B units dispensed in multiple settings, whereas the denominator (unit sales used to calculate AMP) represents units typically dispensed only in the retail community pharmacy setting. Additionally, the proposed estimation percentage would represent the total number of 340B units dispensed as a proportion of total units dispensed, irrespective of insurance/payor type. Further, we noted that certain 340B purchases may not be reported to the PVP if those purchases were made through alternative distribution models. Many commenters agreed with these data limitations, strongly objected to the proposed estimation methodology, and suggested CMS not finalize this approach.

In the CY 2025 PFS proposed rule, CMS also solicited comments on a Medicare Part D Claims Data 340B Repository (hereinafter, ''340B repository''). This approach would require that covered entities submit certain data elements from Part D 340B claims to the 340B repository on a retrospective basis. In response to this comment solicitation, many commenters expressed strong support for a 340B repository.

In the CY 2025 PFS final rule (89 FR 98593), CMS finalized the proposal at § 428.203(b)(2)(i) to exclude from the total number of units determined under § 428.203(a) units for which a manufacturer provided a discount under the 340B Program (''340B units''), as well as the proposal at § 428.203(b)(2)(ii) to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. However, after consideration of the data limitations of the proposed estimation methodology and public comments, CMS did not finalize the proposed estimation methodology for the applicable period that begins on October 1, 2025. Instead, CMS stated that it would explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a 340B repository.

CMS is not reproposing the estimation methodology proposed in the CY 2025 PFS proposed rule, but did consider this estimation percentage as an alternative to the proposal this year, as described in section III.E.3.c.iii. of this proposed rule titled ''Alternative Policy Considered''. Rather, we are proposing to implement § 428.203(b)(2) using a claims-based methodology to remove 340B units beginning January 1, 2026. We also propose the establishment of a Part D claims data 340B repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying 340B units for removal in a future applicable period.

ii. Claims-Based Methodology to Remove 340B Units from Rebate Calculations

We are proposing to implement § 428.203(b)(2) using a claims-based methodology[277] to remove 340B units from the Part D drug inflation rebate calculations by evaluating whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered 340B covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE as a 340B contract pharmacy (hereinafter ''Prescriber-Pharmacy Methodology''). CMS is proposing to use the described methodology unless and until a different method to remove 340B units is proposed and finalized. CMS acknowledges that the 340B OPAIS database may not list all pharmacies

[277] The 340B claims-based methodology described herein uses elements of the 340B simulation described in the published work: Nikpay, S., Bruno, J. P., & Carey, C. (2024). Recent court ruling could increase the size and administrative complexity of the 340B program. *Health affairs scholar, 2*(12), qxae157. *https://doi.org/10.1093/haschl/qxae157.*

that dispense 340B eligible drugs, including covered entities that have ''in-house'' pharmacies that are not registered in the 340B OPAIS database or 340B-eligible Aids Drug Assistance Programs (ADAPs) that collect rebates to receive 340B discounts instead of receiving such discount at the time of purchase from a contract pharmacy registered in the 340B OPAIS database. CMS is soliciting comments on whether and how to account for this limitation in the identification of 340B dispenses in the Prescriber-Pharmacy Methodology.

For the Prescriber-Pharmacy methodology, once a PDE record is identified as potentially 340B-eligible, the units associated with that PDE record would be removed from the rebate calculation. We understand that the determination of potential 340B-eligibility of a PDE record using the methodology described herein does not necessarily mean that the covered entity replenished (or can in the future replenish) the units at the 340B price, and we therefore believe the proposed claims-based methodology may overestimate the number of units that are potentially 340B-eligible. Examples of PDE records that would be identified as being potentially 340B-eligible by the claims-based methodology, but for which the covered entity may not be able to make a corresponding purchase of the accumulated units at the 340B price, include those for which: (1) a drug manufacturer placed restrictions on the contract pharmacy that resulted in a non-340B price; (2) the NDC dispensed on the claim was discontinued, in shortage, or generally unavailable from the pharmaceutical wholesaler; (3) the covered entity did not accumulate enough units to replenish a full bottle of the drug; or (4) the prescription was subsequent to care provided outside of a 340B covered entity. The approach described in this section would identify PDE records as potentially 340B-eligible based on two criteria: (1) the prescriber with the NPI listed on the PDE record provides care at a 340B covered entity, and (2) the pharmacy NPI on the PDE record is a contract pharmacy for that same 340B covered entity.

To establish a list of providers considered to be 340B-affiliated providers, we propose to first create a list of prescriber NPIs from PDE records with dates of service within each applicable period. This file would be generated at the prescriber-month level and capture prescriber NPIs with active billing histories for specific months within the applicable period. CMS would then crosswalk this list of prescriber NPIs and months to the provider fields[278] on Medicare Fee-For-Service (FFS) Part A inpatient claims and Part B outpatient claims and professional claims to identify the Medicare Provider Numbers (MPNs)[279] through which each prescriber NPI billed for each month they were active in the PDE data. The resulting file would include prescriber NPI, MPN, and month combinations within the applicable period. We then propose to filter the collated list of prescriber NPI and MPN combinations using the 340B Office of Pharmacy Affairs Information System (OPAIS) database,[280] which records the available MPNs for covered entities that are actively participating in the 340B program during the applicable period. Each prescriber NPI affiliated with an MPN that was also an active 340B covered entity listed on the OPAIS database for that particular month would be considered a 340B-affiliated prescriber for the month within the applicable period.

CMS acknowledges that not all covered entities have an MPN or report their MPN in the 340B OPAIS database, which may result in an inability for CMS to designate claims affiliated with such covered entities as being potentially 340B-eligible using this methodology. Notably, we understand that hospitals are required to report their MPN in the 340B OPAIS database if they intend to use 340B drugs for their Medicaid patients[281], and that hospitals make up the significant majority of 340B volume. To address the missing MPN scenarios, we are soliciting comments on a methodology to augment the prescriber NPI and MPN file described above by using NPI when the NPI is listed in the 340B OPAIS database, but MPN is not. We would use additional data sources such as CMS' Integrated Data Repository to map 340B OPAIS provided organizational NPIs to corresponding individual NPIs and MPN, when possible, to establish a supplemental list of prescriber NPIs that are associated with covered entities. Each prescriber NPI that is determined to be associated with a covered entity NPI, as listed in the 340B OPAIS database, would be considered a 340B-affiliated prescriber for the month within the applicable period. The resulting augmented 340B-affiliated prescriber NPI file would help to ensure a broader possible combination of prescriber-covered entity pairings than using the covered entity's organizational NPI from the 340B OPAIS database alone. CMS is soliciting comments on the benefits of using this augmented 340B-affiliated prescriber NPI approach to address covered entities that do not have MPN's listed in the 340B OPAIS database, as well as alternative methods to consider for how CMS could address the described scenario.

Next, we propose to use the 340B OPAIS database to identify registered contract pharmacies that have an active agreement with a 340B covered entity in the 340B OPAIS database during months within the applicable period and develop a list of 340B contract pharmacy names, addresses, and active months for each associated covered entity. We would then merge pharmacy NPIs onto this file using the name and address fields reported to the National Council for Prescription Drug Programs (NCPDP). We understand that matching the list of contract pharmacy names and addresses to the NCPDP database will not rely on the use of a single discrete data field and may require CMS to utilize a methodology that includes: (1) cleaning addresses to account for variations in spelling, abbreviations, punctuations, etc. between the pharmacy names and addresses from both sources; (2) geocode matching between the pharmacy addresses contained in each source; and (3) fuzzy string matching on pharmacy name and address fields after cleaning these fields. Specifically, CMS may conduct a cartesian join to generate potential matches between pharmacies from each data source located in the same state, limit these potential matches to pharmacies estimated to be within 0.2 miles of one another,[282] and select a final match for each HRSA OPAIS pharmacy based on fuzzy string matching between the pharmacy name and address fields in each database.[283]

[278] Provider field types include billing, rendering, attending, operating, other, and referring.

[279] There exist inconsistencies between how MPN is described in the 340B OPAIS database and the 2007 CMS System Manual, which states ''In order to avoid confusion with the NPI, the Medicare/Medicaid Provider Number (also known as the OSCAR Provider Number, Medicare Identification Number or Provider Number) has been renamed the CMS Certification Number (CCN).'' For the purpose of this discussion, CMS uses MPN interchangeably with CCN.

See:*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r29soma.pdf.*

[280] See: *https://340bopais.hrsa.gov/home.*

[281] See: *https://www.hrsa.gov/opa/registration.*

[282] The 0.2 mile threshold was previously adopted in Nikpay, S., Bruno, J. P., & Carey, C. (2024). Recent court ruling could increase the size and administrative complexity of the 340B program. *Health affairs scholar, 2*(12), qxae157. *https://doi.org/10.1093/haschl/qxae157.*

[283] CMS proposes to use a fuzzy-matching approach that matches the similarity between the names and addresses. This approach first counts the characters that match. Next, it examines how close those characters are, accounting for transpositions in each name or address. Accounting for

Using a targeted analysis, CMS intends to conduct a manual review of this matching algorithm to identify and correct errors or omissions. CMS acknowledges that this matching algorithm may result in an inability to associate a small percentage of contract pharmacies with NPIs.

The output of the two preceding processes would be: (1) a month-level file containing 340B-affiliated prescriber NPIs and their associated MPNs, and (2) a month-level file containing pharmacy NPIs for contract pharmacies of 340B covered entities and the MPNs of these covered entities. CMS would join these two files by MPN and month to create a month-level file containing 340B-affiliated prescriber NPIs and pharmacy NPIs for contract pharmacies associated with these 340B covered entities. Based on preliminary analyses of this claims-based methodology, for most Part D drugs, CMS expects to remove about 10 percent to 35 percent of the total number of units [284] determined under § 428.203(a) used to calculate the total rebate amount determined under § 428.201(a). We emphasize that this approximation is preliminary and may vary significantly across different Part D rebatable drugs.

CMS notes that a prescriber NPI may have multiple affiliated covered entities, and that a 340B covered entity may have multiple contract pharmacies. Using this set of prescriber and pharmacy pairings, CMS would identify PDE records during the applicable period that have prescriber ID, service provider ID, and claim date fields that match one of the paired combinations of 340B-affiliated prescriber NPI, pharmacy NPI, and month. For PDE records that match against these pairings, the units associated with those PDE records would be considered 340B units and would be removed from the total number of units dispensed under Part D (as determined under § 428.203) used to calculate the total rebate amount.

CMS has considered an alternative methodology to the Prescriber-Pharmacy Methodology (hereinafter, ''the Beneficiary-Pharmacy Methodology''). In contrast to the Prescriber-Pharmacy Methodology, the Beneficiary-Pharmacy Methodology would identify potentially 340B-eligible units (that will be treated as 340B units for purposes of effectuating the exclusion at § 428.203(b)(2)) associated with PDE records that are: (1) dispensed by a pharmacy currently under contract with a 340B covered entity, and (2) for beneficiaries who receive care from a 340B covered entity affiliated with that pharmacy. To implement this methodology, CMS would create beneficiary-pharmacy pairs that meet the defined criteria by combining two files: (1) the same monthly file used in the Prescriber-Pharmacy Methodology that links 340B covered entities (identified by MPN or NPI) with pharmacy NPIs for those covered entities, and (2) a monthly file containing beneficiaries associated with PDE records from the applicable year and the MPNs of providers from which those beneficiaries received care. CMS would generate this latter file by identifying beneficiary-month combinations based on the date of dispense on the PDE record, then determining the MPNs (or NPIs) where those beneficiaries received services during those months. The identification of MPNs (or NPIs) where beneficiaries receive care would rely on inpatient, outpatient, and professional claims within both Medicare FFS and Medicare Advantage claims data.

To establish beneficiary-pharmacy pairs, CMS would merge the two files described above by MPN and month, producing month-level combinations that link beneficiaries to contract pharmacies. These combinations would reflect the universe of beneficiaries who receive services at a 340B covered entity and the associated contract pharmacies for those covered entities. To identify associated PDE records, CMS would filter for records with beneficiary ID, service provider ID, and claim date combinations that align with one of the beneficiary-pharmacy-month combinations. For any PDE record that matches these pairings, the units associated with the record would be considered 340B units.

While CMS anticipates the degree of overlap between the two methodologies to be high, CMS may consider revisions to the Prescriber-Pharmacy Methodology based on further analyses of the Beneficiary-Pharmacy Methodology—such as defining 340B units using the union of units identified by both methodologies or refining the Prescriber-Pharmacy Methodology. CMS is soliciting comments on the potential benefits and drawbacks of using a Beneficiary-Pharmacy Methodology and on whether a Beneficiary-Pharmacy Methodology could be combined with the Prescriber-Pharmacy Methodology to validate 340B units identified, such as via a union of the two methodologies.

iii. Alternative Policy Considered: Estimation Percentage Using PVP and AMP Data

As described in section III.E.3.c.i of this proposed rule, CMS considered an alternative estimation methodology to remove units from the total number of units dispensed of a Part D rebatable drug for each applicable period that would be based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. This alternative estimation methodology was proposed in the CY 2025 PFS rule (89 FR 61969), in which we proposed to use an estimation percentage that would equal the total number of units purchased by covered entities under the 340B Program for an NDC–9, divided by the total units sold of that NDC–9. CMS included more detail in section III.E.3.c.i of this proposed rule regarding the estimation percentage methodology originally discussed in the CY 2025 PFS proposed rule.

We acknowledged some limitations of this methodology in the CY 2025 PFS proposed and final rules, as noted above in section III.E.3.c.i of this proposed rule. After further consideration of comments received in response to the CY 2025 PFS proposed rule, CMS is no longer pursuing this policy at this time but may consider it in future rulemaking.

iv. Proposal To Establish a Medicare Part D Claims Data 340B Repository

In the initial Medicare Part D Drug Inflation Rebate Guidance, CMS solicited comments on the best mechanism to identify 340B units dispensed under Part D.[285] CMS discussed requiring the dispensing entity to include a 340B claims indicator on the Part D drug claim to be included in PDE records.[286] Many commenters disagreed that requiring the dispensing entity to include a 340B claims indicator on the Part D drug claim to be included on the PDE record was the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with both point-of-sale modifiers and retrospective

transpositions addresses common typing mistakes such as entering the right characters in the wrong order.

[284] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

[285] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

[286] Currently, a pharmacy may voluntarily use the value of ''AA'' in the Submission Type Code (D17–K8) field to indicate use of a 340B drug at the time of the adjudication or dispensing of the claim. See: National Council on Prescription Drug Program (NCPDP) 340B Information Exchange Reference Guide Version 2.0, June 2019, *https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.*

340B identifiers. In addition, a wide array of interested parties recommended that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B claims dispensed under Part D. Interested parties urged that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors.

In response to this feedback from interested parties, in the CY 2025 PFS proposed rule (89 FR 61971 through 61972) we solicited comments on establishing a repository in a future year of the Medicare Part D Drug Inflation Rebate Program to comply with the requirement under section 1860D–14B(b)(1)(B) of the Act that CMS shall exclude from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program. In the CY 2025 PFS proposed rule (89 FR 61971), we stated that this approach would require that covered entities submit certain data elements from Part D 340B claims to the repository, and we solicited comments on such a requirement. In the CY 2025 PFS final rule (89 FR 98293), we stated that we would explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a repository. To inform policy development for this rulemaking, we reviewed and considered the comments received on the CY 2025 PFS proposed rule. We are proposing to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program in a future applicable period. We intend to allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository.

We propose that the 340B repository would receive, via submission by covered entities that choose to submit data to the repository, data elements (as described in the next section) from all claims with dates of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provides a discount under the 340B program (''Part D 340B claims'') for all covered Part D drugs billed to Medicare Part D. As requested by interested parties in comments on the initial Medicare Part D Drug Inflation Rebate Guidance and the CY 2025 PFS proposed rule, the 340B repository would allow covered entities to submit these data directly to CMS (or a contractor), rather than through claims that dispensers submit to Part D plan sponsors. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims; that is, the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data.

Under this process, CMS intends to require a certification from covered entities that the covered entity has submitted all Part D 340B claims with dates of service during the relevant time period and that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for the applicable period. We would require covered entities to certify the completeness and accuracy of the data submitted, and attest that the submitter is authorized to submit on behalf of the entity. We are exploring approaches to confirming completeness and accuracy of data submissions to the 340B repository and are soliciting comments on methods to review and ensure the accuracy of reported data. CMS would match the stored data elements in the 340B repository to PDE transactions for each Part D rebatable drug dispensed during the applicable period. If we determine that the data reported to the repository is usable and reliable and, in the future, propose and finalize a policy to use such data to exclude 340B units from rebate calculations, then units associated with PDE transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provides a discount under the 340B Program and therefore would be removed from the total number of units used to calculate the total rebate amount. We understand the importance of maintaining the confidentiality of data submitted to the 340B repository. We do not expect concerns about the privacy of data submitted to the 340B repository, as this data would not be made available to external parties, including manufacturers and Part D plan sponsors.

v. Proposal for Covered Entities To Submit 340B Claims Data to the 340B Repository

We are proposing that covered entities would optionally begin submitting the fields specified by CMS below to the 340B repository beginning in 2026 for Part D 340B claims with dates of service on or after January 1, 2026 to allow for CMS to begin usability testing for the 340B repository. CMS would not use the data submitted during the testing period to remove units from Part D inflation rebates unless and until a policy to do so is proposed and finalized. CMS expects that hospitals receiving Medicare Disproportionate Share Hospital (DSH) payments, Federally Qualified Health Centers (FQHCs), and Critical Access Hospitals (CAHs) would begin to submit data elements to the 340B repository during the testing period. CMS strongly encourages all covered entities to submit data elements to the 340B repository during the testing period beginning in 2026, as this participation would allow for robust testing of data quality and completeness. It would also provide an opportunity for covered entities to develop and test their data submission processes. CMS will address the possibility of mandatory reporting of data elements to the 340B repository by covered entities in future years in future rulemaking. Many covered entities are providers and suppliers regulated by CMS under Title XVIII of the Social Security Act, including hospitals receiving DSH payments, CAHs and FQHCs. CMS is actively considering options for mandatory reporting to the 340B repository in the near future and recommends that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting.

We understand covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B-eligibility of claims using data submitted by covered entities and their contractors. We would allow covered entities that choose to submit data to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. Covered entities would certify and would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf.

We propose to require entities (whether a 340B covered entity, or a vendor on their behalf) that choose to submit data to the 340B repository during the testing period beginning in

2026 to provide information identifying the 340B covered entity, which could include information such as the covered entity's 340B ID and name as designated in the 340B OPAIS database, when submitting claim information to the 340B repository. We propose to use the collected identifying information to: (1) perform analyses to assess suitability of the data for future use in removing 340B units; and (2) provide a means to follow up with the covered entity on questions related to claims data submission. In addition to this identifying information, we propose to require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy NPI; and (5) NDC–11. We propose to use these data elements to match claims to PDE transactions and perform further analyses to assess suitability of the data for future use in removing 340B units from Part D drug inflation rebate calculations.

In the CY 2025 PFS proposed rule (89 FR 61971), we solicited comments from interested parties on the first four data elements in the list referenced in the previous paragraph ((1) Date of Service; (2) Prescription or Service Reference Number; (3) Fill Number; and (4) Dispensing Pharmacy NPI) and whether these data elements would be accessible to covered entities to submit to CMS. In comments on the CY 2025 PFS proposed rule and summarized in the CY 2025 PFS final rule (89 FR 98293), many interested parties recommended that CMS collect additional data elements, such as the NDC, stating that the NDC would help CMS better match the data submitted by the covered entity to the PDE data for Part D rebatable drugs dispensed during an applicable period. We believe that collecting the NDC would provide useful information for analysis of the data submitted, in addition to the four data elements on which we solicited comment in the CY 2025 PFS proposed rule, and which are the minimum elements that would be necessary to match a submission to a PDE transaction to exclude units from inflation rebate calculations, were the repository to be used for such purpose in the future. The NDC is also a required data element collected under an existing state-based program that operates to match and identify 340B units, similar to the 340B repository that we are proposing to establish.[287] Therefore, we believe that requiring covered entities participating in the 340B repository during the testing period beginning in 2026 to submit the NDC in addition to the four data elements listed previously ((1) Date of Service, (2) Prescription or Service Reference Number; (3) Fill Number; and (4) Dispensing Pharmacy NPI) is reasonable and would not create substantial additional burden.

We are issuing an Information Collection Request alongside this proposed rule entitled ''Information Collection Request (ICR) for the Medicare Prescription Drug Inflation Rebate Program under Section 11101 and 11102 of the Inflation Reduction Act (IRA)'' (CMS–10930, OMB 0938–TBD) for submission to the 340B repository (by covered entities that choose to submit) of certain data elements from all 340B identified claims for all covered Part D drugs billed to Medicare Part D with dates of service during the relevant period. Section VI: The Collection of Information Requirements section of this proposed rule addresses the burden associated with the collection of data for the 340B repository. The Information Collection Request includes more details regarding how covered entities can submit data to the 340B repository, including the format for data submission.

vi. Timing Requirements for Covered Entity Submissions to a Medicare Part D Claims Data 340B Repository

CMS expects the Medicare Part D claims data 340B repository to launch in Fall 2026, meaning it would be available to collect 340B data from covered entities for claims with dates of service on or after January 1, 2026. To foster robust data reporting by covered entities, CMS understands that covered entities will need time to develop a process for collecting the 340B data elements described above and preparing the data in the form and manner prescribed by CMS. Additionally, given the variety in the scope of provider types and organizations that participate in the 340B Program, CMS recognizes the amount of preparation time varies. In consideration of these factors and the anticipated launch date for the 340B repository in Fall 2026, we are proposing to require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the fields specified by CMS to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. Covered entities that choose to submit data would submit data elements related to Part D 340B claims with dates of service on or after January 1, 2026. At a point in the future, if this proposal is finalized, CMS would provide a deadline that CMS believes will allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. CMS would provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate ICR is finalized. During the rest of the testing period, CMS anticipates that covered entities will be expected to report data on a quarterly basis within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2026, through December 31, 2026, covered entities that choose to submit data elements from Part D 340B claims would submit the data to the 340B repository no later than March 31, 2027. The data from these submissions would be used to assess the usability of such data to remove 340B units from the total number of units and total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at §§ 428.401(b) and (c), respectively.

We are proposing to provide covered entities that choose to submit data to the 340B repository with additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the covered entity previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the covered entity had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. In instances where the covered entity submits 340B Part D claims data to the repository that is either (1) incomplete, or (2) contains invalid data, we may inform the covered entity of such error

[287] The state of Oregon allows 340B covered entities to avoid duplicate 340B discounts and Medicaid rebates when contracting with one or more retail pharmacies to dispense drugs purchased at the 340B price by using a retroactive 340B claims submission process. The NDC–11 is one required data element in Oregon's retroactive 340B claims submission process. See: *https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx.*

and request that the covered entity resolve and resubmit the 340B Part D claims data in order to process the submission successfully. We will provide details on the process and timing for covered entities to submit revised data to the 340B repository after the end of the reporting period in the future.

d. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 428.400 through 428.405)

Section 1860D–14B(a)(1) of the Act requires the Secretary to report to each manufacturer of a Part D rebatable drug the following information not later than 9 months after the end of the applicable period: (1) the amount, if any, of the excess AnMP increase described in section 1860D–14B(b)(1)(A)(ii) of the Act for each Part D rebatable drug, and (2) the rebate amount for each Part D rebatable drug. In compliance with section 1860D–14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug must provide a rebate for each Part D rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1860D–14B(a)(1) of the Act.

In accordance with §§ 428.404 and 428.405, CMS has established a standard method and process to issue Rebate Reports to manufacturers of Part D rebatable drugs and to accept manufacturer rebate payments. CMS has established an online portal, the ''Manufacturer Payment Portal'' (MPP), administered by a CMS contractor, through which manufacturers will access their Rebate Reports, submit Suggestions of Error, as applicable, and pay rebate amounts due, as described in §§ 428.404 and 428.405. Manufacturers of Part D rebatable drugs should provide points of contact to view Preliminary Rebate Reports and Rebate Reports, enter and modify banking information, and initiate payments of rebate amounts through the MPP.

i. Rebate Reports and Reconciliation (§ 428.401); Deadline and Process for Payment of Rebate Amount (§ 428.405)

As stated in the CY 2025 PFS final rule (89 FR 98264), we codified a multi–step process to provide a manufacturer as set forth in § 428.20 with the rebate information specified in section 1860D–14B(a) of the Act. Specifically, as stated in the CY 2025 PFS final rule (89 FR 98264), we established the information that will be included in a Rebate Report at § 428.401, which includes the NDC(s) identified for the Part D rebatable drug, the total number of units dispensed under Part D for the Part D rebatable drug for the applicable period, and the rebate amount due, among other items specified in § 428.401. Additionally, we established that payment for a rebate amount due must be paid by the 30th day after the date of the receipt of the information containing the rebate amount.

Consistent with the approach specified in section 40 of the revised Medicare Part D Drug Inflation Rebate Guidance, we propose to add paragraph (c)(3) in § 428.401 to clarify that CMS will report the manufacturer's rebate amount due as a dollar amount that is rounded to the nearest cent. CMS did not specify an approach to reporting of the rebate amount in the CY 2025 PFS final rule, and we believe it is necessary to provide this information to manufacturers to provide notice of CMS' approach to rounding of the rebate amount. The calculation steps specified in subpart C of part 428 will not include rounded values.

Additionally, we propose a clarifying edit at § 428.405(a)(1) to specify that the manufacturer must pay the rebate amount due no later than on the 30th calendar day after the date of receipt of the information regarding the rebate amount. The current language specifies that the payment is due ''30 calendar days'' after the date of receipt of information regarding the rebate amount. CMS does not believe this edit substantively revises the due date.

In the CY 2025 PFS final rule (89 FR 98588), to determine which data elements would be included when CMS reports the rebate amount to the manufacturer, we stated that we considered the statutory requirements outlined in section 1860D–14B(a)(1)(A) through (B) of the Act to determine what information is necessary for manufacturers to review the accuracy of the rebate amount while also protecting proprietary information. As stated on page 98588 of the CY 2025 PFS final rule, CMS structured a two-step reporting process to first include a Preliminary Rebate Report to provide an initial notice to manufacturers regarding whether they may owe a rebate amount, followed by the Rebate Report. Further, we proposed and finalized additional data elements within the Preliminary Rebate Reports and the Rebate Reports not listed in statute based on input from public comments (for example, the payment amount benchmark period, the applicable period CPI–U). CMS did not finalize additional elements suggested, such as data at the prescription drug event (PDE) record level, after weighing whether any such additional information fulfilled CMS' statutory obligation and the potential benefits to manufacturers against the administrative burdens additional reporting would impose on the agency and operational feasibility. The elements that are set forth in §§ 428.401(b)(1) and (c)(1) satisfy these considerations.

In this proposed rule, CMS clarifies that certain data elements provided to manufacturers in Preliminary Rebate Reports, Rebate Reports, and reconciled reports of a rebate amount (which may each include the same elements, revised as applicable due to updates in the data), are provided to manufacturers of a Part D rebatable drug in alignment with § 1927(b)(3)(D) of the Act. This section of the Act provides an exception to the confidentiality of information disclosed by manufacturers or wholesalers under section 1927(b)(3) of the Act as the Secretary determines to be necessary to carry out certain sections of the Act, including section 1860D–14B of the Act (that is, the Part D Drug Inflation Rebate Program).

Specifically, CMS anticipates that most data included in Preliminary Rebate Reports, Rebate Reports, reconciled Preliminary Rebate Reports, and reconciled Rebate Reports will not implicate § 1927(b)(3)(D) of the Act, as CMS anticipates that in most cases the party that will receive these reports will be the same party that reported the relevant information. However, CMS acknowledges that some situations may raise a possibility of disclosure by the Secretary of AMP information, or information derived therefrom, to a party besides the party that reported the information originally; such situations could implicate confidentiality under section 1927(b)(3)(D) of the Act. Such situations may include, but are not necessarily limited to, (1) transfer of a rebatable drug from one manufacturer to another manufacturer, such that the manufacturer identified in the Rebate Report differs from the manufacturer that originally reported certain benchmark pricing information, and (2) information about initial drugs associated with line extensions. In instances where the parties may be different, CMS emphasizes that the data included in a report of the rebate amount is based on CMS's independently performed calculations. Though these calculations rely on information disclosed by manufacturers as inputs, the data reported in a Preliminary Rebate Report and a Rebate Report (or a reconciled version of these reports) will not be identical to the information reported by manufacturers (for example, manufacturers report quarterly AMP values, whereas the benchmark period manufacturer price is an aggregate amount using AMP values

across multiple quarters when available). Therefore, reporting such data elements to another manufacturer for purposes of the Rebate Program would not violate the confidentiality requirements in sections 1927 of the Act. Additionally, CMS notes that section 1927(b)(3)(D)(i) of the Act provides an exception from the confidentiality provision in 1927(b)(3)(D) of the Act based on what the ''Secretary determines to be necessary to carry out'' under 1860D–14B of the Act (among other listed statutory provisions). CMS is applying this exception to the data elements in the Preliminary Rebate Report for the purpose of carrying out the Rebate Program.

Second, on page 98266 of the CY 2025 PFS final rule, CMS stated that the purpose of providing additional data elements not explicitly listed in sections 1860D–14B(a)(1)(A) through (B) of the Act (for example, benchmark period manufacturer price, the annual manufacturer price) is based on CMS' assessment of what data elements are necessary to review the Preliminary Rebate Report for a Suggestion of Error. Providing these data in the Preliminary Rebate Report (and corresponding reports) ensures that (1) manufacturers will be able to submit a Suggestion of Error, thereby promoting accuracy in the implementation of the rebate program, and (2) manufacturers will have advanced notice of a potential rebate amount due.

ii. Rebate Reports for the Applicable Periods Beginning October 1, 2022, and October 1, 2023 (§ 428.402)

As stated in the CY 2025 PFS final rule (89 FR 97710), we codified at § 428.402 the options afforded to CMS in section 1860D–14B(a)(3) of the Act to delay sending the information required by section 1860D–14B(a)(1) of the Act for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025. Specifically, per § 428.402(c), CMS will issue a Preliminary Rebate Report for each applicable period followed by issuance of the Rebate Report for each applicable period no later than December 31, 2025. Additionally, for the applicable period beginning October 1, 2022, CMS will conduct a single reconciliation 21 months after issuance of the Rebate Report for this applicable period (see § 428.402(c)(1)(ii)). As set forth in § 428.402(c)(2)(ii), for the applicable period beginning October 1, 2023, the rebate amount will be reconciled twice at 9 and 33 months after the Rebate Report was issued for the applicable period. We stated in the CY 2025 PFS proposed rule (89 FR 61983) that this approach aligns claims and payment data run-out with the run-out used during a regular reconciliation cycle. However, CMS finalized the regulatory text specifying the time periods for regular reconciliation cycles at § 428.401(d) with text that provides CMS with operational flexibility as to the exact date the report with the reconciled rebate amount will be provided to each manufacturer of a Part D rebatable drug by including the word ''within'' prior to the specified date. We propose to amend §§ 428.402(c)(1)(ii) and (c)(2)(ii) to add the word ''within'' prior to the specified number of months (for example, 21 months for the applicable period beginning October 1, 2022, and 9 and 33 months for the applicable period beginning October 1, 2023) to be consistent with the regulatory text and cadence for regular reconciliation cycles, as well as to provide operational flexibility on the timing of the release of the report with the reconciled rebate amount.

F. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

As of January 1, 2025, the Medicare Shared Savings Program (Shared Savings Program) has 477 accountable care organizations (ACOs) with over 650,000 healthcare providers and organizations providing care to over 11.2 million assigned beneficiaries.[288] Eligible groups of providers and suppliers, such as physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or joining an ACO and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare FFS beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases healthcare spending.

We continue to gain experience with and observe the impact of changes to the Shared Savings Program's quality performance standard and other quality reporting requirements, financial methodology, beneficiary assignment methodology, participation options, and availability of new payment options, among other changes, finalized in recent years through the annual PFS rulemaking process.[289] Section III.F. of this proposed rule addresses proposed changes to the Shared Savings Program regulations to allow for timely improvements to program policies and operations as summarized in section III.F.1.c of this proposed rule.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 et seq.) by adding section 1899 of the Act to establish the Medicare Shared Savings Program to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary

[288] See ''Shared Savings Program Fast Facts—As of January 1, 2025'', available at *https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf.*

[289] Refer to the CY 2023 PFS final rule (87 FR 69777 through 69979), CY 2024 PFS final rule (88 FR 79093 through 79232), and CY 2025 PFS final rule (89 FR 98081 through 98213).

identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent update to the program rules appeared in the June 9, 2015, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016, **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act,'' appeared in the November 23, 2018, **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018, **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017; final rule (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020, **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction that prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the public health emergency (PHE) for coronavirus disease 2019 (COVID–19) (85 FR 19267 and 19268).

In the IFC titled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which was effective on May 8, 2020, and appeared in the May 8, 2020, **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), the CY 2023 PFS final rule (87 FR 69779 and 69780), the CY 2024 PFS final rule (88 FR 79094 and 79095) and the CY 2025 PFS final rule (89 FR 98082 and 98083). In the CY 2025 PFS final rule (89 FR 98081 through 98213), we finalized changes to Shared Savings Program policies, including to: sunset a requirement under which CMS would terminate an ACO's participation agreement, under certain circumstances, if it failed to maintain at least 5,000 assigned beneficiaries during an agreement period; revise the requirement that newly formed ACOs must agree to allow CMS to share a copy of their application with the Antitrust Agencies; update the definition of primary care services used in beneficiary assignment; revise the Shared Savings Program regulations to broaden a limited exception to the program's voluntary alignment policy; make changes to the quality performance standard and other quality reporting requirements, including to: (1) require Shared Savings Program ACOs to report the Alternative Payment Model (APM) Performance Pathway (APP Plus) quality measure set beginning in performance year 2025 and for subsequent performance years; (2) focus the collection types available to Shared

Savings Program ACOs for reporting the APP Plus quality measure set to electronic clinical quality measures (eCQMs) and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) by performance year 2027 and make Merit-based Incentive Payment System clinical quality measures (MIPS CQMs) available in performance years 2025 and 2026; (3) establish a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs; score measures of the Medicare CQM collection type using flat benchmarks for their first two performance periods in MIPS; and (4) extend the eCQM/MIPS CQM reporting incentive for meeting the Shared Savings Program quality performance standard to performance years 2025 and 2026 and extend the eCQM reporting incentive for performance year 2027 and subsequent performance years; allow ACOs receiving advance investment payments to voluntarily terminate from the payment option while remaining in the Shared Savings Program; codify a policy for recouping advance investment payments from ACOs whose participation agreements are terminated by CMS; make modifications to the Shared Savings Program's financial methodology, including to (1) establish a third possible upward adjustment to an ACO's historical benchmark—the health equity benchmark adjustment—based on the number of beneficiaries the ACO serves who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS); (2) establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination; (3) establish a methodology for excluding payment amounts for Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes exhibiting significant, anomalous, and highly suspect (SAHS) billing activity during CY 2024 or subsequent calendar years that warrant adjustment; and (4) make technical changes in provisions of the Shared Savings Program regulations on financial calculations, to align and clarify the language used to describe weights applied to the growth in ACO and regional risk scores for each Medicare enrollment type, as part of the calculation for capping ACO and regional risk score growth; and modify beneficiary notification requirements.

In a final rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023,'' which was effective on October 15, 2024, and appeared in the September 27, 2024, **Federal Register** (89 FR 79152) (hereinafter referred to as the ''SAHS billing activity final rule''), we finalized an approach to address the SAHS billing activity CMS identified for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations.

Policies applicable to Shared Savings Program ACOs for purposes of quality reporting for other programs have also continued to evolve based on changes in statute, such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), which established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Proposals

In sections III.F.2. through III.F.9. of this proposed rule, we propose modifications to the Shared Savings Program's policies. As a general summary, we are proposing the following changes to Shared Savings Program policies to:

- Modify requirements for determining an ACO's eligibility for Shared Savings Program participation options, for agreement periods beginning on or after January 1, 2027, to limit participation in a one-sided model to an ACO's first agreement period under the BASIC track's glide path (if eligible), and require ACOs inexperienced with performance-based risk Medicare ACO initiatives (defined at § 425.20) to progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both, from participating in the ENHANCED track under the proposals at section III.F.4.b.(2).(b). of this proposed rule), compared to existing policies (section III.F.2 of this proposed rule).

- Modify Shared Savings Program eligibility requirements to require ACOs to make certain changes to their ACO participant list when an ACO participant experiences a change of ownership (CHOW) where the surviving Taxpayer Identification Number (TIN) is newly enrolled in the Provider Enrollment, Chain, and Ownership System (PECOS) with no prior Medicare billing claims history, during the performance year and outside of the annual change request cycle, and similarly allow for changes during the performance year to the ACO's Skilled Nursing Facility (SNF) affiliate list if a SNF affiliate undergoes a CHOW resulting in change to the Medicare enrolled TIN (section III.F.3 of this proposed rule).

- Modify Shared Savings Program eligibility requirements and financial reconciliation requirements in connection with the statutory requirement that ACOs have at least 5,000 assigned Medicare FFS beneficiaries to:

++ Require ACOs applying to enter a new agreement period to have at least 5,000 assigned beneficiaries in BY3, while allowing the ACO to have under 5,000 assigned beneficiaries in BY1, BY2, or both (section III.F.4.b.(2)(a) of this proposed rule).

++ Require ACOs that enter a new agreement period with less than 5,000 assigned beneficiaries in BY1, BY2, or both to enter the BASIC track (section III.F.4.b.(2).(b). of this proposed rule).

++ Cap shared savings and shared losses at a lesser amount for ACOs with fewer than 5,000 assigned beneficiaries in any of the three BYs, to help ensure the amounts reflect the ACO's performance in the program rather than normal variation in expenditures (section III.F.4.c.(1). of this proposed rule).

++ Exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to leverage existing policies that provide certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings (section III.F.4.c.(2). of this proposed rule).

- Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.F.5. of this proposed rule).

• Revise the quality performance standard and other quality reporting requirements, including the following (section III.F.6. of this proposed rule):

++ Revise the definition of a beneficiary eligible for Medicare CQMs at § 425.20 for performance year 2025 and subsequent performance years so that the population identified for reporting within the Medicare CQM collection type would have greater overlap with the beneficiaries that are assignable to an ACO (section III.F.6.b. of this proposed rule).

++ Remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 and revise the terminology used to describe the health equity adjustment and other related terms for performance years 2023 and 2024 (section III.F.6.c. of this proposed rule).

++ Update the APP Plus quality measure set for Shared Savings Program ACOs including the removal of Quality ID: 487 Screening for Social Drivers of Health (section III.F.6.d of this proposed rule).

++ Require CMS-approved survey vendors to administer the CAHPS for MIPS Survey via a web-mail-phone protocol beginning with 2027 (section III.F.6.e. of this proposed rule).

• Expand the application of the Shared Savings Program quality and finance extreme and uncontrollable circumstances (EUC) policies to an ACO that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years (section III.F.7 of this proposed rule).

• Revise the Shared Savings Program regulations for performance year 2025 and subsequent performance years to rename the ''health equity benchmark adjustment'' to the ''population adjustment'' (section III.F.8. of this proposed rule).

• Modify the Shared Savings Program quality reporting monitoring requirements at § 425.316 to specify for performance years beginning on or after January 1, 2026, requirements to monitor ACOs for failure to meet both the quality performance standard and the alternative quality performance standard, the latter of which (established in the CY 2023 PFS final rule) was inadvertently omitted from the existing framework. Similarly, modify § 425.224(b)(1)(ii)(A) related to reviewing applications for renewing and re-entering ACOs with a demonstrated pattern of failure to meet both the quality performance standard and the alternative quality performance standard (section III.F.9 of this proposed rule).

Taken together, the Shared Savings Program proposals in this proposed rule are anticipated to reduce program spending by $20 million in total through the end of the 10-year period 2026 through 2035, ranging from approximately $590 million lower spending at the 10th percentile to $670 million higher spending at the 90th percentile (as described in section VII of this proposed rule).

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposal to change the requirements for ACOs' progression to performance-based risk under the program's participation options (described in section III.F.2 of this proposed rule); the proposal to potentially apply an alternative loss recoupment limit, in conducting financial reconciliation for each performance year, for an ACO with fewer than 5,000 assigned beneficiaries in any BY, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c of this proposed rule); the proposal to exclude ACOs that fall below 5,000 assigned beneficiaries in any BY from being eligible to benefit from the policies providing certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c of this proposed rule); and the proposal to mitigate shared losses for an ACO determined to be affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years (described in section III.F.7.c of this proposed rule). As described in the Regulatory Impact Analysis in section VII. and elsewhere in this proposed rule, these proposed changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

2. Shared Savings Program Participation Options Under the BASIC Track

a. Background on Shared Savings Program Participation Options

Section 1899(d) of the Act establishes the general requirements for shared savings payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act specifies that providers of services and suppliers participating in an ACO will continue to receive payments under the original Medicare FFS program under Parts A and B in the same manner as would otherwise be made, and that an ACO is eligible to receive payment for a portion of savings generated for Medicare provided that the ACO meets both the quality performance standards established by the Secretary and achieves savings against its benchmark. Additionally, section 1899(i)(3) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

Since its inception in 2012, the Shared Savings Program has included both one-sided shared savings only models incorporating the statutory payment methodology under section 1899(d) of the Act, and two-sided shared savings and losses models that were also based on the payment methodology under section 1899(d) of the Act but incorporated performance-based risk using the authority under section 1899(i)(3) of the Act to use other

payment models.[290] Under the Shared Savings Program regulations at § 425.20, we defined a one-sided model to mean a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under 42 CFR part 425 subpart G. At § 425.20, we defined a two-sided model to mean a model under which an ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G. Subpart G of the program's regulations includes provisions on the calculation of shared savings and losses (as applicable) under the program's tracks, among other policies.

At § 425.600, we describe the options for an ACO's selection of risk model. This section includes the criteria used by CMS to determine an ACO's eligibility to participate under the program's tracks or levels of participation, as well as limitations on the amount of time an ACO may participate under a one-sided model, options and requirements for an ACO to participate under a two-sided model, and provisions governing the progression from a one-sided model to higher levels of risk and potential reward under a two-sided model (as applicable).

Over time, we have modified the available financial models under the Shared Savings Program, and approaches to determining an ACO's eligibility to participate under these financial models, which we refer to as the ACO's participation options. For additional information on the changes to the Shared Savings Program's available financial models, including finalization of the existing policies and background on earlier requirements, we refer readers to the discussion in the CY 2023 PFS final rule, at 87 FR 69805 through 69821.

As finalized with the December 2018 final rule (see 83 FR 67831 through 67841), for agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs enter into an agreement period of not less than 5 years under one of two tracks of the Shared Savings Program, either the BASIC track (see §§ 425.600(a)(4) and 425.605) or the ENHANCED track (see §§ 425.600(a)(3) and 425.610). The BASIC track includes a glide path from one-sided model Levels A and B [291] to incrementally higher levels of performance-based risk under Levels C, D, and E. [292] The ENHANCED track offers the highest level of risk and potential reward under the Shared Savings Program. Level E of the BASIC track and the ENHANCED track each qualify as an Advanced APM under the Quality Payment Program.[293]

In rulemaking following the December 2018 final rule, we modified the approach for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track, along with the number of performance years an ACO may remain under a one-sided model of the BASIC track's glide path.[294] As finalized with the CY 2023 PFS final rule (87 FR 69805 through 69821), for agreement periods beginning on or after January 1, 2024, § 425.600(g) specifies the criteria CMS uses to determine an ACO's eligibility to enter an agreement period under the BASIC track's glide path, Level E of the BASIC track, or the ENHANCED track. Under these policies, CMS determines an ACO's eligibility for participation options in the BASIC track and ENHANCED track based on the ACO's experience and its ACO participants' experience with the Shared Savings Program and other performance-based risk Medicare ACO initiatives.[295] In accordance with § 425.600(g), we use the following approach:

- If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20),[296] the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward (Levels A through E), or the ENHANCED track. In accordance with § 425.600(g)(1)(i)–(iii), an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of two agreement periods:

++ An ACO that enters an agreement under the BASIC track's glide path at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following: (A) the ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time; or (B) for a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

++ An ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track.

- If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20), the ACO may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track.

Section 425.600(a)(4)(i)(C) specifies glide path progression for agreement

[290] For additional background, we refer readers to the CY 2023 PFS final rule (87 FR 69805 and 69806) for a summary of changes to the program's financial models, or ''tracks,'' over time.

[291] For details on the Level A financial model, see §§ 425.600(a)(4)(i)(A)(*1*) and 425.605(d)(1)(i). For details on the Level B financial model see §§ 425.600(a)(4)(i)(A)(*2*) and 425.605(d)(1)(ii).

[292] For details on the Level C financial model, see §§ 425.600(a)(4)(i)(A)(*3*) and 425.605(d)(1)(iii). For details on the Level D financial model, see §§ 425.600(a)(4)(i)(A)(*4*) and 425.605(d)(1)(iv). For details on the Level E financial model, see §§ 425.600(a)(4)(i)(A)(*5*) and 425.605(d)(1)(v).

[293] For related information, on Advanced APM status under the Quality Payment Program for each track/level, see the December 2018 final rule, Table 3 ''Comparison of Risk and Reward Under BASIC Track and ENHANCED Track'', and table notes at 83 FR 67852 and 67853.

[294] We refer readers to discussions in earlier rulemaking, including: December 2018 final rule (83 FR 67863 through 67922); May 8, 2020 COVID–19 IFC (85 FR 27575 and 27576) and CY 2021 PFS final rule (85 FR 84767 through 84769); Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (86 FR 45502 through 45506); and CY 2023 PFS final rule (87 FR 69805 through 69821).

[295] See the definitions of ''experienced with performance-based risk Medicare ACO initiatives,'' ''inexperienced with performance-based risk Medicare ACO initiatives,'' and ''performance-based risk Medicare ACO initiative'' under § 425.20.

[296] In accordance with § 425.20 ''inexperienced with performance-based risk Medicare ACO initiatives'' means an ACO that CMS determines meets all of the following: (1) the ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined at § 425.20, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model at § 425.200(e); and (2) less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model at § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years. For brevity, we sometimes refer to such ACOs as ''inexperienced with performance-based risk'' or ''inexperienced with risk.''

periods beginning on or after January 1, 2024. Under these requirements, an ACO eligible to enter the BASIC track's glide path may elect to enter its agreement period at any of the levels of risk and potential reward available under Levels A through E. An ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track, except in the following circumstances: (1) the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided at § 425.226(a)(2)(i); (2) the ACO elects to maintain its level of participation as provided at § 425.600(a)(4)(i)(C)(*3*); [297] or (3) the ACO elected to participate under a one-sided model, but is determined to be experienced with performance-based risk Medicare ACO initiatives and will be automatically advanced to Level E within the BASIC track at the start of the next performance year and will remain in Level E for all subsequent performance years of the agreement period, in accordance with § 425.600(h)(2)(i).[298]

Under our existing policies, new ACOs inexperienced with performance-based risk Medicare ACO initiatives may participate in a BASIC track one-sided model for up to 7 performance years before being required to transition to performance-based risk. For example, an eligible ACO may enter a first BASIC track agreement period in the glide path and elect to remain under Level A for all 5 performance years of this agreement period. If the ACO is eligible to enter a second BASIC track agreement period in the glide path and enters at Level A for its first performance year, the ACO would be automatically advanced to Level B in its second performance year, respectively its sixth and seventh cumulative performance years under a one-sided model. The ACO would participate under performance-based risk for the third and subsequent performance years of its second agreement period under the BASIC track, either by being automatically advanced to Level C, D and E for each of the 3 remaining performance years of its second agreement period under the glide path, or electing to advance more rapidly to higher levels of risk and reward along the glide path.

ACOs that initially elect to remain in Level A of the BASIC track for all 5 performance years for their first agreement period under the BASIC track have the option to subsequently elect to transition to performance-based risk during this agreement period in accordance with § 425.226(a)(2)(i) and § 425.600(a)(4)(i)(C)(*3*)(*iii*), and (a)(4)(i)(C)(*4*) to (*6*). For example, an ACO inexperienced with performance-based risk Medicare ACO initiatives that enters an agreement period under the BASIC track at Level A and elects to maintain participation at Level A for the second and subsequent performance years of this agreement period may subsequently elect to advance to a two-sided model along the BASIC track's glide path (Level C, D or E) for performance year 3, 4 or 5 of this agreement period. In such a case, in accordance with § 425.600(a)(4)(i)(C)(*6*), when an ACO elects to transition to a higher level of risk and reward available under the BASIC track's glide path, the ACO would be automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available. Further, in progressing to performance-based risk in the BASIC track's glide path, the ACO would be considered experienced with performance-based risk Medicare ACO initiatives for purposes of determining the ACO's participation options for a future agreement period, and therefore eligible to enter either the BASIC track Level E for all performance years or the ENHANCED track in accordance with § 425.600(g)(2).

CMS accepts applications for ACOs to participate in the Shared Savings Program annually. Applicant ACOs are required to make a track selection when submitting their application, which is reviewed by CMS to determine the ACO's eligibility for the selected option.[299] During the annual change request cycle, for ACOs currently participating in the program, ACOs participating in the BASIC track's glide path have the opportunity to submit participation options change requests, in connection with their level of participation, among other change requests, prior to the start of the next performance year in the program. For instance, ACOs participating in the BASIC track's glide path may elect to remain in Level A (if participation in Level A was previously elected), or to advance to higher levels of risk and reward along the glide path.[300] The timing of the annual application cycle and change request cycle typically coincide, and span a period from Spring through Fall in advance of the start of the upcoming performance year beginning on January 1st.[301] During the application and change request cycles, CMS communicates information about an ACO's experience with performance-based risk Medicare ACO initiatives, and track/level eligibility, among other information, at standardized intervals, to applicant ACOs and currently participating ACOs.

b. Considerations for Timing of ACOs' Progression to Performance-Based Risk in the Shared Savings Program

As we have explained in earlier rulemaking, and as we continue to believe, financial models under which ACOs bear a degree of financial risk have potential to induce more meaningful systematic change in providers' and suppliers' behavior towards meeting the Shared Savings Program's goals, compared to one-sided models (see for example, 76 FR 67904 through 67909, 80 FR 32758 through 32760, and 83 FR 67967 through 67968). As described in section III.F.2.a. of this proposed rule, our policies on the amount of time an ACO can participate under a one-sided model of the Shared Savings Program, and progression to two-sided risk, have varied over time, including as a result of changes finalized with the CY 2023 PFS final rule. In the CY 2023 PFS final rule (87 FR 69808), we explained our ongoing consideration for how long ACOs should be allowed to participate under a one-sided model (including through prior rulemaking). In explaining what

[297] In accordance with § 425.600(a)(4)(i)(C)(*3*), a new ACO (not a renewing ACO or re-entering ACO as defined at § 425.20) participating in its first agreement period under the BASIC track that enters the glide path at Level A may elect to remain under Level A for all subsequent performance years of the agreement period. As described in the CY 2023 PFS final rule, an ACO must make this election prior to its automatic advancement to Level B for performance year 2 of its agreement period under the BASIC track's glide path. See 87 FR 69810.

[298] We refer readers to the CY 2023 PFS final rule (87 FR 69811 and 69812), in which we finalized the approach to monitoring of risk experience for agreement periods under Level A of the BASIC track, for performance years beginning on or after January 1, 2024, for a detailed explanation and examples of the approach.

[299] See Medicare Shared Savings Program, Application Reference Manual (April 2025, version 7), available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/ssp-application-reference-manual.pdf*.

[300] See Medicare Shared Savings Program, Managing Program Participation Guidance (April 2025, version 2), available at *https://www.cms.gov/files/document/managing-program-participation-guidance.pdf*.

[301] For resources and information on the Shared Savings Program application and change request cycles, refer to the Shared Savings Program website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos* (including the Application Types & Timelines webpage, and Application Toolkit webpage).

has contributed to this consideration, we identified the importance of balancing our goal of driving the greatest possible shift to high-value care delivery, which we believe may be incentivized most effectively under a two-sided model, with a concern that requiring ACOs to take on too much downside risk too quickly may disincentivize program participation and reduce the program's potential to positively affect the quality and cost of care furnished to beneficiaries. As described in the CY 2023 PFS final rule, a number of factors informed our proposal and decision to finalize the current approach that allows eligible ACOs to participate for a 5-year agreement period under Level A of the BASIC track with the opportunity to enter a second agreement period under the BASIC track's glide path beginning under a one-sided model. In the following discussion, we summarize these considerations.

In the CY 2023 PFS final rule (see 87 FR 69806 through 69807), we provided background on comments summarized in the December 2018 final rule, which finalized our proposal to limit ACOs to two performance years under a one-sided model (or three performance years for eligible low revenue ACOs).[302] We explained that most commenters on that proposal recommended that CMS extend the time any ACO can participate in a one-sided model to 3 performance years, as opposed to the 2 performance years proposed for ACOs eligible to participate under the BASIC track with participation agreements beginning on or after January 1, 2020 that do not qualify for a third year under the one-sided model under the exception at § 425.600(a)(4)(i)(B)(*2*)(*ii*), stating that it takes longer than 2 performance years to implement meaningful changes in a healthcare delivery model and among healthcare provider and patient populations. Other commenters believed that the progression to two-sided risk that we proposed and ultimately finalized was far too aggressive and would deter participation. These commenters generally suggested allowing for 4 or 5 performance years (or a full agreement period) under a one-sided model. Some commenters suggested that rural ACOs should be allowed at least two, 5-year agreement periods under a one-sided model (83 FR 67847).

In the CY 2023 PFS final rule (see 87 FR 69807 through 69808), we described participation trends for PY 2022 and explained that while many ACOs had agreed to participate under a two-sided model, not all ACOs appeared to be ready to take on performance-based risk. In particular, we described our experience with policies finalized in connection with the PHE for COVID–19, in which ACOs participating in the BASIC track's glide path could forgo automatic advancement and ''freeze'' their participation for PY 2021 and PY 2022 at their PY 2020 and PY 2021 levels, respectively.[303] We observed that when given the opportunity to freeze at the ACO's current BASIC track level of the glide path, most eligible ACOs under a one-sided model (Level A or Level B) chose to remain in a one-sided model. More generally, we explained that although we continued to believe there are stronger incentives for increased efficiency when ACOs are in a two-sided risk track, ACOs had continued to report that they were constrained by the participation options finalized with the December 2018 final rule, and needed more time to invest in infrastructure and redesigned care processes for high quality and efficient healthcare service delivery before transitioning to performance-based risk. See 87 FR 69808.

We noted our determination that allowing a maximum of 7 years under the one-sided model, as finalized in the CY 2023 PFS final rule, would strike a more appropriate balance within the structure of 5 performance year agreement periods, than only allowing for 2 years under a one-sided model. See 87 FR 46114; see also 87 FR 69809. We also noted that giving ACOs longer than 7 years or potentially unlimited time under a one-sided model would dilute the program's ability to meaningfully influence expenditures and quality through the incentives provided by ACO risk assumption. Moreover, we explained that the approach that would extend the time an eligible ACO could participate under a one-sided model to 7 years would allow ACOs more time to make investments in care improvement and to capitalize on these investments, while still working to lower costs and improve the quality of care for their assigned beneficiaries. 87 FR 69809. We also recognized that ACOs are best able to select their participation options to meet the needs of their organizations, including when to time their transition to performance-based risk, including within an agreement period. *Id.* We also explained our intention with these changes was to provide ACOs with a more gradual ''on-ramp'' to taking on two-sided risk and to allow them the flexibility to best ensure their readiness to take on two-sided risk, and our belief that the approach would encourage more ACOs to form and join the program, as well as encourage currently participating ACOs to remain in the program. See 87 FR 69812; see also 87 FR 69816.

In the CY 2023 PFS final rule, we also recognized differing potential barriers to program participation by low revenue ACOs, and high spending ACOs, among other ACOs with particular characteristics or compositions. For instance, we recognized the importance of finalizing the participation option under which an eligible ACO may stay in a one-sided model of the BASIC track for the full 5-year agreement period for growing participation in the Shared Savings Program by eligible ACOs serving higher spending populations, particularly low revenue, physician-led ACOs. See 87 FR 70195. In combination with the expanded time under a one-sided model, policies finalized with the CY 2023 PFS final rule to allow the option for eligible new, low revenue ACOs inexperienced with risk to receive advance investment payments (see § 425.630), and expanded opportunities for certain low revenue ACOs participating in the BASIC track to share in savings even if they do not meet the MSR (see § 425.605(h)), were designed to support program participation by low revenue ACOs. See 87 FR 70195. Additionally, in the CY 2023 PFS final rule (87 FR 70192), we explained that in combination with modifications to the benchmarking methodology to reduce the impact of the negative regional adjustment also being finalized in that rule, offering eligible ACOs a shared savings-only BASIC track participation option for a full 5-year agreement period, was expected to significantly re-engage participation for ACOs serving higher cost beneficiaries. We also explained our belief that flexibility with respect to the timeline for progression to two-sided risk would be important in the Shared Savings Program to encourage small, rural, safety-net providers to form ACOs or to join larger, more urban practices to share resources,

[302] See § 425.600(a)(4)(i)(B)(*2*)(*i*)–(*ii*) for provisions on automatic advancement along the BASIC track's glide path. Note, ACOs with an agreement period beginning on July 1, 2019 could participate under a one-sided model for up to 3 performance years under the exception to automatic advancement along the BASIC track's glide path in accordance with § 425.600(a)(4)(i)(B)(*2*)(*i*), or for four performance years under the exception for eligible low revenue ACOs in accordance with § 425.600(a)(4)(i)(B)(*2*)(*ii*).

[303] The PHE for COVID–19 was in effect starting in January 2020, and ongoing at the time of the CY 2023 PFS rulemaking during 2022, and expired on May 11, 2023. See for example, U.S. Department of Health and Human Services website, COVID–19 Public Health Emergency webpage, available at *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

which among other factors could help provide high need beneficiaries served by small, rural, safety-net providers with the resources to better coordinate their care and improve outcomes. See 87 FR 69809; see also 87 FR 69813.

Recently, CMS has announced a vision to Make America Healthy Again.[304] Relatedly, the Innovation Center announced a strategy to focus on testing models that transform the U.S. health system into one that builds healthier lives through prevention, individual empowerment, and choice and competition, under which people achieve their health goals and the providers caring for them are directly accountable for their health outcomes and the costs of their care.[305] This strategy includes, among other objectives for protecting Federal taxpayers, to require all models to have downside financial risk and require providers to assume some of the financial risk. Similarly, with the Shared Savings Program, we are examining approaches to encourage ACO participation under two-sided models.

In light of CMS' current vision and strategic direction, we are revisiting Shared Savings Program policies on the amount of time an ACO can remain under a one-sided model, and the progression to performance-based risk, and in particular the current policy that allows ACOs to participate for up to 7 performance years under a one-sided model. Specifically, we are considering the effectiveness of the current requirements for determining an ACO's participation options, finalized with the December 2018 final rule, and modified through subsequent rulemaking, including the CY 2023 PFS final rule, as summarized elsewhere in this section of this proposed rule, in achieving a balance between encouraging transition to two-sided risk and a concern that requiring ACOs to take on too much downside risk too quickly may disincentivize program participation. In the following discussion, we describe more recent trends in ACO participation in the Shared Savings Program (including as a result of changes to program requirements through rulemaking) and ACO financial performance, which inform our consideration of our current policies on ACOs' progression to performance-based risk under the Shared Savings Program. This discussion focuses on Shared Savings Program participation trends in general between PY 2018 and PY 2025; participation trends among new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives, and ACOs serving medically complex, high-cost populations, for which we have finalized policies to facilitate program participation through CY 2023, 2024, and 2025 PFS rulemaking; our experience with the timing of ACO progression to performance-based risk under participation options that allow an eligible ACO to participate for up to 7 performance years under a one-sided model; and financial performance trends for recent performance years, among ACOs transitioning from one-sided to two-sided levels of the BASIC track, or remaining under the BASIC track's two-sided model levels.

The redesign of participation options with the December 2018 final rule greatly increased ACO participation in two-sided models.[306] For PY 2018, 82 percent of ACOs were participating under a one-sided model, and 18 percent of ACOs were participating under a two-sided model.[307] For PY 2025, 29 percent of ACOs are participating under a one-sided model, and 71 percent of ACOs are participating under a two-sided model.[308] With respect to recent trends, Table 47 shows the number of ACOs participating in the BASIC track (by Level) and ENHANCED track for PYs 2022 through 2025.[309] As shown in Table 47, participation in one-sided models is lower in PY 2025 (29 percent of ACOs) compared to PY 2022 (41 percent of ACOs), and PY 2023 and PY 2024 (33 percent of ACOs for each PY). Further, from program participation for PYs 2022 through 2025, we have observed that when ACOs participate under two-sided risk they opt for higher levels of risk and reward. Very few ACOs are participating under Levels C or D of the BASIC track's glide path, compared to participation in Level E of the BASIC track or the ENHANCED track. Among ACOs participating under two-sided risk, more ACOs are participating under the highest level of risk and potential reward offered by the ENHANCED track than in Levels C, D and E of the BASIC track combined.

[304] See CMS Press Release, ''Dr. Mehmet Oz Shares Vision for CMS'', April 10, 2025, available at *https://www.cms.gov/newsroom/press-releases/dr-mehmet-oz-shares-vision-cms* (explaining CMS will work to modernize Medicare, the Marketplaces and Medicaid, so Americans get the care that they want, need, and deserve, including by holding healthcare providers accountable for health outcomes).

[305] See Sutton, Abe, White Paper ''CMS Innovation Center Strategy to Make America Healthy Again'', May 13, 2025, available at *https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again*.

[306] For data on ACO participation in the Shared Savings Program by track/level and performance year, see Shared Savings Program ''Fast Facts'' available through the Medicare Shared Savings Program website, Program Data webpage at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/data* (including the ''Fast Facts Archives'' (zip file), available at *https://www.cms.gov/media/638196*). See also, Data.CMS.gov, Medicare Shared Savings Program, Accountable Care Organizations, Public Use File (by performance year), available at *https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations*. We note that some observations described in this section of this proposed rule, particularly for PY 2025 data, are based on internal analysis.

[307] See ''Medicare Shared Savings Program Fast Facts (January 2018)'', within ''Fast Facts Archives'', available at *https://www.cms.gov/media/638196*.

[308] See ''Shared Savings Program Fast Facts—As of January 1, 2025'', available at *https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf*.

[309] See ''Shared Savings Program Fast Facts—As of January 1, 2025'', available at *https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf*. See also, ''Shared Savings Program Fast Facts—As of January 1, 2022,'' ''Shared Savings Program Fast Facts—As of January 1, 2023,'' and ''Shared Savings Program Fast Facts—As of January 1, 2024'', within ''Fast Facts Archives'', available at *https://www.cms.gov/media/638196*.

TABLE 47: COUNT OF ACOs PARTICIPATING IN BASIC TRACK LEVELS AND ENHANCED TRACK FOR PYs 2022 THROUGH 2025

Performance Year	Total	BASIC Track			ENHANCED track
		Levels A and B	Levels C and D	Level E	
PY 2022	483	199 (41%)	40 (8%)	98 (21%)	146 (30%)
PY 2023	456	151 (33%)	19 (4%)	125 (28%)	161 (35%)
PY 2024	480	159 (33%)	10 (2%)	104 (22%)	207 (43%)
PY 2025	477	137 (29%)	5 (1%)	81 (17%)	254 (53%)

Shared Savings Program participation with the two most recent start dates shows that nearly one-half of new ACOs are entering a one-sided model of the BASIC track, while the vast majority of ACOs continuing their participation in the program are participating under a two-sided model. Among the 140 ACOs entering a new agreement period for the January 1, 2024 start date, 51.6 percent (or 31 of 60) of ACOs participating in their first agreement period entered the BASIC track at Level A, while 2.5 percent (or 2 of 80) of ACOs participating in their second or subsequent agreement period entered the BASIC track at Level A. Among the 229 ACOs entering a new agreement period for the January 1, 2025 start date, 45.9 percent (or 17 of 37) of ACOs participating in their first agreement period entered the BASIC track at Level A or B, while 17.7 percent (or 34 of 192) of ACOs participating in their second or subsequent agreement period entered the BASIC track at Level A.

We have gained experience with ACOs' participation under changes to the Shared Savings Program policies more recently finalized with CY 2023, 2024 and 2025 PFS rulemakings, which include policies to encourage participation by new, low revenue ACOs, such as through the availability of a payment option for eligible ACOs to receive advance investment payments, and ACOs serving medically complex, high-cost patient populations, such as through changes to the program's benchmarking methodology. Our initial experience with ACOs entering agreement periods beginning on January 1, 2024 and January 1, 2025, offers insight into participation among such ACOs.

For agreement periods beginning on January 1, 2024, and subsequent years, eligible new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives may receive advance shared savings payments in the form of advance investment payments designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program (see 87 FR 69782 through 69806). To be eligible to receive advance investment payments for the first two performance years of the ACO's agreement period, the ACO must enter the program under BASIC track Level A and remain under a one-sided model level of the BASIC track's glide path (Level A or B) for its second performance year, among other requirements specified at § 425.630(b). Among the new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives recently entering a first agreement period in the Shared Savings Program under a one-sided model, 19 of 21 of these new, low revenue ACOs inexperienced with performance-based risk entering an agreement period beginning on January 1, 2024 opted to receive advance investment payments for at least one performance year, while 10 of 12 of these new, low revenue ACOs inexperienced with performance-based risk entering an agreement period beginning on January 1, 2025 are receiving advance investment payments for PY 2025.[310]

Further, through recent rulemaking, we have refined the Shared Savings Program's financial benchmarking methodology to support participation by ACOs serving medically complex, high-cost populations. For instance, with the CY 2025 PFS final rule (89 FR 98155 through 98166), we established an approach applicable for agreement periods beginning on January 1, 2025, and in subsequent years, under which we adjust an ACO's historical benchmark based on the highest of three positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or health equity benchmark adjustment, in accordance with § 425.652(a)(8)(ii). As we explained in the CY 2025 PFS final rule (see 89 FR 98157), the health equity benchmark adjustment (HEBA), was designed to encourage new participation from ACOs serving medically complex, high-cost populations that are receiving lower regional adjustments or lower prior savings adjustments, or receiving neither adjustment. As described in the CY 2025 PFS final rule (89 FR 98523 through 98524), increased program participation by these ACOs as a result of these benchmark changes are expected to generate $260 million greater net savings for Medicare over 10 years.

Based on early experience with program participation for the January 1, 2025 agreement period start date, the HEBA (as proposed to be renamed the ''population adjustment'' as described in section III. F.8 of this proposed rule) is anticipated to provide an upward adjustment to ACO historical benchmarks for 33 of 229 ACOs that began a new agreement period for the 2025 start date (which includes new, renewing and re-entering ACOs and is approximately 14 percent of ACOs beginning a new agreement period with a January 1, 2025 start date). From an internal analysis of PY 2025 preliminary benchmarks for ACOs entering an agreement period beginning on January 1, 2025, we estimate that among the 33 ACOs that are anticipated to receive a HEBA to their historical benchmark, 13 are new ACOs participating in their first agreement period and would otherwise not have received a positive adjustment to the benchmark, 7 are in a one-sided model, and 6 are in a two-sided model. While we are still gaining experience with the impact of the HEBA on ACO benchmarks and ACO participation, these early findings suggest that the HEBA may incentivize participation in the Shared Savings Program from ACOs serving high spending and high risk populations, including encouraging participation in two-sided models.

More generally, we considered participation trends among ACOs that are higher spending compared to their

[310] See Medicare Shared Savings Program, Accountable Care Organizations, Public Use Files, for PY 2024 and PY 2025, available at *https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations*. We note that one ACO that began receiving advance investment payments in PY 2024 is no longer receiving these payments in PY 2025.

regional service area, which would have a negative regional adjustment value, and ACOs with lower spending compared to their regional service area, which would have a positive regional adjustment value (see §§ 425.601(f)(5) and 425.656(e)(5)). Based on internal analysis, among both groups of ACOs—higher spending or lower spending compared to their regional service area—entering the program for an initial agreement period with the 2022, 2023, 2024 or 2025 start date,[311] either an equal number of ACOs, or more ACOs, entered two-sided models compared to one-sided models. We also observe that the number of ACOs with higher spending compared to their regional service area that are entering the program for an initial agreement period has generally increased with recent start dates, with 6 of such ACOs entering in 2022, 9 of such ACOs entering in 2023, 16 of such ACOs entering in 2024, and approximately 14 of such ACOs entering in 2025. These trends suggest that the policies adopted in CY 2023, 2024, and 2025 PFS rulemaking cycles, applicable for the January 1, 2024 and January 1, 2025 start dates, are encouraging participation from ACOs serving high spending and high risk populations. As a more general consideration, we continue to recognize there are ACOs that may need time to gain experience with the Shared Savings Program by participating in a one-sided model prior to transitioning to two-sided risk, which may be indicated by entry of some higher spending ACOs in the Shared Savings Program under a one-sided model for their first agreement period.

Additionally, the experience of new ACOs entering the program with July 1, 2019 or January 1, 2020 agreement period start dates provides insight into participation options in which ACOs are allowed to participate for a first agreement period in the BASIC track's glide path under a one-sided model and renew their participation agreements to continue their participation in the glide path.[312] We analyzed program participation by ACOs that entered a first agreement period beginning on July 1, 2019 or January 1, 2020,[313] and renewed to continue their participation in the Shared Savings Program for a second or subsequent agreement period, for trends in whether ACOs have chosen to enter and remain in a one-sided model (if eligible) or progress to performance-based risk. For July 1, 2019 starters, our observations span a period of 7 performance years (the 6-month performance year from July 1, 2019 through December 31, 2024, and PYs 2020 through 2025). For 2020 starters, our observations span a period of 6 performance years (PYs 2020 through 2025). As shown in Table 48, many ACOs appear prepared to participate under two-sided risk after 5 or fewer years under a one-sided model. Approximately 16 percent (or 4 of 25) of July 1, 2019 starters, and 10.5 percent (or 2 of 19) of 2020 starters chose to enter and remain under one-sided for their first agreement period and upon renewal in a second agreement period of the BASIC track's glide path, while the vast majority of ACOs elected to participate under performance-based risk either during their first agreement period or upon renewal.

TABLE 48: Participation as of PY 2025 for ACOs that Entered a First Agreement Period Beginning on either July 1, 2019 or January 1, 2020 and Renewed to Continue Participation in the Shared Savings Program

Track / Level for ACO's First Agreement Period and as of PY 2025	New ACOs for 7/1/2019 Start Date	New ACOs for 1/1/2020 Start Date
Participated in one-sided model of the BASIC track for 1st agreement period; entered 2nd agreement period in the BASIC track's glide path at Level A	4 (16.0%)	2 (10.5%)
Participated in one-sided model of the BASIC track for 1st agreement period; entered 2nd agreement period under two-sided risk at renewal	9 (36.0%)	9 (47.4%)
Entered a one-sided model of the BASIC track at the start of its 1st agreement period and progressed to a two-sided model of the BASIC track during 1st agreement period	6 (24.0%)	2 (10.5%)
Participated in two-sided model for 1st agreement period; continued participation in two-sided model for 2nd agreement period	6 (24.0%)	6 (31.6%)
Total	25 (100%)	19 (100%)

Note: The total number of ACOs excludes ACOs with a participation agreement effective termination date prior to January 1, 2025: 19 ACOs with a July 1, 2019 start date of which 13 ACOs were participating in a one-sided model; and 17 ACOs with a 2020 start date of which 10 ACOs were participating under a one-sided model.

As described in the Regulatory Impact Analysis, section VII. of this proposed rule, we analyzed financial performance of groups of ACOs that participated in both PYs 2022 and 2023. Cohorts were assembled based on the track/level of participation of the ACOs in PY 2022 and PY 2023. This analysis shows the highest rates of average net savings among the following groups: (1) ACOs remaining in two-sided models of the BASIC track (Levels C, D or E) over the

[311] Based on analysis of preliminary benchmark data among ACOs entering an initial agreement period with a 2025 start date.

[312] Eligible ACOs that participated under the BASIC track's glide path for an agreement period beginning on July 1, 2019 or January 1, 2020, and entered in Level A or Level B, were allowed to elect to continue their participation in a one-sided model for the duration of their agreement period, as a result of a series of policy changes. See § 425.600(a)(4)(i)(B)(*1*), (a)(4)(i)(B)(*2*)(*i*), (a)(4)(i)(B)(*2*)(*iii*)–(*iv*) and (a)(4)(i)(B)(*2*)(*vi*). If eligible, these ACOs could enter a second agreement period under the BASIC track's glide path in accordance with § 425.600(g)(1).

[313] The agreement period from July 1, 2019 through December 31, 2024 spanned 5 years and 6 months, across 6 performance years, in accordance with § 425.200(b)(4)(ii) and (c)(3). The agreement period from January 1, 2020 through December 31, 2024 spanned 5 years, in accordance with § 425.200(b)(5).

2-year period; and (2) ACOs moving from a one-sided model of the BASIC track (Level A or B) to a two-sided model of the BASIC track (Level C, D or E) over PY 2022 to PY 2023. These cohorts also demonstrated the lowest average unadjusted per capita spending growth rates over this 2-year period. These findings suggest that ACOs transitioning to or remaining in two-sided model levels of the BASIC track outperform ACOs remaining in one-sided models of the BASIC track.

To follow is a summary of the key points from our observations previously described in this section of this proposed rule. Based on early experience with ACO participation under policies applicable with agreement periods beginning on January 1, 2024, or January 1, 2025, and subsequent years, the option for ACOs to enter a one-sided model for a first agreement period in the BASIC track appears to be an important pathway for attracting new ACOs to enter the Shared Savings Program, including new, low revenue ACOs, particularly in combination with the option to receive advance investment payments, and ACOs serving higher spending populations, particularly in combination with the benchmarking methodology applicable for agreement periods beginning on January 1, 2025, and subsequent years, under which an ACO may receive an upward adjustment to its benchmark through the application of the HEBA. From participation trends of ACOs entering the Shared Savings Program for a first agreement period beginning on July 1, 2019 or January 1, 2020, few ACOs choose to remain under a one-sided model beyond an initial agreement period under the BASIC track's glide path, and many more ACOs were prepared to participate under a two-sided model either during their first agreement period or upon renewal. Further, based on participation data from PYs 2022 through 2025, ACOs are tending to enter the program's two-sided models under the highest levels of risk and potential reward, under Level E of the BASIC track or the ENHANCED track. Additionally, ACOs transitioning from one-sided to two-sided levels of the BASIC track, or remaining under the BASIC track's two-sided model levels, are anticipated to generate higher levels of average net savings compared to ACOs that remain in a one-sided model of the BASIC track, based on internal analysis of PY 2022 and PY 2023 financial performance.

c. Proposal To Limit Participation in a One-Sided Model to an ACO's First Agreement Period Under the BASIC Track's Glide Path

We believe that an approach under which we limit the amount of time an ACO can remain under a one-sided model of the Shared Savings Program and thereby encourage ACOs to transition to performance-based risk, would be aligned with our current strategic direction, as part of achieving CMS' vision to Make America Healthy Again. In light of the previously described findings from our experience with ACOs' participation in the Shared Savings Program under agreement periods beginning on or after July 1, 2019 through January 1, 2025 (discussed in section III.F.2.b of this proposed rule), we believe that allowing eligible ACOs inexperienced with performance-based risk Medicare ACO initiatives to participate for a 5-year agreement period under the BASIC track's glide path, in which they could elect to remain under a one-sided model for 5 years, remains an important option to attract participation by ACOs that may need to gain experience with the accountable care model and invest in infrastructure and redesigned care processes for high quality and efficient healthcare service delivery before transitioning to performance-based risk. In particular, we continue to believe that this participation option serves as an important pathway for program entry and participation by eligible new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives, particularly in combination with the option to receive advance investment payments, and by eligible ACOs serving medically complex, high-cost populations, in combination with the program's current benchmarking methodology. We also believe that this participation option would remain important for attracting small, rural, safety-net providers to join or form ACOs.

However, as a departure from our position as described in CY 2023 PFS rulemaking, we are concerned that the current participation option permitting eligible ACOs to extend participation under the BASIC track's glide path to a second agreement period, in which they can participate under a one-sided model for the first two performance years (thereby allowing eligible ACOs to remain under a one-sided model for up to 7 performance years) prior to progressing to two-sided risk, may weaken the incentives for ACOs to transition to two-sided risk, and for ACOs to make more meaningful changes to healthcare delivery during their first 5-year agreement period, or at the start of their second agreement period. Based on our experience with participation by ACOs that entered a first agreement period beginning on July 1, 2019 or January 1, 2020, and renewed to continue their participation in the Shared Savings Program for a second or subsequent agreement (as described in section III.F.2.b of this proposed rule), ACOs tend to accept performance-based risk by their sixth performance year in the program, suggesting that one 5-year agreement period under a one-sided model would be sufficient for eligible ACOs to gain experience with the Shared Savings Program prior to accepting performance-based risk. Permitting ACOs to participate for longer periods under a one-sided model could impede CMS' achievement of the Shared Savings Program's goals. Alternatively, disallowing a second agreement period under the BASIC track's glide path, thereby requiring an ACO to enter Level E or the ENHANCED track by their second agreement period, would create greater incentives for ACOs to make the most meaningful changes in healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population.

Therefore, we propose to use our authority under section 1899(i)(3) of the Act to limit the amount of time an ACO may participate in the Shared Savings Program under a one-sided model, and require ACOs to more rapidly progress to higher levels of risk and potential reward under a two-sided model. We propose that for agreement periods beginning on or after January 1, 2027, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives entering the BASIC track's glide path at Level A may continue to elect to remain under a one-sided model for all subsequent performance years of its first 5-year agreement period. However, we propose such an ACO must enter its second or subsequent agreement period under Level E of the BASIC track or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track under the proposals at section III.F.4.b.(2).(b) of this proposed rule). In so doing, this proposal limits the amount of time an ACO can participate under the BASIC track's glide path to one agreement period, and also limits the amount of time under a one-sided model to, at most, 5 performance years.

We believe this proposed approach strikes a balance between (1) policies that support growth of the Shared Savings Program by allowing for participation under a one-sided model for up to the entirety of an eligible ACO's first agreement period, and (2) policies encouraging participation in performance-based risk which we believe have the potential for increased effectiveness towards meeting the program's goals. This proposed approach retains an option for ACOs inexperienced with performance-based risk Medicare ACO initiatives, and that have no prior participation in the Shared Savings Program, to participate for their first agreement period under the BASIC track's glide path, with the option for ACOs to elect to remain under a one-sided model for this 5-year agreement period, or to advance along the glide path to higher levels of risk and potential reward. We recognize that commenters in earlier rulemaking have made various suggestions for the amount of time an ACO should be allowed to remain under a one-sided model, including 4 or 5 performance years or a full agreement period (as described in section III.F.2.b of this proposed rule). See 87 FR 69806 through 69807; see also 83 FR 67847. We prefer an approach that continues to allow eligible ACOs to participate for up to 5 performance years (the duration of such ACOs' first 5-year agreement period) under a one-sided model, which we believe is effective in attracting new ACOs to enter the Shared Savings Program, based on our analysis of participation trends, as we describe in section III.F.2.b of this proposed rule. Additionally, using an approach that leverages the existing structure of the regulations for how we identify participation options for an ACO inexperienced with performance-based risk Medicare ACO initiatives entering a first agreement period reduces complexity in the program's policies, thereby facilitating ACOs' ability to ascertain the available participation options and allowing CMS to more readily implement the proposed approach to determining ACO eligibility for participation options. This proposed approach would also encourage ACOs inexperienced with performance-based risk Medicare ACO initiatives participating in the BASIC track's glide path for a first agreement period to prepare to take on two-sided risk no later than the start of their next 5-year agreement period in the Shared Savings Program, and thereby more quickly make meaningful changes to healthcare delivery, than the current approach.

To create the most meaningful incentive to change healthcare delivery and based on our experience with ACOs' selection of participation options, we believe it is appropriate to require ACOs to transition to participation in Level E of the BASIC track or the ENHANCED track after no more than 1 agreement period under the BASIC track's glide path, which could include up to 5 performance years of participation under a one-sided model (for eligible ACOs). A number of factors informed our consideration of this approach. For one, under the benchmarking methodology applicable to agreement periods beginning on January 1, 2025, and in subsequent years, in accordance with § 425.652(a)(8)(ii), we adjust an ACO's historical benchmark based on the highest of three positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or HEBA. This approach to upwardly adjusting the benchmark could bolster the value of the rebased benchmark, calculated at § 425.652(c), for the ACO's second and subsequent agreement period. The potential upward adjustment to an ACO's benchmark through a regional adjustment, prior savings adjustment or HEBA, in combination with other policies under the existing financial methodology specified in subpart G, could help ensure there is sufficient incentive for ACOs to continue to participate in the program under higher levels of risk and potential reward.

Additionally, although we recognize participation in Level C and Level D may serve as a means for some ACOs to gain experience with performance-based risk, we believe the relatively low interest in participation in these financial models suggests it would be sufficient to only allow for participation in these lower levels of risk within the ACO's first agreement period under the BASIC track's glide path. As discussed in section III.F.2.b of this proposed rule, in recent performance years (PY 2023 through 2025) there has been limited and declining participation in Level C and Level D of the BASIC track's glide path. Further, as we have observed based on more recent participation trends, once ACOs progress to performance-based risk, most ACOs do so by participating under Level E of the BASIC track, or the ENHANCED track. We believe that limiting additional participation in Levels C and D of the BASIC track to an ACO's first and only agreement period in the glide path (if eligible) will support our programmatic goals by facilitating ACOs' transition to two-sided models under which they have greater potential for risk and reward, and make more meaningful changes to healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population.

We propose to specify related requirements in amendments to the Shared Savings Program regulations at § 425.600 and propose technical and conforming changes elsewhere within § 425.600 and at § 425.605. We propose to amend § 425.600(g) introductory text, to limit the applicability of the requirements in this paragraph for determining an ACO's eligibility for the Shared Savings Program participation options to agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

At § 425.600, we propose to redesignate paragraph (h) as paragraph (i), and propose to add a new paragraph (h) that specifies the requirements CMS would use to determine an ACO's eligibility for Shared Savings Program participation options for agreement periods beginning on or after January 1, 2027, as described in further detail in the discussion that follows. Additionally, as we describe in section III.F.4.b.(2).(b) and in greater detail in the discussion that follows, § 425.600(h)(3) would include a limited proposed exception for participation in the ENHANCED track by ACOs with less than 5,000 assigned beneficiaries in certain benchmark years. This limited proposed exception reflects our proposal that for agreement periods beginning on or after January 1, 2027, an ACO with fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both may only enter the BASIC track.

We propose to specify in new § 425.600(h)(1) how CMS determines an ACO's eligibility for participation options, for agreement periods beginning on or after January 1, 2027, if an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20). We propose to specify at § 425.600(h)(1) introductory text that if an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E, or the ENHANCED track, subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track specified in new § 425.600(h)(3)

(described in section III.F.4.b.(2).(b) of this proposed rule).

We propose to specify under new § 425.600(h)(1)(i) that, for agreement periods beginning on or after January 1, 2027, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of one agreement period, and for which the progression along the glide path is specified at § 425.600(a)(4)(i)(C). We propose to specify under new § 425.600(h)(1)(ii) that an ACO that enters an agreement period under the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E, would be deemed to have completed one agreement period under the BASIC track's glide path. For the purpose of determining the ACO's prior participation in the BASIC track's glide path, we would consider whether the ACO satisfies either of the following: (A) the ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path; or (B) for a new ACO identified as a re-entering ACO (as defined at § 425.20), the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path.

We propose to specify under new § 425.600(h)(1)(iii) that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but which is not eligible to enter the BASIC track's glide path, in accordance with the provisions of § 425.600(h)(1), may enter BASIC track Level E for all performance years of the agreement period, or the ENHANCED track, subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track specified in new § 425.600(h)(3) (described in section III.F.4.b.(2).(b) of this proposed rule).

We would adopt an approach similar to our existing requirements for determining the participation options of an ACO that is experienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20). We propose to specify in new § 425.600(h)(2), for agreement periods beginning on or after January 1, 2027, if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track, subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track specified in new § 425.600(h)(3) (described in section III.F.4.b.(2).(b) of this proposed rule).

Additionally, as discussed in section III.F.4 of this proposed rule, we propose at § 425.600(h)(3) to require, for agreement periods beginning on or after January 1, 2027, that if an ACO is determined to have fewer than 5,000 assigned beneficiaries in either the first benchmark year, second benchmark year, or both, in accordance with § 425.110(a)(3), the ACO may only enter the BASIC track. Under this approach, an ACO prohibited from participating in the ENHANCED track because it has fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, may enter an agreement period beginning on or after January 1, 2027, in the BASIC track, at a level of risk and potential reward otherwise determined in accordance with the proposed requirements of new § 425.600(h), as follows:

- An ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives may enter the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E (if eligible in accordance with the proposed requirements at new § 425.600(h)(1)), or BASIC track Level E for all performance years of the agreement period.
- An ACO determined to be experienced with performance-based risk Medicare ACO initiatives may enter BASIC track Level E for all performance years of the agreement period.

We are proposing to apply this modified approach in determining ACOs' participation options for agreement periods beginning on or after January 1, 2027, since the application cycle for the January 1, 2027 start date (anticipated to occur in CY 2026) would be the next cycle following the anticipated effective date for the CY 2026 PFS final rule of January 1, 2026. The majority of the application cycle for the January 1, 2026 start date, spanning Spring—Fall 2025, will occur before this rule is finalized.

The criteria CMS used to determine an ACO's eligibility to enter an agreement period, at § 425.600(g), that were applied in determining participation options for ACOs entering an agreement period beginning on January 1, 2024 or January 1, 2025, would also be applied in determining participation options for ACOs entering an agreement period beginning on January 1, 2026. If finalized, the proposed criteria to determine an ACO's eligibility to enter an agreement period, specified under new § 425.600(h), would be applied in determining participation options for ACOs entering an agreement period beginning on or after January 1, 2027. That is, we would apply the modified approach (if finalized) consistently across new ACO applicants, renewing ACOs (as defined at § 425.20) and re-entering ACOs (as defined at § 425.20) in determining ACO participation options for agreement periods beginning on or after January 1, 2027.

We recognize that with the changes in the program's policies over time, there are currently ACOs participating in agreement periods, to which different requirements apply for determining the ACO's participation options, in accordance with § 425.600. This proposed approach would change how we determine an ACO's eligibility for Shared Savings Program participation options, program-wide. If we finalize the proposed approach, ACOs currently participating in a first agreement period under the BASIC track's glide path (with 2022, 2023, 2024, and 2025 start dates) and ACOs entering a first agreement period in the BASIC track's glide path with the January 1, 2026 start date, would be ineligible to enter a subsequent agreement period under the BASIC track's glide path, with a start date on or after January 1, 2027. Instead, such ACOs, should they continue their participation in the Shared Savings Program for a second or subsequent agreement period, would be limited to participation in Level E of the BASIC track or the ENHANCED track (subject to the exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track). Based on the number of ACOs currently participating in a first agreement period under a one-sided model of the BASIC track's glide path, we anticipate the proposed approach could limit participation in a one-sided model to a maximum of 5 performance years (instead of 7 performance years) for 57 ACOs currently participating in Level A of the BASIC track (7 2022 starters, 7 2023 starters, 26 2024 starters, and 17 2025 starters).[314] At the time of this proposed rule, the number of eligible 2026 starters

[314] Total count of ACOs participating in Level A of the BASIC track, among ACOs entering a first agreement period in the Shared Savings Program by start date, as of performance year 2025. See *Data.CMS.gov,* Medicare Shared Savings Program, Accountable Care Organizations, Public Use File (by performance year, for PY 2025), available at *https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations.*

that may enter the BASIC track's glide path at Level A is yet to be determined.

We acknowledge that ACOs currently participating in Level A of the BASIC track may have joined or remained in the Shared Savings Program relying on the availability of participation options established with the CY 2023 PFS final rule. We further acknowledge that the proposed modifications to limit participation in the BASIC track's glide path and the amount of time an ACO may remain under a one-sided model, if finalized, may alter the ACOs' incentives to remain in the Shared Savings Program. As discussed in the Regulatory Impact Analysis, in section VII of this proposed rule, we project that discontinuing the option for ACOs to participate under a second agreement period in the BASIC track's glide path may create potential uncertainty for some ACOs on continuing in the program. We further explain that, notwithstanding this uncertainty for some ACOs, the proposed changes have the potential to improve care management and increase savings from other ACOs that successfully manage the transition to performance-based risk earlier than they would have. At this juncture, we do not find the concern about the potential attrition by ACOs unwilling to transition to performance-based risk a compelling reason to forgo the proposed changes to the Shared Savings Program's participation options. As we have explained elsewhere in this section of this proposed rule, we believe the program's benchmarking methodology includes sufficient incentive for ACOs to continue to participate in the program. Additionally, based on trends in program participation, we anticipate that at least some of the ACOs currently participating under Level A of the BASIC track may elect to transition to a two-sided model level of the BASIC track during the remaining performance years of their current agreement period or would transition to a two-sided risk model at the beginning of their next agreement period notwithstanding the proposed change. More generally, we believe the concern about potential for loss of participation by ACOs unwilling to progress to two-sided risk with their second agreement period is balanced against, and outweighed by, the potential for increased effectiveness from other ACOs that continue to participate and successfully manage an earlier transition to performance-based risk, and establishing a policy that we believe will further advance the program's goals.

To follow are several examples, to illustrate how the proposed policies for determining ACO participation options would apply. Take for example a new ACO inexperienced with performance-based risk Medicare ACO initiatives that enters the BASIC track's glide path at Level A for an agreement period beginning on January 1, 2027, and concluding December 31, 2031, based on the criteria used to determine ACO participation options specified under new § 425.600(h) (as proposed). Under this example, the ACO would be able to elect to remain under Level A for all subsequent performance years of its agreement period (performance years 2028 through 2031) in accordance with § 425.600(a)(4)(i)(C)(*3*). Assume for this example the ACO chooses to remain under Level A for the duration of its first agreement period, and applies to renew to continue its participation in the Shared Savings Program for a new agreement period beginning on January 1, 2032. Under the proposed approach, the ACO would be considered inexperienced with performance-based risk Medicare ACO initiatives, and would be identified by CMS as having previously entered an agreement period under the BASIC track's glide path and deemed to have completed one agreement period under the BASIC track's glide path. As a result, the ACO would be ineligible to enter the BASIC track's glide path and would be limited to participating under Level E of the BASIC track, or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track) for its second agreement period beginning on January 1, 2032, or a subsequent agreement period.

As another example, consider a new ACO inexperienced with performance-based risk Medicare ACO initiatives that enters the BASIC track's glide path at Level A for an agreement period beginning on January 1, 2026, based on the criteria used to determine ACO participation options specified at § 425.600(g). Under this example, the ACO elects to remain under Level A for all subsequent performance years of its agreement period in accordance with § 425.600(a)(4)(i)(C)(*3*). If the ACO applies to renew to continue its participation in the Shared Savings Program for a new agreement period, beginning on January 1, 2031, under the proposed approach, the ACO would be considered inexperienced with performance-based risk Medicare ACO initiatives, and would be identified by CMS as having previously entered an agreement period under the BASIC track's glide path and deemed to have completed one agreement period under the BASIC track's glide path. As a result, the ACO would be ineligible to enter the BASIC track's glide path and would be limited to participating under Level E of the BASIC track, or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track) for its second agreement period beginning on January 1, 2032, or a subsequent agreement period. Similarly situated ACOs that entered an agreement period beginning on January 1, 2022, January 1, 2023, January 1, 2024, or January 1, 2025 that elected to remain under a one-sided model of the BASIC track's glide path for the duration of their 5-year agreement period, and are applying to renew to continue their participation in the program for a new agreement period, would have the same participation options as the ACO in this example.

We are proposing to use our authority under section 1899(i)(3) of the Act to change the requirements for ACOs' progression to performance-based risk under the program's participation options. To adopt requirements in connection with participation under a two-sided model of the Shared Savings Program under section 1899(i)(3) of the Act, we must determine that doing so will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. As we have discussed in earlier rulemaking, in connection with the use of this authority for establishing the program's participation options (see 76 FR 67904 through 67909, 80 FR 32771 and 32772, 83 FR 67834 through 67841), the program's two-sided models provide an additional opportunity for ACOs to enter a risk-sharing arrangement and accept greater responsibility for beneficiary care. Under the proposed approach we would modify the Shared Savings Program participation options to reduce the maximum amount of time an ACO may participate under the BASIC track's glide path from two agreement periods to one agreement period, thereby limiting the amount of time an ACO may remain under a one-sided model to at most 5 performance years. We would also require ACOs inexperienced with performance-based risk Medicare ACO initiatives to progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track, compared to the current requirements. Under the

proposed approach, ACOs entering and continuing their participation in the Shared Savings Program would continue working towards meeting the program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries. As we have described elsewhere in this section of this proposed rule, we believe that requiring ACOs to more quickly progress to performance-based risk would create incentives for ACOs to make more meaningful changes to healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population. As discussed in the Regulatory Impact Analysis, in section VII of this proposed rule, we project that the proposed changes in participation options, in combination with other proposed changes to the statutory payment model in this proposed rule, as well as current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program, and would not be expected to increase program expenditures relative to those of the statutory payment model.

We will continue to reexamine this projection to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

Additionally, we propose to make the following technical and conforming changes, for completeness and clarity, to reflect our proposals to redesignate existing § 425.600(h) as paragraph (i), and to specify in a newly added paragraph (h) of § 425.600 the requirements for determining an ACO's eligibility for Shared Savings Program participation options for agreement periods beginning on or after January 1, 2027.

- Amending a cross-reference within § 425.600(a)(4)(i)(C)(*1*) to include a reference to proposed new paragraph (h)(1) at § 425.600.
- Amending cross-references within § 425.600(a)(4)(ii) and § 425.605(d)(1) introductory text to include a reference to proposed new paragraph (h) at § 425.600.
- Amending cross-references within § 425.600(a)(4)(i)(C)(*2*)(*iii*) and § 425.605(b)(2)(ii)(E) to refer to provisions within proposed newly redesignated paragraph (i) at § 425.600 instead of existing paragraph (h).
- Revising § 425.605(d)(2), describing the level of risk and reward specified for Level E of the BASIC track. Currently this paragraph specifies Level E risk and reward at § 425.605(d)(1)(v) applies to an ACO eligible to enter the BASIC track that is determined to be experienced with performance-based risk Medicare ACO initiatives as specified at § 425.600(d) or § 425.600(g). We propose to amend this provision for greater consistency with the proposed approach to determining participation options described in this section of this proposed rule and new § 425.600(h)(1)(iii) and (h)(2), under which for agreement periods beginning on or after January 1, 2027, an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives that is not eligible to enter the BASIC track's glide path, or an ACO that is determined to be experienced with performance-based risk Medicare ACO initiatives may enter either the BASIC track Level E for all performance years of the agreement period (among other participation options). Therefore, we propose to revise § 425.605(d)(2) to state more generally: if the ACO enters the BASIC track at Level E as specified at § 425.600(d), (g), or (h), the level of risk and reward specified at § 425.605(d)(1)(v) applies to all performance years of an ACO's agreement period.

We seek comment on the proposed changes to the requirements for determining an ACO's eligibility for Shared Savings Program participation options, for agreement periods beginning on or after January 1, 2027. We seek comment on the proposal to limit the amount of time an ACO can participate under the BASIC track's glide path to one agreement period, and thereby to limit the amount of time an ACO (if eligible) can participate under a one-sided model to, at most, 5 performance years instead of 7 performance years. We also welcome comments on requiring ACOs that are determined to be inexperienced with performance-based risk Medicare ACO initiatives, and identified by CMS as having previously entered an agreement period under the BASIC track's glide path, to progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track), thereby limiting ACOs' participation in lower levels of risk and potential reward to their first and only agreement period under the BASIC track's glide path.

3. Eligibility Requirements

a. ACO Participant Change of Ownership (CHOW) Scenarios

(1) Background

In the June 2015 final rule (80 FR 32707 through 32712), we added § 425.118(a) and (b) to establish requirements for maintaining, updating, and submitting to CMS an accurate and complete ACO participant list.

Section 425.118(a) includes requirements for ACOs to submit and certify their ACO participant lists before the start of each agreement period and each performance year thereafter, as well as at other times. Section 425.118(b)(1) and (2) authorize ACOs to make additions or deletions to their ACO participant lists, and § 425.118(b)(3) authorizes CMS to make annual adjustments based upon ACO participant list additions or deletions for purposes of the ACO's assignment, historical benchmark, financial calculations, and quality reporting. Additionally, CMS has the authority at § 425.305(a) to screen ACOs, ACO participants, and ACO providers/suppliers for program integrity purposes, as well to impose safeguards where negative program integrity history is present.

To be eligible to participate in the Shared Savings Program, as specified at § 425.118(a)(1), an ACO must maintain, update, and submit to CMS an accurate and complete ACO participant list. The ACO participant list identifies each ACO participant by its Medicare-enrolled TIN and legal business name (LBN). ACO participant agreements must require an ACO participant to report changes in enrollment information to the ACO within 30 days of the change (§ 425.116(a)(6)) and in accordance with Shared Savings Program requirements (§ 425.116(a)(3)).

CMS uses the certified ACO participant list to conduct critical oversight functions of the Shared Savings Program for downstream operations, such as establishing historical benchmarks; data sharing; financial performance; quality reporting; public reporting; and program eligibility. Changes to the certified ACO participant list can impact an ACO's overall eligibility to participate in the Shared Savings Program. For example, removing an ACO participant could drop the ACO's overall number of assigned Medicare fee-for-service beneficiaries below the 5,000 minimum

required for participation in the Shared Savings Program (§ 425.110(a)(1)). Additionally, modifications to the certified ACO participant list can affect whether an ACO is determined to be a ''low revenue ACO'' or ''high revenue ACO,'' as well as CMS' determination regarding whether an ACO is ''experienced with performance-based risk Medicare ACO initiatives'' or ''inexperienced with performance-based risk Medicare ACO initiatives,'' as defined in § 425.20.

Because of the ACO participant list's downstream effects on an ACO's participation in the Shared Savings Program, changes to the certified ACO participant list are only permitted during the annual Shared Savings Program change request cycle. Absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the performance year (§ 425.118(b)(3)(ii). This includes adjustments of the ACO's obligation to report on behalf of eligible professionals that bill under the TIN of an ACO participant to reflect the addition or deletion of entities from the ACO participant list that occurred during the performance year (§ 425.118(b)(3)(i)). Limiting additions of new ACO participants or revisions to an existing ACO participant on an ACO's participant list to one annual change request cycle ensures the integrity of program operations for both CMS and ACOs. CMS has sole discretion to determine whether unusual circumstances exist that would warrant such adjustments (§ 425.118(b)(3)(ii)).

Before the start of an agreement period, before each performance year thereafter, and at such other times as specified by CMS, the ACO must submit to CMS an ACO participant list (§ 425.118(a)(2)). As operationalized, ACOs are able to add an entity to their previously certified ACO participant list according to the form and manner specified by CMS (§ 425.118(b)(1)). To add a new ACO participant TIN, an ACO must submit a change request by the final deadline established by CMS (§ 425.118(b)(1)). Currently, change requests are only accepted by CMS during the change request cycle. All additions to the ACO participant list approved by CMS during the change request cycle are effective on January 1 of the next performance year (§ 425.118(b)(1)(ii)).

A change of ownership (CHOW) can occur when an ACO participant is purchased (or leased) by another organization. In such a case, the CHOW often results in the transfer of the previous owner's Medicare Identification Number and provider agreement (including the previous owner's outstanding Medicare debts) to the new owner. (See generally, § 489.18(c).) If the purchaser or lessee elects not to accept a transfer of the provider agreement, then the old agreement should be terminated, and the purchaser or lessee is considered a new applicant and must initially enroll in Medicare.[315]

To notify CMS of the CHOW, an ACO participant submits the appropriate Medicare Enrollment Application form to their Medicare Administrative Contractor (MAC) or in the Provider Enrollment, Chain, and Ownership System (PECOS).[316] The MAC uses the forms and required supporting documentation to document and identify changes in ownership and/or subsequent changes in TINs and Medicare Identification Numbers. When an ACO participant undergoes a CHOW resulting in a change to the TIN used for the Shared Savings Program, the ACO must provide documentation of the CHOW in a new change request to add the surviving Medicare enrolled TIN with no prior Medicare billing claims history to its ACO participant list. This allows CMS to appropriately track eligibility and other program requirements as well as perform other program operations such as beneficiary assignment, benchmark and performance year expenditure calculations, and determinations of shared savings and losses for ACOs with ACO participants that have undergone a CHOW.

In some circumstances, an ACO participant CHOW could result in one Medicare-enrolled TIN being absorbed into an existing Medicare-enrolled TIN. This would mean the surviving ACO participant TIN would have Medicare billing claims history or other factors affecting an ACO's overall performance or benchmarking. Under this scenario, the surviving TIN could have a patient population and providers and suppliers who were not accounted for when CMS established the ACO's benchmarks. Such a scenario could lead to variation in the patient population seen during the performance year compared to the ACO's historical benchmark.

In a dynamic healthcare environment, ACO participants may experience CHOWs and/or subsequent TIN changes during the performance year that affect their ability to continue in the Shared Savings Program. ACOs and ACO participants have requested that we establish a process whereby an ACO participant[317] that experiences a CHOW resulting in a surviving Medicare enrolled TIN with no prior Medicare billing claims history can be submitted by the ACO for CMS to review during the performance year.

Currently, there are 477 ACOs participating in the Shared Savings Program with more than 15,000 ACO participant TINs and 650,000 ACO providers and suppliers who have agreed to participate in ACOs. Due to the volume of data that we utilize to operationalize the Shared Savings Program, allowing for frequent or high volumes of changes to occur to an ACO's certified participant list during a performance year can increase the risk of errors, as well as uncertainty surrounding what data is utilized to produce a report. Additionally, it is important to ensure a degree of finality to reports for CMS and for ACOs to use during their participation in the Shared Savings Program and not allow data to constantly change. Therefore, it is important to limit the circumstances in which we allow ACOs to modify their certified ACO participant lists during a performance year, as well as the operational processes we allow to account for changes to occur during the performance year.

(2) Proposal To Allow Modifications to the Certified ACO Participant List for ACO Participant CHOWs During a Performance Year

We recognize that requiring ACOs to wait until the upcoming change request cycle each performance year to update their certified ACO participant list to reflect an ACO participant's CHOW can, in some cases, present operational

[315] If the purchaser (or lessee) elects not to accept a transfer of the provider agreement, then the old agreement is terminated, and the purchaser or lessee is considered a new applicant. (See generally Enrollment Applications at *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/enrollment-applications.*)

[316] Medicare provider and suppliers can enroll using the Provider Enrollment, Chain, and Ownership System (PECOS). PECOS is a web-based platform managed by CMS that facilitates the enrollment process for Medicare providers and suppliers. See *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos.*

[317] A ''certified ACO participant'' means ''an ACO participant that an ACO has listed on the ACO's certified ACO participant list.'' *See* 425.118(a)(3): ''The ACO must certify the submitted lists in accordance with § 425.302(a)(2).''

difficulties for ACOs. This gap may interfere with an ACO's ability to provide coordinated care to an ACO participant's patient population and negatively impact the ACO's participation in the Shared Savings Program. To account for such scenarios and to support ACOs' participation, effective January 1, 2026, we propose ACOs that experience certain ACO participant CHOWs outside of the change request cycle must update their certified ACO participant list to reflect such ACO participant's CHOW. This applies to instances in which an ACO participant has undergone a CHOW resulting in a change to its Medicare enrolled TIN whereby the surviving Medicare enrolled TIN has no Medicare billing claims history. Without the ability to report an ACO participant's CHOW and effectuate a change in the ACO's participant list during the performance year, the ACO may be unable to provide coordinated care to an ACO participant's patient population, which may cause the ACO's beneficiary count to fall below 5,000. An ACO participant change in ownership that reduces the ACO's number of assigned beneficiaries could constitute a significant change (as described at § 425.214) for the ACO, adversely affecting the ACO's participant agreement and jeopardizing the ACO's continued participation in the Shared Savings Program. At § 425.214(a)(3), a significant change occurs when an ACO is no longer able to meet the eligibility or requirements of the Shared Savings Program.

To avoid confusion for ACOs and their ACO participants as well as to establish a clear and consistent process for the recognition of claims billed by the TIN of an ACO participant that has recently experienced a CHOW, we propose to add new paragraph § 425.118(b)(3) to require an ACO to submit to CMS for review an ACO participant change request for a CHOW resulting in a change to the ACO participant's Medicare enrolled TIN whereby the surviving Medicare enrolled TIN has no Medicare billing claims history in a form and manner set by CMS. We are proposing to require an ACO to submit an ACO participant change request for a CHOW resulting in a change to the TIN throughout the performance year, no later than 30 days after the CHOW and outside of the change request cycle. We propose that this requirement be limited to instances where the surviving TIN is newly enrolled in PECOS with no prior Medicare billing claims history to limit program disruption such as adversely affecting quality performance. We propose at § 425.118(b)(3) that if CMS approves the change request containing a new ACO participant TIN, the ACO participant list would be updated in the form and manner specified by CMS. We propose that CMS would have sole discretion whether to approve the ACO participant change request for a CHOW.

In alignment with proposed § 425.118(b)(3) and (b)(4)(iii) and upon CMS approval of the change request submitted with the TIN, we would adjust the ACO's assignment, performance year financial calculations, and the requirement that the ACO must submit quality data as described at §§ 425.508 and 425.510 for the applicable performance year on behalf of eligible professionals that bill under the TIN of an ACO participant. We would process these adjustments during the applicable Quality Payment Program (QPP) snapshot dates for the relevant Performance Period. The adjustments would reflect the addition of the surviving Medicare enrolled TIN with no prior Medicare billing claims history as a result of a CHOW to the ACO participant list as the changes become effective during the performance year.

While we considered allowing ACOs to submit all change of ownership requests outside of the change request cycle, we propose limiting the out-of-cycle change of ownership requests to those ACO participant TINs without a prior Medicare billing claims history to avoid large discrepancies between the benchmark year patient population and the performance year patient population. To mitigate any disruptions in program calculations, we would require the surviving Medicare enrolled TIN to have no Medicare billing claims history, meaning that the TIN does not have any paid claims for prior benchmark or performance years. This proposal does not apply to a CHOW in which a TIN is absorbed into an existing TIN and the surviving TIN has prior Medicare billing claims history. Approval of the change request would not allow prior claims from the certified ACO participant TIN to be reprocessed under the surviving ACO participant TIN. Additionally, this proposal would mitigate operational impacts, including determining expenditures used in financial reconciliation, determining an ACO's quality sample, and producing quarterly and annual reports.

We propose to incorporate the ACO participants' surviving Medicare enrolled TINs with no prior Medicare billing claims history into the ACO's assignment, historical benchmark, performance year financial calculations, or the obligation of the ACO to report quality data on behalf of eligible professionals that bill under the TIN of an ACO participant, when processed during applicable QPP snapshot dates for the relevant Performance Period, during the performance year in which they are approved (§ 425.118(b)(4)(iii)). Effectuating an ACO participant change request for a CHOW resulting in a surviving Medicare enrolled TIN with no prior Medicare billing claims history during the performance year could prevent an ACO participant from losing its status to participate in an ACO. This proposal, if finalized, would support such ACO participant's ability to retain its assigned beneficiaries and facilitate the provision of high-quality, value-based, evidence-based care.

Under our proposal at § 425.118(b)(4)(iii), it is important to consider the operational impact. For example, the Quality Payment Program (QPP) updates eligibility data at multiple points throughout the year to assist ACOs in planning their Shared Savings Program participation. The QPP updates are based on past and current Medicare Part B claims and PECOS data. The Shared Savings Program sends ACO participant files to QPP, which then applies specific criteria to inform ACO eligibility reports. We review Alternative Payment Model (APM) participation four times for every performance year for clinicians and practices that are members of APMs (each review is called a ''snapshot''). The first three snapshots are processed using the most current data available at the time. For CMS to meet operational processes such as QPP Determinations and APM Incentive Payments, ACOs would need to submit a change request in sufficient time for CMS to review, approve, and the ACO certify, the revised ACO participant list without affecting annual adjustments under proposed § 425.118(b)(4)(iii). We will make available the operational considerations each PY to ensure ACOs are aware of the schedule considerations impacting the QPP Determination and APM Incentive Payments schedule.

Additionally, under proposed § 425.118(b)(4)(iii), CMS would then adjust the ACO's assignment, financial calculations, the requirement for submission of quality data at § 425.508 and § 425.510 on behalf of eligible professionals that bill under the TIN of an ACO participant to reflect the addition of entities to the ACO participant list as they become effective during the performance year. This would be accomplished by providing ACOs with a mechanism to report an ACO participant CHOW that resulted in a new ACO participant TIN with no

prior claims history on their certified ACO participant list and requiring that ACOs submit supporting documentation in the form and manner specified by CMS under proposed § 425.118(b)(3).

Our proposal would redesignate the current § 425.118(b)(3) as § 425.118(b)(4) and add new paragraph § 425.118(b)(3), and § 425.118(b)(4)(iii). We propose to add new § 425.118(b)(3) to require an ACO to submit notice and supporting documentation according to the form and manner specified by CMS to demonstrate that a CHOW resulting in a change to the Medicare enrolled TIN has taken place. This supporting documentation would include information and material currently collected by CMS during the annual change request cycle when an ACO participant has merged with or been acquired by another entity.

Should we finalize our proposals for § 425.118(b)(3) and (b)(4)(iii), we would provide additional guidance on the types of documentation that would suffice to meet the form and manner requirements. This supporting documentation could include a bill of sale, joinder agreement, or other legal document demonstrating a CHOW resulting in a new Medicare-enrolled TIN. Documentation demonstrating the surviving Medicare enrolled TIN with no prior Medicare billing claims history could also include documentation from the Internal Revenue Service (IRS) or from a state's Secretary of State (for example, IRS W–9, Employer Identification Number registration, or TIN assignment notice), or an affidavit explaining the CHOW resulting in the surviving Medicare enrolled TIN and confirming reassignment from the original ACO participant TIN to the surviving ACO participant TIN. This could include an attestation from the ACO that all the providers and suppliers that previously assigned their right to receive Medicare payment to the original ACO participant entity's TIN have reassigned such right to the surviving Medicare enrolled TIN with no prior Medicare billing claims history for the identified ACO participant and will be added to the ACO provider/supplier list within 30 days in accordance with § 425.118(a)(4). As noted, we would provide guidance on the types of documentation that would suffice, should we finalize our proposals.

We propose that the change have an effective date of January 1, 2026, and anticipate this approach would allow some ACOs to remain in the Shared Savings Program without interruption by continuing to utilize ACO participants who may have experienced a CHOW resulting in a surviving Medicare enrolled TIN with no prior Medicare billing claims history.

We seek comments on this proposal.

b. SNF Affiliate Change of Ownership (CHOW) Scenarios

(1) Background

The Medicare Skilled Nursing Facility (SNF) benefit applies to beneficiaries who require a short-term intensive stay in a SNF and skilled nursing and/or skilled rehabilitation care. Pursuant to section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days to be eligible for Medicare coverage of inpatient SNF care. This requirement is referred to as the SNF 3-Day Rule. Section 1899(f) of the Act permits the Secretary to waive certain payment or other program requirements necessary to carry out the Shared Savings Program. Specifically, CMS has used the authority under section 1899(f) to waive section 1861(i) of the Act to allow coverage of certain SNF services that are not preceded by a qualifying 3-day inpatient hospital stay. The Shared Savings Program's SNF 3-day rule waiver waives the requirement for a 3-day inpatient hospital stay prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries if certain conditions are met.

The SNF 3-day rule waiver at § 425.612(a)(1) allows for Medicare payment for otherwise covered SNF services when ACO providers/suppliers participating in ACOs participating under a two-sided model admit eligible beneficiaries, or certain excluded beneficiaries during a grace period, to an eligible SNF affiliate without a 3-day prior inpatient hospitalization. All other provisions of the section 1861(i) of the Act and regulations regarding Medicare Part A post-hospital extended care services continue to apply. This waiver became available starting January 1, 2017, and all ACOs participating under, or that apply to participate under, Levels C–E of the BASIC track or under the ENHANCED track are eligible to apply for the waiver.

It is important to note that the Shared Savings Program SNF 3-day rule waiver does not create a new benefit or extend Medicare SNF coverage to patients who could be treated in outpatient settings or who require long-term custodial care. Also, the SNF 3-day rule waiver does not restrict a beneficiary's choice of provider or supplier. A beneficiary continues to have the option to seek care from any Medicare FFS provider or supplier, including from a SNF or other facility that is not an affiliate of an ACO participating in the Shared Savings Program. If a beneficiary that is assigned to an ACO chooses to receive care from a SNF or other facility that is not an affiliate of the ACO, normal Medicare requirements apply, including the requirement for a 3-day inpatient hospitalization. The SNF 3-day rule waiver is intended to provide ACOs that are participating in certain performance-based risk tracks with additional flexibility to increase quality and decrease costs. As described at § 425.612(d)(2), CMS monitors and audits the use of the SNF 3-day rule waiver in accordance with § 425.316.

As part of the 3-day rule waiver supplemental application information requirements, at § 425.612(a)(1)(i)(B), ACOs must provide to CMS the list of SNFs with whom the ACO will partner along with executed SNF affiliate agreements between the ACO and each listed SNF. The SNF affiliate agreement with the ACO includes all individual SNFs identified by a CMS Certification Number (CCN) under the Medicare-enrolled SNF TIN that agree to partner with the ACO for purposes of a SNF 3-day rule waiver. The SNF 3-day rule waiver enables eligible SNFs to admit eligible beneficiaries to their SNF without a prior 3-day inpatient hospitalization. To identify an eligible SNF for purposes of a SNF 3-day rule waiver, the SNF's Medicare enrolled TIN and CCN must appear on the SNF affiliate list.

To have and maintain a SNF 3-day rule waiver, an ACO must have at least one approved SNF on its SNF affiliate list to meet the requirements of § 425.612(a)(1)(i)(B). Similar to the certified ACO participant list, ACOs can submit modifications to their SNF affiliate list in the form and manner specified by CMS (currently submitted during the annual change request cycle), and approved additions to the list become effective on January 1 of the following performance year.

Operationally, the Shared Savings Program does not provide a mechanism by which an ACO can add a new TIN to its SNF affiliate list outside of the annual change request cycle, including in situations where a SNF affiliate experiences a CHOW resulting in a change to the Medicare-enrolled TIN. ACOs and SNF affiliates may encounter the same CHOW scenario as described in section III.F.3.a. of this proposed rule for ACO participants. If a SNF affiliate experiences a CHOW resulting in a change to the Medicare-enrolled TIN, it can no longer admit eligible beneficiaries without a prior 3-day inpatient hospitalization due to the

change in Medicare enrollment and our current operational processes for receiving and reviewing SNF affiliate list modifications on an annual basis.

(2) Proposal To Allow Modifications to the SNF Affiliate List for SNF Affiliate CHOWs During a Performance Year

ACOs have requested that we establish a mechanism to report a CHOW which results in a change in the Medicare-enrolled TIN for an approved SNF affiliate, which can be reviewed and effectuated by CMS during the performance year. This would enable the SNF affiliate to continue to participate with the ACO in the SNF 3-day rule waiver during the performance year and not have to wait until the next change request cycle to notify CMS of the change to the Medicare-enrolled TIN for the approved SNF affiliate.

We recognize that requiring ACOs to wait until the upcoming change request cycle each performance year to update their SNF affiliate list to reflect an SNF affiliate's CHOW can interrupt ACO operations. This gap may prevent an ACO from utilizing a SNF affiliate that has undergone a CHOW resulting in a change in Medicare-enrolled TIN for the approved SNF affiliate under the SNF 3-day rule waiver. Therefore, we propose to amend § 425.612(a)(1)(i)(B) by moving the text to § 425.612(a)(1)(i)(B)*(1)* and revising it to specify that the list of SNFs must include the Medicare enrolled TIN and the CCN of each SNF. We propose this revision to ensure that we can link the SNF CCN with the correct Medicare enrolled TIN. We also propose adding § 425.612(a)(1)(i)(B)*(2)* to require ACOs to notify CMS no later than 30 days after the change of ownership of a SNF affiliate, identified in accordance with paragraph (a)(1)(i)(B)(1), that has resulted in a change to the Medicare enrolled TIN of the SNF affiliate in the form and manner specified by CMS.

We propose to require an ACO to submit such a notification at any point during the performance year that is 30 days after the change in ownership, which would include times outside of the change request cycle. This proposal is limited to a change of ownership of a SNF affiliate that has resulted in a change to the Medicare-enrolled TIN, as the CHOW affects the SNF affiliate's ability to participate under the 3-day rule waiver. This proposal would not allow an ACO to add a new SNF affiliate as the result of a CHOW. Additionally, we propose to require an ACO to submit supporting documentation demonstrating the change in SNF affiliate TIN similar to that described in section III.F.3.a. of this proposed rule, and in accordance with the form and manner specified by CMS. Supporting documentation could include information from the Internal Revenue Service (IRS) or the State's Secretary of State, IRS W–9, Employer Identification Number registration, TIN assignment notice, or an affidavit explaining the TIN change and confirming reassignment from the original SNF affiliate TIN to the new SNF affiliate TIN.

Following CMS approval of the ACO's change request under proposed § 425.612(a)(1)(i)(B) we would send an updated list of approved SNF affiliates to the Medicare Administrative Contractor (MAC). The MAC would process the change; however, an ACO would still need to confirm with its MAC that the change has been fully effectuated. Our proposal does not impact assignment of beneficiaries to an ACO, and therefore would not impact the ACO beneficiaries eligible for the SNF 3-day rule waiver. It would only impact the SNFs that are approved as affiliates to provide care without the required three -day inpatient hospital stay.

A recent report released by the Assistant Secretary for Planning and Evaluation (ASPE) found frequent changes of ownership in hospitals and SNFs between 2016 and 2021, reporting that more than 3,200 SNFs experienced a CHOW.[318] Requiring an ACO to submit updates to its SNF affiliate list during the performance year if one of its SNF affiliates experiences a CHOW requires clear policies and procedures associated with such changes. It is important to avoid a scenario where CMS or an ACO is unclear whether a SNF is approved to use the SNF 3-day rule waiver and when that information has been shared with the MAC for proper claims processing. Therefore, it is important to limit the circumstances which allow for ACOs to modify their SNF affiliate lists during a performance year outside of the scenario a CHOW.

Overall, the proposal to allow modifications to the SNF affiliate list for SNF affiliate CHOWs resulting in a change to the TIN would benefit CMS, ACOs and their SNF affiliates, and beneficiaries. This change would support continuous operations that improve access to quality care and care coordination as beneficiaries transition to a SNF. Historically, SNFs that undergo a CHOW that result in a change to the TIN have been unable to continue participation in the SNF 3-day rule waiver until the next change request cycle. Our proposal, if finalized, would ensure more timely access to skilled nursing care for Medicare beneficiaries.

We propose that the change have an effective date of January 1, 2026, and anticipate this approach would provide ACOs the flexibility to continue to utilize the SNF 3-day rule waiver for SNF affiliates who may have experienced a CHOW resulting in a change to the TIN.

We seek comments on our proposal.

4. ACO Eligibility and Related Financial Reconciliation Requirements

a. Overview

Under the Shared Savings Program regulations, CMS ''deems'' an ACO to have initially satisfied the statutory requirement to have at least 5,000 assigned Medicare FFS beneficiaries (section 1899(b)(2)(D) of the Act), if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the three historical benchmark years as defined at § 425.110(a)(2). Since the start of the Shared Savings Program, we have denied the applications of ACOs applying to participate in the program if the number of assigned beneficiaries was below 5,000 beneficiaries in any historical benchmark year. This policy was established to align with the statutory requirement and to ensure CMS is able to reliably and accurately assess ACO financial and quality performance. The purpose of the historical benchmark is to establish a fair and reliable baseline to compare with performance year expenditures in the calculation of an ACO's shared savings or losses. As an ACO's assigned beneficiary population decreases, the ability of CMS to reliably and accurately assess ACO financial and quality performance also decreases. In the November 2011 final rule (see for example, 76 FR 67807 and 67808), we expressed the benefit of a 5,000-beneficiary minimum to maintain program eligibility and allow CMS to assess ACO financial and quality performance, while also planning a course of action for when an ACO falls below the 5,000-beneficiary minimum.

[318] *Changes in Ownership of Skilled Nursing Facilities from 2016–2021: Variations by Size, Occupancy Rate, Penalty Amount, and Type of Ownership*, May 10, 2024, *https://aspe.hhs.gov/sites/default/files/documents/9c4c5c8f2d48309c83e87f544b1aed90/snf-ownership-changes-variations.pdf.*

Furthermore, CMS finalized the minimum savings rate (MSR) for ACOs with at least 5,000 assigned beneficiaries such that the MSR for each ACO would be based on increasing confidence intervals as the number of assigned beneficiaries increases (76 FR 67928 and 67929). At the same time, CMS recognized the higher uncertainty regarding expenditures for smaller ACOs and CMS's desire to encourage program participation by smaller ACOs. Accordingly, CMS set the confidence interval at 90 percent for ACOs with 5,000 beneficiaries assigned, resulting in an MSR of 3.9 percent for those ACOs. For ACOs with 20,000 and 50,000 assigned beneficiaries, CMS set the confidence interval at 95 percent and 99 percent, respectively, for those ACOs, resulting in MSRs of 2.5 percent and 2.2 percent (76 FR 67928). As ACO size increases from 5,000 to 20,000 assigned beneficiaries (or similarly from 20,000 to 50,000), CMS blends the MSRs between the two neighboring confidence intervals, resulting in the MSRs as shown in Table 6 of the November 2011 final rule (76 FR 67928).

Building on the November 2011 final rule, in the December 2018 final rule, CMS finalized a variable MSR and Minimum Loss Rate (MLR) for ACOs that fall below 5,000 beneficiaries in the performance year according to assigned beneficiary ranges and based on a confidence interval of 90 precent, as a way to better ensure that the program is rewarding or holding accountable ACOs for actual performance, not normal expenditure fluctuations (83 FR 67927) (§§ 425.605 and 425.610).

Although most ACOs are able to reach the 5,000 beneficiaries assigned minimum, we recognize that this requirement does prevent some applicants from participating in the Shared Savings Program. Since the inception of the program, we have gained additional experience with the requirement to have 5,000 beneficiaries assigned in each benchmark year, and experience with how this requirement relates to the integrity and stability of financial performance calculations. This experience has provided additional information that shows we can both retain the financial integrity of benchmark calculations and ensure CMS can reliably and accurately assess ACO financial and quality performance while allowing for ACOs that have fewer than 5,000 beneficiaries assigned in their benchmark years to enter the program, if we implement additional safeguards that protect ACOs and the Trust Funds. As described in this section of this proposed rule, we propose changes to the Shared Savings Program eligibility requirements to allow for participation by ACOs with a minimum of 5,000 assigned beneficiaries in their third benchmark year, even if the ACO has fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both (see section III.F.4.b.(2)(a)). Further, we propose safeguards to limit ACOs entering a new agreement period with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, at the time of application, to participation in the BASIC track (see section III.F.4.b.(2)(b) of this proposed rule). We also propose additional safeguards for ACOs with fewer than 5,000 assigned beneficiaries in any of their benchmark years, by applying an alternative performance payment limit and loss recoupment limit for these ACOs (see III.F.4.c.(1).(b) of this proposed rule), and excluding these ACOs from leveraging policies providing certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings (see III.F.4.c.(2).(b) of this proposed rule).

b. ACO Eligibility Requirement

(1) Background

(a) Background on Assigned Beneficiary Minimum Requirement

Section 1899(b)(2)(D) of the Act requires participating ACOs to include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO and that, at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it under section 1899(c) of the Act in order to be eligible to participate in the Shared Savings Program.

In the November 2011 final rule (76 FR 67808), in alignment with the statutory requirement at section 1899(b)(2)(D) of the Act, CMS established that for an ACO to satisfy the requirement to have at least 5,000 assigned beneficiaries, the ACO must have 5,000 or more beneficiaries historically assigned to the ACO participants in each of the 3 benchmark years. See § 425.110(a)(2). We described the importance of maintaining at least 5,000 assigned beneficiaries with respect to both eligibility of the ACO to participate in the program and the ability of CMS to reliably and accurately assess ACO financial and quality performance. However, we also noted in that rule (76 FR 67807) that we understood circumstances may change during an ACO's agreement period, and that an ACO's assigned population may vary accordingly, and if the ACO falls below 5,000 beneficiaries during the agreement period, the ACO will be subject to compliance actions (described at §§ 425.216 and 425.218).

Additionally, in the November 2011 final rule (76 FR 67929), we finalized the MSR/MLR with a sliding scale that varies based on the number of beneficiaries assigned to the ACO from 5,000 up to 60,000. The largest ACOs with over 50,000 assigned beneficiaries had 99 percent confidence intervals. At the same time, CMS also recognized ACOs with the minimum 5,000 assigned beneficiaries must meet a higher MSR of 3.9 percent to be eligible for shared savings payments, based on a confidence interval of 90 percent (76 FR 67927).

In the CY 2025 PFS final rule (89 FR 98085 through 98086), we finalized a policy to sunset the requirement at § 425.110(b)(2) that CMS will terminate an ACO's participation agreement and determine that an ACO is not eligible to share in savings for that performance year if an ACO's assigned beneficiary population is not at least 5,000 by the end of the performance year specified by CMS in its request for a corrective action plan. We explained that this requirement could be sunset because the policy finalized in the December 2018 final rule (83 FR 67925 through 67929), to use a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO's assigned beneficiary population fell below 5,000 for the performance year, was effective in protecting both CMS and the ACO from inappropriate overpayments or underpayments and reduced the financial risk of allowing ACOs to continue to participate in the Shared Savings Program if they experience a reduction in assigned beneficiaries. As we have explained in prior rulemaking, the MSR/MLR protects against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than actual program performance (see, for example, 83 FR 67923 through 67926).

After gaining 13 years of experience administering the Shared Savings Program, including lessons learned from applying the requirement at section 1899(b)(2)(D) of the Act that ''[a]t a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it [. . .] in order to be eligible to participate in the ACO program,'' we have determined it is in the best interest of Medicare beneficiaries, the Trust Funds, and participating ACOs to modify the requirement at § 425.110(a)(2) so that it better supports the goals of the Shared Savings Program. As the program grows in experience, the

programmatic guardrails can be changed to better incentivize ACOs, especially those that have successfully participated in the program, to participate in the program while maintaining CMS's ability to reliably and accurately assess ACO financial and quality performance. Historically, the 5,000 assigned beneficiary benchmark year minimum has been implemented across all benchmark years to assess an ACO's financial and quality performance. However, after reviewing historical data and program operations, we believe the 5,000 -beneficiary benchmark year minimum can be applied to BY3 only, which provides the most recent data available prior to an ACO entering an agreement period, to maximize the goals and benefit of the Shared Savings Program.

The 5,000-beneficiary benchmark year minimum applied across all benchmark years helps to ensure that CMS is able to reliably and accurately assess ACO financial and quality performance during the Shared Savings Program application process. However, this beneficiary threshold is most critical in assessing BY3. Specifically, during the application cycle, CMS makes available to all currently participating ACOs and all applicant ACOs estimates of the number of assigned beneficiaries for each of the three benchmark years. The BY3 assignment provided is based on the most recently available 24 months of Medicare beneficiary claims data. The application cycle occurs during the calendar year that corresponds to BY3, and we run assignment based upon the 24 months prior to the end date of the most recent quarter available. Therefore, BY3 is the most current assignment run we produce during the application cycle for assessing the number of assigned beneficiaries an ACO has at the time they are applying to participate in the Shared Savings Program.

(b) Background on Track Specific Requirements for Participation Options

With the December 2018 final (83 FR 67831 through 67841), we finalized the availability of participation options under the BASIC track and ENHANCED track for ACOs entering an agreement period beginning on July 1, 2019, and in subsequent years. We refer readers to section III.F.2.a of this proposed rule for a detailed description of background on Shared Savings Program participation options. The BASIC track and the ENHANCED track offer differing levels of risk and potential reward. See §§ 425.600(a)(3) to (4), 425.605, and 425.610. In general, an ACO that meets or exceeds its MSR, and otherwise qualifies for a shared savings payment, shares in savings at a sharing rate specified by the ACO's participation track (and level, if applicable), not to exceed a performance payment limit (a percentage of the ACO's updated historical benchmark). There is a limited exception for eligible low revenue ACOs participating under the BASIC track, under which an ACO that does not meet the MSR requirement but meets other criteria may qualify for a shared savings payment, at a lower sharing rate, in accordance with § 425.605(h). An ACO under a two-sided model that meets or exceeds its MLR shares in losses at a shared loss rate specified by the ACO's participation track (and level, if applicable), not to exceed a loss recoupment limit (a percentage of the ACO's updated historical benchmark). In summary:

- The BASIC track (see §§ 425.600(a)(4) and 425.605) includes a ''glide path'', from one-sided model Levels A and B to incrementally higher levels of performance-based risk under Levels C, D, and E.

++ Under Level A and B of the BASIC track, an ACO may share in savings at a sharing rate of up to 40 percent (§ 425.605(d)(1)(i)(A) and (d)(1)(ii)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(i)(B) and (d)(1)(ii)(B)).

++ Under Level C of the BASIC track, an ACO may share in savings at a sharing rate of up to 50 percent (§ 425.605(d)(1)(iii)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(iii)(B)), and may share in losses at a loss sharing rate of 30 percent (§ 425.605(d)(1)(iii)(C)), not to exceed 2 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 1 percent of updated benchmark (§ 425.605(d)(1)(iii)(D)).

++ Under Level D of the BASIC track, an ACO may share in savings at a sharing rate of up to 50 percent (§ 425.605(d)(1)(iv)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(iv)(B)), and may share in losses at a loss sharing rate of 30 percent (§ 425.605(d)(1)(iv)(C)), not to exceed 4 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 2 percent of updated benchmark (§ 425.605(d)(1)(iv)(D)).

++ Under Level E of the BASIC track, an ACO may share in savings at a sharing rate of up to 50 percent (§ 425.605(d)(1)(v)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(v)(B)), and may share in losses at a loss sharing rate of 30 percent (§ 425.605(d)(1)(v)(C)), not to exceed 8 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 4 percent of updated benchmark (§ 425.605(d)(1)(v)(D)). The loss recoupment limit is the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (42 CFR 414.1415(c)(3)(i)(A)) capped at 1 percentage point higher than the expenditure-based nominal risk amount (§ 414.1415(c)(3)(i)(B)).

- Under the ENHANCED track (§§ 425.600(a)(3) and 425.610), with the highest level of risk and potential reward under the Shared Savings Program, an ACO may share in savings at a sharing rate of up to 75 percent (§ 425.610(d)), not to exceed 20 percent of updated benchmark (§ 425.610(e)), and may share in losses at a loss sharing rate not less than 40 percent and not to exceed 75 percent (§ 425.610(f)), capped at 15 percent of updated benchmark (§ 425.610(g)).

Currently, CMS allows ACOs to choose to participate in either the BASIC track or ENHANCED track (see § 425.600(a), and see also § 425.226(a)), provided the ACO meets the eligibility criteria set forth in 42 CFR part 425 Subpart B. An ACO must select a Shared Savings Program participation option for which CMS determines it is eligible under § 425.600(g). An ACO entering the BASIC track may elect to start at any level for which it is eligible, based on its experience with performance-based risk Medicare ACO initiatives (refer to § 425.600(a)(4)(i)(C)(1) and (g)). During the application cycle, CMS conducts a prescreening assessment to evaluate an ACO's eligibility for its selected level. The evaluation includes verifying whether the ACO complies with general program requirements and the ability of the ACO to take on risk (83 FR 41806). *See* §§ 425.202(a) and 425.204. Also, part of this check assesses the ACO's ability to provide an adequate repayment mechanism for shared losses if the chosen track is two-sided (§ 425.204(f)(3)(i)). CMS may deny an ACO applicant's application if the ACO applicant fails to satisfy the requirements of the Shared Savings Program on the basis of information contained in and submitted with the application per § 425.206(a)(1).

(2) Proposed Revisions

(a) Allow ACOs To Enter the Shared Savings Program With Fewer Than 5,000 Assigned Beneficiaries in BY1, BY2, or Both

The present requirement in § 425.110(a)(2) for an applicant ACO to have at least 5,000 assigned Medicare

FFS beneficiaries in each of the 3 historical benchmark years, as described in section III.F.4.b.(1)(a), is the most common reason we deny ACO applicants' applications. In evaluating potential changes to this eligibility policy at § 425.110(a), we considered ways to increase flexibility regarding the minimum number of assigned beneficiaries required in benchmark years, to continue to support new and previously successful renewing and re-entering ACOs participating in the Shared Savings Program, while minimizing adverse financial impacts to ACOs and the Shared Savings Program that may arise from program participation by ACOs with fewer than 5,000 beneficiaries assigned in one or more historical benchmark years.

Consequently, we propose to amend our requirements at § 425.110(a)(2) to specify that, for agreement periods beginning on or after, January 1, 2027, ACOs applying to enter a new agreement period would be required to have at least 5,000 assigned beneficiaries in the ACO's BY3 but could be under 5,000 assigned beneficiaries in BY1, BY2, or both. Currently, on the basis of § 425.110(a)(2), we deny an applicant ACO's application to enter or renew its participation in the program if the ACO would be assigned fewer than 5,000 beneficiaries in any of benchmark years 1 to 3. Under the policy we are proposing, ACOs would not be prevented, on the basis of § 425.110(a)(2), from entering the program if they are below 5,000 assigned beneficiaries in BY1, BY2, or both. We propose to sunset the current policy regarding ACOs with fewer than 5,000 assigned beneficiaries in any of the benchmark years after December 31, 2026, and make this change applicable for ACOs applying to enter new agreement periods beginning January 1, 2027, and for subsequent agreement periods. We are proposing to apply this modified approach for agreement periods beginning January 1, 2027, instead of January 1, 2026, because the application cycle for agreement periods starting January 1, 2026, is underway and this proposal, if finalized, would not be finalized until November 2025, by which point we will be preparing to grant or deny applications for agreement periods starting January 1, 2026, in early December.[319]

We believe this proposal is consistent with the statutory requirements at section 1899(b)(2)(D) of the Act that ''At a minimum, the ACO shall have at least 5,000 [Medicare FFS] beneficiaries assigned to it under subsection (c) in order to be eligible to participate in the ACO program,'' because the proposal requires that an ACO must meet the 5,000-beneficiary minimum before entering an agreement period. While the statute established this requirement, subsequent rulemaking defines its specific implementation parameters such as benchmark years. This proposed update aligns with both the statutory requirements at section 1899(b)(2)(D) of the Act and requirements of this proposed rule.

Over the last several Shared Savings Program application cycles for ACOs entering a new agreement period, about 2 percent of applicants on average were denied participation in the program due to the ACOs having fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, while still having more than 5,000 assigned beneficiaries in BY3 and meeting all other program eligibility requirements. Additionally, the proposed revisions would allow new, renewing, and re-entering ACOs that have been successful in the program previously and who fall under 5,000 assigned beneficiaries in BY1 and/or BY2 to continue to participate in the Shared Savings Program as long as such ACOs meet all other Shared Savings Program requirements.

This proposal would provide greater flexibility on the requirement to have 5,000 assigned beneficiaries in each benchmark year, but it also could introduce risk for both the ACO and the program. For example, as an ACO's assigned beneficiary population decreases, variability in the population's expenditures increases because a few beneficiaries with unusually high or unusually low expenditures could have a substantive impact on an ACO's overall expenditures. The reduction in the size of the ACO's assigned beneficiary population in benchmark years could result in variability in benchmark calculations that could cause shared savings payments or shared losses owed to be based on normal expenditure fluctuations, rather than reflect ACO performance in the program. Accordingly, we are also proposing safeguards to address variability in calculations and to protect both ACOs and Medicare Trust Funds in the proposals discussed in sections III.F.4.b. and III.F.4.c. of this proposed rule.

We propose to revise § 425.110 as follows. At § 425.110(a), we propose to revise paragraph (2) by adding the introductory phrase, ''For agreement periods beginning before January 1, 2027'', to limit the timing of applicability of the provision.

We propose to add new paragraph (3) to § 425.110(a) specifying that for agreement periods beginning on or after January 1, 2027, we determine whether an ACO has 5,000 or more beneficiaries historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. We also propose to specify under new § 425.110(a)(3) that we would use the most recent data available to estimate the number of assigned beneficiaries in the third benchmark year. Additionally, we propose to specify in new § 425.110(a)(3)(i) through (ii) the following provisions in connection with our determination of whether an ACO has 5,000 or more assigned beneficiaries in its benchmark years.

- We would deem an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified at § 425.110(a)(1) if 5,000 or more beneficiaries are historically assigned to the ACO participants in the third benchmark year.
- If an ACO has fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, the ACO may only participate under the BASIC track in accordance with new § 425.600(h)(3) (as described in sections III.F.2. and III.F.4.b.(2)(b) of this proposed rule).

(b) Require an ACO With Fewer Than 5,000 Assigned Beneficiaries in BY1, BY2, or Both To Participate Only Under BASIC Track

Providing greater flexibility around the requirement to have 5,000 assigned beneficiaries in BY1, BY2, or both may introduce risk to the program. As explained in section III.F.4.b.(1)(b) of this proposed rule, as an ACO's assigned beneficiary population decreases, variability in the population's average expenditures increases. The reduction in the size of the ACO's assigned beneficiary population in benchmark years could result in variability in benchmark calculations that could cause shared savings payments or shared losses owed to be based on normal variation in expenditures, rather than reflect ACO performance in the program. We propose that if an ACO, when entering a new agreement period, is under the 5,000-beneficiary minimum in BY1, BY2, or both, but meets this requirement in BY3, the ACO may only enter an agreement period in the BASIC track, to

[319] See Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Period Beginning on January 1, 2026, available at *https://www.cms.gov/files/document/key-application-dates-and-deadlines-2026.pdf.*

reduce the potential risk to the ACO and to the Shared Savings program as described in section III.F.4.b.(2)(a) of this proposed rule.

Currently, we allow ACOs to choose to participate in either the BASIC track or ENHANCED track, as long as they meet all applicable eligibility criteria, including the requirements to participate under performance-based risk, as described in section III.F.4.b.(1).(b) of this proposed rule. *See* § 425.600(a)(4)(i)(C)(*4*), and (g). We apply eligibility checks for an applicant ACO's track selection during the annual application cycle and communicate track eligibility to the ACO through the Participations Options Report. Under the proposed approach, during the application cycle, we would review an ACO's track selection in combination with its number of assigned beneficiaries in each benchmark year and provide information to the ACO about its participation options. ACOs would receive an opportunity to correct deficiencies and/or make updates or modifications to the ACO's change request(s) during two rounds of RFI (Request for Information) submission periods in Phase 1 of the application cycle. We would also provide a final disposition of an ACO's eligibility for program participation, and we would deny applicants from participation in the program if they do not meet all eligibility criteria.

We propose that this change would be applicable for ACOs applying to enter new agreement periods beginning on or after January 1, 2027.

As described in section III.F.4.c.(1)(b). of this proposed rule, an ACO with fewer than 5,000 assigned beneficiaries in one or both of benchmark years 1 and 2 could experience variability in benchmark calculations which could cause shared savings payments or shared losses owed to be based on normal expenditure fluctuations, rather than reflect actual program performance, because a small number of beneficiaries either with unusually high or unusually low expenditures could substantially affect the variability of the benchmark calculations. This proposal to limit ACOs in this situation to the BASIC track protects these ACOs from incurring a larger shared losses rate of up to 75 percent (*see* § 425.610(f)(4)), and it protects the Medicare Trust Funds from paying a larger shared savings rate of up to 75 percent (*see* § 425.610(d)(4)), which could result under the ENHANCED track, attributable to variability in benchmark calculations associated with ACOs with fewer than 5,000 assigned beneficiaries in one or both of benchmark years 1 and 2 rather than actual program performance.

We seek comments on the proposals to allow ACOs to enter the Shared Savings Program if they have fewer than 5,000 assigned beneficiaries in BY1, BY2, or both (but have at least 5,000 assigned beneficiaries in BY3) and the requirement that these ACOs may only enter an agreement period in the BASIC track.

As described in sections III.F.2 and III.F.4.b.(2).(a) of this rule, we propose to specify a related provision in new § 425.600(h)(3), applicable for agreement periods beginning on or after January 1, 2027, that if an ACO is determined to have fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, in accordance with § 425.110(a)(3) (as proposed to be revised), the ACO may only enter the BASIC track. As described in further detail in section III.F.2 of this proposed rule, under this proposed approach, an ACO may enter a level of risk and potential reward under the BASIC track in accordance with the requirements of new § 425.600(h).

c. Calculating Shared Savings and Losses for ACOs That Fall Below 5,000 Assigned Beneficiaries

(1) Apply an Alternative Performance Payment Limit and Loss Recoupment Limit During Financial Reconciliation for ACOs That Fall Below 5,000 Assigned Beneficiaries in any Benchmark Year

(a) Background

Section 1899(d)(2) of the Act addresses how payments for shared savings are to be determined and states that the Secretary shall establish limits on the total amount of shared savings that may be paid to an ACO under that provision. Section 1899(i) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model(s) will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We have used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models.[320] Under the authority granted by sections 1899(d)(2) and 1899(i)(1) of the Act, over time we have adopted methods to determine and limit performance payments and loss recoupment. We refer readers to discussions in earlier rulemaking on establishing the performance payment limit and loss recoupment limit for Levels A through E of the BASIC track (83 FR 67842 through 67857) and the ENHANCED track (formerly named Track 3, see 80 FR 32778 and 32779). The track- or level- specific caps are described in section III.F.4.b.(1)(b) of this proposed rule.

When we calculate the performance payment limit, which is the maximum amount of earned shared savings an ACO can receive in a performance year, in the determination of an ACO's shared savings, we first calculate an ACO's per capita updated benchmark expenditures for the performance year and then multiply this value by the ACO's assigned beneficiary person years[321] for the performance year, which equals their total benchmark expenditures. We then calculate the performance payment limit as a percentage of total benchmark expenditures, with the applicable percentage dependent on the ACO's track/level of participation (either 10 percent for all levels of the BASIC track, or 20 percent for the ENHANCED track). An ACO's earned shared savings payment is capped at the ACO's performance payment limit amount. See §§ 425.600(a)(3)–(4), 425.605, and 425.610 and the discussion in section III.F.4.b.(1).(b) of this proposed rule.

When we calculate the benchmark-based loss recoupment limit, which is the maximum amount of losses an ACO can owe in a performance year, in the determination of an ACO's shared losses, we calculate an ACO's per capita benchmark expenditures and then multiply this value by the ACO's assigned beneficiary person years for the performance year, which equals their total benchmark expenditures. CMS then calculates the loss recoupment limit as a percentage of total benchmark expenditures, with the applicable

[320] See earlier rulemaking establishing two-sided models, including Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 and 32772), and the BASIC track (83 FR 67834 through 67841). We also used our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID–19 (see § 425.611(c)(3) and 85 FR 27577 through 27582), SAHS billing activity for CY 2023 (see § 425.670(c)(3) and 89 FR 79161), and SAHS billing activity, from ACO participants' Medicare FFS revenue used to determine the loss recoupment limit in the two-sided models of the BASIC track for CY 2024 and subsequent calendar years (see § 425.672(c)(3) and 89 FR 98199 and 98200).

[321] Person years are the fraction of the year during which the beneficiary was enrolled in each Medicare enrollment type. To calculate person years: CMS sums the number of Shared Savings Program-eligible months for the beneficiary for each Medicare enrollment type; CMS then divides this number by 12 (the number of months in a calendar year).

percentage dependent on the ACO's track/level of participation as described at §§ 425.600(a)(3) through (4), 425.605, and 425.610 and in section III.F.4.b.(1).(b).: either 1 percent for Level C, 2 percent for Level D, or 4 percent for Level E of the BASIC track, or 15 percent for the ENHANCED track.

With respect to ACOs participating in two-sided model levels of the BASIC track, the loss recoupment limit is a percentage of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO (revenue-based loss recoupment limit) not to exceed a percentage of the ACO's updated benchmark (benchmark-based loss recoupment limit). CMS calculates the revenue-based loss recoupment limit as a percentage of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO. If the amount of the ACO's revenue-based loss recoupment limit exceeds the amount of the benchmark-based loss recoupment limit, CMS applies the benchmark-based loss recoupment limit. Refer to § 425.605(d)(1)(iii)(D), (d)(1)(iv)(D), and (d)(1)(v)(D). The percentages of the revenue-based and benchmark-based loss recoupment limits vary based on the Level of the BASIC track, as described in section III.F.4.b.(1).(b)., providing for increasing performance-based risk along the two-sided model levels of the BASIC track's glide path: 2 percent of ACO participant revenue capped at 1 percent of updated benchmark under Level C; 4 percent of ACO participant revenue capped at 2 percent of updated benchmark under Level D; and 8 percent of ACO participant revenue capped at 4 percent of updated benchmark under Level E.

We detailed how CMS performs the calculation of the benchmark-based performance payment limits and loss recoupment limits in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications, (December 2024, Version #12), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-3* (see section 4.3 ''Performance Year Financial Reconciliation Calculations'' and section 3.3 ''ACO Participants' Revenue'').

(b) Proposed Revisions

For ACOs with fewer than 5,000 assigned beneficiaries in any benchmark year, we are proposing an alternative limit to performance payments and loss recoupment applicable for these ACOs in agreement periods beginning on or after January 1, 2027. We propose that this policy would apply during financial reconciliation for any performance year in an agreement period for which the ACO was assigned fewer than 5,000 beneficiaries in any benchmark year. These alternative caps would help to safeguard ACOs and the Medicare Trust Funds by imposing stricter limits on performance payments and loss recoupment for ACOs with fewer than 5,000 assigned beneficiaries in any of their benchmark years at the time of financial reconciliation compared to the limits on performance payments and loss recoupment under the current methodology. The proposed timing of applicability for this policy would be consistent with the timing of applicability for our proposed approach to allow participation by ACOs with 5,000 assigned beneficiaries in BY3, and fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, described in section III.F.4.b.(2) of this proposed rule.

There are a number of possible circumstances that could cause an ACO's assigned beneficiary population in the benchmark years to fall below 5,000 assigned beneficiaries. Under our proposal, for agreements periods beginning on or after January 1, 2027, we would allow for participation by ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both (as described in section III.F.4.b.(2) of this proposed rule). Additionally, regardless of the number of assigned beneficiaries an ACO has at the time of program entry, the ACO's assigned population for its benchmark years may be adjusted during the course of its 5year agreement period. For example, as described in § 425.652(a)(9), an ACO may receive an adjusted historical benchmark because of changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection at § 425.226(a)(1), or changes to the beneficiary assignment methodology specified in 42 CFR part 425 Subpart E, among other changes. Participant list changes occurring within an agreement period, for example, could result in an ACO falling below 5,000 historically assigned beneficiaries in any benchmark year, including BY3, for the purpose of the performance year financial reconciliation.

Under this proposed approach, we would use an alternative calculation for the benchmark-based [322] performance payment limits and loss recoupment limits, in which we would compute an ACO's total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures and the ACO's assigned beneficiary person years from the benchmark year with the lowest number of assigned beneficiaries. We note that we only would use this alternative calculation if an ACO has fewer than 5,000 historically assigned beneficiaries in a benchmark year; otherwise, we would use our current performance payment limit calculation that uses the ACO's assigned beneficiary person years from Benchmark Year 3 (BY3). More specifically, we would multiply the person years for assigned beneficiaries for the benchmark year with the lowest number of assigned beneficiaries by the ACO's per capita benchmark expressed as a single value to get an ACO's alternative total benchmark expenditures. We would calculate the product of the track/level specific percentage used to calculate the benchmark-based performance payment limit, as described in section III.F.4.b.(1).(b).) or loss recoupment limit, as described in section III.F.4.b.(1).(b)) and the ACO's alternative amount of total benchmark expenditures. We would also continue to compute a benchmark-based performance payment limit and loss recoupment limit for the ACO, as described in section III.F.4.b.(1).(b)), specified for the ACO's track/level of participation.

We propose to compare the alternative benchmark-based performance payment limit or loss recoupment limit (calculated using assigned beneficiary person years from the benchmark year with the lowest number of assigned beneficiaries) with the benchmark-based performance payment limit or loss recoupment limit calculated with assigned beneficiary person years for the performance year. We would apply the lesser of these two aforementioned amounts (in absolute value) in determining the final performance payment limit or loss recoupment limit. This approach would ensure that no ACO would receive a larger cap with the alternative performance payment limit or loss recoupment limit than it would receive under the current methodology.

[322] This proposal would not change the calculation of the revenue-based loss sharing limit.

We propose to specify the proposed approach in amendments to the Shared Savings Program regulations at new § 425.605(i) (BASIC track) and new § 425.610(l) (ENHANCED track).

At new § 425.605(i), we propose to include provisions to codify the existing approach to calculating the performance payment limit under new paragraph (i)(1)(i), and the loss recoupment limit under new paragraph (i)(2)(i). We propose to specify under new paragraphs (i)(1)(ii) and (i)(2)(ii) of § 425.605 provisions for how CMS determines whether to apply an alternative performance payment limit or loss recoupment limit (respectively), if an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or BY3, in conducting financial reconciliation for each performance year, for agreement periods beginning on or after January 1, 2027. At this new § 425.610(l)(1) to (2), we propose to include provisions to codify the existing approach to calculating the performance payment limit, and the loss recoupment limit. We propose to specify under new paragraph (l)(3) of § 425.610 provisions for how CMS determines whether to apply an alternative performance payment limit or loss recoupment limit if an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or BY3, in conducting financial reconciliation for each performance year, for agreement periods beginning on or after January 1, 2027.

This proposed policy to potentially reduce the limit on performance payments and loss recoupment limit when an ACO falls below 5,000 assigned beneficiaries in any benchmark year would safeguard the overall financial integrity of the Shared Savings Program, including the Trust Funds, and protect ACOs. The proposed policy would potentially limit shared savings and shared losses in the event that a historical benchmark may be less reliable due to a smaller (fewer than 5,000) assigned beneficiary population size in any benchmark year. As previously discussed in this section, as an ACO's assigned beneficiary population decreases, variability in the population's expenditures increases. The reduction in the size of the ACO's assigned beneficiary population in benchmark years could result in variability in benchmark calculations, which could cause shared savings payments made to the ACO or shared losses owed to be based on normal expenditure fluctuations, rather than reflect actual program performance. We expect these alternative caps to apply to ACOs rarely; when applied, we expect these alternative caps to have limited reductions to an ACO's shared savings or shared losses payments but to provide adequate protections and risk mitigation in outlier cases. In an analysis of performance year reconciliation data for performance years 2020–2023, CMS found that on average, only 2 percent of ACOs at the time of financial reconciliation have at least one benchmark year below 5,000 assigned beneficiaries.

Tables 49 and 50 below provide examples of the alternative performance payment limit and alternative loss recoupment limit calculations that would apply for an ACO with fewer than 5,000 assigned beneficiaries in at least one benchmark year under this proposal.

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TABLE 49: EXAMPLE ALTERNATIVE PERFORMANCE PAYMENT LIMIT CALCULATION

Determine which BY corresponds with the lowest number of assigned beneficiaries as determined at the time of financial reconciliation.	Number of assigned beneficiaries for each BY, determined at the time of financial reconciliation. BY1: 4,300 BY2: 3,900 BY3: 5,500 BY with lowest number of assigned beneficiaries: **BY2**
Determine number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries, determined at the time of financial reconciliation.	Number of assigned beneficiary person years for each BY, determined at the time of financial reconciliation. BY1: 3,550 BY2: 3,250 BY3: 5,050 Number of assigned beneficiary person years for BY2: **3,250**
Calculate alternative total benchmark expenditures based on number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries.	Per capita benchmark expenditures[1]: $13,000 Alternative total benchmark expenditures: $13,000 * 3,250 = **$42,250,000**
Calculate alternative performance payment limit based on Track-specific percentage.	ACO Track: BASIC Track Level E Alternative performance payment limit: 10% * $42,250,000 = **$4,225,000**
Compare alternative performance payment limit to existing performance payment limit and apply the lesser value.	Existing performance payment limit: ($13,000 per capita benchmark expenditures * 5,050 PY person years) *10% = **$6,565,000** Final performance payment limit: **$4,225,000**

Notes: [1] Updated Per Capita Benchmark Expenditures expressed as a single value ($).

TABLE 50: EXAMPLE ALTERNATIVE LOSS RECOUPMENT LIMIT CALCULATION

Determine which BY corresponds with the lowest number of assigned beneficiaries as determined at the time of financial reconciliation.	Number of assigned beneficiaries for each BY, determined at the time of financial reconciliation. BY1: 4,300 BY2: 3,900 BY3: 5,500 BY with lowest number of assigned beneficiaries: **BY2**
Determine number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries, determined at the time of financial reconciliation.	Number of assigned beneficiary person years for each BY, determined at the time of financial reconciliation. BY1: 3,550 BY2: 3,250 BY3: 5,050 Number of assigned beneficiary person years for BY2: **3,250**
Calculate alternative total benchmark expenditures based on number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries.	Per capita benchmark expenditures[1]: **$13,000** Alternative total benchmark expenditures: $13,000 * 3,250 = **$42,250,000**
Calculate alternative loss recoupment limit based on Track-specific percentage.	ACO Track[2]: BASIC Track Level E 8% of ACO Participant Total Medicare Parts A and B FFS Revenue: **$2,750,000** 4% of Alternative total benchmark expenditures: **$1,690,000** Alternative loss recoupment limit: -4% * $42,250,000 = **-$1,690,000**
Compare alternative loss recoupment limit to existing loss recoupment limit and apply the lesser absolute value.	Existing loss recoupment limit [3]: ($13,000 per capita benchmark expenditures * 5,050 PY person years) *-4% = -$**2,626,000** Final loss recoupment limit: **-$1,690,000**

Notes: [1] Updated Per Capita Benchmark Expenditures expressed as a single value ($).

[2] For BASIC Track Level E, if 8 percent of total Medicare Parts A and B FFS Revenue for ACO Participants is greater than 4 percent of Total Benchmark Expenditures, then the loss recoupment limit is equal to -4 percent of Total Benchmark Expenditures.

[3] In this case, the ACO's revenue-based loss sharing limit exceeds the benchmark-based loss sharing limit; therefore, the ACO's loss sharing limit is based on total benchmark expenditures.

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As explained elsewhere in this section of this proposed rule, we have used our authority under section 1899(i)(3) of the Act to establish the two-sided payment models of the BASIC track and ENHANCED track, including the existing approach to calculating the loss recoupment limits (based on the ACO's assigned beneficiary person years for the performance year). Therefore, we propose to continue to use our authority under section 1899(i)(3) of the Act to implement our proposal to apply the lower of a loss recoupment limit calculated based on performance year assigned beneficiary person years, or an alternative loss recoupment limit calculated based on the ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries, in conducting financial reconciliation for a performance year in agreement periods beginning on or after January 1, 2027.To implement this alternative payment model under the Secretary's authority under section 1899(i) of the Act, we must determine that it would improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. As discussed further in the Regulatory Impact Analysis, in section VII. of this proposed rule, we project that the proposed change to apply an alternative loss recoupment limit for ACOs with fewer than 5,000 assigned beneficiaries in any BY, in combination with other proposed changes to the statutory payment model in this proposed rule, as well as current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program, and would not be expected to increase program expenditures relative to those of the statutory payment model. As described in the Regulatory Impact Analysis for this proposed rule, by potentially reducing shared savings payments to outliers with sharp growth in beneficiary assignment during the agreement period despite benchmark year counts dropping below the current minimum, the program may see additional net savings to the Medicare Trust Funds as compared to the current existing policy. Meanwhile, the alternative loss recoupment limit is not

expected to materially reduce shared losses collected by the program as only a few ACOs have shared losses, and those losses rarely approach the regular benchmark-based loss recoupment limit. Also, the alternative loss recoupment limit would potentially marginally increase participation in the Shared Savings Program by providing certain ACOs greater assurance that they would be protected from elevated exposure to unusually large shared loss liabilities in rare situations where their assignment counts could decrease well below 5,000. Attracting additional ACOs to the Shared Savings Program increases the number of providers and suppliers who are working together to coordinate care for beneficiaries, providing quality care at lower cost.

We seek comments on the proposals to apply an alternative performance payment limit and loss recoupment limit during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries in any BY.

(2) Exclude ACOs That Fall Below 5,000 Assigned Beneficiaries in any BY From Policies Providing Certain Low Revenue ACOs Participating in the BASIC Track Increased Opportunities To Share in Savings

(a) Background

With the CY 2023 PFS final rule (87 FR 69946 through 69952), we finalized an approach, under our authority of section 1899(i)(3) of the Act,[323] to expand the eligibility criteria to qualify for shared savings payments to enable certain low revenue ACOs participating in the BASIC track to share in savings even if the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act. In accordance with § 425.605(h), ACOs participating in the BASIC track that do not meet the MSR requirement, but that do meet the quality performance standard or the alternative quality performance standard at § 425.512 and otherwise maintain eligibility to participate in the Shared Savings Program, qualify for a shared savings payment if all the following criteria are met:

- The ACO has average per capita Medicare Parts A and B FFS expenditures for the performance year below the updated benchmark (§ 425.605(h)(1)(i)).
- The ACO is a low revenue ACO as defined at § 425.20 as determined at the time of financial reconciliation for the performance year (§ 425.605(h)(1)(ii)).
- The ACO has at least 5,000 assigned beneficiaries for the performance year at the time of financial reconciliation for the performance year (§ 425.605(h)(1)(iii)).
- The ACO is participating in an agreement period beginning on January 1, 2024, or in subsequent years (§ 425.605(h)(1)(iv)).

Section 425.605(h)(2) specifies the sharing rate applied for ACOs that meet the aforementioned criteria, which is one-half the applicable percentage described at § 425.605(d). As we explained in the CY 2023 PFS final rule (see 87 FR 69948 and 69949), under this approach, an eligible ACO that does not meet the MSR but meets the quality performance standard required to share in savings at the maximum sharing rate receives half of the maximum sharing rate for their level of participation (20 percent instead of 40 percent under Levels A and B, and 25 percent instead of 50 percent under Levels C, D, and E). Where an eligible ACO does not meet the MSR or the quality performance standard required to share in savings at the maximum sharing rate but meets the alternative quality performance standard, the sharing rate is further adjusted according to a sliding scale approach for determining shared savings.

(b) Proposed Revisions

We propose to exclude ACOs that fall below 5,000 assigned beneficiaries in any BY from being eligible to benefit from the policies at § 425.605(h) that provide certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings. As we have explained in prior rulemaking, the MSR/MLR protects against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than actual program performance. ACOs with assigned beneficiary populations below 5,000 raise concerns that any shared savings payments made to the ACO would not reward true cost savings but instead would pay for normal expenditure fluctuations (see 83 FR 67923 through 67926 for prior discussion). To protect against issuing payments to certain low revenue ACOs participating in the BASIC track related to normal or random variation in expenditures, we propose revising § 425.605(h) to include an additional criterion that ACOs must have at least 5,000 assigned beneficiaries in all three benchmark years at the time of financial reconciliation for a performance year to qualify for a shared savings payment at § 425.605(h). Specifically, we propose to amend § 425.605(h)(1) by adding new paragraph (v) that specifies: ''For agreement periods beginning on or after January 1, 2027, the ACO has at least 5,000 assigned beneficiaries in each of the ACO's benchmark years.'' The proposed timing of applicability for this policy would be consistent with the timing of applicability for our proposed approach to allow participation by ACOs with 5,000 assigned beneficiaries in BY3, and fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, described in section III.F.4.b.(2). of this proposed rule.

We seek comments on the proposal to exclude ACOs that fall below 5,000 assigned beneficiaries in any BY from being eligible to benefit from policies at § 425.605(h) providing certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings.

5. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

a. Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), for performance years beginning on or after January 1, 2019. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747

[323] Refer to Executive Order 14192 ''Unleashing Prosperity Through Deregulation'' *https://www.federalregister.gov/documents/2025/02/06/2025–02345/unleashing-prosperity-through-deregulation.*

through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825; 88 FR 79163 through 79174; 89 FR 98087 through 98101) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program. For the performance year beginning on January 1, 2025, and subsequent performance years, we defined primary care services for purposes of assigning beneficiaries to ACOs under § 425.402 at § 425.400(c)(1)(ix).

b. Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently used for payment under the PFS or that we are proposing to use for payment under the PFS starting in CY 2026, we have determined it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes for the performance year starting on January 1, 2026, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

We propose to specify a revised definition of primary care services used for assignment for the performance year starting on January 1, 2026, and subsequent performance years in a new provision of the Shared Savings Program at § 425.400(c)(1)(x) to include the list of HCPCS and CPT codes specified at § 425.400(c)(1)(ix), as well as the following additions: Enhanced Care Model Management Services (HCPCS codes (GPCM1, GPCM2, and GPCM3), and the deletion of Social Determinants of Health Risk Assessment Services (HCPCS code G0136), if finalized under Medicare FFS payment policy.

We propose to use the new provision at § 425.400(c)(1)(x) for determining beneficiary assignment for the performance year starting on January 1, 2026, and in subsequent performance years.

The following provides additional information about the CPT and HCPCS codes that we are proposing to add to the definition of primary care services used for purposes of beneficiary assignment:

Enhanced Care Model Management Services (HCPCS Codes GPCM1, GPCM2, and GPCM3): In section II.G of this proposed rule, we are proposing three new add-on HCPCS codes to allow for payment under the PFS when BHI or CoCM are furnished in conjunction with APCM services for practitioners who meet the requirements to furnish both services. Specifically, we are proposing to allow for payment of the following codes, discussed in more detail below, under the PFS: GPCM1, an add-on code that mirrors 99492 (CoCM initial month), GPCM2, an add-on code that mirrors 99493 (subsequent months) for CoCM services delivered to patients also receiving APCM services, and GPCM3, an add-on code for general behavioral health integration services that mirrors CPT code 99484 (20 minutes or more of BHI services) for BHI services delivered to patients also receiving APCM services.

- *HCPCS code GPCM1* (Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan, if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, *and* participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately and in addition to the Advanced Primary Care Management code.)).
- *HCPCS code GPCM2*(Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment. (list separately and in addition to Advanced Primary Care Management code)).
- *HCPCS code GPCM3*(Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team (list separately and in addition to Advanced Primary Care Management cod)).

All of these codes are proposed as optional add-on codes for APCM services that would facilitate providing complementary BHI services by removing the time-based requirements and reducing documentation requirements of the existing BHI and CoCM CPT codes. We believe removing the time-based requirements and reducing the documentation requirements may make primary care practitioners more likely to offer BHI and CoCM services, which would improve access to BHI and CoCM for primary care patients and access to primary care for BHI and CoCM patients.

These new HCPCS codes are designed to allow for the payment of services that, when reported as standalone services, are currently included in the definition of primary care services used for purposes of assignment when furnished in conjunction with APCM services: BHI (CPT codes 99484, 99492, 99493 and 99494), CoCM (HCPCS code G2214), and APCM (HCPCS codes G0556, G0557, and G0558) (refer to 82

FR 53212 through 53213, 85 FR 84750 through 84755, and 89 FR 98087 through 98097, respectively).

The new HCPCS codes also are similar to CPT codes 99354 and 99355 (83 FR 59965 through 59968), which likewise are included in the definition of primary care services used for purposes of assignment. Including these new HCPCS codes for BHI and CoCM APCM add-on services into the definition of primary care services used for purposes of assignment would increase the accuracy of assignment based on the provision of primary care by ensuring that all expenditures for BHI and CoCM are used to determine beneficiary assignment.

The following provides additional information about the CPT and HCPCS codes that we are proposing to remove from the definition of primary care services used for purposes of beneficiary assignment:

HCPCS code G0136 (Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5–15 minutes): In section II.I of this rule, we are proposing to delete HCPCS code G0136 as we have come to believe that the resource costs described by HCPCS code G0136 are already accounted for in existing codes, including but not limited to evaluation and management visits. Accordingly, we are proposing to not include this HCPCS code in the definition of primary care services used for purposes of assignment, beginning January 1, 2026, and in subsequent years, if the deletion is finalized.

As part of this revised definition of primary care services used for assigning beneficiaries at § 425.402, we propose to incorporate a provision at § 425.400(c)(1)(x)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified at § 425.400(c)(1)(x)(A) or a HCPCS code specified at § 425.400(c)(1)(x)(B), when the assignment window or expanded window for assignment (as defined at § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under Medicare FFS.

We seek comments on these proposed changes to the definition of primary care services used for assigning beneficiaries at § 425.400(c)(1)(x) to Shared Savings Program ACOs for the performance year starting on January 1, 2026, and subsequent performance years. We also seek comments on any other existing or new HCPCS or CPT codes proposed elsewhere in this proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

6. Quality Performance Standard & Other Quality Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality healthcare at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care and wherever practicable, caregiver experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, 2021, 2023, 2024, and 2025 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80489, 83 FR 59708 through 59715, 85 FR 84733 through 84734, 87 FR 69860 through 69863, 88 FR 79112 through 79114, and 89 FR 98124 through 98132, respectively).

b. Proposal To Revise the Definition of a ''Beneficiary Eligible for Medicare CQMs''

(1) Background

In the CY 2024 PFS final rule (88 FR 79097 through 79107), for performance year 2024 and subsequent performance years, we established Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs within the APP quality measure set and for which the ACO reports quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20. This option has allowed and continues to allow ACOs to develop experience aggregating data for their Medicare fee-for-service (FFS) patients across their participant TINs and provides ACOs with opportunities to develop workflows to allow them to transition to reporting quality data for their entire population through digital quality measurement.

As stated in the CY 2024 PFS final rule (88 FR 79101), Medicare CQMs have served and continue to serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment. Specifically, Medicare CQMs addressed the concern raised by ACOs that for ACOs with a higher proportion of specialty practices, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, given ACOs are commonly made up of multiple practices using multiple EHRs, ACOs have been able to utilize Medicare Part A and B claims data to help identify the ACO's eligible population and validate the ACO's patient matching and deduplication efforts. We also stated that Medicare CQMs are an all-beneficiary Medicare measure (not just ACO assigned beneficiaries) and are designed to help ACOs address challenges with aggregating patient data required to report Medicare CQMs and the all payer/all patient MIPS CQMs and eCQMs in the future (88 FR 79102).

In the CY 2024 PFS final rule (88 FR 79107), we also finalized the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

- A Medicare FFS beneficiary (as defined at § 425.20) who—

++ Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

++ Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

- A Medicare FFS beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

We discussed in the CY 2024 PFS final rule that, in response to our proposed definition of a ''beneficiary eligible for Medicare CQMs'' in the CY 2024 PFS proposed rule, many commenters raised questions and concerns regarding how CMS will determine the appropriate Medicare CQM population for these measures (88 FR 79102). Some commenters noted that the proposed denominator eligibility criteria are similar to, but differ in timeline from, the current assignment methodology and that this creates unnecessary complexity, potentially leading to concerns in identifying the appropriate Medicare ACO population. A few commenters suggested we combine the new Medicare CQM methodology with the existing assignment methodology, which would mitigate potential challenges and ensure a smoother implementation process. Several commenters asked that we clarify if the list of ''beneficiaries eligible for Medicare CQMs'' is limited to assigned beneficiaries or if it includes all assignable beneficiaries eligible for the measure.

In the CY 2024 PFS final rule (88 FR 79102), in response to commenters' suggestions to align the definition of ''beneficiary eligible for Medicare CQM'' with our assignment methodology, we noted that our definition of a beneficiary eligible for Medicare CQMs aims to align Medicare CQMs with the all payer/all patient measure specifications because Medicare CQMs are intended to support ACOs in the transition to all payer/all patient measures. We stated that the definition would limit Medicare CQM reporting to beneficiaries that had an encounter with an ACO professional with a specialty used in assignment or who were voluntarily assigned to the ACO. We noted that our approach would also balance our commitment to the transition to all payer/all patient measures with the need to provide additional support to some ACOs as they build the skills and infrastructure necessary to report digital quality measures.

To support ACOs in reporting Medicare CQMs, we finalized that we would provide each ACO with a list of beneficiaries eligible for Medicare CQMs each quarter throughout the performance year as part of the ACO's Quarterly Informational Reports Packages to give ACOs access to the full 12 months of encounters necessary to report Medicare CQMs (88 FR 79104 through 79105). We stated that the list would be cumulative and updated quarterly to reflect the most recent quarter's data, and the fourth quarter list of beneficiaries eligible for Medicare CQMs would include encounters with dates of service January 1st through December 31st of the performance year. We stated that the quarterly list would include beneficiary-level age, diagnosis, encounter, and exclusion flags on the list of beneficiaries eligible for Medicare CQMs to aid ACOs in identifying the denominator eligible population for each measure to the extent that such data can be identified through claims and Medicare administrative systems. We also stated that it was important to note that these flags are meant to assist ACOs in the aggregation of data and do not replace the need for ACOs to evaluate their patient population against each Medicare CQM specification prior to submission, including determining the beneficiaries that meet the denominator criteria for the measure. We now note, by way of additional explanation, that since the list does not apply measure-specific eligibility criteria, the list may include Medicare FFS beneficiaries who are not eligible for inclusion in any of the three Medicare CQMs in the APP quality measure set.

Based on our experience with providing ACOs with the quarterly lists of beneficiaries eligible for Medicare CQMs for performance year 2024, we have learned that the complexity of the current definition of a ''beneficiary eligible for Medicare CQMs'' has continued to create confusion for some Shared Savings Program ACOs. Some of these ACOs have sought additional clarification and guidance from CMS. Revising the definition of a ''beneficiary eligible for Medicare CQMs'' would be responsive to these ACOs and other stakeholder feedback and would reduce ACOs' burden with respect to the patient matching necessary to report Medicare CQMs. Some of the ACO feedback we have received has been based on the differences between the Medicare CQM beneficiary lists that they have received from CMS and the assignable or assigned beneficiary files that ACOs also receive from CMS. Differences in the beneficiary information obtained from these files has contributed to concerns from ACOs about which beneficiaries to use for quality data reporting through Medicare CQMs.

The methodology used to generate the list of ''beneficiaries eligible for Medicare CQMs'' differs from the methodology described at §§ 425.400, 425.401, 425.402, and 425.404 used to generate the list of beneficiaries assignable to an ACO, that is the universe of beneficiaries who receive at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included at § 425.402(c). These methodologies differ in time frames and encounter codes used, which has led to inquiries by ACOs and increased burden due to marginal differences in overlapping populations that meet these criteria. Our current definition of a ''beneficiary eligible for Medicare CQMs'' was intended to create alignment with the all payer/all patient MIPS CQM Specifications. The use of the terms of ''claim'' and ''measurement period'' in the definition of a ''beneficiary eligible for Medicare CQMs'' are consistent with the application of all payer/all patient MIPS CQM Specifications. The codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications only partially overlap with the HCPCS and revenue center codes designated at § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program. Similarly, the measurement period applicable to each measure in the all payer/all patient MIPS CQM Specifications only partially overlaps with the 12-month period used in assignment (88 FR 79098). These differences mean an ACO may have beneficiaries eligible for Medicare CQMs that are not part of an ACO's assigned or assignable population. For example, this may occur if the beneficiary has a claim by an ACO professional or specialty designation that is not a primary care service or a claim that occurs during the measurement period but outside the assignment window.

(2) Proposed Revisions

Considering the concerns raised by ACOs and other interested parties, and our commitment to supporting ACOs in the transition to digital quality measure reporting, we propose to revise the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 effective January 1, 2025, meaning we propose to apply the revised definition for performance year 2025, as well as for subsequent performance years. Specifically, beginning with performance year 2025 and continuing in subsequent performance years, we propose to revise the definition to require, in (1)(ii)(B) of the definition, ''at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included at

§ 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.'' We would redesignate the existing (1)(ii) as (1)(ii)(A). The current definition of ''beneficiary eligible for Medicare CQMs'' requires, in (1)(ii), ''at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.'' For performance year 2025 and subsequent performance years, the revised definition we are proposing in (1)(ii)(B) would align with our modifications to the stepwise assignment methodology and approach to identifying the beneficiaries assignable to an ACO, as finalized in the CY 2024 PFS final rule (88 FR 79162) and described at § 425.402(a)(5), where nurse practitioners, physician assistants, and clinical nurse specialists were added to the process for identifying beneficiaries assignable to an ACO beginning in performance year 2025. Specifically, the revised definition we are proposing in (1)(ii)(B) uses ''primary care services'' and ''performance year,'' instead of ''claims'' and ''measurement period,'' respectively, as used in the current definition. The proposed definition in (1)(ii)(B) would continue to align with the special assignment conditions for ACOs, including Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs), as described at § 425.404. We provide a list of ''beneficiaries eligible for Medicare CQMs'' to each ACO. We would continue to include on that list all beneficiaries for whom a service is reported on an FQHC/RHC claim. As described at § 425.404, we treat a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

The proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' would reduce ACOs' burden in the patient matching necessary to report Medicare CQMs because the list of ''beneficiaries eligible for Medicare CQMs'' would have greater overlap with the list of beneficiaries that are assignable to an ACO. Specifically, more closely aligning these definitions would mean that, for most ACOs, the large majority of an ACO's beneficiaries eligible for Medicare CQMs would be part of the list of beneficiaries assignable to an ACO. Therefore, under the proposed definition of a ''beneficiary eligible for Medicare CQMs,'' most ACOs would have to do less patient matching than they presently do because there would be fewer differences between the definition of ''beneficiary eligible for Medicare CQMs'' and ''assignable beneficiary.'' The proposal would also help each ACO identify its eligible population and validate the ACO's patient matching and deduplication efforts because ACOs would see fewer differences between the Medicare CQM beneficiary list and the list of beneficiaries assignable to the ACO. We believe our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' would substantially address ACOs' and interested parties' concerns by better aligning the definitions and clarifying which beneficiaries' data to use for quality data reporting through Medicare CQMs.

We conducted a gap analysis using performance year 2024 data to analyze the overlap of our proposed definition of a ''beneficiary eligible for Medicare CQMs'' and the current performance year 2025 methodology used to identify beneficiaries assignable to an ACO. The goal of this analysis was to determine whether the proposed change in the definition of a ''beneficiary eligible for Medicare CQMs'' would accomplish our goal of aligning that population with the list of beneficiaries assignable to an ACO. With the addition of nurse practitioners, physician assistants, and clinical nurse specialists beginning in performance year 2025 for identifying assignable beneficiaries, as well as the proposed change to the definition of a ''beneficiary eligible for Medicare CQMs'' to require ''primary care services,'' the overlap between the Medicare CQM eligible population and the list of beneficiaries assignable to an ACO is expected to increase, on average, to 85 percent for most ACOs. We note that the amount of overlap between assignable beneficiaries and beneficiaries eligible for Medicare CQMs will vary across ACOs due to factors like different population composition and different use patterns of non-physician care codes. Overall, we believe that the proposed changes will generally help ACOs identify and collect data for the population of beneficiaries eligible for Medicare CQMs and support adoption of Medicare CQMs. Therefore, we propose to revise the definition of a ''beneficiary eligible for Medicare CQMs,'' at § 425.20, for performance year 2025 and subsequent performance years, to require at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

To support ACOs in preparing for this proposed change, we will continue to provide the quarterly list based on the definition of a ''beneficiary eligible for Medicare CQMs'' as finalized in the CY 2024 PFS final rule (88 FR 79097 through 79107) and will add an additional variable to the quarterly list to flag each beneficiary who had a primary care service visit, beginning with the performance year 2025 Quarter 2 list, to identify ''beneficiaries eligible for Medicare CQMs'' under the proposed definition. If this proposal is finalized, then the quarterly list, starting with performance year 2025 Quarter 4, would be based on the finalized definition of a ''beneficiary eligible for Medicare CQMs.''

Section 1871(e)(1)(A) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. It is in the public interest to apply our proposed changes to the definition of a ''beneficiary eligible for Medicare CQMs'' beginning in performance year 2025. Applying these changes starting with performance year 2025 is in the public interest because, absent the proposed changes in the definition, the current definition is an ongoing contributor to ACOs' confusion regarding which beneficiaries to use for quality data reporting through Medicare CQMs and creates burden for ACOs in patient matching and quality reporting. Minimizing this complexity through our proposed changes in definition will reduce the burden on ACOs that elect to report Medicare CQMs and better enable them to gain experience with aggregating and deduplicating data, since Medicare CQMs are intended to aid in the transition to digital quality measure reporting quality data for an ACO's entire population. The proposed changes to the definition, and resulting burden reduction, will allow ACOs to devote greater resources to improving care coordination so that they are better positioned to deliver the right care at the right time, all to the benefit of Medicare beneficiaries served by the ACO and Medicare Trust Funds. We believe the proposed changes would have minimal impact on ACOs' existing processes because the ACO would continue to apply the measure specifications to the population of beneficiaries eligible for Medicare

CQMs, but the beneficiary population would be based on a list of beneficiaries that better reflects the ACO's assigned population.

We propose to revise the definition of ''Beneficiary eligible for Medicare CQMs'' at § 425.20, as follows:

- We are adding a new paragraph (A) to paragraph (1)(ii) of the definition of ''beneficiary eligible for Medicare CQMs'' at § 425.20 to establish that, in addition to the requirement in paragraph (1)(i) and for performance year 2024, a beneficiary eligible for Medicare CQMs ''had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.'' This proposal would effectively move the existing text of paragraph (1)(ii) to paragraph (1)(ii)(A) and limit the application of the existing text of paragraph (1)(ii) to performance year 2024.
- We are adding a new paragraph (B) to paragraph (1)(ii) of the definition of ''beneficiary eligible for Medicare CQMs'' at § 425.20 to establish that, in addition to the requirement in paragraph (1)(i) and for performance year 2025 and subsequent performance years, a beneficiary eligible for Medicare CQMs ''had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.''

We are seeking public comments on the proposed changes to the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20.

c. Proposals To Remove the Health Equity Adjustment Applied to an ACO's Quality Score and Revise Certain Terminology in the Shared Savings Program Regulations

(1) Background

In the CY 2023 PFS final rule (87 FR 69838 through 69857), we finalized a health equity adjustment that would be available for performance year 2023 and subsequent performance years to an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey. We finalized that such ACOs may receive up to a maximum of 10 additional points added to their MIPS quality performance category score. The level of the adjustment is based on the joint consideration of an ACO's performance on quality measures and the population served by the ACO, such that ACOs that perform well on quality measures and serve a high proportion of beneficiaries who are from underserved neighborhoods (residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85); or who are eligible for the Medicare Part D Low-Income Subsidy (LIS), or are dually eligible for Medicare and Medicaid would receive a higher number of bonus points added to their MIPS quality performance category score. In the CY 2024 PFS final rule (88 FR 79110 through 79111), we finalized that ACOs reporting Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score.

The health equity adjustment was designed to further several goals, including supporting ACOs transitioning to all payer/all patient quality measure reporting, incentivizing ACOs to report eCQMs/MIPS CQMs/Medicare CQMs, improving quality, and recognizing high-performing ACOs serving underserved populations (87 FR 69841 through 69842; 88 FR 79097). The regulation at § 425.512(b) specifies how we calculate an ACO's health equity adjusted quality performance score for performance year 2023, performance year 2024, and performance year 2025 and subsequent performance years. We also incorporated references to an ACO's health equity adjusted quality performance score at §§ 425.512(a), 425.512(c), 425.605(d), and 425.610(d) and (f), as applicable.

In the CY 2025 PFS final rule, we established or extended additional scoring adjustments for ACOs, such as the Complex Organization Adjustment (89 FR 98116 through 98117 and 89 FR 98105) and the eCQM/MIPS CQM reporting incentive (89 FR 98121 through 98124), respectively.

Complex Organization Adjustment: In the CY 2025 PFS final rule (89 FR 98116 through 98117), we established a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year to account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs. A Virtual Group and an APM Entity will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Each reported eCQM may not score more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment will be added for each eCQM submitted at the individual measure level. Since Shared Savings Program ACOs are APM Entities, this policy is applicable to Shared Savings Program ACOs reporting the APP Plus quality measure set beginning in performance year 2025.

eCQM/MIPS CQM Reporting Incentive: We originally adopted an incentive for ACOs to begin transitioning to eCQM/MIPS CQM reporting (herein referred to as the ''eCQM/MIPS CQM reporting incentive'') in the CY 2022 PFS final rule (86 FR 65261 through 65262). In the CY 2023 PFS final rule, we extended the eCQMs/MIPS CQM reporting incentive through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures are required beginning in performance year 2025 (87 FR 69836 through 69838). We further extended the eCQM/MIPS CQM reporting incentive in the CY 2025 PFS final rule (89 FR 98124) to continue to support ACOs in the transition to eCQMs for digital quality measurement reporting. Meeting the criteria for the eCQM/MIPS CQM incentive allows an ACO to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

The extension of the eCQM/MIPS CQM reporting incentive ensures continued support for ACOs as they gain experience reporting all payer/all patient measures. Specifically, for performance year 2025 and subsequent performance years for ACOs reporting eCQMs, and performance years 2025 and 2026 for ACOs reporting MIPS CQMs, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the MIPS

data completeness requirement for all eCQMs/MIPS CQMs;

- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set; and
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set (89 FR 98122 through 98124).

We stated in the CY 2025 PFS final rule (89 FR 98123) that we believe the increased number of quality measures that will be phased into the APP Plus quality measure set over time will afford ACOs expanded opportunities to satisfy the eCQM/MIPS CQM reporting incentive criteria. For instance, the number of eCQMs/MIPS CQMs in the APP Plus quality measure set will increase from four in performance year 2025 to five in performance year 2026. Once MIPS CQMs are removed from the APP Plus quality measure set in performance year 2027, the number of eCQMs in the APP Plus quality measure set will increase from 5 to 6 in performance year 2027. With the proposed removal of Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in section III.F.6.d.(2) of this proposed rule, once all of the eCQMs are incorporated into the APP Plus quality measure set and if that proposal is finalized, there would be seven eCQMs. Out of these seven eCQMs, two of them (Quality ID: 001 Diabetes: Glycemic Status Assessment Greater Than 9% and Quality ID: 236 Controlling High Blood Pressure) are outcome measures and focus on the management of chronic conditions. There are also three eCQMs (Quality ID: 112 Breast Cancer Screening, Quality ID: 113 Colorectal Cancer Screening, and Quality ID: 493 Adult Immunization Status) that focus on wellness and prevention.

(2) Proposal To Remove the Health Equity Adjustment Applied to an ACO's Quality Score

After further consideration and experience implementing the eCQM/MIPS reporting incentive and the Complex Organization Adjustment, in conjunction with the previous policies we have finalized with respect to the health equity adjustment, we have concluded that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment provide duplicative incentives to the incentive provided by the health equity adjustment, for ACOs to meet the quality performance standard under the Shared Savings Program.

As described in section III.F.6.c.(1) of this proposed rule, an ACO that is eligible for the health equity adjustment may receive up to a maximum of 10 additional points that are added to its MIPS quality performance category score, and the sum of which then becomes the ACO's health equity adjusted quality performance score (87 FR 69831). The application of the health equity adjustment to an ACO's MIPS quality performance category score allows the ACO to achieve a higher quality score that would be used to determine whether the ACO meets the quality performance standard. For performance year 2024 and subsequent performance years, if the ACO's health equity adjusted quality performance score is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, then the ACO is determined to have met the quality performance standard under the Shared Savings Program and is eligible to receive maximum shared savings and avoid maximum shared losses (if applicable), at which point additional ACO quality performance points provide no further benefit.

Another pathway for an ACO to meet the quality performance standard is to meet the criteria for the eCQM/MIPS CQM reporting incentive as described in section III.F.6.c.(1) of this proposed rule. ACOs that meet the criteria for the eCQM/MIPS CQM reporting incentive would meet the quality performance standard regardless of what their MIPS quality performance category score is and be eligible to receive maximum shared savings and avoid maximum shared losses, if applicable.

Based on performance year 2023 ACO quality results, among 71 ACOs that qualified for the health equity adjustment in performance year 2023, 13 ACOs earned health equity adjustment bonus points with an average of 3.54 bonus points (out of 10) awarded. Since all 13 of the ACOs that received health equity adjustment bonus points also met the criteria for the eCQM/MIPS CQM reporting incentive, these ACOs would have met the quality performance standard to be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable) even if the health equity adjustment bonus points were not applied. This demonstrates the duplicative nature of the health equity adjustment and the eCQM/MIPS CQM reporting incentive. Although limited data is currently available, we expect that this trend will continue and that ACOs that would have received health equity adjustment bonus points are likely to also meet the criteria for the eCQM/MIPS CQM reporting incentive and meet the quality performance standard in future performance years.

The Complex Organization Adjustment upwardly adjusts an ACO's MIPS quality performance category score when the ACO reports eCQMs. As described in section III.F.6.c.(1) of this proposed rule, an ACO will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340, and the Complex Organization Adjustment may be up to 10 percent of the total available measure achievement points in the quality performance category. Based on the quality measures finalized for the APP Plus quality measure set for the Shared Savings Program (89 FR 98128 through 98130), ACOs that report eCQMs will receive the Complex Organization Adjustment to their MIPS quality performance category score on up to four measures (that is, four points) in performance year 2025, 5 measures (that is, five points) in performance year 2026, and 6 measures (that is, six points) in performance year 2027, if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Should we finalize our proposal to remove Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in section III.F.6.d.(2) of this proposed rule, for performance year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493 Adult Immunization Status, whichever is later, ACOs that report eCQMs would receive the Complex Organization Adjustment on up to seven measures (that is, seven points) if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. As the number of eCQMs that ACOs are required to report in the APP Plus quality set grows, the relative value of the Complex Organization Adjustment will increase. Both the health equity adjustment and the Complex Organization Adjustment serve to upwardly adjust an ACO's quality score in order to increase the ACO's ability to meet the quality performance standard by achieving a quality score that is

equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring. The health equity adjustment and Complex Organization Adjustment are duplicative because they serve a similar function. The Complex Organization Adjustment is accounted for in the calculation of the ACO's MIPS quality performance category score; whereas, the health equity adjustment bonus points are added to the ACO's MIPS quality performance category score. Both ultimately increase an ACO's MIPS quality performance category score and, therefore, improve the ACO's ability to meet the quality performance standard.

As discussed in the CY 2023 PFS final rule, we finalized the health equity adjustment to support ACOs that report all payer/all patient eCQMs/MIPS CQMs, perform high on quality, and serve a high proportion of underserved beneficiaries (87 FR 69838). We further stated that, because every year a greater proportion of ACOs are making the switch to eCQMs, instituting a health equity adjustment for those ACOs making the switch to eCQMs would allow us to study the impacts and make refinements during subsequent rulemaking (87 FR 69839). Moreover, in the CY 2023 PFS final rule, we expressed our concern that ACOs that serve a large portion of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS may receive lower quality scores during the switch to eCQMs without an adjustment and, in turn, be incentivized to avoid these populations, delay switching to eCQMs for as long as possible, or even cease participation in the Shared Savings Program altogether (87 FR 69839).

We believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment sufficiently support ACOs to address the unique challenges they face when reporting all payer/all patient measures and sufficiently support ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS. Both the eCQM/MIPS reporting incentive and the Complex Organization Adjustment have broader applicability than the health equity adjustment. The eCQM/MIPS CQM reporting incentive is available to all ACOs that report eCQMs/MIPS CQMs and meet the criteria for the reporting incentive; whereas the Complex Organization Adjustment is available to all ACOs that report eCQMs and meet the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340 for each eCQM. Due to the criteria that need to be met for an ACO to be eligible to receive the health equity adjustment, it only applies to a select group of ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS. Furthermore, unlike the eCQM/MIPS CQM reporting incentive, the health equity adjustment does not guarantee that ACOs will meet the quality performance standard.

We believe that the application of the Complex Organization Adjustment and the extension of the eCQM/MIPS CQM reporting incentive, as finalized in prior rules, have made it unnecessary to continue the policy of applying the health equity adjustment to an ACO's quality score. The Complex Organization Adjustment and the extension of the eCQM/MIPS CQM reporting incentive underscore our commitment to all payer/all patient quality measure reporting and are more broadly applicable than the health equity adjustment. Therefore, we propose to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025. In alignment with the Administration's priority to streamline regulations,[324] our proposal to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 would de-duplicate scoring factors and simplify our quality scoring methodology, without reducing the support available under our policies for ACOs to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

Additionally, in the CY 2024 PFS final rule, we finalized that ACOs that report Medicare CQMs would be eligible to have the health equity adjustment added to their quality performance category score when calculating shared savings payments (88 FR 79110). In the CY 2025 PFS final rule, we finalized that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for the measure's first two performance periods in MIPS (89 FR 98120 and 98121). In performance year 2025, all four Medicare CQMs that are in the APP Plus quality measure will be scored using a flat benchmark. We believe that the use of flat benchmarks in a measure's first two performance periods in MIPS may allow ACOs with high scores to earn maximum or near maximum measure achievement points while allowing for room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks in a measure's first two performance periods in MIPS also helps to ensure that ACOs with high quality performance on a measure are not penalized as low performers (89 FR 98105). There are scoring scenarios in which ACOs would earn higher measure achievement points under flat benchmarks than they would earn under performance period benchmarks, most notable being scenarios in which ACOs have a tight distribution of performance rates on a measure (89 FR 98119). We anticipate that flat benchmarks would provide benefits that are duplicative of the health equity adjustment for ACOs reporting Medicare CQMs for performance year 2025, where performance year 2025 is the measure's first or second performance period in MIPS using the Medicare CQM collection type.

Section 1871(e)(1)(A)(ii) of the Act prohibits the Secretary from retroactively applying a substantive change in Medicare regulations unless, as applicable here, the Secretary determines that failure to apply the change retroactively would be contrary to the public interest. We believe it would be contrary to the public interest to apply the proposed removal of the health equity adjustment applied to an ACO's quality score prospectively only. As such, we have proposed to apply the removal retroactively, beginning in performance year 2025. Performance year 2025 will be the first performance year when the Complex Organization Adjustment will apply to ACOs for reporting eCQMs. In performance year 2025, the eCQM/MIPS CQM reporting incentive will continue to be applicable to ACOs, and all Medicare CQMs in the APP Plus quality measure set will be scored using flat benchmarks.

As we discussed earlier in this section, the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment provide duplicative incentives alongside the incentive provided by the health equity adjustment, for ACOs to meet the quality performance standard under the Shared Savings Program. Performance year 2023 ACO quality results demonstrate the duplicative nature of the health equity adjustment and the eCQM/MIPS CQM reporting incentive, where the ACOs that earned health equity adjustment bonus points also met

[324] Refer to Executive Order 14192 ''Unleashing Prosperity Through Deregulation'' *https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation.*

the criteria for the eCQM/MIPS CQM reporting incentive. The health equity adjustment is added to an ACO's MIPS quality performance category score. ACOs that achieve the quality performance standard by meeting the eCQM/MIPS CQM reporting incentive are evaluated on their performance on measure-level quality performance scores, not the ACO's MIPS quality performance category score. As such, health equity adjustment bonus points are not used in the determination of the quality performance standard for ACOs that achieve the quality performance standard by meeting the eCQM/MIPS CQM reporting incentive. This dynamic further adds to the confusion and operational complexity of having multiple duplicative incentives for ACOs to meet the quality performance standard under the Shared Savings Program. Both the health equity adjustment and the Complex Organization Adjustment serve to upwardly adjust an ACO's quality score in order increase the ACO's ability to meet the quality performance standard. Furthermore, we noted earlier in this section that we anticipate that flat benchmarks would provide benefits that are duplicative of the health equity adjustment for ACOs reporting Medicare CQMs for performance year 2025, where performance year 2025 is the measure's first or second performance period in MIPS using the Medicare CQM collection type.

We also discussed that we believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment sufficiently support ACOs to address the unique challenges they face when reporting all payer/all patient measures and sufficiently support ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS (these are the goals of the health equity adjustment) due to the broader applicability of both the eCQM/MIPS reporting incentive and the Complex Organization than the health equity adjustment.

We believe that it is in the public interest to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 to simplify our quality scoring methodology for ACOs, while maintaining sufficient support for ACOs to meet the quality performance standard through the application of the eCQM/MIPS CQM reporting incentive, the Complex Organization Adjustment, and use of flat benchmarks for Medicare CQMs. Our proposal would allow ACOs to focus on a simpler scoring methodology that includes more widely applicable incentives, determine how to improve the quality of care furnished to their beneficiaries, and operate with greater focus to improve care coordination activities, thus resulting in the improvement of their performance on quality measures and ability to serve their beneficiaries. Making this change retroactively would provide greater clarity for ACOs by establishing continuity in resource language between performance year 2025 and subsequent performance years, allowing ACOs to plan ahead and have additional time to update internal operations and more easily prepare for consistent quality performance standards.

Specifically, we propose to revise and republish paragraph (b) of § 425.512, to include the following proposed amendments:

- At § 425.512 removing paragraph (b)(3).
- At § 425.512 redesignating paragraphs (b)(4) and (b)(5) as paragraphs (b)(3) and (b)(4), respectively.
- Revising references to paragraphs (b)(4) and (b)(5) (which we propose to redesignate as paragraphs (b)(3) and (b)(4)), as follows:

++ At § 425.512 in paragraphs (b)(1) and (b)(2), removing the reference ''paragraph (b)(4)'' and adding in its place the reference ''paragraph (b)(3)''.

++ At § 425.512 in paragraph (b)(4)(iii) (which we propose to redesignate as paragraph (b)(3)(iii)), removing the reference ''paragraph (b)(4)(ii)'' and adding in its place the reference ''paragraph (b)(3)(ii)''.

++ At § 425.512 in paragraph (b)(4)(iv)(A)(*2*) (which we propose to redesignate as paragraph (b)(3)(iv)(A)(*2*)) introductory text, removing the reference ''paragraph (b)(4)(iv)(A)(*1*)(*ii*)'' and adding in its place the reference ''paragraph (b)(3)(iv)(A)(*1*)(*ii*)''.

++ At § 425.512 in paragraph (b)(4)(iv)(B) (which we propose to redesignate as paragraph (b)(3)(iv)(B)), removing the reference ''paragraph (b)(4)(iv)(A)'' and adding in its place the reference ''paragraph (b)(3)(iv)(A)''.

++ At § 425.512 in paragraph (b)(4)(v) (which we propose to redesignate as paragraph (b)(3)(v)), removing the references to ''paragraph (b)(4)(iv)(B)'', ''paragraph (b)(4)(iii)'', and ''paragraph (b)(4)(iv)'' and adding in their place the references to ''paragraph (b)(3)(iv)(B)'', ''paragraph (b)(3)(iii)'', and ''paragraph (b)(3)(iv)'', respectively.

- At § 425.512 in paragraph (b)(4)(iv)(A)(*2*)(*ii*) (which we propose to redesignate as paragraph (b)(3)(iv)(A)(*2*)(*ii*)), removing the phrase ''For performance year 2024 and subsequent performance years'' and adding in its place the phrase ''For performance year 2024''.
- At § 425.512 in paragraph (b)(5) (which we propose to redesignate as paragraph (b)(4)), revising the introductory text and paragraph references to read as follows: ''Use of ACO's quality score. The ACO's quality score, determined in accordance with paragraphs (b)(1) through (3) of this section, is used as follows:''.

(3) Proposal To Revise the Terminology in the Shared Savings Program Regulations Used To Describe the Health Equity Adjustment and Other Related Terms

To accurately reflect the data used to calculate the health equity adjustment in performance years 2023 and 2024, we propose to revise the terminology used to describe this adjustment and other related terms in the Shared Savings Program regulations. Previously, the term health equity was used in a broad way that could lead to confusion regarding whether or not impermissible features, such as race and ethnicity, were included in Shared Savings Program policies (which they are not). No changes in the methodology currently used to calculate the health equity adjustment bonus points or the health equity adjusted quality performance score are being proposed for performance years 2023 and 2024.

In revising the terminology used to describe the health equity adjustment, we found that our use of the terms ''quality score'' and ''quality performance score'' could lead to confusion. As such, we also propose to revise the terms ''quality score'' and ''quality performance score'' at § 425.512. We propose to apply the term ''quality score'' consistently throughout § 425.512 to mean an ACO-level quality score and also apply the term ''quality performance score'' to consistently mean a measure-level score.

Additionally, we propose to update the cross-references in §§ 425.605 and 425.610 to reference the entirety of § 425.512. With respect to § 425.512(b), we note that the amendments are specified in revised and republished paragraph (b). Specifically, we propose the following conforming revisions to terminology used in the Shared Savings Program at §§ 425.512, 425.605, and 425.610:

- At § 425.512 in paragraphs (a)(3)(i), (b)(5)(iv) (which, as discussed later in this section, we propose to redesignate as paragraph (b)(4)(iv)), (c)(2)(i), (c)(2)(ii), and (c)(3)(i) removing the phrase ''quality performance score'' and adding in its place the phrase ''quality score''.

• At § 425.512 in paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(1), (a)(5)(i)(B)(1), (a)(5)(i)(C)(1), (a)(7), (b)(1), (b)(2), (c)(3)(ii), (c)(3)(iii), and (c)(3)(iv) removing the phrase ''health equity adjusted quality performance score'' and adding in its place the phrase ''quality score''.

• At § 425.512 in paragraph (b) subject heading revising to read as follows: ''Calculation of an adjustment to an ACO's quality score for performance years 2023 and 2024''.

• At § 425.512 in paragraphs (b)(1) and (b)(2), removing the phrase ''health equity adjustment bonus points'' and adding in its place the phrase ''population and income adjustment bonus points''.

• At § 425.512 in paragraph (b)(4) (which we propose to redesignate as paragraph (b)(3)), revising the introductory text to read as follows: ''Calculation of ACO's population and income adjustment bonus points. CMS calculates the ACO's bonus points as follows:''.

• At § 425.512 in paragraph (b)(4)(iv) (which we propose to redesignate as paragraph (b)(3)(iv)), removing the phrase ''an underserved multiplier'' and adding in its place the phrase ''a multiplier''.

• At § 425.512 in paragraph (b)(4)(iv)(A)(*1*) (which we propose to redesignate as paragraph (b)(3)(iv)(A)(*1*)), removing the phrase ''that is considered underserved''.

• At § 425.512 in paragraph (b)(4)(iv)(B) (which we propose to redesignate as paragraph (b)(3)(iv)(B)), removing the phrase ''health equity adjustment bonus points'' and adding in its place the phrase ''bonus points''.

• At § 425.512 in paragraph (b)(4)(v) (which we propose to redesignate as paragraph (b)(3)(v)): removing the phrase ''underserved multiplier'' and adding in its place the phrase ''multiplier''; and removing the phrase ''health equity adjustment bonus points'' and adding in its place the phrase ''bonus points''.

• At § 425.605 in paragraphs (d)(1)(i)(A)(*3*)(*ii*), (d)(1)(i)(A)(*4*)(*ii*), (d)(1)(ii)(A)(*3*)(*ii*), (d)(1)(ii)(A)(*4*)(*ii*), (d)(1)(iii)(A)(*3*)(*ii*), (d)(1)(iii)(A)(*4*)(*ii*), (d)(1)(iv)(A)(*3*)(*ii*), (d)(1)(iv)(A)(*4*)(*ii*), (d)(1)(v)(A)(*3*)(*ii*), and (d)(1)(v)(A)(*4*)(*ii*) removing the phrase ''health equity adjusted quality performance score calculated according to § 425.512(b)'' and adding in its place ''quality score calculated according to § 425.512''.

• At § 425.610 in paragraphs (d)(3)(ii), (d)(4)(ii), (f)(3)(i)(A) and (f)(4)(i)(A) removing the phrase ''health equity adjusted quality performance score calculated according to § 425.512(b)'' and adding in its place the phrase ''quality score calculated according to § 425.512''.

We seek public comments on these proposed changes. These proposed changes are reflected in Tables 52 and 53 in section III.F.6.f. of this proposed rule.

d. Proposal To Update the APP Plus Quality Measure Set

(1) Background

In the CY 2025 PFS final rule, we created the APP Plus quality measure set to align with the Adult Universal Foundation measures (89 FR 98356) and finalized a phase-in schedule for incorporating measures into the APP Plus quality measure set.

We finalized in the CY 2025 PFS final rule (89 FR 98105) that, for performance year 2025 and subsequent performance years, Shared Savings Program ACOs will be required to report the APP Plus quality measure set. We also finalized that Shared Savings Program ACOs will be required to report on and will be scored on all applicable quality measures in the APP Plus quality measure set according to the phase-in schedule for incorporating measures into the APP Plus quality measure set. We also stated in the CY 2025 PFS final rule (89 FR 98116 through 98117) that the APP Plus quality measure set for Shared Savings Program ACOs will include 11 measures (eight eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with performance year 2028 or the performance year that is one year after the eCQM specifications become available for Quality ID: 487 Screening for the Social Drivers of Health and Quality ID: 493 Adult Immunization Status, whichever is later, and ACOs will be scored on the required 11 measures.

The final APP Plus quality measure set for Shared Savings Program ACOs, for performance year 2025 and subsequent performance years, was specified in Tables 39 through 42 of the CY 2025 PFS final rule (89 FR 98128 through 98132).

(2) Proposed Revisions

Proposed changes to the following measures that are included in the APP Plus quality measure set are discussed in section IV.A.4.b.(2) of this proposed rule:

- Breast Cancer Screening (Quality ID: 112)
- Colorectal Cancer Screening (Quality ID: 113)
- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134) (eCQM collection type only)
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484)
- Screening for Social Drivers of Health (Quality ID: 487)

Further discussion and our rationale for the proposed modification or removal of these measures is provided in Table Groups D and DD, and C, respectively, in Appendix 1 of this proposed rule.

With the proposed removal of Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in section IV.A.4.b.(2) and Table Group C in Appendix 1 of this proposed rule, we propose that the APP Plus quality measure set for Shared Savings Program ACOs would include ten measures (seven eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493 Adult Immunization Status, whichever is later. ACOs would be scored on the required ten measures. The proposed APP Plus quality measure set for Shared Savings Program ACOs, for performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later, is specified in Table 51 of this proposed rule.

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TABLE 51: MEASURES INCLUDED IN THE APP PLUS QUALITY MEASURE SET FOR SHARED SAVINGS PROGRAM ACOs BEGINNING WITH PERFORMANCE YEAR 2028 OR THE PERFORMANCE YEAR THAT IS ONE YEAR AFTER THE ECQM SPECIFICATION BECOMES AVAILABLE FOR QUALITY ID: 493, WHICHEVER IS LATER

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
493	Adult Immunization Status	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

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e. Proposal To Add a Web-Based Survey Mode to the CAHPS for MIPS Survey

(1) Background

The CAHPS for MIPS Survey is an annual survey available to MIPS groups in Traditional MIPS and MIPS Value Pathways (MVPs), and APM Entities. As required at § 425.510(b)(2), for performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367 according to the method of submission established by CMS. The CAHPS for MIPS Survey is a quality measure in the APP Plus quality measure set (89 FR 98367 through 98371). Therefore, Shared Savings Program ACOs are required to administer the CAHPS for MIPS Survey (except if an ACO does not meet the required sample size specified at § 414.1380(b)(1)(vii)(B)) in order to meet the quality reporting requirement under the Shared Savings Program. Currently, data is collected using a mail-phone survey administration protocol administered in English and Spanish, with additional translations available. The CAHPS for MIPS Survey may only be administered by CMS-approved survey vendors.

In the CY 2025 PFS proposed rule (89 FR 61869, 62042, and 62043), we included a request for information (RFI) on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. We solicited public comment on this new protocol given the positive results found from our 2023 CAHPS for MIPS Web Mode Field Test. The field test added the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS Survey administration, and we found that the addition resulted in an increased response rate (89 FR 62043). Commenters widely supported an expansion of CAHPS for MIPS Survey modes to include a web-based survey protocol, emphasizing that this could help increase response rates.

(2) Proposed Revisions

Based on the results of the field test, and informed by the responses from commenters in response to our RFI, we propose to require that beginning with 2027, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. Additionally, under this proposal and pursuant to the policy we finalized in the CY 2025 PFS final rule to require, beginning with the 2026 performance period/2028 MIPS payment year, CMS-approved survey vendors to submit the range of costs of their services (89 FR 98459 through 98460), the cost of adding the web survey mode would be included as part of the overall costs of CAHPS for MIPS Survey administration publicly reported by vendors. We refer readers to section IV.B.4.a.(5). of this proposed rule for additional information on this proposal.

f. Summary of Proposals

In Tables 52 and 53 of this proposed rule, we summarize the quality reporting requirements and quality performance standard policies for performance year 2025 and subsequent performance years, including our proposals in this proposed rule. These tables reflect our proposal to remove the health equity adjustment applied to an ACO's quality score and use of the term ''quality score'' beginning in performance year 2025, as discussed in section III.F.6.c. of this proposed rule. Table 52 also reflects the proposed removal of Quality ID: 487 Social Drivers of Health from the APP Plus quality measure set for Shared Savings Program ACOs, as discussed in section III.F.6.d. of this proposed rule, for performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later.

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TABLE 52: PROPOSED APP PLUS QUALITY MEASURE SET REPORTING REQUIREMENTS AND QUALITY PERFORMANCE STANDARD POLICIES FOR SHARED SAVINGS PROGRAM ACOS FOR PERFORMANCE YEARS 2025 AND 2026

	Performance Year 2025	Performance Year 2026
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report the **4** eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 1 claims-based measure.	ACOs are required to report **5** eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the 4 eCQMs/MIPS CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 4 eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 3 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 5 measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 3 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 4 eCQMs /MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and (2) does not administer a	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the 5 eCQMs/MIPS CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 5 eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 7 measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 5 eCQMs /MIPS CQMs/Medicare CQMs in the APP Plus quality measure

	Performance Year 2025	Performance Year 2026
	CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

TABLE 53: PROPOSED APP PLUS QUALITY MEASURE SET REPORTING REQUIREMENTS AND QUALITY PERFORMANCE STANDARD POLICIES FOR SHARED SAVINGS PROGRAM ACOs FOR PERFORMANCE YEAR 2027 AND SUBSEQUENT PERFORMANCE YEARS

	Performance Year 2027	Beginning with Performance Year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493, whichever is later
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report **6** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.	ACOs are required to report **7** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **6** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 6 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **8** measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale**	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **7** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 7 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **9** measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale**

	Performance Year 2027	Beginning with Performance Year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493, whichever is later
	methodology: An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the **6** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	**methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 7 eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

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g. Toward Digital Quality Measurement in CMS Quality Programs Including for the Medicare Shared Savings Program—Request for Information

As stated in the CY 2025 PFS final rule (89 FR 98106), CMS aims to fully transition to digital quality measurement (dQM) in CMS quality reporting and value-based purchasing programs. Including eCQMs as a collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set aligns with our goal to transition to digital quality measurement, including the alignment and development of Fast Healthcare Interoperability Resources (FHIR) standards and tools for eCQM reporting.

In support of these goals, we direct interested parties to section IV.A.4.c.of this proposed rule, which contains a Request for Information (RFI) to gather public input on the transition to dQM for CMS programs and on our anticipated approach on the use of FHIR standards in eCQM reporting. In that section, we describe the current state and request input on key components of the ongoing dQM transition related to FHIR-based eCQMs for the Shared Savings Program and the MIPS quality performance category. These components include: (1) FHIR-based eCQM conversion progress; (2) Data standardization for quality measurement and reporting; (3) The timeline under consideration for FHIR-based eCQM reporting; (4) Measure development and reporting tools; and (5) FHIR Reporting and Data Aggregation for ACOs.

7. Proposal To Revise the Extreme and Uncontrollable Circumstances Policies To Determine Quality and Financial Performance

a. Overview

In the interim final rule with comment period (IFC) entitled ''Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'', which appeared in the December 26, 2017 **Federal Register** (82 FR 60912 through 60919) (herein referred to as the ''December 2017 IFC''), we established automatic extreme and uncontrollable circumstances (EUC) policies under the Shared Savings Program for performance year 2017 due to the urgency of providing relief to ACOs impacted by natural disasters (Hurricanes Harvey, Irma, and Maria, and California wildfires). We agreed with interested parties that the financial and quality performance of ACOs located in areas subject to EUCs could be significantly and adversely affected. For example, natural disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals (82 FR 60913). We stated that these disruptions could hinder quality performance in ACOs and thus could result in shared losses for which the ACO might be held responsible (82 FR 60914).

Since their establishment, we have revised our EUC policies and expanded them in response to PHEs, to determine the duration of the PHE and the percentage of ACOs' performance year assigned beneficiary populations that were EUC-affected (83 FR 68037), and to specify policies for addressing the effect of EUCs on ACOs' quality performance (85 FR 27576 and 27577; 85 FR 84746).

The current Shared Savings Program quality and finance EUC policies at §§ 425.512(c), 425.605(f), and 425.610(i) have been for ACOs affected by natural disasters or PHEs as determined by the Quality Payment Program; however, current policies do not unambiguously address ACOs affected by an EUC due

to a cyberattack, including ransomware/malware.

Cyberattacks, including ransomware/malware, can be circumstances that are outside of the ACO's control and may have several possible effects on our ability to accurately and effectively measure ACOs' quality performance. For instance, a breach of confidential medical records of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting. Cyberattacks could inhibit the operation of EHR systems and thus render data submitted by ACOs inaccurate and unusable; failure to report quality data that comes from EHR systems could cause ACOs to fail the Shared Savings Program's quality reporting requirements and, therefore, fail to meet the quality performance standard. Further, for ACOs impacted by ransomware/malware, the medical records needed for quality reporting may be inaccessible. Effects due to cyberattacks, including ransomware/malware, on ACO participants and their beneficiary populations could impact the ACO's ability to successfully meet the Shared Savings Program quality performance standard.

Currently the Shared Savings Program's EUC policies regarding calculation of the ACO's quality performance score and mitigating shared losses for ACOs participating under a two-sided model are aligned with the Quality Payment Program's automatic EUC policy, to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. We believe that there is a need to revise the quality and finance EUC policies to plainly account for an ACO affected at the legal entity level by an EUC due to a cyberattack, including ransomware/malware, where such a determination is made by the Quality Payment Program through the MIPS EUC Exception application process.

b. Proposal To Revise the EUC Policy To Determine Quality Performance

(1) Background

The current Shared Savings Program quality EUC policies are codified in the regulation at § 425.512(c). These policies were described in the December 2017 IFC (82 FR 60912 through 60919), March 31, 2020 COVID–19 IFC (85 FR 19267 through 19268), CY 2021 PFS final rule (85 FR 84744 through 84747), and CY 2023 PFS final rule (87 FR 69857 through 69858). In the CY 2021 PFS final rule (85 FR 84744 through 84747),we established at § 425.512(c) that, for performance year 2021 and subsequent performance years, including the applicable quality data reporting period for the performance year, we use an alternative approach to calculating the quality score, as described at § 425.512(c), for ACOs affected by EUCs, instead of using the approach as described at § 425.512(a). We determine the ACO was affected by an EUC based on either of the following:

- Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an EUC.
- The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an EUC.

As we established in the CY 2022 PFS final rule (86 FR 65271 and 65272), if CMS determines the ACO meets these requirements, then CMS calculates the ACO's quality score based on the following: For performance year 2024 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year (§ 425.512(c)(2)(ii)).

Further, as stated in § 425.512(c)(3)(iv), if the ACO reports quality data on the APP Plus quality measure set, then CMS calculates the ACO's quality score based on the following: For performance year 2025 and subsequent performance years, if the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 and receives a MIPS quality performance category score, then CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

At § 425.512(c)(4), CMS applies determinations made under the Quality Payment Program with respect to—

- Whether an EUC has occurred; and
- The affected areas.

At § 425.512(c)(5), CMS has sole discretion to determine the time period during which an EUC occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

(2) Proposed Revisions

We are proposing that, for performance year 2025 and subsequent performance years, we would expand the application of the quality and finance EUC policies to an ACO, as defined at § 425.20, and as an APM Entity as defined at § 414.1305, that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. Specifically, we are proposing to add § 425.512(c)(1)(iii) to state: For performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

If an ACO is affected at the legal entity level (as the term is commonly used throughout 42 CFR part 425) by an EUC due to a cyberattack, including ransomware/malware, and wants relief from Shared Savings Program quality reporting requirements, then the ACO must submit a MIPS EUC Exception application to the Quality Payment Program as an APM Entity for the affected performance year. If the Quality Payment Program approves an ACO's MIPS EUC Exception application, as an APM Entity, for a cyberattack, including ransomware/malware, for the affected performance year, then we would apply the Shared Savings Program quality and finance EUC policies at §§ 425.512(c), 425.605(f), and 425.610(i) to provide relief to the ACO from the Shared Savings Program quality reporting requirements and mitigate shared losses for the affected performance year. Under our proposal, the Shared Savings Program would not apply the quality and finance EUC policies to an ACO that submits a MIPS EUC Exception application as an individual, group, or virtual group.

For information on how to submit a MIPS EUC Exception application for performance year 2025, ACOs can refer to the Quality Payment Program Exception Application website (https://qpp.cms.gov/mips/exception-applications?py=2025) and 2025 MIPS EUC Exception Guide (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3239/2025-MIPS-Extreme-and-Uncontrollable-Circumstances-Exception-Application-Guide.pdf*).

Under our proposal, in alignment with § 425.512(c)(3)(iv), beginning in performance year 2025, if an ACO with an approved MIPS EUC Exception application for a cyberattack, including ransomware/malware, reports the APP Plus quality measure set, meets the data

completeness requirement at § 414.1340, and receives a MIPS quality performance category score, then we would use the higher of the ACO's quality score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. Under our proposal, in alignment with § 425.512(c)(2)(ii), if CMS determines the ACO meets the requirements of § 425.512(c)(1), then the ACO's minimum quality performance score would be set to the equivalent of the 40th percentile MIPS quality performance category score, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. This proposal would allow an ACO affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, to meet the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track and to have any shared losses pro-rated based on the length of the cyberattack, including ransomware/malware, as described in section III.F.7.c.(2) of this proposed rule.

Section 1871(e)(1)(A)(ii) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. We are aware that cyberattacks, including ransomware/malware, have increased in recent years. It is in the public interest to revise the Shared Savings Program quality and finance EUC policies (the latter of which we discuss in section III.F.7.c. of this proposed rule) to expand the application of these policies to an ACO at the legal entity level that is affected by an EUC due to a cyberattack, including ransomware/malware, beginning in performance year 2025. Because ACOs rely heavily on digital infrastructure and third-party vendors, they are increasingly vulnerable to ransomware, data breaches, and system outages. Cyberattacks, including ransomware/malware, can severely disrupt care coordination, compromise patient data, and disrupt the patient care environment. These disruptions can delay necessary treatments or procedures and reduce the quality of care provided to beneficiaries. We have heard from ACOs that have experienced cyberattacks about the adverse impact on clinical processes. For example, we have heard from ACOs that as a result of a cyberattack, impacted systems were unavailable and manual processes were implemented, including moving to paper records for certain clinical processes in order to continue to provide patient care. For these reasons, we understand that cyberattacks can disrupt the patient care environment, and we want ACOs to be able to continue to prioritize patient care during and in the aftermath of a cyberattack. As such, we believe that it is in the public interest to provide relief from the Shared Savings Program quality reporting requirements and by mitigating shared losses to any ACO that has an approved MIPS EUC Exception application due to cyberattack during performance year 2025 so that those ACOs can prioritize patient care during and in the aftermath of a cyberattack.

A cyberattack could interfere with the operation of electronic health record systems, affect the integrity of the data used to meet quality reporting requirements, and as a result render ACOs unable to report data that is true, accurate, and complete. Failure to meet the quality performance standard could result in an ACO owing maximum shared losses through no fault of the ACO. If the result of a cyberattack is that an ACO cannot satisfactorily meet the quality performance standard, then the ACO may not receive funds they could otherwise use to reinvest into the ACO and continue to improve the quality of care provided. Therefore, should any ACOs experience a cyberattack during 2025, we do not believe it is in the best interest of an ACO's patient population to disadvantage an ACO from earning shared savings (or for an ACO to incur shared losses) as a result of a disruption caused by a cyberattack.

Additionally, a cyberattack could contribute to unpredictable changes to utilization and spending that may have an impact on expenditures for the applicable performance year beyond the ACO's control. The impact of cyberattacks on physician practices were underscored in a 2024 survey conducted by the American Medical Association, with 90% of respondents at the time of the survey noting that they continued to lose revenue from unpaid claims, 63% noted that they were losing revenue due to the inability to charge patient co-pays or remaining obligations, and 91% had to commit additional staff time and resources to complete revenue cycle tasks.[325] Additionally, 42% of respondents were unable to purchase supplies, 29% of respondents were reliant upon private bank loans to fund their practice operations, 42% of respondents noted patients were unable to access coverage and cost information, and 25% shared that patients at the time of the survey continued to face difficulties getting their prescriptions filled.[326] These examples illustrate how a cyberattack could impact clinical processes that could contribute to unpredictable utilization and spending. This unpredictable utilization could further skew the results of the data used for quality reporting and assessing whether ACOs met the quality performance standard. Coupled with the previously mentioned impact to data integrity due to the possible need to use paper records to collect and submit quality data, cyberattacks could cause ACOs to submit quality data that is not a true, accurate, and complete reflection of their quality performance.

If cyberattacks occur during performance year 2025 and subsequent performance years, we do not wish to hold ACOs who are experiencing extreme and uncontrollable circumstances accountable to a quality performance standard that could be based on inaccurate assessment of their beneficiaries' utilization of care and to apply the Shared Savings Program finance EUC policies §§ 425.605(f), and 425.610(i) to 100 percent of the ACO's assigned beneficiaries when an ACO has a MIPS EUC Exception application for a cyberattack, including ransomware/malware. Thus, we believe it is in the public interest to grant ACOs who have an approved MIPS EUC application relief from the Shared Savings Program quality performance standard so that the standard is accurately assessed and ACOs are not held accountable to an inaccurate assessment of the quality of care they provide based on potentially skewed health care utilization as the result of a cyberattack and to provide relief to the ACO by mitigating shared losses for the affected performance year. Our proposal would grant relief to ACOs that submit a MIPS EUC Exception application to the Quality Payment Program for a cyberattack, including ransomware/malware, and for which the Quality Payment Program approves the ACO's MIPS EUC Exception application.

We propose the following revisions to the Shared Savings Program regulation at § 425.512(b):

[325] American Medical Association (2024). *Change Healthcare cyberattack impact: Key takeaways from informal AMA follow-up survey,* available at https://www.ama-assn.org/system/files/change-healthcare-follow-up-survey-results.pdf.

[326] Ibid.

• We are revising paragraph (b)(5)(iv) (which we propose to redesignate as paragraph (b)(4)(iv)), to remove the reference to ''paragraphs (c)(3)(ii) through (c)(3)(iv)'' and add in its place reference to ''paragraphs (c)(3)(ii) and (c)(3)(iii)'' consistent with our proposal to limit the applicability of § 425.512(b) to performance years 2023 and 2024, as discussed in section III.F.6.c.(2) of this proposed rule.

We propose the following revisions to the Shared Savings Program quality EUC regulation at § 425.512(c):

• We are revising paragraph (c)(1) to read as follows, ''CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on any of the following:''

• We are adding a new paragraph (iii) to (c)(1) to establish that for performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

We seek public comments on the proposed changes to the quality EUC policy. We also seek comment on whether there are other scenarios we should consider recognizing under the Shared Savings Program quality and finance EUC policies, while safeguarding against overly broad EUC policies that would allow ACOs to circumvent quality reporting requirements or avoid shared losses.

c. Proposal To Revise the EUC Policy To Determine Financial Performance

(1) Background

As discussed in section III.F.7.a. of this proposed rule, the December 2017 IFC established policies for assessing the financial and quality performance of Shared Savings Program ACOs that were affected by EUCs during performance year 2017. These policies, and their subsequent revisions, are equally applicable for the finance EUC policies.

We further refined the finance EUC policies in the May 8, 2020 COVID–19 IFC (85 FR 27550), where we clarified the applicability of the program's EUC policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020. We explained that catastrophic events outside an ACO's control could increase the difficulty of coordinating care for patient populations and, due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year (85 FR 27577). These factors could jeopardize the ACO's ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program (85 FR 27577).

Under our current policies at §§ 425.605(f)(2) and 425.610(i)(2), ACOs (as defined at § 425.20) that CMS determines to have been affected by an EUC will have their shared losses (if applicable) reduced by an amount that is proportional to the percentage of the year (determined by total months) affected by the EUC(s) and the percentage of the ACO's performance year-assigned beneficiaries residing in EUC-affected areas.

At §§ 425.605(f)(3) and 425.610(i)(3), we apply determinations made by the Quality Payment Program with respect to the following:

• Whether an extreme uncontrollable circumstance has occurred; and
• The affected areas

At §§ 425.605(f)(4) and 425.610(i)(4), CMS has sole discretion to determine the time period during which an EUC occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

(2) Proposed Revisions

If the Quality Payment Program approves an ACO's MIPS EUC Exception application, as an APM Entity, for a cyberattack, including ransomware/malware, for the affected performance year, we propose to apply the Shared Savings Program finance EUC policies at §§ 425.605(f) and 425.610(i) to provide relief to the ACO by mitigating shared losses for the affected performance year.

As discussed in section III.F.7.c.(1) of this proposed rule, currently ACOs that we determine to have been affected by an EUC will have their shared losses (if applicable) reduced by an amount that is proportional to the percentage of the year (determined by total months) affected by the EUC(s) and the percentage of the ACO's performance year-assigned beneficiaries residing in EUC-affected areas. Unlike the determination of an EUC for a natural disaster or PHE that distinguishes the geographic locations impacted by the EUC, the MIPS EUC Exception application captures the APM Entity's (such as an ACO's) request for the EUC but does not differentiate geographic area(s) impacted by the EUC. Therefore, we would be unable to determine the percentage of the ACO's performance year-assigned beneficiaries residing in an EUC-affected area based on the ACO's submission of an EUC application to the Quality Payment Program in the case of a cyberattack, including ransomware/malware. So, we are proposing to apply the Shared Savings Program finance EUC policies §§ 425.605(f), and 425.610(i) to 100 percent of the ACO's assigned beneficiaries when an ACO has a MIPS EUC Exception application for a cyberattack, including ransomware/malware, approved by the Quality Payment Program for the affected performance year.

The MIPS EUC Exception application contains fields that allow an ACO to enter both a start date and an end date for the EUC. The application allows an ACO to provide either a start date and an end date or a start date only (if the EUC still persists at the time the application is submitted to CMS). We propose that if an ACO provides a start date and an end date for the EUC in its application to the Quality Payment Program, then we would use those dates to determine the duration of the EUC. The start date must be provided in the application. The end date may also be provided in the application but is not required. An ACO may subsequently update the end date by contacting the Quality Payment Program Service Center.

We further propose that, if an ACO does not provide an end date in the ACO's MIPS EUC Exception application or by contacting the Quality Payment Program Service Center to provide an end date prior to the end of the application submission period, then we would apply a 90-day default duration for purposes of mitigating shared losses. This 90-day default duration is consistent with the timeframe used for determining a PHE declaration by the Secretary (the declaration lasts for the duration of the emergency or 90 days but may be extended by the Secretary).[327]

If the ACO's MIPS EUC Exception application has a start date that occurs less than 90 days before the end of the performance year, and the ACO's MIPS EUC Exception application does not include an end date for the EUC and the ACO does not provide an end date to CMS in the form and manner CMS specifies, then we propose that December 31 of the performance year would be the end date for which the ACO was impacted by the EUC, since that is when both the MIPS EUC Exception and the performance year

[327] See *Administration for Strategic Preparedness & Response* website, *Declarations of a Public Health Emergency* webpage, at *https://aspr.hhs.gov/legal/PHE/pages/default.aspx* (describing duration of a public health emergency, among other information).

used to calculate shared savings and shared losses end.

If an ACO is affected by an EUC that persists from one performance year to a subsequent performance year, then the ACO would be required to submit a MIPS EUC Exception application for each affected performance year.

Moreover, as we discussed in the December 2017 IFC (82 FR 60916 through 60917), to exercise our authority under section 1899(i)(3) of the Act to use other payment models, we must demonstrate that the payment model—(1) ''. . . does not result in spending more for such ACO for such beneficiaries than would otherwise be expended . . . if the model were not implemented. . . .'' and (2) ''will improve the quality and efficiency of items and services furnished under'' Medicare. As described in section III.F.7.b.(2) for this proposed rule, we assessed the impacts of our proposal for mitigating shared losses for ACOs affected by extreme and uncontrollable circumstances due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. We considered the following: the impact of the potential loss of participation in the program by ACOs affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, should we not implement the policy described in this section of this proposed rule, and the anticipated minimal impact of adjusting losses for ACOs affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. On the basis of this assessment, we believe incorporating this extreme and uncontrollable circumstances policy into the payment methodologies would meet the requirements of section 1899(i) of the Act by not increasing expenditures above the costs that would be incurred under the statutory payment methodology under section 1899(d) of the Act and by encouraging affected ACOs to remain in the program, which we believe will increase the quality and efficiency of the items and services furnished to the beneficiaries they serve. For these reasons, we conclude that our proposal is permissible under our authority as described in section 1899(i)(3) of the Act.

Therefore, we propose the following revisions to the Shared Savings Program finance EUC regulations at §§ 425.605 and 425.610:

- At § 425.605, we are adding paragraph (f)(2)(ii) to read as follows, ''For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area.''
- At § 425.605, we are revising paragraph (f)(3) to read as follows, ''CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):''
- At § 425.605, we are removing the punctuation ''; and'' at the end of paragraph (f)(3)(i) and adding in its place a period.
- At § 425.605, we are adding a new paragraph (f)(3)(iii) to indicate the following: ''The time period during which the ACO was affected by a cyberattack, including ransomware/malware.''
- At § 425.605, we are redesignating the paragraph (f)(4) as paragraph (f)(5).
- At § 425.605, we are adding a new paragraph (f)(4) to indicate the following: ''CMS will determine the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

++ At § 425.605 paragraph (f)(4)(i), CMS will use the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

++ At § 425.605 paragraph (f)(4)(ii), except as specified in paragraph (f)(4)(iii), if no end date is indicated on the ACO's application or otherwise provided to us in a form and manner specified by us, described in paragraph (f)(4)(i), we will apply a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

++ At § 425.605 paragraph (f)(4)(iii), if the start date indicated on the ACO's application described in paragraph (f)(4)(i), is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, we will apply an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.''

- At § 425.610, we are adding paragraph (i)(2)(ii) to read as follows, ''For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area.''
- At § 425.610, we are revising paragraph (i)(3) to read as follows, ''CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):''
- At § 425.610, we are removing the punctuation ''; and'' at the end of paragraph (i)(3)(i) and adding in its place a period.
- At § 425.610, we are adding a new paragraph (i)(3)(iii) to read as follows: ''The time period during which the ACO was affected by a cyberattack, including ransomware/malware.''
- At § 425.610, we are adding a new paragraph (i)(4) to indicate the following: ''CMS will determine the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

++ At § 425.610 paragraph (i)(4)(i), we will use the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

++ At § 425.610 paragraph (i)(4)(ii), and except as specified in paragraph (i)(4)(iii), if no end date is indicated on the ACO's application or otherwise provided to us in a form and manner specified by us, described in paragraph (i)(4)(i), we will apply a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

++ At § 425.610 paragraph (i)(4)(iii), if the start date indicated on the ACO's application described in paragraph (i)(4)(i) is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS will apply an end date of December 31st of the

performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.''

• We are redesignating paragraph (i)(4) as paragraph (i)(5).

We seek public comments on these proposed changes to the finance EUC policies.

d. Proposed Scenarios for the Start and End Dates Provided by ACOs When the MIPS EUC Exception Application Is Submitted to CMS and Applying Our Existing Regulations

Scenario 1: ACO provides a start date and end date for the EUC in the application, or the ACO contacts the Quality Payment Program Service Center to provide an end date for the EUC prior to the end of the application submission period.

• *Application of the quality EUC policy:* The quality EUC policy would apply to the ACO for the entire performance year, where we would use the higher of the ACO's quality score (if the ACO reports quality data on the APP Plus quality measure set) or the equivalent of the 40th percentile MIPS quality performance category score, as established at § 425.512(c)(3)(iv).

• *Application of the finance EUC policies:* The finance EUC policies as established at § 425.605 and § 425.610 would apply for the timeframe captured by the start and end date for the EUC and would apply to 100 percent of the ACO's assigned beneficiaries for the duration of the EUC.

Scenario 2: ACO provides a start date of March 1 for the EUC, but no end date in the application and the ACO does not contact the Quality Payment Program Service Center to provide an end date prior to the end of the application submission period.

• *Application of the quality EUC policy:* The quality EUC policy would apply to the ACO for the entire performance year, where we would use the higher of the ACO's quality score (if the ACO reports quality data on the APP Plus quality measure set) or the equivalent of the 40th percentile MIPS quality performance category score, as established at § 425.512(c)(3)(iv).

• *Application of the finance EUC policies:* The finance EUC policies as established at §§ 425.605 and 425.610 would apply a start date of March 1 and an end date that would be 90 days from the start date and will apply to 100 percent of the ACO's assigned beneficiaries for the duration of the EUC.

Scenario 3: ACO provides a start date of November 1 for the EUC, but no end date in the application and the ACO does not contact the Quality Payment Program Service Center to provide an end date prior to the end of the application submission period.

• *Application of the quality EUC policy:* The quality EUC policy would apply to the ACO for the entire performance year, where CMS would use the higher of the ACO's quality score (if the ACO reports quality data on the APP Plus quality measure set) or the equivalent of the 40th percentile MIPS quality performance category score, as established at § 425.512(c)(3)(iv).

• *Application of the finance EUC policies:* The finance EUC policies as established at §§ 425.605 and 425.610 would apply a start date of November 1 and an end date of December 31, which is the last day of the performance year, and will apply to 100 percent of the ACO's assigned beneficiaries for the duration of the EUC.

8. Population Adjustment—Financial Benchmarking Methodology

a. Overview

In the CY 2025 PFS final rule (89 FR 98574 through 98576), we finalized the Health Equity Benchmark Adjustment (HEBA), aimed at increasing participation in the Shared Savings Program by ACOs that serve an above-average proportion of Medicare Part D enrollees receiving Low Income Subsidy (LIS) or dually eligible beneficiaries and incentivizing ACOs to provide coordinated care to these populations. We believe this policy encourages participation in the Shared Savings Program from ACOs that otherwise may not have considered entering the program, as 45 percent of the ACOs receiving the HEBA in 2025 would not have qualified for the prior savings adjustment or positive regional adjustments, and therefore would have had a less favorable benchmark, had they not received the HEBA. However, since finalizing this policy, we believe it would add clarity to rename the HEBA to ''population adjustment.'' This proposed revision would more accurately reflect the nature of the adjustment, which accounts for the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

This proposed change seeks to harmonize the adjustment's name with the naming convention used for the other adjustments—the regional and prior savings adjustments—where the titles explicitly reflect key aspects of their underlying methodology. The adoption of the term ''population adjustment'' would reflect the specific data inputs and population focus of this adjustment, while also promoting consistency in nomenclature across adjustments.

We recognize that the revisions proposed herein differ from the approach proposed in the amendments to the Health Equity Adjustment applied to an ACO's quality score as described in section III.F.6.c. of this proposed rule. However, the intent and effect of these respective sections are distinct and therefore the proposed revisions reflect a separate rationale and methodology. Accordingly, the two sections serve different purposes and warrant distinct treatment within the rule.

b. Revise the Terminology in the Shared Savings Program Regulations Used To Describe the Adjustment

(1) Background

(a) Context for the HEBA

Relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we finalized the health equity adjustment to the historical benchmark for agreement periods beginning on January 1, 2025, and in subsequent years (89 FR 98155 through 98166). We finalized provisions of the regulation in 42 CFR part 425, subpart G (see §§ 425.652(a)(8) and 425.662) specifying the methodology for calculating the health equity adjustment to the historical benchmark, determining an ACO's eligibility for the adjustment, and the applicability of the adjustment. The text included the terms ''health equity benchmark adjustment,'' ''Health Equity Benchmark Adjustment (HEBA) scaler,'' and ''HEBA.'' In the CY 2025 PFS final rule, we noted the limitations of benchmarks based on historically observed spending, as they could be set too low if they are based on the spending of a population of underserved communities. We discussed that without appropriate adjustments, ACOs caring for these populations may face financial penalties even if they succeed in improving access to high-value care during their agreement periods. Additionally, we noted that the Congressional Budget Office (CBO) reported high start-up costs for providers in rural and underserved communities as a barrier to forming ACOs.[328] We stated in the CY 2025 PFS proposed rule that these providers may want to participate in ACOs but are disincentivized due to steep start-up costs. The HEBA was finalized to provide additional financial

[328] Congressional Budget Office. (April 16, 2024). Medicare Accountable Care Organizations: Past Performance and Future Directions (59879). *https://www.cbo.gov/publication/59879.*

resources to ACOs serving these populations, and to encourage those ACOs to attract and retain beneficiaries from communities that have faced challenges accessing care. The adjustment is calculated based on the number of beneficiaries an ACO serves who are either enrolled in the LIS program or are dually eligible for Medicare and Medicaid, offering a targeted mechanism to reflect the needs of higher-risk populations.

(b) HEBA Provisions Finalized in CY 2025 PFS Final Rule

For agreement periods beginning on January 1, 2025, and in subsequent years, the Shared Savings Program utilizes three key mechanisms to upwardly adjust ACO benchmarks: the HEBA, the positive regional adjustment, and the prior savings adjustment. The positive regional adjustment evaluates an ACO's efficiency compared to its regional service area. The prior savings adjustment reflects an ACO's historical success in reducing Medicare fee-for-service (FFS) spending growth. The HEBA can increase benchmarks for ACOs with 15 percent or more assigned beneficiaries enrolled in LIS or dually eligible for Medicare/Medicaid, offering a targeted mechanism to reflect the needs of higher-risk populations.

These adjustments are not cumulative: ACOs receive the highest applicable adjustment, capped at 5 percent of national FFS per capita expenditures (89 FR 98158). For ACOs serving medically complex and high-cost beneficiaries, the HEBA often becomes their most favorable adjustment as they may not qualify for the regional adjustment or prior savings adjustments. While risk adjustment accounts for patient health status and dual eligibility status and benchmark calculations stratify expenditures by dual eligibility status, these mechanisms may fall short in fully reflecting costs for ACOs serving LIS or dually eligible beneficiaries in regions with high proportions of dual eligible and LIS populations. This can leave ACOs caring for these populations with unfavorable benchmarks and may reduce their incentive to participate in the program. As explained earlier in this section of this proposed rule, the HEBA addresses this gap by directly increasing benchmarks for ACOs with a significant proportion of LIS or dually eligible beneficiaries, providing a meaningful financial incentive for participation by those ACOs and retention of such beneficiaries.

(c) HEBA Impact—Initial Observations

As described in the CY 2025 PFS final rule (89 FR 98158), CMS finalized a process to provide ACOs with a preliminary HEBA calculation at the start of their agreement period, using the ACO's BY3 assigned population. This preliminary calculation uses the proportion of the ACO's BY3 assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. We specified that we would then update the calculation when the ACO's historical benchmark is updated at the time of financial reconciliation for the performance year to reflect the ACO's performance year-assigned population in the calculation of the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

Based on internal analysis of PY 2025 preliminary benchmarks,[329] among 33 ACOs estimated to receive a HEBA, 13 are new ACOs participating in their first agreement period and would otherwise not have received a positive regional adjustment to the benchmark (for example, ACO spending is above their region's expenditures) or a prior savings adjustment, since these ACOs are in their first agreement period. This early observation suggests that the HEBA is encouraging more participation in the Shared Savings Program, as intended, by high-cost ACOs[330] that may otherwise not have elected to apply and participate in the program and whose assigned beneficiary populations have the greatest potential to benefit from care coordination and quality improvement. Our initial analysis of the preliminary benchmarks suggests that these ACOs could see an approximate 1.36 percent increase in their benchmark compared to an approximate 2.29 percent for ACOs that received either a prior savings adjustment or positive regional adjustment. These figures are provisional as they rely on preliminary BY3 population data. Final figures will depend on the ACO's final PY 2025 assigned population, which is not determined until financial reconciliation, consistent with § 425.662(b)(4).

The regulatory impact analysis of the HEBA from the CY 2025 PFS final rule (89 FR 98523 through 98524) estimated that total net savings is projected to grow over ten years by approximately $260 million as a result of the HEBA attracting additional high-cost ACOs to join the program and creating savings for the Medicare program, ranging from $1.2 billion cost to a $2.2 billion savings at the 10th and 90th percentiles.

(d) Expanding Participation

The HEBA policy aligns with CMS' aims of advancing prevention, wellness, and chronic disease management, while supporting the growth and expansion of the Shared Savings Program. Analysis reveals significant untapped potential to increase Shared Savings Program participation among practices currently not participating in the program, in particular among providers serving higher cost populations.[331]

We conducted an analysis of Taxpayer Identification Numbers (TINs) associated with medical providers and/or practices not part of ACOs participating in the Shared Savings Program during PY 2022. The analysis compared TINs that participated in the Shared Savings Program with those that did not. Results indicated that many non-participating TINs served a larger share of beneficiaries with disabled or aged/dual enrollment status and had greater presence in rural areas. The study also found that of all the TINs serving beneficiaries eligible to participate in a Shared Savings Program ACO, 84 percent (or 58,000 TINs) were not participating in the Shared Savings Program. By contrast, only about 11,000 TINs with at least one ACO-assigned beneficiary participated in a Shared Savings Program ACO. Among these non-participants, two-thirds were small practices that furnish care to 100 or fewer beneficiaries. The analysis also highlighted key differences between ACO participating and non-participating TINs in terms of the population they served and their geographic distribution. We observed that TINs associated with medical providers and/or practices not participating in Shared Savings Program ACOs are in regions with low Shared Savings Program ACO penetration and have a greater presence in rural areas. These practices serve larger shares of dual eligible and disabled beneficiaries and have higher spending per beneficiary driven primarily by inpatient and SNF expenditures.

Encouraging participation in ACOs by practices serving these higher-cost

[329] These benchmarks are preliminary because they are established at the start of an ACO's agreement period and include incomplete data from benchmark year 3.

[330] By ''high-cost ACOs,'' we refer in this rulemaking to those ACOs with spending above their region expenditures.

[331] CMS, Press Release ''Dr. Mehmet Oz Shares Vision for CMS'' (April 10, 2025), available at *https://www.cms.gov/newsroom/press-releases/dr-mehmet-oz-shares-vision-cms.*

beneficiaries remain crucial to the Shared Savings Program. Our internal analysis shows that Shared Savings Program ACOs have been successful in reducing inpatient and SNF spending. The HEBA accounts for a higher proportion of dual eligible and LIS beneficiaries, and therefore can strengthen the business case for providers that serve these populations to join and form ACOs and participate in the Shared Savings Program.

The adjustment is particularly critical in rural areas where the CBO has identified high start-up costs as a significant barrier to ACOs formation.[332] By enabling ACOs in rural and resource-limited areas to operate under more viable and realistic financial benchmarks, the HEBA policy aims to expand participation in the Shared Savings Program and increase the likelihood that these ACOs can succeed financially while delivering high-quality care.

(2) Proposed Revisions

We are proposing to update the language used to describe this adjustment to the benchmark to more accurately reflect the populations served by the ACOs receiving the adjustment as discussed in section III.F.8.b.(1) of this proposed rule. This change reflects efforts to harmonize terminology across benchmark-related methodologies—regional and prior savings adjustments—where the titles explicitly reflect key features of their underlying methodology. The revision to ''population adjustment'' more accurately reflects the population of beneficiaries that are captured by this adjustment (ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid), as well as promote consistency in nomenclature across adjustment.

Specifically, we propose to revise Shared Savings Program regulations that include references to ''health equity benchmark adjustment'' or HEBA to ''population adjustment''. We also propose to revise the term ''HEBA scaler'', which is a component in the calculation to ''scaler''. The naming changes would apply for performance year 2025 and subsequent performance years. This proposal would revise only the terminology in the regulations. The calculation described in the regulations would be unchanged, if the proposed changes are finalized. This proposal, if finalized, would have a minimal impact on Shared Savings Program operations. CMS would only need to update the language used in historical benchmark reports and the assignment summary report, beginning with report deliveries occurring after the rule is finalized., and certain other programmatic materials, for example, the Medicare Shared Savings Program Assignment List Report and Assignment Summary Report User's Guide, and the Medicare Shared Savings Program's Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications.

These proposed revisions reflect changes to the terminology used in the regulations at §§ 425.652, 425.658, 425.662 and 425.672. No changes in the methodology currently used to calculate the health equity benchmark adjustment are being proposed. Specifically, we propose the following revisions to provisions of the regulation:

- At § 425.652(a)(8)(ii)(A), we propose to remove the phrase ''health equity benchmark adjustment (HEBA)'' and add in its place the phrase ''population adjustment''.
- At § 425.652 in paragraphs (a)(8)(ii)(B), (a)(8)(ii)(B)(*2*), (a)(9)(v),and (a)(9)(vi), we propose to remove the phrase ''HEBA'' and add in its place the phrase ''population adjustment''.
- At § 425.652(a)(9)(v), we propose to remove the phrase ''HEBA scaler used in calculating the HEBA at § 425.662(b)(2)'' and add in its place the phrase ''scaler used in calculating the population adjustment at § 425.662(b)(2)''.
- At § 425.658 in paragraph (d), we propose to remove the phrase ''HEBA'' and add in its place the phrase ''population adjustment''.
- At § 425.662, we propose to revise the section heading to read as follows: ''Calculating the population adjustment to the historical benchmark.''
- At § 425.662 we propose to revise paragraph (a) to read as follows: ''*General.* For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates the population adjustment to the historical benchmark''.
- At § 425.662 in paragraph (b) introductory text, we propose to remove the phrase ''health equity benchmark adjustment'' and add in its place the phrase ''population adjustment''.
- At § 425.662 in paragraph (b)(2), and we propose to remove the phrase ''Calculates the HEBA scaler'' and add in its place the phrase ''Calculates a scaler''.
- At § 425.662, we propose to revise paragraph (b)(3) to read as follows: ''Determines the ACO's eligibility for the population adjustment based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is only eligible for the population adjustment if this proportion is greater than or equal to 15 percent. An ACO with a proportion less than 15 percent is ineligible to receive the population adjustment.''
- At § 425.662, we propose to revise paragraph (b)(4) to read as follows: ''Calculates the population adjustment. If the ACO is eligible for the population adjustment as determined in paragraph (b)(3) of this section, the adjustment is equal to the product of the scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.''
- At § 425.662 in paragraph (c), we propose to remove the phrase ''HEBA'' and add in its place the phrase ''population adjustment''.
- At § 425.672 in paragraph (c)(2)(iv), we propose to remove the phrase ''and calculating the HEBA scaler'' and add in its place the phrase ''and calculating the scaler''.

We seek public comments on this proposed change.

9. Shared Savings Program Quality Reporting Monitoring Provisions

a. Overview

In this section, we propose to revise our regulations at § 425.316(c)(2) related to monitoring of ACOs for compliance with the quality performance standards. Relatedly, we propose to revise § 425.224(b)(1)(ii)(A) related to reviewing applications for renewing and re-entering ACOs. The purpose of these proposed changes is to revise our regulations to ensure that ACOs continue to satisfy program requirements or to identify a pattern of noncompliance with ACOs meeting both the quality performance standard and the alternative quality performance standard. We believe these revisions would not significantly impact the program as currently implemented.

b. Background

In the CY 2021 PFS final rule (85 FR 84740 through 84743), we finalized changes to the Shared Savings Program quality performance standard and quality reporting requirements for performance years beginning on January 1, 2021. The regulation we finalized at

[332] Congressional Budget Office (CBO), ''Medicare Accountable Care Organizations: Past Performance and Future Directions,'' April 2024, available at *https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.*

§ 425.316(c)(2) aligned the Shared Savings Program quality reporting requirements with the requirements that applied under the APP under the Quality Payment Program (85 FR 85039 and 85040). We have subsequently updated the quality performance standard and reporting requirements through rulemaking in the CYs 2022, 2023, 2024, and 2025 PFS final rules (86 FR 65255 through 65272, 87 FR 69860 through 69863, 88 FR 79112 through 79114, and 89 FR 98101 through 98132, respectively).

In the CY 2023 PFS final rule (87 FR 70234), we finalized an alternative quality performance standard at § 425.512(a)(4)(ii) and (a)(5)(ii) for performance year 2023 and subsequent performance years. Specifically, to meet the alternative quality performance standard for performance year 2025 and subsequent years as described at § 425.512(a)(5)(ii)(B), an ACO must report quality data on the APP Plus quality measure set established at § 414.1367 according to the method of submission established by CMS and achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set. An ACO that does not meet the quality performance standard but does meet the alternative quality performance standard is eligible to share in savings on a sliding scale as described at §§ 425.605 and 425.610. Additionally, ACOs that do not meet both the quality performance standard and the alternative quality performance standard will not be eligible for shared savings and will have a shared loss rate not exceeding 75 percent as described at § 425.610(f)(3)(ii) for performance year 2023 and subsequent performance years.

The PHE for COVID–19 was in effect starting in January 2020 and expired on May 11, 2023.[333] All Shared Savings Program ACOs were deemed affected by the PHE for COVID–19 under the program's quality EUC policy for performance years 2022 and 2023 as defined at § 425.512(c) and were determined to have met the quality performance standard at § 425.512(a) (85 FR 84746). ACOs received a minimum quality performance score equal to the 30th percentile Merit-based Incentive Payment System (MIPS) Quality performance category score in PY 2022, and a score equal to the equivalent of the 40th percentile in PY 2023 across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. ACOs that were able to successfully report quality data received the higher of their own MIPS Quality performance category score (adjusted for health equity for performance year 2023, if applicable) or the applicable 30th percentile score. As such, all ACOs that qualified for shared savings for performance years 2022 and 2023 were eligible to receive the maximum sharing rate for their track (or performance level within a track) and, for performance year 2022, any shared losses determined to be owed to CMS using either a fixed (BASIC Track) or scaled loss rate (ENHANCED Track) were fully offset by the EUC policy and any shared losses determined for performance year 2023 were reduced by a least five-twelfths.

To ensure that the ACO continues to satisfy Shared Savings Program requirements, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers. The monitoring policies at § 425.316(c) apply to compliance with quality performance standards. To identify ACOs that are not meeting the quality performance standards, we will review an ACO's submission of quality measurement data at §§ 425.500 or 425.512. Currently, as specified at § 425.316(c)(2)(i), if the ACO fails to meet the quality performance standard, we may take one or more of the actions prior to termination specified at § 425.216. As further specified at § 425.316(c)(2)(i), depending on the nature and severity of the noncompliance, we may forgo pre-termination actions and may immediately terminate the ACO's participation agreement at § 425.218. While § 425.316(c)(2) addresses the quality performance standard, it fails to acknowledge the alternative quality performance standard. When we established the alternative quality performance standard in the CY 2023 PFS final rule, we inadvertently did not also propose to modify the corresponding monitoring policies at § 425.316(c)(2). Due to the quality EUC policies in effect until 2023, we did not encounter this discrepancy when monitoring ACO compliance with quality performance standards.

c. Proposed Revisions

We propose to add § 425.316(c)(3) to apply to performance years beginning on or after January 1, 2026. Under our proposal, if an ACO fails to meet both the quality performance standard and the alternative quality performance standard, as determined at § 425.512, we would be authorized to take one or more of the actions prior to termination as specified at § 425.216. Under the proposal, if an ACO is unable to meet the quality performance standard, then the ACO could still meet the alternative quality performance standard without CMS taking one of the prescribed actions prior to termination. However, if an ACO fails to meet both standards, then we believe it would be appropriate for CMS take one of the actions described at § 425.216 (provide a warning notice to the ACO, request a corrective action plan from the ACO, or place the ACO on a special monitoring plan) for noncompliance with the quality performance standards. We inadvertently did not modify the monitoring portion of the regulation, § 425.316(c), when we established the alternative quality performance standard in the CY 2023 PFS final rule and believe that it would be appropriate to revise the regulation at § 425.316(c) to be consistent with our longstanding practice to monitor ACOs for their compliance with our quality reporting and quality performance standard requirements. Specifically, we propose to add a new paragraph (c)(3) to § 425.316 to recognize that, for performance years beginning on or after January 1, 2026, if an ACO fails to meet both the quality performance standard and the alternative quality performance standard, as determined at § 425.512, CMS may take one or more of the actions prior to termination specified at § 425.216. Additionally, in keeping with our established policies at § 425.316(c)(2)(ii), we propose to continue to terminate an ACO's participation agreement if it: (1) fails to meet both the quality performance standard and alternative quality performance standard for 2 consecutive PYs within an agreement period; (2) fails to meet both the quality performance standard and alternative quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order; (3) are a renewing ACO or re-entering ACO that fails to meet both the quality performance standard and alternative quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of

[333] *See* Administration for Strategic Preparedness & Response website, Declarations of a Public Health Emergency webpage, at https://aspr.hhs.gov/legal/PHE/pages/default.aspx (listing declarations of a public health emergency, among other information). *See also* U.S. Department of Health and Human Services website, COVID–19 Public Health Emergency webpage, available at https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.

failed quality performance during the previous agreement period; or (4) are a renewing ACO or re-entering ACO fails to meet both the quality performance standard and alternative quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

As part of the Shared Savings Program application process, we identify applicant ACOs that have previously participated in the Shared Savings Program. If the applicant ACO has a history of noncompliance with the requirements of the Shared Savings Program, we may request the ACO demonstrate that it has corrected the deficiencies that caused any noncompliance under their previous participation agreement (§ 425.224(b)(1)(iii)). The list of criteria we review for previous noncompliance includes, but is not limited to, whether the ACO demonstrated a pattern of failure to meet the quality performance standards, whether, for 2 PYs, the average per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiary population exceeded its updated benchmark, whether the ACO failed to repay shared losses in full within 90 days, whether the ACO failed to repay shared losses for any performance year while participating under a model authorized under section 1115A of the Act. In alignment with our proposal above, we also propose to modify § 425.224(b)(1)(ii)(A) to include the alternative quality performance standard. Specifically, we propose to modify § 425.224(b)(1)(ii)(A) to state that, as part of the factors we evaluate when determining whether to approve a renewing ACO's or re-entering ACO's application, we will evaluate whether the ACO demonstrated a pattern of failure to meet the quality performance standard and alternative quality performance standard (if applicable), or met any of the criteria for termination at § 425.316(c)(1)(ii), (c)(2)(ii), or (c)(3)(ii).

We seek comments on these proposals.

G. Changes to the Regulations Associated With the Ambulance Fee Schedule

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. (For a discussion about the ambulance inflation factor (AIF), please see CY 2011 PFS final rule (75 FR 73397). We stated in the CY 2011 PFS final rule that the AIF will be announced by instruction and on the CMS Web site. AIF transmittals are available on CMS' website: *https://www.cms.gov/medicare/payment/fee-schedules/ambulance/afs-regulations-and-notices* and in the Medicare Claims Processing Manual, Chapter 15, section 20.4). The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments in § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, enacted July 15, 2009) (MIPPA), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Section 3203 of the American Relief Act of 2025 (Pub. L. 118–158, December 21, 2024) extended these provisions through March 31, 2025. Most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4, March 15, 2025) amended section 1834(l)(13) of the Act to extend the payment add-ons through September 30, 2025. Thus, these payment add-ons apply to covered ground ambulance transports furnished before October 1, 2025. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072), the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682), and the CY 2024 PFS final rule with comment period (88 FR 79292–79293)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004, interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment

increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Section 3203 of the American Relief Act of 2025 extended this provision through March 31, 2025. Most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through September 30, 2025. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before October 1, 2025, where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072), the CY 2019 PFS final rule with comment period (83 FR 59682) and the CY 2024 PFS final rule with comment period (88 FR 79293)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through September 30, 2025, and does not require any substantive exercise of discretion on the part of the Secretary.

IV. Updates to the Quality Payment Program

A. CY 2026 Modifications to the Quality Payment Program Reporting and Data Submission

1. Executive Summary

a. Overview

This section of this proposed rule outlines changes to the Quality Payment Program starting January 1, 2026, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on alignment between the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APM) tracks of participation, alignment with broader CMS initiatives, and new options for clinicians to participate in more meaningful ways. We aim to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the MIPS and Advanced APMs for the CY 2026 performance period/2028 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a value-based payment program, by which the Medicare program rewards clinicians who provide high-value, high-quality care to their patients in a cost-efficient manner. There are two ways for clinicians who provide services under the Medicare program to participate in the Quality Payment Program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined at § 414.1305) [334] are subject to a MIPS payment adjustment (positive, neutral, or negative) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight under these exceptions, for the CY 2026 performance period/2028 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment factor for a MIPS eligible clinician, CMS accounts for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act. CMS then applies the MIPS payment adjustment factor to amounts otherwise paid under Medicare Part B with respect to covered professional services for the MIPS eligible clinician for the applicable MIPS payment year such that their payments for such covered professional services are increased, decreased, or not adjusted based on the MIPS eligible clinician's final score relative to the performance threshold.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

For the Advanced APM track, if an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to participate in MIPS and be subject to the MIPS reporting requirements and payment adjustment). Under current law, eligible clinicians who are QPs for the 2024 performance period and beyond will receive an increased physician fee schedule update of 0.75 percent based on the QP conversion factor in the corresponding payment year. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year. We note that, historically, QPs received a lump sum APM Incentive Payment in the corresponding payment year,

[334] We note that the term MIPS eligible clinician is defined at § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. We refer readers to our policies governing group reporting and scoring under MIPS as set forth at § 414.1310(e).

calculated as a specified percentage of the QP's paid claims for covered professional services from the base year. Under current law, payment year 2026 is the last year for these payments. Only legislation enacted by Congress can make changes to either the enhanced QP conversion factor updates or the APM Incentive Payment.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We continue to implement MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the ninth year of the Quality Payment Program, we will be implementing the updates set forth in this section of this proposed rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

b. Summary of Major Proposals

(1) Transforming the Quality Payment Program

We continue to align with broader CMS initiatives, such as the Universal Foundation (*https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation*) in an effort to promote the highest quality outcomes and safest care for all individuals. The Universal Foundation focuses on provider attention, reducing burden, prioritizing development and movement toward interoperable digital quality measures, allowing for comparisons across CMS programs, and helping to identify measurement gaps.

We are implementing meaningful improvements designed to strengthen healthcare delivery and advance patient outcomes. Through these efforts, we strive to create a healthcare system that not only responds to chronic disease but works proactively to prevent it. In alignment with our goal of promoting preventive care and fostering a more proactive approach to health management, we propose adding a new ''Advancing Health and Wellness'' subcategory within the improvement activities performance category. Through the proposals described in this proposed rule, we intend to transform and simplify MIPS, promote the use of connected measures and activities, continue rewarding clinicians for providing high value care, and use data-driven information to help all clinicians improve care and engage patients.

Separately, we propose expanding our portfolio of available MVPs for the CY 2026 performance period/2028 MIPS payment year and remain committed to our goal of ensuring more meaningful participation in the Quality Payment Program through MVPs. We have revised the format of each MVP to categorize the quality measures by clinical conditions or episodes of care. The new format offers a streamlined set of quality measures to aid clinicians in selecting the most clinically relevant measures. While traditional MIPS continues to be a reporting option, we intend to propose ending traditional MIPS in the future, at which point MVPs would become mandatory. That future date has not been determined and will be established through notice and comment rulemaking.

We are issuing a request for information (RFI) to address the use of Fast Healthcare Interoperability Resources (FHIR)-based electronic clinical quality measures (eCQMs) in quality reporting and payment programs as discussed in section IV.A.4.c. of this proposed rule. In section IV.A.3. of this proposed rule, we seek feedback on two RFIs related to MVPs to address: (1) potential Core Elements MVP reporting requirements; and (2) functions utilizing Medicare procedural codes to further facilitate more MVP specialty reporting. Additionally, we are seeking feedback on future use of well-being and nutrition measures in the Quality Payment Program. We are issuing three additional RFIs in section IV.A.4.d.(4) of this proposed rule related to enhancing healthcare data quality and monitoring systems. These RFIs address: (1) potential future modifications to the Query of Prescription Drug Monitoring Program (PDMP) measure (2) potential modifications to the Promoting Interoperability performance category's objectives and measures and (3) potential improvements to enhance health information MIPS eligible clinicians are exchanging across systems. These initiatives reflect our commitment to advancing interoperability, improving patient safety, and supporting the transition to value-based care through modern technology and standardized data exchange practices.

(a) Transforming MIPS: MVP Strategy

To support our goal of phasing out traditional MIPS and transitioning to MVP reporting, we are proposing policies, that if finalized, would encourage increased participation from specialists. Our proposals seek to specify which groups fall under the multispecialty subgroups requirement that begins in CY 2026 through self-attestation and to maintain flexibility for multispecialty small practices to report MVPs as groups. Specifically, we are proposing updates to two MVP subgroup policies as follows: (1) update the MVP group registration process to add the multispecialty self-attestation requirement; and (2) maintain the MVP group reporting option for multispecialty groups with a small practice designation.

We are also seeking feedback via three RFIs. First, we are seeking feedback on the development of a subset of key quality measures within each MVP, referred to as ''Core Elements,'' from which an MVP Participant would be required to report one Core Element that would highlight measures that represent the foundation and focus of an MVP and would better enable comparison of clinician performance. This would provide for more accurate comparisons of similar clinicians and would give patients the best information available about clinicians so they can make the most informed decisions about their care. Second, we are also seeking feedback on identifying Medicare Part B procedural billing codes that align with each MVP to encourage specialists to report the relevant MVP based on their use of the procedural billing codes. Third, we are seeking feedback on well-being and nutrition tools and measures that assess overall health, happiness, and satisfaction in life.

(b) MIPS Value Pathways Development and Maintenance

To continue moving the healthcare community toward value-based, high-quality, safe, and cost-efficient care, we are proposing six new MVPs around the following topics: Diagnostic Radiology, Interventional Radiology, Neuropsychology, Pathology, Podiatry, and Vascular Surgery.

We are also proposing MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria and take into consideration feedback from interested parties we have received through the maintenance process. Additionally, we have updated the format of the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP identified as ''Clinical Groupings''. When applicable, an ''Advancing Health and Wellness'' and/or ''Experience of Care'' clinical grouping is included for cross-cutting quality measures. This new stratified

format offers a streamlined set of quality measures to aid clinicians in selecting the most clinically relevant measures applicable to their clinical area and identifies when quality and cost measures are linked.

Finally, we are proposing to provide additional flexibilities to allow qualified clinical data registries (QCDRs) and qualified registries additional time to fully support finalized MVPs. Specifically, we are proposing to sunset the current requirement and modify § 414.1400(b)(1)(ii) to state that QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data through CY 2025 performance period/2027 MIPS payment year. We are also proposing to modify the requirement at § 414.1400(b)(1)(ii) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than one year after finalization of the MVP. We are proposing to retain the remaining language currently set forth at § 414.1400(b)(1)(ii) without modification.

(c) APM Performance Pathway

We are proposing to update some quality measures in the APM Performance Pathway (APP), original quality measure set and the APP Plus quality measure set to reflect our proposed changes to measures specified for the quality performance category as discussed section IV.A.4.b. of this proposed rule.

(d) Fast Healthcare Interoperability Resources (FHIR) Request for Information

We want to engage interested parties, ahead of future policy decisions, on the timeline and measure development of FHIR-based eCQMs in quality reporting and payment programs. In this RFI, we are providing updates on our activities since prior RFIs and are seeking information from interested parties on a range of issues to better inform future proposals. More specifically, the RFI is seeking feedback, related to the digital quality measurement (dQM) transition, on the following:

- What challenges providers and health information technology vendors anticipate during the transition.
- What guidance may be required from CMS to support the transition.
- Feedback on the stepwise approach to FHIR-based eCQM reporting.
- What challenges Accountable Care Organizations (ACOs) specifically have with reporting via FHIR, to include challenges about aggregated data.
- Any other implementation concerns.

(e) MIPS Quality Performance Category

For the CY 2026 performance period/2028 MIPS payment year, we are proposing to establish a measure set inventory of 190 MIPS quality measures, of which 187 are available in traditional MIPS and three are available only for utilization in MVPs.

The proposed measure removals focus on process measures, measures reaching extremely topped out status or the end of the topped-out measure lifecycle, measures no longer aligned with clinical guidelines and measures the steward would no longer maintain. The measure additions focus on measuring outcomes and increasing the number of eCQMs. Substantive changes to measures would ensure the measures included in MIPS continue to be meaningful and drive improvements in quality of care.

Additionally, as discussed in section IV.A.4.d.(1).(b). of this proposed rule, we are proposing to revise the definition of a ''high priority measure'' to remove health equity.

(f) MIPS Cost Performance Category

We are proposing to modify the Total Per Capita Cost (TPCC) measure beginning in the CY 2026 performance period/2028 MIPS payment year. We are also proposing to update the operational list of care episodes and patient condition groups and codes to reflect coding changes identified through our annual maintenance process for MIPS cost measures. Lastly, we are proposing to adopt a 2-year informational-only feedback period for newly implemented MIPS cost measures, which we are also proposing to codify at § 414.1380(b)(2).

(g) MIPS Improvement Activities Performance Category

We are proposing the following updates to the MIPS Improvement Activity Inventory beginning with the CY 2026 performance period/2028 MIPS payment year. First, we propose to add a new subcategory to the Improvement Activities performance category: Advancing Health and Wellness. Second, we propose to remove the Achieving Health Equity subcategory. Third, we propose to add three new improvement activities into two of our existing subcategories: (1) Population Management and (2) Patient Safety and Practice Assessment. Fourth, we propose to modify seven existing improvement activities currently specified for the performance category. Fifth, we propose to remove eight improvement activities currently specified for the performance category.

(h) MIPS Promoting Interoperability Performance Category

Beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing several policies and measure updates for the MIPS Promoting Interoperability performance category. Specifically, for the MIPS Promoting Interoperability performance category, we are proposing to modify the Security Risk Analysis measure and the High Priority Practices Safety Assurance Factors for Electronic Health Record (EHR) Resilience (SAFER) Guide measure, and adopt one new optional bonus measure, the Public Health Reporting Using Trusted Exchange Framework and Common Agreement™ (TEFCA™) measure.

Promoting Interoperability Program, we are proposing the following:

- Adopt and codify at § 414.1380(b)(4)(iii) and § 495.24(f)(3), respectively, a measure suppression policy beginning with the CY 2026 performance period/2028 MIPS payment year and the EHR reporting period in CY 2026.
- Suppress the Electronic Case Reporting measure by excluding the measure from scoring for MIPS eligible clinicians for the CY 2025 performance period/2027 MIPS payment year and eligible hospitals and critical access hospitals for the EHR reporting period in CY 2025.

Additionally, we include the following RFIs in section IV.A.4.d.(4) of this proposed rule.

- RFI Regarding the Query of PDMP Measure seeks public comment on potential future modifications to the Query of PDMP measure that would transition the measure from attestation-based reporting to performance-based reporting and expand the types of drugs that apply to the measure to include all Schedule II drugs.
- RFI Regarding performance-based measures seeks public comment on the potential modifications to the Promoting Interoperability performance category's objectives and measures that would transition from attestation-based reporting to performance-based reporting.
- RFI Regarding Data Quality seeks public comments on the improvements to enhance overall healthcare data quality, addressing current gaps in accuracy, completeness, and consistency of health information MIPS eligible clinicians are exchange across systems.

(i) MIPS Final Score Methodology (Scoring the Quality Performance Category)

We are proposing to update our approach for identifying measures impacted by limited measure choice to apply the analysis and criteria finalized in the CY 2025 PFS final rule (89 FR 98432 and 98433) to MVPs, in addition to specialty measure sets. MVPs, similar to specialty measure sets, contain a limited set of quality measures for a clinician to choose from. We are also proposing a list of topped out measures impacted by limited measure choice and subject to the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

Lastly, we are proposing to modify the methodology for scoring the administrative claims-based measures within the quality performance category beginning with the 2025 performance period/2027 MIPS payment year. The proposed administrative claims-based quality measure scoring methodology would be based on standard deviation, median, and an achievement point value derived from the performance threshold.

(j) MIPS Payment Adjustment

We are proposing to continue using the CY 2017 performance period/2019 MIPS payment year to establish the performance threshold. We are also proposing to establish a performance threshold of 75 points for the CY 2026 performance period/2028 MIPS payment year through the CY 2028 performance period/2030 MIPS payment year.

(k) Third Party Intermediaries

We are proposing to codify at § 414.1400(d)(9) a policy we previously finalized in the CY 2025 PFS final rule to require CMS-approved survey vendors to submit a range of the cost of their services with their application beginning with the CY 2026 performance period/2028 MIPS payment year (89 FR 98459 and 98460). We are also proposing to codify at § 414.1400(d)(3)(iv)(A) a policy previously finalized in the CY 2024 PFS final rule to require an entity to administer the CAHPS for MIPS Survey Spanish translation to Spanish-preferring patients (88 FR 79332 through 79334).

We are proposing to require that, beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. We are proposing to codify this proposed requirement at § 414.1400(d)(10). In addition, we propose to modify our requirements at § 414.1400(d)(3) for an entity applying to become a CMS-approved survey vendor to ensure the entity is capable of administering a web-mail-phone protocol prior to CMS approval.

Lastly, we are proposing to sunset one of the requirements to apply to become a CMS-approved survey vendor at § 414.1400(d)(8).

(2) Advanced APM Proposals

We are proposing to modify the methodology we use to calculate QP status at § 414.1425 to include an individual calculation for all eligible clinicians in Advanced APMs. Additionally, we are proposing to use Covered Professional Services to identify beneficiaries, as described at § 414.1305 to define an Attribution-eligible beneficiary, in our calculations for all Advanced APMs.

We are proposing to sunset our Advanced APM criterion at § 414.1415(c)(7), and § 414.1420, which currently sets a limit on the number of clinicians belonging to an APM Entity participating in a Medical Home Model.

We are also proposing to modify the language at § 414.1455(b)(3)(ii) and § 414.1455(b)(3)(vi) that establishes Targeted Review for QPs to ensure that the Targeted Review timeline described in such section is the same timeline as that established for MIPS Targeted Reviews specified at § 414.1385(a)(2) and § 414.1385(a)(5).

2. Definitions

At § 414.1305, we are proposing to revise the definition of the following terms:

- High priority measure
- Attribution-eligible beneficiary
- Multispecialty group
- MVP Participant
- Single specialty group

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

3. Transforming the Quality Payment Program

Section 1848(q)(1)(D) of the Act requires that the Secretary establish and apply a process that includes features of the provisions of section 1848(m)(3)(C) of the Act for MIPS eligible clinicians in a group practice reporting for the quality performance category and provides that the Secretary may establish such a process for the other three MIPS performance categories. Section 1848(q)(1)(D)(ii) of the Act requires that the process we establish and apply under section 1848(q)(1)(D)(i) of the Act, to the extent practicable, must reflect the range of items and services provided by the MIPS eligible clinicians within the group practice. In accordance with the statute, in the CY 2022 PFS final rule, we finalized the MIPS Value Pathways (MVP) reporting option for MIPS eligible clinicians beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). To support CMS' goal of phasing out traditional MIPS and transitioning to MVP reporting, we are proposing policies that would enable groups to self-identify their specialty composition and submit MVP data that appropriately reflects the diverse range of services provided by the clinicians within the group. These policies would also help groups in assessing whether they would need to participate as subgroups, based on the scope of care provided by the clinicians within a group. Additionally, the proposed subgroup policies would continue the voluntary subgroup participation option for multispecialty group practices that qualify as small practices. Additionally, we seek feedback on developing a subset of key quality measures within MVPs to better enable comparison of clinician performance and emphasize measures that reflect the core of a specialty. We also seek feedback on the consideration to identify Medicare Part B procedural billing codes that align with each MVP, and to encourage, or potentially require, specialists to report the relevant MVP based on their use of the procedural billing codes.

a. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized the option for MIPS eligible clinicians to participate as subgroups for reporting MVPs beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to regulations at §§ 414.1305, 414.1318, and 414.1365 and the CY 2022 PFS final rule (86 FR 65398 through 65405), the CY 2023 PFS final rule (87 FR 70038 through 70045), and the CY 2024 PFS final rule (88 FR 79323 through 79328) for additional details on previously finalized subgroup policies.

In the CY 2022 PFS final rule (86 FR 65392 through 65394), we finalized the definition of an MVP participant at § 414.1305. Beginning with the CY 2023 performance period/2025 MIPS payment year, an MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM

Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. We also finalized at § 414.1305 that, beginning with the CY 2026 performance period/2028 MIPS payment year, an MVP Participant means an individual MIPS eligible clinician, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories (86 FR 65392 through 65394). We excluded ''multispecialty group'' from the MVP participant definition beginning with the CY 2026 performance period/2028 MIPS payment year and replaced the term with ''subgroup'' to account for the requirement for multispecialty groups to divide into subgroups if they choose to report MVPs.

Under the MVP Participant definition codified at § 414.1305, multispecialty groups and single specialty groups may report as groups or choose to form subgroups to report MVPs for the CY 2023 performance period/2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year. Beginning with the CY 2026 MIPS performance period/2028 MIPS payment year, multispecialty groups will no longer be able to report MVP as a single group. This will mean that if a multispecialty group would like to report an MVP, beginning with the CY 2026 MIPS performance period/2028 MIPS payment year, MIPS eligible clinicians in multispecialty groups must divide into and report as subgroup or report as an individual to report an MVP. Alternatively, MIPS eligible clinicians in multispecialty groups may continue to participate in traditional MIPS reporting. In the CY 2023 PFS final rule (87 FR 70038 through 70040), we finalized at § 414.1305 the definitions of a single specialty group and a multispecialty group. Specifically, a single specialty group means a group as defined at § 414.1305 consisting of one specialty type, as determined by CMS using Medicare Part B claims. A multispecialty group means a group as defined at § 414.1305 consisting of two or more specialty types, as determined by CMS using Medicare Part B claims.

In the CY 2022 PFS final rule (86 FR 65415 through 65418), we also established a registration process at § 414.1365(b) for clinicians who choose to participate in MVP reporting. Under this policy, an MVP participant must register between April 1 and November 30 of the applicable calendar year performance period, or a later date specified by CMS. An MVP participant that elects to report the CAHPS for MIPS Survey associated with an MVP must complete their registration by June 30 of the applicable performance period. Section 414.1365(b)(2)(i) further provides that the MVP participant must select an MVP they intend to report and may select an outcomes-based administrative claims measure if available in the selected MVP (86 FR 65416 through 65417). We refer readers to the CY 2022 PFS final rule (86 FR 65415 through 65418) for additional details on MVP and subgroup registration requirements.

In this section, we propose to: (1) maintain the MVP group reporting option for multispecialty groups with a small practice designation and (2) modify the MVP group registration process to add the self-attestation requirement.

(2) Maintain the MVP Group Reporting Option for Small Practices

At § 414.1305, beginning with the CY 2019 performance period/2021 MIPS payment year, we define a small practice to mean a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. As discussed in section IV.A.3.a.(1) of this proposed rule, we previously finalized subgroup reporting requirements for multispecialty groups beginning in the CY 2026 performance period/2028 MIPS payment year (86 FR 39360). Under this policy, a multispecialty group designated as a small practice (with 15 or fewer eligible clinicians) will not be allowed to participate as a single group in MVP reporting. If clinicians in such groups would like to participate in MVP reporting, beginning in the CY 2026 performance period/2028 MIPS payment year, such groups will currently need to divide into subgroups. Alternatively, clinicians in these groups could participate as individuals in MVP reporting or continue to report at the group level in traditional MIPS reporting.

We acknowledge that, like large groups, small practices could be classified as a single specialty or multispecialty groups. However, we do not believe there are additional benefits to require a small practice of 15 or fewer clinicians to further divide into smaller subgroups as we anticipate that multiple subgroups within a small practice could choose to report the same set of measures within the same MVP. Historically, we have received feedback from MIPS eligible clinicians in small practices expressing concerns regarding the lack of adequate resources for these clinicians to meet MIPS reporting requirements. Additionally, we are concerned that requiring small practices to divide into smaller subgroups could negatively impact small practices as the subgroups may not meet the established case minimums for the quality measures in the selected MVP, resulting in lower scores. We recognize the challenges for small group practices to allocate the resources needed to administer quality reporting requirements. We are concerned that if we require multispecialty groups that qualify as small practices to divide and report as subgroups, these practices would avoid participating in MVP reporting and continue to participate in traditional MIPS reporting. Based on the 2022 Quality Payment Program Experience Report (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2817/2022ExperienceReport.pdf*), there is a decrease in MIPS participation from clinicians in small practices from the CY 2021 performance period/2023 MIPS payment year to the CY 2022 performance period/2024 MIPS payment year. Given that we intend to sunset traditional MIPS in a future year, we want to adopt policies which would reduce barriers for small group practices to transition to MVP reporting. Therefore, it would be beneficial to continue the MVP group reporting option for small practices regardless of the specialty composition of the clinicians within the small practices.

For the above reasons, we propose to modify the definition of an MVP participant at § 414.1305 to provide that multispecialty groups that meet the requirements of a small practice may be MVP participants. Because multispecialty groups that meet the requirements of a small practice would meet the definition of an MVP participant, they would, unlike other multispecialty groups, be permitted to report an MVP as a single group. Specifically, we propose to modify the definition of an MVP participant at § 414.1305 to provide that, for the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

Under this proposal, to utilize the MVP reporting option, a multispecialty group that meets the requirements of a small practice would not be required to divide and report as subgroups, although it could still do so if it chooses.

We seek comments on the above proposal to modify the MVP participant definition at § 414.1305 by adding the

term ''multispecialty group that meets the requirements of a small practice'' to maintain the MVP group reporting option for groups with a small practice designation.

(3) Proposal To Modify the MVP Group Registration Process

Beginning in the CY 2026 performance period/2028 MIPS payment year, to implement the subgroup reporting requirement for multispecialty groups as previously discussed, we would need to determine the specialty composition of a group as a single specialty or multispecialty group as defined at § 414.1305. Currently in the Quality Payment Program, we assign specialty type for MIPS eligible clinicians at the individual clinician (or TIN–NPI) level and not collectively at the group (or TIN) level. As discussed in the CY 2023 PFS final rule (87 FR 70039), we currently use the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and Medicare Part B claims data to identify clinician specialty for different purposes. For public reporting purposes, we rely on PECOS as the primary data source, and for purposes of MIPS eligibility determination, we use both PECOS and claims data. Additionally, we use the information on claims to identify clinician specialty when attributing some of the measures in the cost and quality performance categories.

As discussed above in section IV.A.3.a.(1) of this proposed rule, we finalized at § 414.1305 in the CY 2023 PFS final rule (87 FR 70038 through 70040) the definition of a single specialty group as a group consisting of one specialty type, and the definition of a multispecialty group as a group consisting of two or more specialty types, as determined by CMS using Medicare Part B claims. In the CY 2023 PFS final rule (87 FR 70039 through 70040), we received mixed feedback from commenters on the proposal to utilize claims data for identifying specialty composition of a group. Many were concerned that the specialty information indicated on Medicare Part B claims is not an accurate representation of the actual care provided by the various clinicians in a multispecialty group. A few commenters recommended the use of a specialty attestation process during subgroup registration instead of using the claims data. In responding to the comments received regarding the recommendation to consider a specialty attestation process, we explained our intent was to provide group specialty designations either as a single specialty or multispecialty group in advance of the MVP registration process, allowing group practices to make changes in their administrative workflows accordingly (87 FR70040).

To operationalize the previously finalized definitions of a single specialty and multispecialty group and to implement the previously finalized CY 2026 subgroup reporting requirement for multispecialty group practices, we considered utilizing claims data to assign these specialty designations to group practices. After further analyzing the claims data, we recognize and agree there are additional nuances to consider in using the claims analysis to accurately identify the specialty composition of a group.

For example, the claims data may not reflect the care provided by certain clinician types in a group, such as nurse practitioners (NPs), and physician assistants (PAs). The NPs and PAs that are part of group practices could be involved in more than one clinical focus and the specialty information on claims for these clinicians reflects their educational credentials rather than the type of care provided.

We recognize there could be instances when a group practice consists of clinicians across multiple specialty types but provides care in a single clinical area. We are also concerned that using the individual clinician (or NPI) level specialty code information available from the claims data to collectively designate a group as either a single specialty or multispecialty would inadvertently misrepresent the specialty composition of a group because of the way clinician specialty is reflected on claims. For example, claims data would indicate that a group practice, focused on providing cardiovascular care for patients and consisting of internists, cardiologists, NPs, and PAs, meets our definition of a multispecialty group. If we use claims data to implement the previously finalized definitions of single specialty and multispecialty groups, this group providing cardiovascular care would be designated as a multispecialty group and will be required to form subgroups for reporting an MVP beginning in the CY 2026 performance period/2028 MIPS payment year. Given the single clinical focus of care provided by all the clinicians in such group practice, we anticipate the multiple subgroups within such group would choose to report the measures and activities in the Advancing Care for Heart Disease MVP, resulting in redundant data submissions. In such instances, we acknowledge utilizing the claims data would result in CMS incorrectly identifying a group's specialty composition as a single specialty or a multispecialty group.

Additionally, we acknowledge that the composition of groups may not be constant due to several factors unrelated to MVP policies (for example, clinician turnover and acquisitions or consolidation of practices). In instances when the overall composition of a group changes due to clinician turnover, consolidation of practices, or other reasons, the specialty designations provided by CMS may not fully capture the changes in the group composition during a performance period. Therefore, we are unable to utilize the claims data at this time to evaluate the specialty composition of a group or to designate a group practice as either a single specialty or a multispecialty group. We recognize we need to conduct a thorough analysis of the claims data to pursue an effective and sophisticated approach for assessing the feasibility of appropriately assigning specialty designations to groups. Please see our discussion in section IV.A.3.c. of this proposed rule for language associated with the Medicare Procedural Codes Request for Information (RFI), where we discuss potential alternative approaches for utilizing Medicare Part B claims to identify clinician specialties within a group for considering policies encouraging MIPS eligible clinicians to report an MVP aligned with the scope of care provided.

In lieu of using the claims data for designating a group as either a single specialty or a multispecialty group, we propose that to report an MVP, a group practice which is either a single-specialty group or a multispecialty group that meets the requirements of a small practice, would be required to attest to its designation as a group that meets the requirements of a single specialty group, or a multispecialty group that meets the requirements of a small practice, respectively. We note that we are not proposing the self-attestation requirement for subgroups because under the current policy at § 414.1365(b), subgroup registration is an additional step in the MVP registration process for multispecialty groups choosing to report an MVP. We refer readers to the CY 2022 and CY 2023 PFS final rules (86 FR 65415 through 65418 and 87 FR 70040 through 70041) for previously finalized MVP subgroup registration requirements.

In section IV.A.3.a.(2) of this proposed rule, we are proposing to expand the definition of MVP Participant to include multispecialty groups meeting the requirements of small practices. Under this proposal, a

multispecialty group practice consisting of 15 or fewer clinicians that chooses to report an MVP would be exempt from the requirement to participate as subgroups. For a group practice consisting of 16 or more clinicians, and the clinicians within the group are involved in a single focus of care, we anticipate the group practice would attest as a single specialty group and register as a single group for MVP reporting. If a group practice consists of 16 or more clinicians and the clinicians within the group are involved in multiple foci of care, the group practice cannot register for MVP reporting as a single group. MIPS eligible clinicians in such groups would need to divide into subgroups or if applicable, participate as individuals for reporting an MVP.

To align with the proposed self-attestation process during MVP registration as a mechanism for identifying the group specialty composition, we propose modifying the definitions of a single specialty group and a multispecialty group. These proposed updates and the self-attestation requirement for groups participating in MVP reporting would enable group practices to assess their need for participation as subgroups based on the scope of care provided by the clinicians within the group. Additionally, the proposed updates would allow either a single-specialty group or a multispecialty group that meets the requirements of a small practice to self-identify themselves and report the MVP as a single group. This proposed process would also alleviate the concerns associated with determining a group's specialty composition due to inaccurate representation of the clinician specialty information on the claims data.

For the above reasons, to implement the previously finalized subgroup reporting requirement for multispecialty group practices beginning with CY 2026 performance period/2028 MIPS payment year and to operationalize the definitions of a single specialty and multispecialty group, we are proposing updates to the previously finalized MVP registration process to include the addition of a self-attestation process for groups to identify themselves as either a single specialty group or a multispecialty group that meets the requirements of a small practice. Specifically, we are proposing that, beginning with the CY 2026 performance period/2028 MIPS payment year, a group practice registering for MVP reporting that intends to participate as a single group would need to attest either as a single specialty group or a multispecialty group that meets the requirements of a small practice during MVP registration.

We propose to codify this proposal at § 414.1365(b)(2)(iv), providing that, beginning with the CY 2026 performance period/2028 MIPS payment year, to report an MVP, a group must attest to being either a single specialty group or a multispecialty group that meets the requirements of a small practice. As discussed above in this section of the proposed rule, at this time, we are unable to utilize claims data for designating a group as either a single specialty group or a multispecialty group. Therefore, we propose to make conforming changes and revise the current definitions of a single specialty group and a multispecialty group at § 414.1305. We propose to revise the definition of a single specialty group at § 414.1305 to mean a group that consists of clinicians in one specialty type or clinicians involved in a single focus of care. We propose to revise the definition of a multispecialty group at § 414.1305 to mean a group that consists of clinicians in two or more specialty types or clinicians involved in multiple foci of care.

We seek public comments on the above proposal to update the MVP group registration by adding a self-attestation requirement. We also seek comment on our conforming proposals to update the definitions of a single specialty group and a multispecialty group. We refer readers to section V.B.5.c.(6).(b). of this proposed rule for discussion on the burden estimates for these proposals.

b. Core Elements Request for Information (RFI)

One of the goals of the transition from traditional MIPS to MVPs is to provide patients with comparative clinician performance data to make better assessments of the care provided to patients by requiring clinicians within an MVP to report on the same group of measures. While MVPs were designed to reduce the burden of measure selection by narrowing the scope of large, unaligned inventories, some MVPs still have a large selection of measures to accommodate the variety of clinicians who may choose to report that MVP. The MVPs finalized for the CY 2025 performance period/2027 MIPS payment year contain an average of 14 quality measures for MVP Participants to select from, ranging from 8 to 24 quality measures in each MVP (89 FR 98972 through 99056). Given this degree of measure volume, we are concerned that MVP reporting may not produce sufficient comparative performance data on standardized measures to support patient choice of care. We are considering policies to ensure more direct comparability by requiring the reporting of a subset of measures within an MVP that are meaningful for clinicians and patients.

Specifically, we are considering a policy to require an MVP Participant to select one quality measure from a subset of quality measures in each MVP, referred to as ''Core Elements.'' MVP Participants would select the other three required quality measures and would still have to meet existing MVP reporting requirements. This policy aims to emphasize and increase reporting on select quality measures that are most important to clinicians and patients and reflect care that is at the crux of the MVP's applicable specialty, medical condition, or episode of care. Core Elements could be, but would not necessarily be, outcomes measures. Core Elements would highlight measures that represent the foundation and essence of an MVP. The resulting standardized reporting would lead to more directly comparable clinician data on a subset of key quality measures within an MVP that constitute critical elements within that specialty which will better enable patients to compare the care provided to patients, emphasize a crucial subset of quality measures, and may also drive quality and outcome improvement.

The quality measures identified as Core Elements for an MVP would be meaningful and reflect the critical care elements for each MVP's relevant specialty, medical condition or episode of care. We may also consider Core Elements from the Adult Universal Foundation quality measures or the MVP's Advancing Health and Wellness quality measures subcategory, when possible.

If we propose implementing Core Elements in MVPs, we would propose Core Elements for existing MVPs via notice and comment rulemaking. When new MVPs are proposed, we would identify the MVP's Core Elements at that time through notice and comment rulemaking. Given the existing quality measure gaps for certain specialists and subspecialists, there may be clinicians for whom there would not be an applicable and available Core Element.

We are considering proposing the Core Elements policy in the CY 2027 PFS proposed rule and proposing the policy for implementation prior to the sunset of traditional MIPS. In the CY 2025 PFS proposed rule, we discussed that we anticipate we may be ready to fully transition to MVPs by the CY 2029 performance period/2031 MIPS payment year (89 FR 62012).

RFI Questions

We request public comment on the following questions related to MVP Core Elements:

- One of the key goals of Core Elements is to provide patients with enough information across different clinicians to compare specialist performance on foundational measures within a clinical area. Are there other ways to ensure MVP reporting results provide comparative performance data for patients on critical measures?
- Core Elements will be selected based on clinical relevance, but for consistency across MVPs, we are considering a set number of Core Elements for all MVPs. We are also considering setting the number of Core Elements in an MVP based on a percentage of the total number of quality measures in an MVP. For example, we may consider a policy that identifies 25 percent of an MVP's quality measures as Core Elements, such that an MVP with 12 quality measures would have three Core Elements measures to choose from. We request feedback on the ideal number or percentage of Core Elements in MVPs.
- One of our concerns is that Core Elements specified for a few collection types, such as electronic clinical quality measures (eCQMs) or Qualified Clinical Data Registry (QCDR) measures, would limit clinician choice and may unintentionally force clinicians to report via intermediaries. One possible solution would be to include Core Elements with several different collection types, when possible, to provide clinicians with some choice of collection type. Are there other flexibilities or options that could reduce this limitation?
- We are considering policies to increase the likelihood that clinicians have an applicable and available Core Element. We request feedback on ways to include measures that are applicable for more clinicians, such as including cross-cutting and broadly applicable measures. We also request feedback on ways to avoid disadvantaging clinicians without an applicable Core Element, such as attesting to no applicable and available Core Element.
- As we consider which measures should be used as Core Elements, we are interested in receiving feedback on specific measures that should or should not be considered for the Core Elements requirement, including measures in the proposed Advancing Health and Wellness quality measures clinical grouping, as discussed in section IV.A.4.a.(2) of this proposed rule, or Adult Universal Foundation quality measures.
- We request feedback on our goal to consider the Core Elements policy for proposal in the CY 2027 PFS proposed rule.
- We understand the Core Elements requirement places a new restriction on MVP reporting. We request feedback on whether the Core Elements reporting requirement would impact your decision to report an MVP while traditional MIPS remains a reporting option.

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

c. Medicare Procedural Codes Request for Information (RFI)

Alongside the proposed subgroup policies and the RFI on MVP Core Elements requirements in sections IV.A.3.a and IV.A.3.b. of this proposed rule, we are considering utilizing Medicare procedural codes to further facilitate more MVP specialty reporting and to encourage and potentially require specialists to report an MVP applicable to their specialty or scope of care. In the CY 2022 PFS final rule, we finalized the MVP reporting option for MIPS eligible clinicians beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). To advance our goal of phasing out traditional MIPS and fully transitioning to MVP reporting, we continue to develop and maintain MVPs that are meaningful and relevant to the clinicians currently participating in MIPS. For the CY 2025 performance period, there are 21 MVPs available, covering the services provided by a wide range of clinician specialty types. Based on internal data, we received over 2,000 MVP registrations (including groups, individual clinicians, and subgroups) for the CY 2024 MIPS performance period/2026 MIPS payment year. Exploring approaches to utilize Medicare procedural billing codes for appropriately identifying MVPs relevant to a clinician specialty type could further increase MVP participation from MIPS eligible clinicians and groups.

Currently, MVP Participants may select any MVP to report. We recognize that a policy to assign clinicians to a particular MVP would limit the ability for clinicians to choose an MVP and therefore limit the measures they can select to report. However, it is important to ensure that clinicians report an MVP that is relevant to their specialty or scope of care to make performance measurement more clinically relevant for specialists and inform patient choice of care with meaningful and comparative clinician performance data. Therefore, we are considering a potential future policy to require clinicians to report a specific MVP based on the procedural codes that they bill. Furthermore, there may be measures within an MVP that are more relevant to an individual specialist based on the types of services they perform, so we are further considering requiring specialists to report specific measures within an MVP. See section IV.A.3.b. of this proposed rule for discussion of the Core Elements RFI.

Efforts were made in the CY 2025 PFS final rule to further the goal of using quality measurement to advance specific types of care. For example, we introduced the Advanced Primary Care Management (APCM) services (89 FR 97858 through 97906) coding and payment. APCM includes a performance measurement requirement for clinicians furnishing APCM services to assess clinicians on primary care quality, total cost of care, and meaningful use of CEHRT. The performance measurement requirements can be met for practitioners who are MIPS eligible clinicians by registering for and reporting the Value in Primary Care MVP. A practitioner who is part of a TIN participating in a Shared Savings Program ACO or REACH ACO, or in a Making Care Primary or a Primary Care First practice satisfies this requirement by virtue of meeting requirements under the Shared Savings Program, CMS Innovation Center ACO REACH, Making Care Primary, or Primary Care First models (89 FR 97879 through 97894).

In section III.D. of this proposed rule, the Innovation Center is proposing to test a mandatory model that focuses on high-volume, high-cost chronic-conditions and directly engages specialists in value-based payment. Specifically, the Ambulatory Specialty Model (ASM) is proposing the identification of a physician's specialty type using the specialty code on the

Medicare Part B claims data, in conjunction with a minimum volume of episodes triggered for the relevant condition-specific episode-based cost measure to identify specialists to include in the model. We refer readers to section III.D. of this rule for additional details on the model requirements and correlation to the existing MVP framework.

The frameworks used in APCM, where practitioners who are MIPS eligible clinicians must register for and report the Value in Primary Care MVP for the performance year in which they bill for APCM services (89 FR 97893 and 97894), and the proposed ASM in section III.D. of this proposed rule where procedural codes from Medicare Part B claims data would attribute clinicians to MVPs via cost measures, may be useful tools for increasing specialty reporting in MVPs and ultimately improving quality performance measurement. We are considering an approach that would identify relevant procedural codes for each MVP, where applicable, and then identify clinicians to report that MVP based on their billing of those procedural codes. We would prioritize linking MVPs with high-utilization and high-cost procedures. For example, quality measures in the Improving Care for Lower Extremity Joint Repair MVP such as 350: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy and 351: Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation would be relevant for clinicians who perform hip replacement surgery and bill hip replacement surgery procedural codes. We therefore may connect the hip replacement surgery procedural codes to the Improving Care for Lower Extremity Joint Repair MVP and the relevant quality measures to encourage clinicians to report measures that are relevant to their scope of care, such as these RFI Questions.

We request public comment on the following questions related to the use of Medicare procedural codes to suggest or assign MVPs:

- If we do not suggest or assign MVPs to clinicians, how else can we encourage specialty reporting of relevant MVPs based on the scope of care provided?
- What data sources should we consider using to assign clinicians to an MVP?

To appropriately determine the relevance of the measures and activities in an MVP to the scope of care provided by the clinicians, we are considering using procedural billing codes from Medicare Part B claims data. We refer readers to section IV.A.3.a.(3) of this proposed rule for a discussion of our concerns for using Medicare Part B claims data to identify the specialty composition of a group.

- The MIPS determination period is used to determine MIPS eligibility and, as defined at § 414.1305, begins the calendar year, 2 years prior to the applicable performance period. Would it be appropriate to align with that timeline and use the procedural billing codes from Medicare Part B claims data from 2 years prior to the performance year in which a clinician would report the particular MVP?
- We are considering setting a volume threshold that clinicians must meet to be assigned to a particular MVP. For example, we may consider a threshold of 20 cases in order to be assigned to the MVP, given the case minimum requirement of 20 cases for most measures. What would be an appropriate volume threshold for the procedural billing codes?
- If we suggest or require the reporting of a particular MVP, we would limit clinicians' current flexibility to choose an MVP. Additionally, it would take time for CMS to identify effective approaches to operationalize this concept. Given these constraints, how long would clinicians need to prepare for a suggested MVP based on Medicare Part B claims data? How long would clinicians need to prepare for a required MVP based on Medicare Part B claims data?

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d. Well-Being and Nutrition Measures Request for Information (RFI)

We are seeking input on well-being and nutrition measures for future years in the QPP. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues.[335] This comprehensive approach emphasizes person-centered care by promoting the well-being of patients and family members. We are seeking comments on tools and measures that assess overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comments on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care. Please provide feedback on the relevant aspects of well-being for the QPP. We refer readers to section IV.A.4.a.(2) of this proposed rule for discussion of the proposed Advancing Health and Wellness quality measure clinical grouping in MVPs.

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4. QPP Reporting and Data Submission

a. CY 2026 MVP Development and Maintenance

(1) Development of New MIPS Value Pathways (MVPs)

In the CY 2023 PFS final rule (87 FR 70035 through 70037), we finalized modifications to the MVP development process to broaden opportunities for the general public to provide feedback on new candidate MVPs prior to the notice and comment rulemaking process. We refer readers to the Quality Payment Program website to review the public feedback we received for each 2026 MVP candidate (*https://qpp.cms.gov/mips/candidate-feedback*).

Through our development processes for new MVPs (85 FR 84849 through 84856; 87 FR 70035 through 70037), we

[335] Well-Being Concepts. (2017). CDC Archives. Available at: *https://www.naspa.org/images/uploads/kcs/WHPL_Canon_WB_WellBeing_Concepts___HRQOL___CDC_2017.pdf.*

aim to gradually develop new MVPs that are relevant and meaningful for MIPS eligible clinicians. In this proposed rule, we are proposing to adopt the following six new MVPs:

- Diagnostic Radiology;
- Interventional Radiology;
- Neuropsychology;
- Pathology;
- Podiatry; and
- Vascular Surgery.

We refer readers to Appendix 3: MVP Inventory, in this proposed rule for a detailed description of each proposed new MVP.

We continue to encourage interested parties to utilize our established pre-rulemaking processes to develop and submit candidate quality and cost measures relevant to their specialty. Furthermore, we continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip),*

(2) MVP Maintenance Updates to Previously Finalized MVPs

Between the CY 2022 PFS final rule (86 FR 65998 through 66031) and the CY 2023 PFS final rule (87 FR 70037), we finalized the following 12 MVPs to be available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Advancing Cancer Care;
- Advancing Care for Heart Disease;
- Advancing Rheumatology Patient Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Improving Care for Lower Extremity Joint Repair;
- Optimizing Chronic Disease Management;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Patient Safety and Support of Positive Experiences with Anesthesia;
- Promoting Wellness; and
- Supportive Care for Cognitive-Based Neurological Conditions.

In the CY 2024 PFS final rule (88 FR 79978 through 80047), we consolidated Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single primary care MVP titled ''Value in Primary Care MVP'' as well as finalized the following five additional MVPs to be available for reporting beginning with the CY 2024 performance period/2026 MIPS payment year:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disorders Including Hepatitis C and Human Immunodeficiency Virus (HIV);
- Quality Care for the Treatment of Ear, Nose, and Throat Disorders;
- Quality Care in Mental Health and Substance Use Disorder; and
- Rehabilitative Support for Musculoskeletal Care.

In the CY 2025 PFS final rule (88 FR 79978 through 80047), we consolidated Optimal Care for Patients with Episodic Neurological Conditions and the Supportive Care for Neurodegenerative Conditions MVPs into a single neurological MVP titled ''Quality Care for Patients with Neurological Conditions MVP'' as well as finalized the following six additional MVPs to be available for reporting beginning with the CY 2025 performance period/2027 MIPS payment year:

- Complete Ophthalmologic Care;
- Dermatological Care;
- Gastroenterology Care;
- Pulmonology Care; and
- Surgical Care.

In this proposed rule, we are proposing modifications to all 21 previously finalized MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria we previously established (85 FR 84849 through 84854). Through these modifications, we can expand upon the clinical concepts, advance health and wellness, address maintenance requests from the public, and remove measures and activities that would either be finalized for removal from their respective MIPS Inventory or replaced by more robust measures or activities.

Additionally, we have updated the format of the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP. The new format does not change the measures and activities included in the MVP. It is intended to provide a more user-friendly format for MIPS eligible clinicians when choosing the measures and activities most applicable to their practice. We refer readers to Appendix 3: MVP Inventory of this proposed rule for the proposed modifications and detailed descriptions to the previously finalized MVPs. We also refer readers to section V.B.5.c.(6)(a) of this proposed rule for discussion on the burden estimates for these proposals.

(3) Third Party Intermediaries Support of MVPs

We refer readers to our regulation at § 414.1400 and section IV.B.4. of this proposed rule for more detailed discussion regarding our previously finalized requirements for third party intermediaries to submit data on behalf of MIPS eligible clinicians for certain MIPS performance categories. In the CY 2022 PFS final rule (86 FR 65542 through 65544), we finalized a new requirement at § 414.1400(b)(1)(ii) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, qualified clinical data registries (QCDRs) and qualified registries (as these terms are defined at § 414.1305) must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. This regulatory provision does not specifically address by when the QCDRs and qualified registries must support the MVPs. However, since finalizing this policy in the CY 2022 PFS final rule, QCDRs and qualified registries have been expected to be ready to support each newly finalized MVP that are applicable to their MIPS eligible clinicians for the first year of the MVP's implementation.

We acknowledge that some QCDRs and qualified registries may have difficulties programming new measures and preparing their systems to support MVP reporting within the brief timeframe from when we typically issue the PFS final rule and its effective date, which only allows 2 months for implementation (typically from November of one year to January of the next year). We have heard concerns from QCDRs and qualified registries regarding feasibility of meeting this requirement at § 414.1400(b)(1)(ii), such as the cost of implementing registry measures and working with other parties who may charge for QCDR measure use. QCDRs and qualified registries that are not ready to support applicable MVPs risk termination as they would not be in compliance with the requirement to support all applicable MVPs. Withdrawal and termination would also result in the removal of QCDR measures implemented in MIPS.

On these bases, we are proposing to modify the language currently set forth at § 414.1400(b)(1)(ii). As discussed previously, § 414.1400(b)(1)(ii) currently provides that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data.

We are proposing to modify § 414.1400(b)(1)(ii) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than one year after finalization of the MVP in accordance with the current requirement. We are also proposing to sunset the current requirement as of the end of the CY 2025 performance period/2027 MIPS payment year. We are proposing to retain the remaining language currently set forth at § 414.1400(b)(1)(ii) without modification.

This proposed modification will provide QCDRs and qualified registries with one year following the effective date of the final rule for programming and system preparation for MVP reporting success and reduce potential of withdrawal or termination.

We invite comments on our proposal.

b. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning with the CY 2021 performance period/2023 MIPS payment year. The APP was designed as a reporting and scoring pathway available only to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM as defined in § 414.1305 (MIPS APM participants) (§ 414.1367(a)). The APP provides a predictable and consistent MIPS reporting option to reduce reporting burden for, and encourage continued APM participation by, these clinicians. We also established in the APM Performance Pathway for Shared Savings Program ACOs providing that, beginning with the Shared Savings Program performance year 2021 (CY 2021 performance period/2023 MIPS payment year), ACOs were required to report quality data for purposes of the Shared Savings Program via the APP (42 CFR 425.512(a)(3); 85 FR 84722).

In that same rule, we finalized a quality measure set (85 FR 84860 and 84861) for purposes of quality performance category scoring for the APP. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we established that such measure would be removed from the quality performance category score for such MIPS eligible clinician, group, or APM Entity (85 FR 84861).

In the CY 2025 PFS final rule (89 FR 98562), we finalized a second, optional quality measure set within the APP, called the APP Plus quality measure set, to align with the Universal Foundation measure set. The measure set currently includes the current APP quality measures and 2 additional quality measures from the Adult Universal Foundation measure set. As discussed in the CY 2025 PFS final rule, we intend to incrementally add the remaining 3 Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. We also finalized a 1-year delay to the CY 2026 performance year/2027 MIPS payment year in the incorporation of the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure.

Further, for MIPS eligible clinicians, groups, and APM Entities reporting through the APP, we established in the CY 2021 PFS final rule (85 FR 84907) that we would not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP quality measure set is determined to be topped out. Because the APP quality measure set is fixed, we noted that it would not be appropriate to limit the maximum quality performance category score available to APP reporters. Should an APP quality measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

In the CY 2024 PFS final rule (88 FR 79329), we established the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP quality measure set and finalized that the Medicare CQM collection type would be available to only ACOs participating in the Shared Savings Program.

(2) Updates to Quality Measures in the APP and APP Plus Quality Measure Sets

In the CY 2021 PFS final rule, we adopted the original APP quality measure set (85 FR 84860 and 84861). Table 52 contains the original APP quality measure set. In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over four years (89 FR 62024), including by incorporating into the APP Plus quality measure set the measures from the original APP quality measure set.

To conform with changes to the MIPS quality measure inventory, as set forth in Table Group DD and Table Group C of this proposed rule, we are proposing to incorporate the updated versions of MIPS quality measures used in the APP quality measure set. We refer to readers the proposed revisions to the following MIPS measures:

- *Preventive Care and Screening:* Screening for Depression and Follow-up Plan (Quality ID: 134).
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484) Because the APP is a reporting pathway within MIPS, all of the quality measures offered through the APP are the MIPS versions of the measures. As such, we generally take the approach of adopting changes to APP and APP Plus quality measures to conform with changes to the same measures within MIPS as a whole.

In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over 4 years (89 FR 62024). As finalized, the APP Plus quality measure set currently consists of all the measures currently within the APP quality measure set (5 Adult Universal Foundation measures and a separate quality measure) plus 1 additional measure from the Adult Universal Foundation measure set, with the intention of incrementally incorporating the remaining measures from the Adult Universal Foundation measure set by the CY 2028 performance year/2030 MIPS payment year. We finalized this incremental approach in part to allow for both the eCQM and, for Shared Savings ACOs, Medicare CQM collection types to be developed and become available.

We refer readers to Table 52 for the APP quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. The APP Plus quality measure sets for the CY 2026, 2027, and 2028 performance periods and subsequent performance periods are displayed in Tables 53, 54, and 55 respectively.

Because the APP is a feature within MIPS and therefore the quality measures used within the APP and APP Plus quality measure sets are all MIPS measures, any updates CMS applies to MIPS measures also are incorporated into the APP and APP Plus quality measure sets, accordingly. As set forth in Table Group DD and Table Group C of this proposed rule, we note that we are proposing changes to the following measures that are part of the APP Plus quality measure set:

- Breast Cancer Screening (Quality ID: 112).
- Colorectal Cancer Screening (Quality ID: 113).
- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134; eCQM collection type only).
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484).
- Screening for Social Drivers of Health (Quality ID: 487).

These changes have been reflected in the Tables 54, 55, 56, and 57. For further discussion and rationale for the proposed modification or removal of these measures is provided at (Table Group DD and Table Group C of this proposed rule). Again, because the APP is a reporting pathway within MIPS, all of the quality measures offered through the APP are the MIPS versions of such measures, and we generally take the approach of adopting updates made to the MIPS measures for use in the APP quality measure sets.

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TABLE 54: APM PERFORMANCE PATHWAY QUALITY MEASURE SET BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/ Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE 55: APP PLUS QUALITY MEASURE SET FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE 56: APP PLUS QUALITY MEASURE SET FOR THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

QUALITY #	MEASURE TITLE	COLLECTION TYPE	SUBMITTER TYPE	MEANINGFUL MEASURES 2.0 AREA	MEASURE TYPE
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process

TABLE 57: APP PLUS QUALITY MEASURE SET BEGINNING WITH THE CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR AND SUBSEQUENT PERFORMANCE PERIODS/MIPS PAYMENT YEARS

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP	MIPS Eligible Clinician Representative of a Practice	Wellness and Prevention	Process

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
		ACOs only)	APM Entity Third Party Intermediary		
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
487*	Screening for Social Drivers of Health	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Equity	Process
493*	Adult Immunization Status	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

* Indicates this measure will be incorporated into the APP Plus quality measure set in the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specification becomes available, whichever is later.

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c. Toward Digital Quality Measurement in CMS Quality Programs—Request for Information

We have previously issued requests for information (RFIs) to gather public input on the transition to digital quality measurement (dQM) for CMS programs.[336] This RFI provides updates on our progress and seeks input as we continue our path forward in the dQM transition.

In this RFI, we are soliciting comments on our anticipated approach to the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting. Currently, several CMS programs use, or are considering using, eCQMs for various clinicians, facilities, providers, and other organizations to report their respective quality performance data. These CMS programs include the Medicare Shared Savings Program (Shared Savings Program) and the Quality Payment Program, particularly the Merit-Based Incentive Payment System (MIPS) quality performance category. We are seeking feedback on FHIR-based eCQM activities in these programs. We included a similar RFI in the FY 2026 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule (90 FR 18323 through 18328) to solicit comments on FHIR-based eCQM activities in the Hospital Inpatient Quality Reporting (IQR) Program, the Hospital Outpatient Quality Reporting (OQR) Program, and the Medicare Promoting Interoperability Program.

We will consider the feedback we receive as we refine our dQM transition efforts and plan the strategic modernization of our quality measurement enterprise.

(1) Background

Having immediate access to electronic health information, in near real-time, supports quality measurement efforts, provides patients the ability to use these data for care considerations, and may lead to improved clinical outcomes. To support this, we aim to transition to a

[336] We refer readers to the following rules which contain the previous RFIs: FY 2022 IPPS/LTCH PPS final rule (86 FR 45342 through 86 FR 45349); FY 2023 IPPS/LTCH PPS final rule (87 FR 49181 through 87 FR 49188); CY 2022 Physician Fee Schedule (PFS) final rule (86 FR 65377 through 86 FR 65382); CY 2023 PFS proposed rule (87 FR 46259 through 87 FR 46262); CY 2022 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule (86 FR 63815 through 86 FR 63822); and CY 2022 End-Stage Renal Disease (ESRD) PPS final rule (86 FR 61941 through 86 FR 61948).

fully dQM landscape that promotes interoperability and increases the value of reporting quality measure data. In the coming years, we will continue to seek ways to advance technical infrastructure, update program regulations, and engage Federal partners and the public to support this dQM transition.[337]

We are collaborating with Federal agencies, including the Assistant Secretary for Technology Policy (ASTP) and Office of the National Coordinator for Health Information Technology (ONC) (collectively referred to as ASTP/ONC)[338] to support data standardization and alignment of requirements for the development and reporting of digital quality measures. Advancements in the interoperability of healthcare data and corresponding requirements from ASTP/ONC have created the technical foundation across health information technology (IT) systems to pursue modernization of CMS' quality measurement systems. The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642) and the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) final rule (89 FR 1192) moved forward policy approaches that enable flexible, granular data sharing from the certified health IT systems used by many healthcare providers, facilities, and clinicians. Aligning technology requirements for healthcare providers, payers, public health agencies, and health IT developers allows for advancement of an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

We continue to collaborate with ASTP on future versions of the United States Core Data for Interoperability (USCDI),[339] which establishes a baseline set of data elements referenced in health information exchange certification criteria under the ONC Health IT Certification Program. In addition, the ASTP USCDI+ program supports identification and establishment of domain-specific datasets that build on the USCDI foundation.[340] The USCDI+ Quality domain,[341] which we discuss in more detail in section IV.A.4.c.(2)(b) of this proposed rule, aims to harmonize data needs for quality measurement across Federal agencies and other interested parties, and inform supplemental standards necessary to support quality measurement. We also continue to work with ASTP to advance the interoperability of patient assessment data through collaboration with interested parties to develop FHIR implementation guides through the CMS-sponsored Post-Acute Care Interoperability (PACIO) Project.[342]

Moreover, the CMS Innovation Center's Enhancing Oncology Model recently completed its first reporting period in which FHIR-based application programming interfaces (APIs) were used by model participants to submit clinical data elements to CMS. This specification for reporting was developed as part of the USCDI+ Cancer domain, in close collaboration with ASTP, the National Institutes of Health (NIH), and the National Cancer Institute (NCI).[343]

We continue to collaborate with the Centers for Disease Control and Prevention (CDC) and other agencies within the U.S. Department of Health and Human Services (HHS) in our dQM transition strategy. The CDC National Healthcare Safety Network (NHSN) is leading the development of fully electronic and automated digital quality measures for patient safety and public health surveillance, preparedness, and response.[344] We are working together with NHSN to explore a modernized approach for reporting quality measures to CMS via the NHSN data pipeline. There are currently multiple digital quality measures soon to be reported to NHSN could be used in CMS programs.[345] CMS and CDC are working together to transition to fully automated digital quality measures using a two-pronged approach: (1) Develop new measures to address patient safety gaps; and (2) Update current measures to a FHIR-based format.

The NHSN dQM approach uses a reusable reporting framework (NHSN Digital Quality Measure Reporting Implementation Guide (IG))[346] in conjunction with content based in national, interoperable data standards (USCDI and USCDI+) that are aligned with CMS requirements, and submitted via secure data transfer via open-source FHIR API (NHSNLink).[347] Promoting the use of these standards-based, flexible, advanced data reporting methods will reduce the reporting burden on clinicians while increasing timeliness and completeness, and will improve the accuracy and quality of data, enhancing health system readiness and response capacity through near real-time data collection.

Our partners at Health Resources and Services Administration (HRSA) are also modernizing reporting of eCQMs.[348] As part of the Uniform Data System (UDS) modernization, HRSA developed the Uniform Data Systems Plus (UDS+), which provides for the electronic submission (using FHIR) of de-identified patient-level data, including data elements aligned to select CMS eCQMs that health centers are required to report.[349] HRSA developed a UDS+ FHIR IG, which specifies the FHIR API requirements for structuring and transmitting these data elements based on program requirements.

All these efforts to leverage standardized data and the FHIR model are intended to accelerate and support the transition to a data-driven healthcare system that will ultimately reduce provider burden, support the patient experience, and improve quality of care. Shifting towards approaches based on the FHIR standard will help us pave the way for future digital quality measures.[350]

We thank the public for providing feedback through industry conferences, direct conversations with CMS and our Federal partners, and submitting comments to RFIs in previous rulemaking. As we support healthcare providers, facilities, and clinicians, the health IT industry, and Federal partners in their respective activities, we are requesting public input on this RFI to better inform our ongoing strategy to transition to a fully digital quality landscape. Note that any substantive updates to program-specific requirements related to providing data

[337] Read more about the dQM transition in the Electronic Clinical Quality Improvement (eCQI) Resource Center here: *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=about-dqms.*

[338] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

[339] *https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.*

[340] *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[341] *https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_domain&sys_id=7ddf78228745b95098e5edb90cbb3525&view=sp.*

[342] *https://pacioproject.org/.*

[343] *https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model.*

[344] *https://www.cdc.gov/nhsn/fhirportal/index.html.*

[345] *https://www.cdc.gov/nhsn/cms/index.html.*

[346] *https://build.fhir.org/ig/HL7/nhsn-dqm/.*

[347] *https://www.cdc.gov/nhsn/fhirportal/about.html.*

[348] *https://bphc.hrsa.gov/data-reporting/uds-training-and-technical-assistance/uniform-data-system-uds-modernization-initiative.*

[349] *https://www.fhir.org/guides/hrsa/uds-plus/dataelements.html.*

[350] *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=about-dqms.*

for quality measurement and reporting would be addressed through future notice-and-comment rulemaking, as necessary.

(2) Approach to eCQM Reporting Using FHIR in CMS Quality Programs

In this section, we describe the current state and request input on key components of the ongoing dQM transition related to FHIR-based eCQMs for the Medicare Shared Savings Program and the MIPS quality performance category. These components include: (1) FHIR-based eCQM conversion progress; (2) Data standardization for quality measurement and reporting; (3) The timeline under consideration for FHIR-based eCQM reporting; (4) Measure development and reporting tools; and (5) FHIR Reporting and Data Aggregation for ACOs.

(a) eCQM FHIR Conversion Activities

Currently, Medicare Shared Savings Program Accountable Care Organizations (ACOs) and eligible clinicians participating in MIPS can report eCQMs for their quality reporting. Electronic health record (EHR) and other health IT systems certified under the ONC Health IT Certification Program use patient data to calculate the results for each eCQM based upon the measure specifications for the eCQM.[351]

An important initial step in our dQM strategy is to ensure current eCQMs are specified using the FHIR standard and allow these measures to be calculated consistently using standardized data represented in FHIR. Standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. The eCQMs currently use structured data defined by the Quality Data Model (QDM) and measure logic in Clinical Quality Language to evaluate a clinician's, provider's, facility's, or organization's performance on a measure concept.[352]

As we move to FHIR-based eCQMs, we continue to convert current eCQMs (authored using the QDM) to eCQMs authored using the HL7 FHIR® Quality Improvement Core (QI-Core) IG, updating to new versions as appropriate. We are conducting advanced validation of FHIR data exchange through ongoing HL7 Connectathons and integrated systems testing, leveraging and refining IGs to enhance interoperability and data standardization.[353] While new eCQMs continue to be developed, proposed, and adopted in existing CMS programs, we are working with measure developers to ensure existing eCQMs are converted to FHIR and that new eCQMs are also natively developed in FHIR. In the future, we are considering a requirement that all quality measures proposed for addition to CMS programs be specified in FHIR.

We are also considering requirements to include FHIR-based specifications for measures developed by Qualified Clinical Data Registries (QCDRs). Additional information and updates regarding eCQMs and the dQM transition can be found on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=dqm-strategic-roadmap.* We continue to explore potential applications of the FHIR standard to the reporting and use of different types of quality measurement data.

We seek feedback on the following questions:

- Are there specific eCQMs or components of existing eCQMs that you anticipate presenting particular challenges in specifying in FHIR?
- Are there gaps in the QI-Core IG that are likely to impact our ability to effectively specify current CMS eCQMs in FHIR?
- What supplementary activities would encourage additional engagement in FHIR testing activities (such as Connectathons) that support the development of current and future IGs to advance adoption and use of FHIR-based eCQMs?

(b) Data Standardization for Quality Measurement and Reporting

We are continuing to collaborate with ONC as it develops a certification approach to enable reporting of FHIR-based eCQMs using technology certified under the ONC Health IT Certification Program. This approach aims to repurpose and harmonize existing FHIR requirements in the ONC Health IT Certification Program whenever possible.[354] It also aims to incorporate industry-developed standards for the exchange of quality measurement data using FHIR.

In this section, we discuss the standards and other artifacts which CMS and ONC are evaluating to serve as the basis for new health IT certification criteria supporting FHIR-based quality measurement and reporting. New health IT certification criteria for quality measurement and reporting could include requirements for certified Health IT Modules to support the consistent capture and exchange of quality data using FHIR APIs. New criteria could also support standardized reporting rules to ensure successful submission of quality measure data for the Medicare Shared Savings Program and the MIPS quality performance category.

A key artifact CMS and ASTP are reviewing as part of this approach is the QI-Core IG, which defines a set of FHIR profiles within a common logic model for clinical quality measurement and clinical decision support intended for use for multiple use cases across domains.[355] As described previously, this IG is used to represent the data elements necessary to support current eCQMs.

The QI-Core IG builds on the HL7 FHIR® US Core IG (US Core IG) which is currently referenced under the ONC Health IT Certification Program and implements the USCDI in FHIR. The US Core IG is incorporated in the ''Standardized API for patient and population services'' health IT certification criterion [356] and is widely implemented across certified health IT systems. Accordingly, we anticipate that developers implementing the QI-Core IG will be able to leverage existing work from implementing the US Core IG. QI-Core is expected to evolve over time to reflect subsequent versions of the US Core IG. For example, QI-Core 6.0 builds upon US Core version 6.1.0, which provides consensus-based capabilities aligned with USCDI version 3 (v3) data elements for FHIR APIs. In the HTI–1 final rule (89 FR 1196), ONC finalized the expiration of USCDI v1 on January 1, 2026, and adopted USCDI v3 as the new baseline version of USCDI after USCDI v1 expires.

We are also supporting ASTP in their work to advance alignment between the QI-Core IG and the USCDI+ Quality data element list, which incorporates additional data elements beyond USCDI. We have collaborated with ASTP around the development of USCDI+ Quality as an extension to USCDI to improve healthcare interoperability across quality programs, establishing a consistent baseline of harmonized data

[351] *https://ecqi.healthit.gov/sites/default/files/eCQM-Basics-508.pdf.*

[352] *https://ecqi.healthit.gov/sites/default/files/Digital%20Quality%20Measurement%20eCQMs%20reference%20brief_508ed.pdf.*

[353] Summaries are available and more information on the most recent Connectathon is available at: *https://confluence.hl7.org/spaces/FHIR/pages/281218287/2025+-+01+Clinical+Reasoning.*

[354] See 45 CFR 170.315(g)(10)—*Standardized API for patient and population services* FHIR certification in the ONC Health IT Certification program.

[355] *https://hl7.org/fhir/us/qicore/index.html.*

[356] 45 CFR 170.315(g)(10).

elements for a wide range of quality measurement use cases.[357] Specifically for CMS programs, USCDI+ Quality includes the data elements to support program-specific measures.[358]

We are also considering the Data Exchange for Quality Measures (DEQM) IG [359] as part of the framework supporting the transition to FHIR-based eCQMs, in particular for supporting FHIR-based reporting to CMS. The DEQM IG provides a framework that defines conformance profiles and guidance to enable the exchange of quality information and enable FHIR-based quality measure reporting. It is based upon other related work in the FHIR and quality measure realm, including the US Core IG, the Healthcare Effectiveness Data and Information Set (HEDIS) IG, and Quality Reporting Document Architecture (QRDA) Category I and III reporting specifications. We are considering the use of the DEQM IG with quality measures specified in accordance with QI-Core.

To facilitate the exchange of significant volumes of data to support quality measurement, we are also evaluating the use of HL7 FHIR ® Bulk Data [360] including analysis of: Potential enhancements to support the use of Bulk paired with the QI Core IG and potential use of Bulk paired with the DEQM IG.[361] The existing Bulk Data Access IG defines a standardized, FHIR-based approach for exporting bulk data from a FHIR server to an authenticated and authorized client. ONC has adopted the Bulk Data Access IG STU 1, version 1.0.0, published on August 8, 2019 (hereafter referred to as version 1), and has incorporated it into the ONC Health IT Certification Program.[362] The Bulk Data Access IG has recently seen considerable revisions and enhancements over version 1 from the HL7 standards community. A new version of the Bulk Data Access IG, planned to be balloted in 2025, is expected to introduce new features such as the capacity to organize output by patient and criteria-based cohort creation, which could significantly enhance the quality reporting use case for the IG.[363] The HL7 community will also continue to prepare additional enhancements to the Bulk Data Access IG throughout 2025, with the Argonaut Project announcing Bulk Import as a 2025 project.[364] Bulk Import is already being used by AHA in their UDS+ IG,[365] and has the potential to enhance the quality reporting use case more broadly. It defines a standardized mechanism for data submitters to upload or submit their Bulk FHIR data to a receiving system when they have their Bulk FHIR data ready to submit, rather than having to reactively respond to a Bulk FHIR export request initiated by a receiving system.

We seek feedback on the following questions:

- Can you share any experiences or challenges reviewing, implementing, or testing the QI-Core, DEQM, or Bulk FHIR standards, including any experiences or challenges unique to Bulk FHIR Import versus Bulk FHIR Export?
- Are there any deficiencies or gaps in the DEQM IG that must be addressed before it can potentially be used for reporting to CMS on eCQMs using FHIR APIs?
- Are there additional baseline requirements or capabilities that need to be considered before FHIR-based eCQMs could be reported to CMS using Bulk FHIR?
- Are there additional supports or enhancements that CMS should consider for the QI Core, DEQM, or Bulk FHIR IGs that would support quality measurement and reporting beyond the CMS eCQMs or potential dQMs?

(c) Timeline Under Consideration for FHIR-Based eCQM Reporting

As we noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 49183), we are considering proposing a transition period during which healthcare providers that satisfy quality reporting requirements by using the eCQM collection type may report using either QDM- or FHIR-based eCQMs.

For MIPS and other programs that use the eCQM collection type, we are considering a similar transition for the eCQM collection type to FHIR, instead of QDM-based eCQMs. This period would provide time for providers and clinicians participating in CMS programs, health IT developers, and CMS to engage in learning to optimize systems and processes. During this period, participants that have chosen to satisfy applicable quality reporting requirements by reporting eCQMs would be able to choose to submit either QDM-based *or* FHIR-based eCQMs to meet respective reporting requirements. For instance, participants who are implementing updated certified health IT and gaining experience with FHIR-based eCQMs could continue submitting QRDA files to meet program requirements, while those who are ready to report FHIR-based eCQMs would be able to do so, for a specified period. For the purposes of this RFI, we refer to this concept as the ''reporting options'' period.

As a note, while MIPS eligible clinicians have the option to satisfy quality reporting requirements by reporting an eCQM, it is currently not required within MIPS. We are not proposing to limit any collection types for MIPS eligible clinicians to report quality measures for the quality performance category.

We acknowledge that participants in the identified CMS programs may proceed with updating certified health IT and implementing dQMs at different speeds. Hence, we are considering the reporting options period to provide additional time for clinicians who elect to report the eCQM collection type, in advance of any future proposal to require FHIR-based reporting for eCQMs. We are considering at least a two-year reporting options period before any future proposal to require only FHIR-based reporting for eCQMs. Note that any updates to specific program requirements related to providing data for quality measurement and reporting would be addressed through future notice-and-comment rulemaking, as necessary.

We seek feedback on the following questions:

- Would a minimum of 24 months from the effective date of a FHIR-based eCQM reporting option using ONC Health IT Certification Program criteria to support quality program submission provide sufficient time for implementation (including measure specification review, certified health IT updates, workflow changes, training, and testing)?
- What resources or guidance could CMS provide to assist with the transition to submission of FHIR-based eCQM data?
- What challenges, if any, do you anticipate with the reporting timeline of FHIR-based eCQMs (beginning with at least a 2-year reporting options period

[357] *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[358] For more information about the USCDI+ Quality data element list please visit*https://uscdiplus.healthit.gov/.*

[359] *https://build.fhir.org/ig/HL7/davinci-deqm/.*

[360] *https://hl7.org/fhir/uv/bulkdata/.*

[361] *https://hl7.org/fhir/us/davinci-deqm/OperationDefinition-bulk-submit-data.html.*

[362] ONC has adopted the Bulk Data Access IG, version 1, in 45 CFR 170.215, and has incorporated this IG into the ONC Health IT Certification Program as part of the ''Standardized API for patient and population services'' certification criterion in 45 CFR 170.315(g)(10).

[363] See Argonaut Bulk Optimize project: *https://confluence.hl7.org/spaces/AP/pages/227213555/Bulk+Optimize.*

[364] *https://confluence.hl7.org/spaces/AP/pages/325453837/Bulk+Import.*

[365] *https://www.fhir.org/guides/hrsa/uds-plus/OperationDefinition-import.html.*

before any future proposal to require FHIR-based reporting)?

- What resources, guidance, or other support could we provide to encourage and facilitate the early adoption and reporting of FHIR-based eCQMs during the data submission period?

(d) Measure Development and Reporting Tools

We develop and maintain tools and resources to assist measure developers in the different stages of the Measure Lifecycle.[366] The Measure Authoring Development Integrated Environment (MADiE) is a free software tool that supports the eCQM development and testing process through dynamic authoring and testing within a single application.[367] MADiE supports QI-Core profile-informed authoring, testing, and verification of the behavior of FHIR-based eCQMs.[368] We encourage measure developers to continue using this environment for the development of FHIR-based eCQMs.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49183), we described plans to modernize programmatic data receiving systems through a unified CMS FHIR receiving system that would provide a single point of data receipt for quality reporting programs. We may also consider separate FHIR receiving systems for some programs initially as the shift to FHIR across CMS programs will be incremental. We will provide information on the form and manner for reporting for each program in respective notice-and-comment rulemaking, as necessary. Our vision remains to ultimately develop and implement a single point of data receipt via a unified CMS FHIR receiving system.

In the CMS Digital Quality Measurement Strategic Roadmap, we noted the development of a FHIR-based measure calculation tool (MCT).[369] After further consideration and testing, we have decided not to advance the MCT as previously described.

We seek feedback on the following questions:

- What capabilities would be most useful for CMS to support in a FHIR-based eCQM reporting model?
- What additional concerns, if any, should CMS take into consideration when developing FHIR-based reporting requirements for systems receiving quality data?

(e) FHIR Reporting and Data Aggregation for ACOs

As finalized in the CY 2025 PFS final rule, Shared Savings Program ACOs are required to report the Alternative Payment Model (APM) Performance Pathway (APP) Plus quality measure set beginning with the 2025 performance year (89 FR 98105). For the 2025 performance year, ACOs will be required to report four measures using one of the three collection types: eCQMs, MIPS Clinical Quality Measure (CQM), or Medicare CQM. We finalized the incremental increase in the number of measures required with each subsequent performance year (89 FR 98105), sunsetting the MIPS CQM collection type beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 98111).

As ACOs bring together health care providers using disparate EHR systems from which data is extracted and aggregated, they have encountered challenges with aggregating, deduplicating, and matching all patient data required under the eCQM and MIPS CQM quality measure collection types. We released a document that describes eCQM and MIPS CQM reporting scenarios specific to Shared Savings Program ACOs and that provides guidance on patient matching and data aggregation, and how MIPS data completeness policy applies to an ACOs eligible and matched patient population, available here: *https://www.cms.gov/files/document/medicare-shared-savings-program-reporting-mips-cqms-and-ecqms-alternative-payment-model-performance.pdf.* While the number of ACOs reporting eCQMs and MIPS CQMs has grown, uptake has been slow. In 2021, 12 ACOs reported using either eCQMs or MIPS CQMs. The number using these collection types increased to 37 ACOs in 2022, and 73 ACOs in 2023.

We have provided reporting incentives specific to eCQMs and MIPS CQMs to encourage the adoption of eCQMs and MIPS CQMs (89 FR 98123). We are interested in how a transition to FHIR-based reporting of eCQMs could help to mitigate the burden ACOs may experience related to aggregating quality data from multiple practices and multiple EHR systems. We note that any updates to specific program requirements related to providing data for quality measurement and reporting requirements would be addressed through future notice-and-comment rulemaking, as necessary.

We seek feedback on the following questions:

- What types of technical support, guidance, and resources would be most beneficial for ACOs in the implementation of FHIR-based eCQMs?
- Are you presently ready and able to report eCQM data using FHIR? Are there any challenges you anticipate facing in transitioning to these reporting methods?
- What changes need to be made to health IT functionality, including EHRs, to better support efforts to aggregate data from multiple settings or health IT systems, including EHRs, to enable ACOs to successfully report eCQMs using FHIR?
- For ACOs developing the infrastructure needed to aggregate data from multiple settings and health IT systems, including EHRs, what are the estimated costs and timelines that your ACO has identified for implementing capabilities necessary to perform this data aggregation? Where applicable, please provide appropriate context.
- What changes could be made to the available eCQMs and eCQM specifications to better support the efficacy and relevance of applicable measures for ACOs reporting from multiple settings?
- What feedback do you have, if any, on ACO experience reporting aggregate quality measure data using the Data Exchange for Quality Measures (DEQM) IG?
- What feedback do you have, if any, on ACO experience using Bulk FHIR?
- What feedback do you have, if any, on ACO experience using the QI Core IG?
- What challenges, if any, do you anticipate for eligible clinicians, group practices, and ACOs transitioning to FHIR-based eCQMs within the anticipated reporting options timeline?

(3) General Solicitation of Comments

In conjunction with the previous questions, we are also seeking input on the following:

- Specific to FHIR-based quality reporting, are there any additional factors, or considerations to account for, that may help reduce reporting burden across entities? Are there any areas CMS should consider that would help reduce burden for reporting quality beyond the scope of CMS eCQMs or potential dQMs?
- Would the ability to reuse or repurpose technology, standards, data elements, and/or specifications reduce burden for healthcare providers in measuring and reporting quality overall?
- The Trusted Exchange Framework and Common Agreement™ (TEFCA™) framework supports nationwide health information exchange by connecting

[366] *https://mmshub.cms.gov/cms-tools.*

[367] *https://www.emeasuretool.cms.gov/.*

[368] *Ibid.*

[369] *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=dqm-strategic-roadmap.*

health information networks (HINs) across the country.[370] Additionally, TEFCA facilitates FHIR exchange by requiring Qualified HINs (QHINs) to perform patient discovery for those querying for data and providing data holders with FHIR endpoints to enable point-to-point exchange via FHIR APIs.

How could this initiative potentially support exchange of FHIR-based quality measures consistent with the FHIR Roadmap (available here: *https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/*)?

How might TEFCA enable the use of data for secondary uses such as treatment and research?

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, CY 2024, and CY 2025 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, 87 FR 70047 through 70055, 88 FR 79329 through 79338, and 89 FR 98373 through 98375 respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In the CY 2026 PFS proposed rule, we are proposing to:

- Amend the definition of the term ''high priority measure'' to remove references to health equity at § 414.1305.
- Modify the MIPS quality measure set as described in Appendix 1 of this proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) High Priority Measure Definition

The Meaningful Measures Initiative provides for the identification of high priority areas for quality measurement and quality improvement, which identifies the core quality of care issues that advances our work to improve patient outcomes (83 FR 59719). To further identify priority areas for MIPS quality measurement, we defined the term high priority measure at § 414.1305, beginning with the CY 2019 performance period/2021 MIPS payment year, as an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure (83 FR 59761). In the 2023 PFS final rule (87 FR 70047 through 70049), we finalized an amended definition of the term ''high priority measure'' to include quality measurement pertaining to health equity. We also codified this revised definition at § 414.1305 beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70047 through 70048).In the CY 2023 PFS final rule (87 FR 70047), we noted significant and persistent inequities in healthcare outcomes exist in the United States and that we are committed to developing innovative solutions that support access to high quality care and promote health equity, including the exploration of solutions to measure health equity within MIPS. Consequently, we stated that we believed it was imperative to include quality measures pertaining to health equity as high priority measures in order to incentivize the adoption of health equity measures by MIPS eligible clinicians. In the 2023 PFS final rule (87 FR 70049) we defined health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identify, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes.''

This definition was adopted during the Public Health Emergency (PHE) for COVID–19. At the time we believed that adding the term health equity to our definition of a high priority measure was the best way to address health disparities exacerbated by the pandemic. On September 12, 2023, Health and Human Services (HHS) announced the end of the Federal PHE for COVID–19 in a statement effective May 11, 2023.[371] Now that the PHE has ended, we believe that these disparities are best addressed through other mechanisms. We believe that our definition of ''health equity'' was confusing and that health disparities are best addressed through efforts to improve overall healthcare quality for all beneficiaries. In section IV.A.3.d of this proposed rule, we requested public input to identify measures around well-being and nutrition as high priority area for quality measurement and quality improvement. Therefore, we propose to remove quality measurement pertaining to health equity from the definition of the term ''high priority measure''

Specifically, we are amending the definition of the term high priority measure at § 414.1305 to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure beginning with the CY 2026 performance period/CY 2028 MIPS payment year.

(c) Selection of Quality Measures

(i) Addition of New Quality Measures

(A) Pre-Rulemaking Process

Prior to introducing a new MIPS quality measure in a proposed rule, we receive public input on measures through the pre-rulemaking process (referred to as the Pre-Rulemaking Measure Review (PRMR)) established in accordance with section 1890A of the Act. Although section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to

[370] For more information about TEFCA, see *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

[371] Available at *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

apply to the selection of MIPS quality measures, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-stakeholder workgroups and have accordingly elected for such measures to be reviewed utilizing the PRMR process (87 FR 70048). Under the established PRMR process (additional information regarding the PRMR process is available at *https://p4qm.org/PRMR*), CMS has contracted with a Consensus-Based Entity (CBE), which is responsible for convening a multi-stakeholder panel comprised of clinicians, patients, measure experts, and health information technology specialists to provide input on measures CMS is considering for use in Medicare.

The pre-rulemaking process begins with CMS's publication of measures under consideration for use in Medicare (the MUC List). Each measure on the MUC List is reviewed by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary. The PRMR process includes opportunities for public comments through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.

The final vote of a multistakeholder committee convened by the CBE may result in the following disposition of a measure: recommended, recommended with conditions, do not recommend, or no consensus. A ''no consensus'' recommendation signals continued disagreement among the committee despite being presented with perspectives from public comments, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. Quality measures that are considered for potential implementation in MIPS starting with CY 2026 performance period/CY 2028 payment year period were included on the 2024 Measures Under Consideration (MUC) List (available at *https://mmshub.cms.gov/sites/default/files/2024-MUC-List.xlsx*). The new MIPS quality measures finalized, as proposed, are described in Table Group A of Appendix 1 of this proposed rule. There may be cases in which the CBE does not recommend a measure to move forward to the rulemaking process and eventual implementation due to a measure not being endorsed by the CBE or other CBE, but we go forth with proposing a measure. We note that section 1848(q)(2)(D)(iii)(v)(III) of the Act does not preclude the Secretary from proposing and implementing measures that are not endorsed by a CBE as long as the measure is evidence-based.

(ii) Removal of Quality Measures

In the CY 2025 PFS final rule, we codified previously established criteria for the removal of MIPS quality measures from the MIPS quality measure inventory at § 414.1330. In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we established the following criteria for measure removal to include: If the Secretary determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out; and, if a measure steward is no longer able to maintain the quality measure. In the CY 2019 PFS final rule (83 FR 59763), we expanded the criteria for measure removal to include MIPS quality measures that reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range); the MIPS quality measure may be proposed for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped-out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Also, in the CY 2019 PFS final rule (83 FR 59764), we established other criteria for measure removal, specifically MIPS quality measures that are: duplicative; not maintained or updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice; and low-bar, standard of care process measures. As described in the CY 2019 PFS final rule (83 FR 59765), we established an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to the following:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the MIPS quality measure addresses a priority area highlighted in the Measure Development Plan: *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measuredevelopment.html.*
- Whether the MIPS quality measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS quality measure is designated as high priority or not.
- Whether the MIPS quality measure has reached extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

In the CY 2020 PFS final rule (84 FR 62958 through 62959), we expanded the criteria for measure removal to include MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods and not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. For MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods, we noted that we will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; and consideration of the MIPS quality measure in developing MVPs) prior to determining whether to remove the MIPS quality measure.

(iii) Inventory of Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2025 PFS final rule (89 FR 98599 through 98954), CY 2024 PFS final rule (88 FR 79556 through 79964), CY 2023 PFS final rule (87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968), CY 2021 PFS final rule (85 FR 85045 through 85377), CY 2020 PFS final rule (84 FR 63205 through 63513), CY 2019 PFS final rule (83 FR 60097 through 60285), CY 2018 Quality

Payment Program final rule (82 FR 53966 through 54174), and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We are proposing changes to the MIPS quality measure inventory, as set forth in Appendix 1 of this proposed rule, including the following: the addition of new measures; updates to specialty sets (that is, creation of new specialty sets; addition and/or removal of measures; and substantive changes to existing measures within specialty sets); removal of existing measures; and substantive changes to existing measures. For the CY 2026 performance period, we are proposing an inventory of 190 MIPS quality measures.

The new MIPS quality measures that we are proposing to include in MIPS for the CY 2026 performance period/CY 2028 payment year and future years can be found in Table Group A of Appendix 1 of this proposed rule. For the CY 2026 performance period, we are proposing 5 new MIPS quality measures, which include 3 high priority measures, one of which is also patient-reported outcome measures.

On January 4, 2025, we announced that we will be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 10 (CY 2017 performance period/2019 MIPS payment year through CY 2026 performance period/2028 MIPS payment year) of MIPS under the Quality Payment Program.[372] The recommendations we received were based on the MIPS quality measures finalized in the CY 2025 PFS final rule and the 2024 MUC List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, and/or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are proposed in this proposed rule. We proposed modifications to existing specialty sets as described in Table Group B of Appendix 1 of this proposed rule. Modifications to specialty sets include the addition of new measures and/or existing measures within the MIPS quality measure inventory, removal of measures, and/or substantive changes to previously finalized measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty. We develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets as described in Tables Group A and Group B of Appendix 1 of this proposed rule, we referred readers to Table Group C of Appendix 1 of this PFS proposed rule for a list of MIPS quality measures proposed for removal and applicable rationale for each measure. In the 2025 PFS final rule (89 FR 98388), we codified previously finalized removal criteria for MIPS quality measures at 42 CFR 414.1330(c). Of the 10 MIPS quality measures proposed for removal, 1 MIPS quality measure is being proposed for removal at the measure steward's request and is not aligned with current clinical guidelines), 4 MIPS quality measures are extremely topped out, 1 MIPS quality measure has reached the topped-out lifecycle, 1 MIPS quality measure is no longer able to be maintained by the measure steward, and 3 are process measures. For a detailed discussion of our rational for the removal of these measures please see Table Group C of Appendix 1 of this proposed rule. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see,* for example, 83 FR 59763 through 59765). The proposal to remove the MIPS quality measures described in Table Group C of Appendix 1 of this proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program.

Also, in Appendix 1 of this proposed rule, we are proposing substantive changes to 42 MIPS quality measures, which can be found in Table Group D of this proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 through 65442). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. The proposed inventory of 190 MIPS quality measures includes 187 MIPS quality measure available for utilization in traditional MIPS and MVPs, and 3 MIPS quality measures available only for utilization in MVPs (as finalized in the CY 2024 PFS final rule (88 FR 79897 through 77902)).

In CY 2026 PFS proposed rule, we are proposing to modify the quality performance category measure inventory, a set of 190 MIPS quality measures for the CY 2026 performance period, which includes the following:

- Implementation of 5 new MIPS quality measures including 3 high priority measures one of which is a patient reported outcome measure;
- Removal of 10 MIPS quality measures: 1 quality measure at the measure steward's request due to not being aligned with current clinical guidelines, 4 quality measures are extremely topped out, 1 quality measure has reached the end of the topped-out lifecycle, 1 measure where the measure steward is no longer able to maintain the quality measure, 3 process measures , and;
- Substantive changes to 42 MIPS quality measures.

We refer readers to Table Groups A through DD of Appendix 1 of this proposed rule for a summary of the new measures proposed, the measures proposed for removal, and the substantive changes proposed. We seek public comments on these proposals.

(2) Cost Performance Category

(a) Background

Section 1848(q)(2)(A)(ii) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the cost performance category.

Section 1848(q)(2)(B)(ii) of the Act provides that, for the cost performance category, the measurement of resource use (that is, cost) for such period must be in accordance with section 1848(p)(3) of the Act, using the methodology under section 1848(r) as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Medicare Part D. Section 1848(p)(3) of the Act provides that costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary that eliminate the effect of geographic adjustments in payment rates, and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals) and other factors determined appropriate by the Secretary. Section 1848(r) of the Act

[372] Message to the Quality Payment Program listserv on January 4, 2025, entitled ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2026 Performance Year of the Merit-based Incentive Payment System (MIPS).''

specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act.

We are proposing the following updates to the cost performance category beginning with the CY 2026 performance period/2028 MIPS payment year:

- Modify the MIPS cost measure inventory as described in Appendix X of this rule;
- Update the operational list of care episode and patient condition groups and codes to reflect changes to service and diagnosis codes that define care episodes and patient condition groups, as identified through the annual maintenance of episode-based measures; and
- Adopt a 2-year informational-only feedback period for new cost measures, where a measure would not impact MIPS cost performance category scores, final scores, or payment adjustments until the third year it is implemented.

For a description of the statutory authority for and existing policies pertaining to the cost performance category, we refer readers to §§ 414.1350 and 414.1380(b)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), and CY 2025 PFS final rule (89 FR 98390 through 98408).

More details on the proposals in this section, which we invite comments on, are provided in section IV.A.4.d.(2)(b) through section IV.A.4.d.(2).(d). of this proposed rule. We also refer readers to section V.B.5.c. of this proposed rule for discussion on the burden estimates for these proposals.

(b) Selection of Cost Measures

In accordance with our statutory authority as described in section IV.A.4.d.(2)(a) of this proposed rule and our regulation at § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category.

We consider adoption of cost measures to support the transition from traditional MIPS to MVPs by allowing new MVPs to be created and enhancing existing MVPs. Additionally, adopting cost measures also increases the cost coverage of care episode and patient condition groups, moving closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act.

In the CY 2022 PFS final rule (86 FR 65455 through 65459), we established common standards to ensure consistency across episode-based measures being considered for potential use in MIPS. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment.

Additionally, in the CY 2025 PFS final rule (89 FR 98405), we codified removal criteria for the removal of MIPS cost measures from the MIPS cost measure inventory at § 414.1350. We may remove a cost measure from MIPS based on one or more of the following factors, provided however that we may retain a cost measure that meets one or more of the following factors if we determine the benefit of retaining the measure outweighs the benefit of removing it.

- It is not feasible to implement the measure specifications.
- A measure steward is no longer able to maintain the cost measure.
- The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- The measure specifications do not reflect current clinical practice or guidelines.
- The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We are not proposing to adopt any new measures for the CY 2026 performance period/2028 MIPS payment year. We are also not proposing to remove any measures for the CY 2026 performance period/2028 MIPS payment year.

(c) Inventory of Cost Measures

As discussed previously, we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. While the requirement to annually issue a list of final measures as set forth in section 1848(q)(2)(D)(i) of the Act only applies to quality measures adopted for the MIPS quality performance category, we have applied some of these requirements for cost measures. Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list of quality measures by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list. In the CY 2022 PFS final rule, we stated that section 1848(q)(2)(D)(i)(II)(cc) of the Act, which requires all substantive changes to quality measures to be proposed and identified through notice-and-comment rulemaking, also should apply to cost measures (86 FR 65459).

On an annual basis, we review the established MIPS cost measure inventory to consider updates to the measures identified through measure maintenance reviews. The CMS Measure Maintenance System (MMS) provides additional information about measure maintenance review processes and best practices (*https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/overview*). Possible updates to measures may be minor or substantive. In the CY 2022 PFS final rule, we finalized several criteria for determining whether a proposed change to a cost measure would be substantive beginning with the CY 2022 performance period/2024 MIPS payment year (86 FR 65459 and 65460).

Section 1848(r)(10) of the Act provides that the pre-rulemaking requirements set forth in sections 1890(b)(7) and 1890A of the Act do not apply to our development of MIPS cost measures under section 1848(r) of the Act. Historically, we have subjected existing cost measures for which we are considering substantive changes to the pre-rulemaking process required by section 1890A of the Act prior to notice-and-comment rulemaking.

There are currently 35 cost measures in the cost performance category for the CY 2025 performance period/2027 MIPS payment year, comprising 33 episode-based measures covering a range of conditions and procedures and 2 population-based measures. Previously finalized MIPS cost measures can be found in the CY 2018 Quality Payment

Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), and CY 2025 PFS final rule (89 FR 98390 through 98408).

We are neither proposing any new MIPS cost measures nor proposing to remove any MIPS cost measures for the CY 2026 performance period/2028 MIPS payment year. We are proposing substantive changes to the Total Per Capita Cost (TPCC) measure, one of the 2 population-based measures, which can be found in Table Group A of Appendix X of this proposed rule, beginning with the CY 2026 performance period/2028 MIPS payment year.

We invite comments on the proposal in this section.

(d) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Generally, to calculate MIPS eligible clinicians' performance on cost measures, we use codes from claims data to identify and apply each cost measure's specifications, which govern the attribution, scope, and calculation of the cost measure. We are proposing revisions to the operational list of care episode and patient condition groups and codes to reflect to reflect coding changes due to annual measure maintenance of implemented cost measures. This section of this proposed rule provides context on the statutory requirements for care episode and patient condition groups and proposes changes to the operational list.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Medicare Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list of care episode and patient condition codes as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties.

For more information about past revisions to the operational list that we made as we developed, proposed, and finalized episode-based measures, we refer readers to the CY 2023 PFS final rule (87 FR 70056 through 70057), CY 2024 PFS final rule (88 FR 79348), and CY 2025 PFS final rule (89 FR 98404). The current operational list and prior operational lists are available at the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

In accordance with section 1848(r)(2)(H) of the Act, we are proposing to revise the operational list beginning with the CY 2026 performance period/2028 MIPS payment year to reflect changes to codes used to identify existing care episode and patient condition groups, based on new information gathered during annual maintenance of episode-based measures and the Medicare Spending Per Beneficiary (MSPB) Clinician measure. We conduct annual maintenance for measures implemented in MIPS to ensure that the codes used for the measure specifications remain up to date. For example, we may update the service or diagnosis codes associated with a cost measure's specifications to retain the intent of the measure when these codes are changed in, added to, or deleted from the applicable code sets. During our annual maintenance review process for MIPS cost measures, we worked with the measure developer to identify several non-substantive changes to service and diagnosis codes that should be reflected in the operational list care episode and patient condition groups so that, to the extent feasible, there is alignment between the operational list and measure specifications. More information on the annual maintenance process is available at the CMS Measures Management System (MMS) page at *https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/annual-update.*

Our proposed revisions to the operational list are available for review on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

We invite public comments on our proposals in this section.

(e) Proposal to Adopt a Two-Year Informational-Only Feedback Period for New MIPS Cost Measures

(i) Background on Informational-Only Feedback Period

Section 1848(q)(2)(B) of the Act provides that MIPS measures and activities must be specified for a performance period for each of the four performance categories, including the cost performance category as set forth in section 1848(q)(2)(B)(ii) of the Act. Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards with respect to applicable measures and activities specified in accordance with section 1848(q)(2)(B) with respect to each performance category. Section 1848(q)(5)(A) of the Act further directs the Secretary to provide for a composite assessment (that is, a MIPS final score) for each MIPS eligible clinician for the applicable performance period for such MIPS payment year using such methodology. At § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category.

Currently, we assess a MIPS eligible clinician's performance on any measure we have specified for the MIPS cost performance category for a performance period that is attributed to a MIPS eligible clinician in accordance with § 414.1350(b)(8), calculating a score on the clinician's performance with respect to the cost measure in accordance with § 414.1380(b)(2). As we discussed in detail in the CY 2025 PFS final rule when we modified our scoring methodology (89 FR 98438 through 98446), we score cost measures by comparing a MIPS eligible clinician's attributed costs to benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the same cost measure, plus or minus standard deviations (§ 414.1380(b)(2)(i)(B)). We then calculate the cost performance category score as set forth in § 414.1380(b)(2)(iii), which we incorporate into our calculation of the MIPS final score in accordance with §§ 414.1380(c) and 414.1350(d). We then compare the MIPS final score with

the performance threshold established for that MIPS payment year to calculate the MIPS payment adjustment in accordance with section 1848(q)(6) of the Act and § 414.1405. Section 1848(q)(12) of the Act further provides that we must make available timely confidential feedback to MIPS eligible clinicians regarding their performance in the cost performance category.

MIPS eligible clinicians receive ample notice in advance of the cost measures on which they may be scored through several avenues: (1) the cost measure development process, which requires input from clinicians, specialty societies, and other interested parties as outlined in section 1848(r)(2) of the Act and the CY 2019 PFS final rule (83 FR 59770); (2) the Pre-Rulemaking Measure Review (PRMR) process, where measures are assessed for their potential use in MIPS; (3) and the notice-and-comment rulemaking process, where we propose and finalize any cost measures for use in a future MIPS performance period. During this time, clinicians have access to measure specifications and testing information for review. Once measures are finalized for use in MIPS, we score MIPS eligible clinicians' performance on these measures as discussed previously and provide feedback to each clinician on their performance after the close of each performance period, as described in the CY 2025 PFS final rule (89 FR 98398 and 98399; 89 FR 98445).

While MIPS eligible clinicians have information available about new cost measures on which they may be assessed prior to the start of the performance period, they do not receive a score or performance feedback on any new cost measure until partially through the second performance period in which the measure is in use. We have received several requests from interested parties that we make performance feedback available earlier to MIPS eligible clinicians, such as prior to or during the performance period for which new measures are used to calculate MIPS performance category scores, final scores, and payment adjustments. Clinicians and specialty societies have provided this feedback through the notice-and-comment rulemaking process (89 FR 98398 and 98399), PRMR public comments, and other engagement not associated with a specific rule or public comment period. PRMR public comments are available for download here: *https://p4qm.org/PRMR/Resources.*

For example, some commenters have stated that MIPS eligible clinicians do not know in real time which cost measures they will be assessed on, which episodes and patients will be attributed to them, and what costs outside of their practice they are being held accountable for until after the performance period is over; they stated that, without frequent and actionable data, MIPS eligible clinicians cannot make changes to their care (89 FR 98398). While we are continuing to work towards providing meaningful and timely information on cost measures generally, we recognize the importance of providing this information for measures implemented in MIPS.

In addition, many commenters on the CY 2025 PFS proposed rule suggested that we adopt an informational-only feedback period for a minimum of 2 years after adoption of a new cost measure (89 FR 98398). Our understanding of this suggestion is that we would score the cost measure as attributed to each MIPS eligible clinician and share that score confidentially with the MIPS eligible clinician for informational-only purposes without including the score in our calculation of the cost performance category score or MIPS final score. Commenters stated this informational-only feedback period would help MIPS eligible clinicians understand which new cost measures they may be assessed on prior to these measures affecting MIPS payment adjustments (89 FR 98398). Similarly, some commenters stated that more timely and detailed performance feedback would provide MIPS eligible clinicians with an opportunity to improve their cost performance (89 FR 98445). We believe that providing feedback prior to MIPS payment adjustments through an informational-only feedback period would allow MIPS eligible clinicians more time to improve their cost performance before new measures affect payment.

We have considered this feedback when exploring an informational-only feedback period for MIPS cost measures. We believe that an informational-only feedback period supports our goals for the Quality Payment Program of encouraging clinicians to provide high-value, high-quality care to their patients in a cost-efficient manner. An informational-only feedback period would allow MIPS eligible clinicians time to develop familiarity with the cost measures and better understand the impact of new measures within the context of MIPS, prior to scores for these measures affecting their MIPS final scores or payment adjustments. Even though MIPS eligible clinicians have ample notice of cost measure specifications prior to the performance period as previously discussed, they may not be able to predict how they will perform on a new cost measure. Specifically, as previously discussed, we score a MIPS eligible clinician's performance on a cost measure based on how their attributed costs compare to benchmark ranges (§ 414.1380(b)(2)). We determine these cost measure benchmarks based on the range of costs attributed to all MIPS eligible clinicians for the same cost measure during the same performance period (§§ 414.1380(b)(2) and 414.1380(b)(2)(i)), rather than a benchmark determined based on historical data, for the reasons discussed in the CY 2025 PFS final rule (89 FR 98440). As a result, MIPS eligible clinicians do not have performance targets by which to predict their performance before or during the performance period. An informational-only feedback period would provide MIPS eligible clinicians with information and time to develop performance improvement strategies before their performance on new cost measures affects payment or is incorporated into MIPS final scores.

(ii) Proposal To Adopt an Informational-Only Feedback Period of Two Years for New Cost Measures

Section 1848(q)(1)(A) of the Act requires that the Secretary develop a methodology for assessing the total performance of each MIPS eligible clinician, provide a MIPS final score for each MIPS eligible clinician using such methodology, and to determine and apply a MIPS payment adjustment factor for each MIPS eligible clinician using the MIPS final score. As discussed previously, section 1848(q)(5) of the Act more specifically requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician on measures and activities specified under section 1848(q)(2)(B) of the Act and to provide for a MIPS final score. As part of this methodology, we are proposing an informational-only feedback period of 2 years for new cost measures finalized for use in MIPS beginning with the CY 2026 performance period/2028 MIPS payment year.

Specifically, we propose that, beginning with the CY 2026 performance period/2028 MIPS payment year, we would score all new cost measures for the first 2 years after the measure is initially finalized for informational-only purposes; we would not incorporate any informational-only scores on cost measures into MIPS eligible clinicians' cost performance category score or MIPS final score. If a MIPS eligible clinician is attributed a

cost measure during its informational-only feedback period, then we would calculate a measure score in accordance with our scoring policies at § 414.1380(b)(2) and confidentially provide the score, as well as MIPS performance feedback (*see* 82 FR 53799 through 53801), to the clinician on an annual basis. As we would not include the informational-only score in our calculation of cost performance category scores or MIPS final scores, MIPS eligible clinicians' performance on the new cost measures would not affect our calculation of their MIPS payment adjustments.

We further propose that we would begin incorporating these cost measures' scores into MIPS eligible clinicians' cost performance category and MIPS final scores beginning with the cost measure's third year in MIPS, after this 2-year informational-only feedback period. Once we begin incorporating these measures' scores into MIPS eligible clinicians' cost performance category and MIPS final scores, then MIPS eligible clinicians' performance on these measures would also affect their MIPS payment adjustments.

While we are not proposing to adopt any new cost measures in this proposed rule, we are proposing that this policy would begin with the CY 2026 performance period/2028 MIPS payment year. If finalized as proposed beginning with the CY 2026 performance period/2028 MIPS payment year, then this policy would be in place prior to any new cost measures being added to the MIPS cost performance category in future rulemaking.

We propose that this informational-only feedback period policy would not be applied to any existing cost measures already finalized for MIPS prior to the CY 2026 performance period/2028 MIPS payment year. We further propose that modifications to existing cost measures would not alter whether a measure is considered a new or existing measure. We are proposing this policy for measures that have not previously been implemented in MIPS so that MIPS eligible clinicians receive initial performance feedback on new cost measures without affecting their MIPS payment adjustments. The measures within the current cost measure inventory have already been implemented through the rulemaking process and are finalized for use in MIPS scoring for the CY 2025 performance period/2027 MIPS payment year. As a result, MIPS eligible clinicians have already made decisions about their MIPS participation for the CY 2025 performance period/2027 MIPS payment year based on the inclusion of existing cost measures in MIPS scoring and payment adjustments. Further, many of the existing cost measures have been in use in MIPS for several years, so MIPS eligible clinicians have become more familiar with the measure specifications and opportunities for improvement. We anticipate that this proposed informational-only feedback period would drive performance improvement for MIPS eligible clinicians, while continuing to support the statutory requirement for clinicians to be scored on cost as part of their composite performance score, as specified under section 1848(q)(5)(A) of the Act.

The timeline for new cost measures adopted after the effective date of this proposal would be as follows:

– First CY Performance Period/MIPS Payment Year: Informational-only feedback period.

– Second CY Performance Period/MIPS Payment Year: Informational-only feedback period.

– Third CY Performance Period/MIPS Payment Year: Cost measure scores would be incorporated into MIPS eligible clinicians' cost performance category and MIPS final scores, affecting their MIPS payment adjustments for the performance period's corresponding payment year.

We also propose that cost measures within an informational-only feedback period can be included in an MVP if they are clinically relevant. MVPs aim to improve value through assessing linked performance categories, including cost and quality (86 FR 65391). As such, we would include cost measures eligible for scoring as well as measures in the informational-only feedback period in MVPs, when appropriate, consistent with § 414.1365(c)(2). CMS may create an MVP that only includes cost measures in an informational-only feedback period in instances where these are the only relevant cost measures for an MVP. Any cost measures would continue to be determined for use in an MVP in accordance with the MVP development criteria and the MVP cost reporting requirements as set forth in the CY 2022 PFS final rule (86 FR 65405 through 65409; 86 FR 65412, respectively).

We propose that an MVP, including any cost measures within their informational-only feedback period, would continue to be scored according to all scoring policies outlined in § 414.1365(d), including § 414.1365(d)(3)(ii). Section 414.1365(d)(3)(ii) provides that we calculate the cost performance category score for the cost measures included in the MVP that an MVP participant selects and reports using the methodology at § 414.1380(b)(2), the same as for any cost measures. As we are proposing to codify this informational-only feedback period policy at § 414.1380(b)(2) as discussed below, cost measures included in an MVP (that an MVP participant selects and reports) that are in their informational-only feedback period would be treated in the same manner as if the MVP participant was attributed the cost measure under traditional MIPS.

In other words, we propose that, if a new cost measure in its informational-only feedback period is included in an MVP, then we would calculate a measure score in accordance with our proposed scoring policy at § 414.1380(b)(2) and confidentially provide the score, as well as MIPS performance feedback, to the MVP participants that select and report that MVP on an annual basis. We would not incorporate any informational-only scores on cost measures into the MVP participant's cost performance category score or MIPS final score.

This proposal would provide MIPS eligible clinicians the ability to receive informational-only feedback on their cost measure performance and their performance within an MVP, without delaying the creation of clinically meaningful MVPs in MIPS. We have also heard feedback from interested parties requesting that we implement MVPs through a gradual process, where there is transparency and time for MIPS eligible clinicians to adapt to changes (86 FR 65394 through 65395). We believe that including cost measures in MVPs that are in the informational-only feedback period aligns with these requests, providing transparency and time to adapt to new cost measures that a MIPS eligible clinician may be attributed within an MVP. In addition, we seek to align scoring of MVPs with scoring of traditional MIPS whenever possible, in accordance with the MVP scoring policy outlined in the CY 2022 PFS final rule (86 FR 65419 through 65421).

We also propose that we would not publicly report MIPS eligible clinicians' performance on cost measures within their informational-only feedback period. Public reporting of information regarding performance of eligible clinicians and groups, as required by section 1848(q)(9) of the Act, allows patients to use data to inform their care decisions. The goal of an informational-only feedback period is to provide MIPS eligible clinicians time and information to become familiar with new cost measures prior to affecting MIPS eligible

clinicians. We believe that public reporting while a measure is within this feedback period would be inconsistent with the goals of this policy.

In addition, the 2-year informational-only feedback period aligns with the current structure of public reporting, where for the first 2 years that a measure is in use in MIPS, it cannot be publicly reported, as outlined in § 414.1395(c). The cost measures would be available for consideration for public reporting starting in the third year that they are in use (that is, the first year that new cost measures are included in MIPS eligible clinicians' cost performance category and MIPS final scores).

Additionally, we propose to codify this informational-only feedback period by amending § 414.1380(b)(2). Specifically, we propose to add this policy under several new paragraphs at § 414.1380(b)(2)(vi). First, we propose that § 414.1380(b)(2)(vi) would provide that, beginning with the 2028 MIPS payment year, CMS will calculate a score for each new cost measure in accordance with the scoring policy set forth in this paragraph (b)(2) for informational-only purposes during the measure's informational-only feedback period.

Second, we propose to define the terms ''new cost measure'' and ''informational-only feedback period'' for the purposes of this paragraph (b)(2)(vi) at § 414.1380(b)(2)(vi)(A). We propose to define ''new cost measures'' at § 414.1380(b)(2)(vi)(A)(*i*) as meaning a measure that CMS has newly specified for the MIPS cost performance category for a performance period under § 414.1350 beginning with the 2028 MIPS payment year. We would further provide at § 414.1380(b)(2)(vi)(A)(*i*) that this term excludes any cost measures that CMS has specified for the MIPS cost performance category prior to the 2028 MIPS payment year or CMS modifies at any time. We propose to define ''informational-only feedback period'' at § 414.1380(b)(2)(vi)(A)(*ii*) as meaning a 2-year period beginning with the first day of the first performance period and ending with the final day of the second performance period for the 2 applicable MIPS payment years for which CMS initially has specified the new cost measure.

Third, we propose to add paragraphs (B), (C), and (D) to § 414.1380(b)(2)(vi) to codify our proposed scoring of a new cost measure during and after its informational-only feedback period. We would provide at § 414.1380(b)(2)(vi)(B) that, during a new cost measure's informational-only feedback period, CMS will not include any scores for the new cost measure calculated for informational-only purposes under this paragraph (b)(2)(vi) in CMS's calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) or a MIPS eligible clinician's MIPS final score under paragraph (c) of § 414.1380. At § 414.1380(b)(2)(vi)(C), we would provide that, during a new cost measure's informational-only feedback period, CMS will confidentially provide each MIPS eligible clinician with their measure score under this paragraph (b)(2)(vi) for informational-only purposes. Also, we would provide at § 414.1380(b)(2)(vi)(C) that CMS will provide performance feedback to the MIPS eligible clinician in accordance with section 1848(q)(12) of the Act. We would provide at § 414.1380(b)(2)(vi)(D) that, upon completion of a new cost measure's informational-only feedback period, CMS will include its calculation of any scores for the cost measure in CMS' calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) and a MIPS eligible clinician's MIPS final score under paragraph (c) of § 414.1380.

Finally, we propose to modify the paragraph at § 414.1380(b)(2)(iii) to exclude cost measure scores calculated for informational-only purposes as provided in paragraph (b)(2)(vi). We are not proposing any modification to the remaining text as currently codified at § 414.1380(b)(2)(iii).

We invite comments on this proposal.

(3) Improvement Activities Performance Category

(a) Background

Section 1848(q)(2)(A)(iii) of the Act includes clinical practice improvement activities as a performance category under MIPS. We refer to this performance category as the improvement activities performance category. As required by section 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the improvement activities performance category.

Section 1848(q)(2)(C)(v)(III) defines the term ''clinical practice improvement activities'' as an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act provides that, for the improvement activities category, the Secretary shall specify subcategories of clinical practice improvement activities, including at least six subcategories as specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act. These statutorily enumerated subcategories are: (1) expanded practice access (such as same day appointments for urgent needs and afterhours access to clinician advice); (2) population management (such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry); (3) care coordination (such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth); (4) beneficiary engagement (such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms); (5) patient safety and practice assessment (such as through use of clinical or surgical checklists and practice assessments related to maintaining certification); and (6) participation in an alternative payment model, as defined in section 1833(z)(3)(C) of the Act (section 1848(q)(2)(B)(iii)(I) through (VI) of the Act).

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), the CY 2023 PFS final rule (87 FR 70057 through 70061), and the CY 2024 PFS final rule (88 FR 79350 and 88 FR 79351). We also refer readers to § 414.1305 for the relevant definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are proposing various updates to the Improvement Activities Inventory beginning with the CY 2026 performance period/2028 MIPS payment year, as described further later

in this section. First, we propose to remove the Achieving Health Equity subcategory. Second, we propose to add a new subcategory to the improvement activities performance category: Advancing Health and Wellness. Third, we propose to add three new improvement activities into two of our existing subcategories: (1) Population Management and (2) Patient Safety and Practice Assessment. Fourth, we propose to modify seven existing improvement activities currently specified for the performance category. Fifth, we propose to remove eight improvement activities currently specified for the performance category.

We refer readers to section V.B.5.e of this proposed rule for discussion of the burden estimates for these proposals.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the first year of MIPS, we implemented the initial Improvement Activities Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities aligned with statutory and program requirements. As part of this process, we conducted numerous interviews with high performing organizations of all sizes and conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, and Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Organizations. In addition, we reviewed the comments we received in response to the MIPS and APMs Request for Information (RFI) related to the improvement activities performance category, as described in the CY 2016 PFS final rule with comment period (80 FR 71259 and 71260). For the MIPS and APMs RFI, we sought input on what activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

Beginning with the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659), we introduced an informal process for interested parties to submit new improvement activities or modifications for our consideration and potential inclusion in the comprehensive Improvement Activities Inventory. In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), beginning with the CY 2019 performance period/2021 MIPS payment year, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the Improvement Activities Inventory. This process requires interested parties to submit a nomination form similar to the one we used for the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing activity, the interested party must submit a nomination form (OMB control # 0938–1314) available at *www.qpp.cms.gov* during the Annual Call for Activities.

(ii) Proposals To Update the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. For our previously finalized Improvement Activities Inventories, we refer readers to Table H in the CY 2017 Quality Payment Program final rule (81 FR 77817) Appendix, Tables F and G in the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) Appendix, Tables A and B in the CY 2019 PFS final rule (83 FR 60286 through 60303) Appendix 2, Tables A, B, and C in the CY 2020 PFS final rule (84 FR 63514 through 63538) Appendix 2, Tables A, B, and C in the CY 2021 PFS final rule (85 FR 85370 through 85377) Appendix 2, Tables A, B, and C in the CY 2022 PFS final rule (86 FR 65969 through 65997) Appendix 2, and Tables A, B, and C in the CY 2023 PFS final rule (70633 through 70650) Appendix 2. We also refer readers to the Quality Payment Program website and the Explore Measures and Activities tool at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2025* for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305, consistent with the statutory definition at section 1848(q)(2)(C)(v)(III) of the Act, to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

We are proposing various updates to the improvement activities performance category, beginning with the CY 2026 performance period/2028 MIPS payment year. First, we propose to remove the Achieving Health Equity subcategory. Second, we propose adding a new subcategory to the improvement activities performance category: Advancing Health and Wellness. Third, we propose adding three new improvement activities into two of our existing subcategories: (1) Population Management and (2) Patient Safety and Practice Assessment. Fourth, we propose modifying seven existing improvement activities currently specified for the performance category. Fifth, we propose to remove eight improvement activities currently specified for the performance category. Generally, the three proposed new activities would fill gaps in the Improvement Activities Inventory and the seven proposed modified activities represent updates to the clinical goals of each modified activity. Our proposal to remove eight improvement activities reflects changes in our priorities and an intent to maintain an inventory of activities that are focused on driving improved patient outcomes directly. While we acknowledge the importance of clinical work and research that address the needs of specific populations, we propose to exclude activities that do not have a direct and measurable impact on improving patient health outcomes. If MIPS-eligible clinicians or groups identify a need for clinical quality improvement specific to a unique population under their care, they can select from existing activities in the Inventory that are designed to support such targeted efforts. Our proposal focuses on removing activities that do not lead to demonstrable improvements in patient outcomes, rather than those that address specific population needs through evidence-based clinical intervention. For example, IA_PSPA_19 (Implementation of formal quality improvement methods, practice changes or other practice improvement processes) allows for significant flexibility in the focus area of the quality improvement completed.

(iii) Proposals To Update Subcategories Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

As discussed previously, section 1848(q)(2)(B)(iii) of the Act provides that the Secretary specifies clinical practice improvement activities under subcategories, which must include at least six enumerated subcategories. Under section 1848(q)(2)(B)(iii) of the

Act, we established the current subcategories for the improvement activities performance category at § 414.1355(c).

(1) Proposal To Remove Achieving Health Equity Subcategory Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

We are proposing to remove of the ''Achieving Health Equity'' (AHE) subcategory beginning with the CY 2026 performance period/2028 MIPS payment year. We would also remove this subcategory from our regulation at § 414.1355(c)(7), replacing it with a new subcategory as described in later in this section.

This proposal to remove the AHE subcategory would not de-emphasize our focus on improving access, enhancing care coordination, and strengthening patient engagement. The removal of this subcategory would also be aligned with other QPP programs that have shifted focus to identifying improvement objectives on topics of prevention, nutrition, and well-being.

As discussed below, we are also proposing to recategorize five existing improvement activities from the Achieving Health Equity (AHE) subcategory to other established subcategories to better align with the substantive focus of these activities' descriptions. This proposed recategorization also reflects a strategic shift to emphasize emerging priorities such as wellness and prevention.

We are seeking public comments on our proposal to remove the Advancing Health Equity subcategory from the improvement activities performance category and from § 414.1355(c)(7) beginning with the CY 2026 performance year/2028 MIPS payment year.

(2) Proposal To Add New Advancing Health and Wellness Subcategory Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

We are proposing to add a new subcategory, titled ''Advancing Health and Wellness'' (AHW), beginning with the CY 2026 performance period/2028 MIPS payment year. This proposed addition would emphasize CMS's priority of overall health promotion and address broader aspects of healthcare that go beyond the direct treatment of diseases.

We are proposing to amend § 414.1355(c)(7) by adding a new subcategory, ''Advancing Health and Wellness'' (AHW), to replace the ''Achieving Health Equity'' subcategory. Our proposal to add the AHW subcategory for the improvement activities performance category would address gaps in MIPS eligible clinicians' involvement in preventive care and health promotion. Our goal for this new subcategory is to ensure that care is tailored to meet the needs of patients, including their mental health and chronic disease management and prevention.

As discussed in sections IV.A.4.d.(3)(b)(iii) and IV.A.4.d.(3)(b)(vii) of this proposed rule, we are also proposing to reassign one existing improvement activity (IA_PM_13 ''Chronic Care and Preventative Care Management for Empaneled Patients'') to this new AHW subcategory. This activity allows a MIPS eligible clinician to manage chronic and preventive care for empaneled patients and would align with the ''Advancing Health and Wellness'' subcategory description. If this proposal to add this subcategory is finalized, we would consider adding more activities to this subcategory in future rulemaking.

We are seeking public comments on our proposal to adopt a new subcategory, ''Advancing Health and Wellness,'' to the improvement activities performance category and at § 414.1355(c)(7) beginning with the CY 2026 performance year/2028 MIPS payment year.

(iv) Proposals To Adopt New Improvement Activities Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

We propose to adopt three new improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year. We propose that the IA_PM_XX (Improvement Detection of Cognitive Impairment in Primary Care) and IA_PM_XX (Integrating Oral Health Care in Primary Care) activities would be included in the Population Management subcategory. We propose that the IA_PSPA_XX (Patient Safety in Use of Artificial Intelligence [AI]) activity would be included in the Patient Safety and Practice Assessment subcategory.

The first new improvement activity, IA_PM_XX, titled ''Improving Detection of Cognitive Impairment in Primary Care,'' would allow MIPS eligible clinicians to increase the detection of cognitive impairment, especially in its early stages, by tracking baseline detection rates for mild cognitive impairment (MCI), dementia, and cognitive impairment. If rates are below 1.0, clinicians would increase Annual Wellness Visit uptake, ensure structured cognitive assessments, and address memory concerns during intake for patients 65+. Detection rates would be remeasured quarterly, with a focus on Medicare patients aged 65 and older. The second new improvement activity, IA_PM_XX, titled ''Integrating Oral Health Care in Primary Care,'' would allow MIPSeligible clinicians to include an oral health risk assessment and intraoral screening in primary care, educate patients on the importance of oral health, and provide counseling on its impact on systemic diseases. For patients without a dental home or those with oral health needs, a dental referral would be provided.

The third new improvement activity, IA_PSPA_XX, titled ''Patient Safety Use of Artificial Intelligence,'' would involve developing a new data-collection field within patient safety reporting systems for AI-attributable events. This would include events where actual harm was caused to a patient because AI technology was used, as well as near misses. Once a MIPS-eligible clinician has identified an event, a process to identify the cause and plan for future mitigation would be documented.

We refer readers to Table F–B1 in Appendix 2 for more information regarding each of these proposed improvement activities.

We are seeking public comments on our proposals to add each of these activities to the improvement activities performance category beginning with the CY 2026 performance period/2028 MIPS payment year.

(v) Proposals To Modify Existing Improvement Activities Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

We are proposing to modify seven existing improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year. First, IA_AHE_1, IA_AHE_3, IA_AHE_6, IA_AHE_7, and IA_AHE_10, currently specified for the Achieving Health Equity subcategory, would be reassigned to other subcategories to better align each individual activity's purpose with its subcategory. We propose to reassign IA_AHE_1 and IA_AHE_6 to the ''Expanded Practice Access'' (EPA) subcategory, IA_AHE_3 and IA_AHE_7 to the ''Beneficiary Engagement'' (BE) subcategory, and IA_AHE_10 to the ''Patient Safety and Practice Assessment'' (PSPA) subcategory. Second, we propose to also reassign IA_PM_13, ''Chronic Care and Preventative Care Management for Empaneled Patients,'' to the new ''Advancing Health and Wellness'' subcategory. Third, we propose several modifications

to IA_BMH_1, currently titled ''Diabetes Screening.'' Specifically, we propose to expand the scope of the activity. Currently, IA_BMH_1 is focused on screening only diabetic patients taking anti-psychotic medications.

The proposed modifications to IA_BMH_1 would broaden the relevant patient population by requiring a comprehensive physical health screening on all patients taking anti-psychotic medications. This modified activity would encompass a broader range of health conditions, beyond just diabetes, that may be impacted by antipsychotic medications. While diabetes remains a key focus due to its significant association with antipsychotic use, the expanded title reflects the inclusion of additional monitoring components, such as obesity, hypertension, dyslipidemia, movement disorders (for example, tardive dyskinesia), and other relevant physical health conditions. Diabetes would remain relevant for this improvement activity as it is a major comorbidity linked to antipsychotic medications, and monitoring for diabetes would remain an integral part of the comprehensive health assessment for these patients under this activity. We also propose to modify the title of IA_BMH_1, renaming it to ''Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring.'' This proposed title better reflects the substantive modifications we are proposing for this activity.

We refer readers to Table F–B2 in Appendix 2 for more information regarding each of these proposed modifications to existing improvement activities.

We are seeking public comments on our proposals to modify each of these activities currently specified for the improvement activities performance category beginning with the CY 2026 performance period/2028 MIPS payment.

(vi) Proposals To Remove Existing Improvement Activities Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

Additionally, we are proposing to remove eight previously finalized improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year: IA_AHE_5, IA_AHE_8, IA_AHE_9, IA_AHE_11, IA_AHE_12, IA_PM_6, IA_PM_26, and IA_ERP_3. We are proposing removal of these specific improvement activities in accordance with our activity removal policy set forth at § 414.1355(d). Specifically, we propose to remove each of these eight improvement activities under Removal Factor 7, which provides that we may remove an improvement activity if we determine it is obsolete (§ 414.1355(d)(7)). When we codified this Removal Factor at § 414.1355(d)(7) in the CY 2025 PFS final rule (89 FR 98408 and 98409), we stated that, when we originally established this removal factor, we employed a commonly used definition of ''obsolete'' as in 'out of date' (89 FR 98409). We further stated that, in the context of the Quality Payment Program, this means an activity that no longer reflects current clinical best practices, that is no longer available for implementation (for example, when a program or initiative upon which an activity depends has been ended or closed), and/or that, because of the nature of the activity, cannot be attested to year after year with a reasonable expectation of clinical quality improvement year after year (89 FR 98409).

We are proposing to remove these activities to evolve the Improvement Activities Inventory and emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Factor 7, Activity is Obsolete, supports our proposals to remove these activities as they do not reflect CMS's current prioritization of best clinical practices and are no longer available for implementation as they have been suspended for CY 2025. Our proposal to remove IA_ERP_3 would also align with recent FDA and CDC guidance regarding updating vaccination recommendations and expiration of the PHE for COVID–19.[373] [374] We refer readers to Table F–B3 in Appendix 2 for more information regarding our proposals to remove each of these existing improvement activities.

We are seeking public comments on our proposals to remove each of these activities from the improvement activities performance category beginning with the CY 2026 performance period/2028 MIPS payment.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A)(iv) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category).

Section 1848(q)(2)(B)(iv) of the Act provides that the requirements established under section 1848(o)(2) of the Act for determining whether a MIPS eligible clinician is a meaningful EHR user also apply to our assessment of a MIPS eligible clinician's performance on measures and activities with respect to the MIPS Promoting Interoperability performance category. Section 1848(o)(2)(D) of the Act generally provides that the requirements for being a meaningful EHR user under section 1848(o)(2) continue to apply for purposes of MIPS.

Under section 1848(o)(2)(A) of the Act, a MIPS eligible clinician must meet three requirements related to the meaningful use of CEHRT during a performance period for a MIPS payment year. Specifically, under section 1848(o)(2)(A) of the Act, the MIPS eligible clinician must: (1) demonstrate to the satisfaction of the Secretary the use of CEHRT in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary; (2) demonstrate to the satisfaction of the Secretary that their CEHRT is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for electronic exchange of health information to improve the quality of care, such as promoting care coordination, and demonstrates (through a process specified by the Secretary, such as use of an attestation), that they have not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the CEHRT; and (3) use CEHRT to submit information on clinical quality measures and such other measures as selected by the Secretary.

For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to our regulations at §§ 414.1375 and 414.1380(b)(4) and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), CY 2023 PFS final rule (87 FR 70060 through 70087), CY 2024 PFS final rule (88 FR 79308

[373] *https://www.nejm.org/doi/full/10.1056/NEJMsb2506929?logout=true.*

[374] *https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/your-health/end-of-phe.html.*

through 79312 and 88 FR 79351 through 79365), the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule (89 FR 54662 through 54718), and CY 2025 PFS final rule (89 FR 98414 through 98427).

In this proposed rule, we are proposing to:

- Modify the Security Risk Analysis measure to include a second component requiring an affirmative attestation of having conducted security risk management in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule;
- Modify the High Priority Practices Safety Assurance Factors for Electronic Health Record (EHR) Resilience (SAFER) Guide Measure by requiring an affirmative attestation of completing an annual self-assessment using the SAFER Guides published in January of 2025; and
- Adopt the Public Health Reporting Using Trusted Exchange Framework and Common Agreement™ (TEFCA™) measure as an optional bonus measure under the Public Health and Clinical Data Exchange objective.

For both the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, we are proposing to:

- Adopt and codify at § 414.1380(b)(4)(iii) and § 495.24(f)(3), respectively, a measure suppression policy beginning with the CY 2026 performance period/2028 MIPS payment year and the EHR reporting period in CY 2026; and
- Suppress the Electronic Case Reporting measure by excluding the measure from scoring for MIPS eligible clinicians for the CY 2025 performance period/2027 MIPS payment year and eligible hospitals and critical access hospitals (CAHs) for the EHR reporting period in CY 2025

(b) Definition of Certified EHR Technology

In accordance with § 414.1375(b)(1), to earn a performance category score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician must be a meaningful EHR user for MIPS and use CEHRT during the performance period, as both terms are defined in § 414.1305. In the CY 2025 PFS final rule, we discussed modifications we had previously finalized related to the CEHRT definition for the Quality Payment Program, including for the MIPS Promoting Interoperability performance category, at § 414.1305 (89 FR 98414 and 98415). Currently, we define CEHRT, for purposes of MIPS, as EHR technology (which could include multiple technologies) certified under the Office of National Coordinator for Health Information Technology's (ONC) [375] Health Information Technology (IT) Certification Program that meets the Base EHR definition at 45 CFR 170.102 and certified as meeting additional ONC health IT certification criteria as adopted and updated in 45 CFR 170.315 as enumerated in paragraph (2) of the CEHRT definition at § 414.1305, including as necessary to report on applicable objectives and measures specified for MIPS. In section IV.A.4.d.(4)(h)(i) of this proposed rule, we provide Table 62, which sets forth the objectives and measures for the Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. Given the central role of using CEHRT that meets this definition at § 414.1305 for purposes of earning a score for the MIPS Promoting Interoperability performance category, we highlight recent updates to the ONC Health IT Certification Program's certification criteria.

In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) final rule (89 FR 1205 through 1210), ONC adopted the certification criterion, ''decision support interventions (DSI)'' at 45 CFR 170.315(b)(11) to replace the ''clinical decision support (CDS)'' certification criterion at 45 CFR 170.315(a)(9), the latter of which is included in the Base EHR definition 45 CFR 170.102 until December 31, 2024. The finalized DSI criterion at 45 CRF 170.315(b)(11) requires that Health IT Modules must, among other functions, enable a limited set of identified users to select (that is, activate) evidence-based DSIs and Predictive DSIs (as defined at 45 CFR 170.102) [376] and support ''source attributes'' [377]—categories of technical performance and quality information—for both evidence-based and Predictive DSIs. ONC further finalized that a Health IT Module may meet the Base EHR definition by either being certified to the existing CDS version of the certification criterion at 45 CFR 170.315(a)(9) or being certified to the revised DSI criterion at 45 CFR 170.315(b)(11), for the period up to, and including, December 31, 2024. On and after January 1, 2025, ONC finalized that only the DSI criterion at 45 CFR 170.315(b)(11) is included in the Base EHR definition (89 FR 1281). ONC further finalized that the adoption of the criterion at 45 CFR 170.315(a)(9) expired on January 1, 2025 (89 FR 1281).

In addition to the DSI criterion, to which Health IT Modules must be certified to meet the Base EHR definition after January 1, 2025, ONC finalized other updates in the HTI–1 final rule, for which health IT developers must update and provide Health IT Modules to their customers by January 1, 2026. These include updates resulting from the following finalized policies:

- The ''[t]ransmission to public health agencies—electronic case reporting'' criterion at 45 CFR 170.315(f)(5) was updated to specify consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace functional, descriptive requirements in the existing criterion (89 FR 1226). We have identified this criterion as required for the Electronic Case Reporting measure.
- The United States Core Data for Interoperability (USCDI) version 3 was adopted at 45 CFR 170.213(b), and ONC finalized that USCDI version 1 at 45 CFR 170.213(a) will expire on January 1, 2026. This change impacts several ONC health IT certification criteria that reference the USCDI, including the ''transitions of care'' certification criterion at 45 CFR 170.315(b)(1), the ''Clinical information reconciliation and incorporation—Reconciliation'' certification criterion at 45 CFR 170.315(b)(2) and the ''View, download, and transmit to 3rd party'' certification criterion at 45 CFR 170.315(e)(1) (89 FR 1214). The ''transitions of care'' certification criterion at 45 CFR 170.315(b)(1) is included in the ''Base EHR definition'' while the ''Clinical information reconciliation and incorporation—Reconciliation'' certification criterion at 45 CFR 170.315(b)(2) is required for the ''Support Electronic Referral Loops by Receiving and Reconciling Health Information'' measure and the ''View, download, and transmit 3rd party'' certification criterion is required for the ''Provide Patients Electronic Access to their Health Information'' measure.

[375] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903). We will continue to refer to ONC in historical actions prior to this date and in actions involving the ONC Health IT Certification Program. We will otherwise use ASTP to refer to the office.

[376] 45 CFR 170.315(b)(11)(iii)(A) and (B).

[377] 45 CFR 170.315(b)(11)(iv)(A) and (B).

• The ''standardized application programming interface (API) for patient and population services'' certification criterion at 45 CFR 170.315(g)(10), which is included in the Base EHR definition, was updated to include newer versions of certain standards, including USCDI version 3 and updated functionality to support the criterion (89 FR 1283).

We refer readers to the HTI–1 final rule (89 FR 1192) and resources available on the ONC's website for complete information regarding the updates to ONC health IT certification criteria.[378]

(c) Proposal to Modify the Security Risk Analysis Measure

(i) Background

The HIPAA Security Rule [379] (45 CFR part 160 and subparts A and C of part 164) contains, among other things, the administrative safeguards that covered entities and business associates (45 CFR 160.103) must implement, such as the standard and implementation specifications for security management processes. Among those safeguards are implementation specifications that require covered entities and business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by the covered entity or business associate (45 CFR 164.308(a)(1)(ii)(A)) and to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306(a) and the risk management requirements at 45 CFR 164.308(a)(1)(ii)(B).

For MIPS eligible clinicians, ensuring the privacy and security of ePHI is essential for demonstrating meaningful use of CEHRT. In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program final rule (Stage 1 final rule) (75 FR 44368 through 44369), the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2 final rule (Stage 2 final rule) (77 FR 54002 and 54003), and the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (Stage 3 final rule) (80 FR 62793 through 62794), we discussed the benefits of safeguarding electronic health information and our determination that protecting electronic health information is essential to all other aspects of meaningful use. In the Stage 1 final rule, we noted that, while CEHRT provides tools for protecting health information, processes and possibly tools outside the scope of CEHRT are required (75 FR 44369). In the Stage 2 final rule, we also noted that unintended, unlawful, or both disclosures of protected health information could diminish individuals' confidence in EHRs and electronic health information exchange; ensuring that health information is adequately protected and secured will assist in addressing the unique risks and challenges that may be presented by EHRs (77 FR 54002). On these bases, we adopted and maintained the Security Risk Analysis measure based on the HIPAA Security Rule risk analysis requirement at 45 CFR 164.308(a)(1)(ii)(A) for the Medicare EHR Incentive Program for Eligible Professionals, the predecessor to the MIPS Promoting Interoperability performance category.[380] Additional information on the initial adoption of this measure can be found in prior rulemakings for the predecessor Medicare EHR Incentive Program for Eligible Professionals, including the Stage 1 final rule (75 FR 44369), Stage 2 final rule (77 FR 54002 and 54003), and Stage 3 final rule (80 FR 62793 through 62794). In the CY 2017 Quality Payment Program final rule (81 FR 77219 through 77220), we adopted the Protect Patient Health Information objective for the MIPS Promoting Interoperability performance category and included the Security Risk Analysis measure within this objective. We subsequently modified this measure in the CY 2019 PFS final rule (83 FR 59790).

To earn a score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician must attest ''Yes'' or ''No'' as to whether they have conducted or reviewed a security risk analysis as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A) during the year in which the performance period occurs. MIPS eligible clinicians must attest ''Yes'' to the measure to be considered a meaningful EHR user. The measure is not scored individually at § 414.1380(b)(4)(ii) and does not contribute to the MIPS eligible clinician's Promoting Interoperability performance category score for the Protect Patient Health Information objective and measures. An attestation of ''No'' demonstrates that the MIPS eligible clinician did not complete the actions included in the measure as required by § 414.1375(b)(2)(ii)(A) and did not satisfy the definition of a meaningful EHR user at § 414.1305. Therefore, if the MIPS eligible clinician submits a ''No'' attestation for this measure, they would not earn a score for the Promoting Interoperability performance category, resulting in a score of zero, in accordance with § 414.1375(b)(2). We refer readers to Tables 59 and 60 in sections IV.A.4.d.(4)(h)(i) and IV.A.4.d.(4)(h)(ii), respectively, of this proposed rule for more information on the proposed objectives and measures and scoring methodology for the Promoting Interoperability performance category, including the Security Risk Analysis measure.

(ii) Proposal To Modify to the Security Risk Analysis Measure Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

While the Security Risk Analysis measure currently requires MIPS eligible clinicians to attest to conducting a security risk analysis as required under the HIPAA Security Rule, the Security Risk Analysis measure does not currently require MIPS eligible clinicians to manage their security risk or attest to having implemented security measures to manage their security risk. Codified at 45 CFR 164.308(a)(1)(ii)(B), the HIPAA Security Rule implementation specification for risk management requires the implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306(a). The HIPAA Security Rule does not prescribe a specific methodology for conducting a risk analysis or managing risk (45 CFR 164.308(a)(1)(ii)(A) and (B)). We refer readers to the Security Risk Assessment Tool (*https://www.healthit.gov/topic/*

[378] For more information, visit: *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

[379] The U.S. Department of Health and Human Services has proposed to modify the HIPAA Security Rule to strengthen the cybersecurity of electronic protected health information, including proposals to revise the existing requirements to conduct a risk analysis and risk management. *See generally* HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule (90 FR 898).

[380] Section 101(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) sunset the Medicare EHR Incentive Program for Eligible Professionals, set forth at section 1848(o) of the Act. As discussed previously, section 1848(o)(2) of the Act has been incorporated into the MIPS Promoting Interoperability performance category's requirements via section 1848(q)(2)(B)(iv) of the Act. *See* CY 2017 Quality Payment Program final rule (81 FR 77018 and 77019) for more information regarding the sunsetting of the Medicare EHR Incentive Program for Eligible Professionals.

privacy-security-and-hipaa/security-risk-assessment-tool) developed by ASTP/ONC in collaboration with the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR), and to OCR's cybersecurity newsletters and other risk analysis materials,[381] for educational resources on conducting a security risk assessment as required by the HIPAA Security Rule. Additional information is also available in the National Institute of Standard and Technology (NIST) special publication, *Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule: A Cybersecurity Resource Guide*.[382]

In this section of the proposed rule, we propose to modify the existing Security Risk Analysis measure to add a second attestation, requiring MIPS eligible clinicians to also attest ''Yes'' to having implemented security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level such that they are compliant with 45 CFR 164.306(a) as required by the HIPAA Security Rule implementation specification for risk management. This second attestation would be in addition to the current requirement under the measure for MIPS eligible clinicians to attest ''Yes'' to having conducted or reviewed a security risk analysis. If the proposed modification to this measure is finalized, MIPS eligible clinicians would be required to submit two affirmative (''Yes'') attestations to comply with § 414.1375(b)(2)(ii)(A), in which they have: (1) conducted or reviewed a security risk analysis as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A); and (2) conduct security risk management activities as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(B), specifically the implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306. Also, we are proposing to modify the measure specifications to better align with the requirements of the HIPAA Security Rule.

The modifications we propose to the Security Risk Analysis measure would increase accountability among MIPS eligible clinicians that have not taken steps to reduce risks and vulnerabilities to ePHI and would provide transparency regarding the efforts of MIPS eligible clinicians that are already taking steps to manage this risk. Furthermore, the proposed modification to the Security Risk Analysis measure would align with the Medicare Promoting Interoperability Program's proposal in the FY 2026 Hospital Inpatient Protective Payment System/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed rule (90 FR 18357 and 18358) to modify its Security Risk Analysis measure.

To reflect the proposed addition of the risk management component, the proposed modified measure would read as follows: First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include addressing the security of data created or maintained by CEHRT (*to include encryption*), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the MIPS eligible clinician would adopt an equivalent alternative measure if it is reasonable and appropriate to do so.

To meet the requirements of the modified measure as proposed, we propose MIPS eligible clinicians would need to separately attest ''Yes'' to both components of the proposed revised Security Risk Analysis measure. A MIPS eligible clinician would be required to both attest ''Yes'' that they have met the existing security risk analysis requirement component, *and* attest ''Yes'' that they have met the security risk management component of the modified Security Risk Analysis measure to be considered a meaningful EHR user beginning with the CY 2026 performance period/2028 MIPS payment year.

We are not proposing to modify when a MIPS eligible clinician must complete the actions specified for the Security Risk Analysis measure as currently provided at § 414.1375(b)(2)(ii)(A). As set forth at § 414.1375(b)(2)(ii)(A), a MIPS eligible clinician may attest ''Yes'' regarding their completion of the actions included in this measure so long as they complete the required actions any time during the calendar year in which the performance period occurs.

We also are not proposing to modify the current scoring approach for the Security Risk Analysis measure, as described in section IV.A.4.d.(4)(h)(ii) of this proposed rule. To meet the requirements of the Promoting Interoperability performance category, MIPS eligible clinicians would need to affirmatively (''Yes'') attest to the two components of the measure; otherwise, MIPS eligible clinicians would receive score of zero for the entire Promoting Interoperability performance category. If a MIPS eligible clinician attests ''No'' because they have not completed the risk analysis component, the risk management component, or neither component, or did not report the measure, then they would fail to earn a score for the Promoting Interoperability performance category (and receive a score of zero) as currently provided at § 414.1375(b)(2)(ii)(A).

We seek public comment on this proposal to modify the Security Risk Analysis measure beginning with the CY 2026 performance period/2028 MIPS payment year. Also, we seek public comment regarding compliance with security risk management requirements and the potential impact the proposed modification to the Security Risk Analysis measure would have on risk management compliance and any potential burden from this proposal.

(d) Proposal To Modify the High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide Measure

(i) Background

The 2025 SAFER Guides are an evidence-based set of recommendations in the form of eight stand-alone, subject-oriented chapters (previously nine chapters comprising the 2016 SAFER Guides) that present the health IT community, including MIPS eligible clinicians that use health IT, with best practice recommendations to improve the safety and safe use of EHRs.[383] The SAFER Guides were first released in 2014 and updated in 2016. In the CY 2022 PFS final rule (86 FR 65475 through 65477), CMS adopted the High Priority Practices SAFER Guide measure under the Protect Patient Health Information Objective in the Promoting Interoperability performance category beginning with the CY 2022 performance period/2024 MIPS payment year. In the CY 2024 PFS final rule, we modified the requirements for the High Priority Practices SAFER Guide measure beginning with the CY 2024 performance period/2026 MIPS payment year (88 FR 79354 through 79356), to require MIPS eligible clinicians to conduct, and attest ''Yes,'' to having completed an annual self-

[381] U.S. Department of Health and Human Services, Office of Civil Rights newsletters and risk analysis materials located at: *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html*.

[382] *See* NIST SP 800–66, rev. 2, located at: *https://csrc.nist.gov/pubs/sp/800/66/r2/final*.

[383] ASTP SAFER Guides located at: *https://www.healthit.gov/topic/safety/safer-guides*.

assessment using the High Priority Practices SAFER Guide.

(ii) Proposed Modification to the High Priority Practices SAFER Guide Measure Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

In January of 2025, ASTP published an updated set of SAFER Guides (hereafter referred to as the 2025 SAFER Guides) located at: *https://www.healthit.gov/topic/safety/safer-guides.* The 2025 SAFER Guides consist of eight guides organized into three broad groups of Foundational Guides, Infrastructure Guides, and Clinical Process Guides. All Guides have been revised and contain new recommendations as well as the comprehensive consolidation of recommendations that were similar and overlap in function or intent with the 2016 SAFER Guides. For example, the ''System Configuration'' and ''System Interfaces'' chapters have been consolidated into a single chapter titled, ''System Management.'' The entirety of the content recommendations, bibliography, and implementation guidance have been organized into a comprehensive table, which promotes the adoption of best safety practices for health IT. This update represents the most comprehensive revision of the SAFER Guides since they were first released. Table 58 provides the titles of the various guides, and chapters within the guides, that collectively comprise the 2016 SAFER Guides and the 2025 SAFER Guides, respectively.

When we finalized requiring a ''Yes'' attestation to account for completion of the self-assessment in the CY 2024 PFS final rule, as opposed to allowing a ''Yes'' or ''No'' attestation, some commenters expressed concern that the 2016 SAFER Guides contained outdated references and did not reflect current practices (88 FR 79355 through 79357). Additionally, some commenters recommended that CMS and ONC review and make updates to the 2016 SAFER Guides, regarding data privacy protections and present-day safety practices (88 FR 79355 through 79357). Our proposal to modify the requirement of the High Priority Practices SAFER Guide measure to reference the updated 2025 version of the High Priority Practices SAFER Guide is a direct response to such concerns. The 2025 version of the High Priority Practices SAFER Guide is updated and streamlined to focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience.

TABLE 58: COMPARISON OF THE 2016 SAFER GUIDES AND THE 2025 SAFER GUIDES

Category	2016 SAFER Guides	2025 SAFER Guides
Foundational Guides	• High Priority Practices • Organizational Responsibilities	• High Priority Practices • Organizational Responsibilities
Infrastructure Guides	• Contingency Planning • System Configuration • System Interfaces	• Contingency Planning • System Management
Clinical Process Guides	• Patient Identification • Computerized Provider Order Entry with Decision Support • Test Results Reporting and Follow-Up • Clinician Communication	• Patient Identification • Computerized Provider Order Entry with Decision Support • Test Results Reporting and Follow-Up • Clinician Communication

We are proposing to modify the High Priority Practices SAFER Guide measure, which currently requires MIPS eligible clinicians to attest ''yes'' to completing an annual self-assessment, by specifying that MIPS eligible clinicians utilize the 2025 version of the High Priority Practices SAFER Guide beginning with the CY 2026 performance period/2028 MIPS payment year. At § 414.1375(b)(2)(ii)(D), to earn a score for the Promoting Interoperability performance category, a MIPS eligible clinician is required to submit an affirmative attestation regarding their completion of the annual self-assessment to meet the requirement of the High Priority Practices SAFER Guide measure during the year in which the performance period occurs. For the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians complete this annual self-assessment using the 2016 version of the High Priority Practices SAFER Guide. We are proposing to modify this measure by requiring that MIPS eligible clinicians complete this annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide beginning with the CY 2026 performance period/2028 MIPS payment year.

We are not proposing any modifications to the scoring policies for this measure as previously finalized. To meet the requirements of the Promoting Interoperability performance category, MIPS eligible clinicians would need to affirmatively (''Yes'') attest to meeting the requirement of the measure; otherwise, MIPS eligible clinicians would receive score of zero for the entire Promoting Interoperability performance category. If a MIPS eligible clinician attests ''No'' because they have not completed an annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide, or did not report the measure, then they would fail to earn a score for the Promoting Interoperability performance category (and receive a score of zero) as currently provided at § 414.1375(b)(2)(ii)(D). We refer readers to the CY 2024 PFS final rule for further information regarding the High Priority Practices SAFER Guide measure and its requirements (88 FR 79354 through 79356).

Both the 2016 and the 2025 SAFER Guides are available on the ASTP/ONC website located at: *https://www.healthit.gov/topic/safety/safer-guides.* We encourage MIPS eligible clinicians to begin to familiarize

themselves with the 2025 SAFER Guides.

We seek public comment on the proposal to modify the High Priority Practices SAFER Guide measure by requiring MIPS eligible clinicians to conduct an annual self-assessment using the 2025 High Priority Practices SAFER Guide (instead of the 2016 version) at any point during the calendar year in which the performance period occurs, beginning with the CY 2026 performance period/2028 MIPS payment year.

(e) Public Health and Clinical Data Exchange Objective: Proposal To Adopt the Public Health Reporting Using the Trusted Exchange Framework and Common AgreementÔ (TEFCA) Measure as an Optional Bonus Measure Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

(i) Background

Under section 1848(o)(2)(A)(ii) of the Act, the MIPS Promoting Interoperability performance category encourages health information exchange, including for public health purposes through the Public Health and Clinical Data Exchange objective. Effective and efficient responses to public health events require rapid, accurate exchange of electronic health information between health care providers, and Federal, State, tribal, local, and territorial public health agencies (PHAs). Health care providers and MIPS eligible clinicians collect this electronic health information for patient care, and PHAs use the information for public health purposes such as tracking a disease, initiating contact tracing, or pinpointing the source of a disease or outbreak of foodborne illness.

Currently, there are five measures under the Promoting Interoperability performance category Public Health and Clinical Data Exchange objective: Immunization Registry Reporting, Electronic Case Reporting, Syndromic Surveillance Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. Two of the measures, Immunization Registry Reporting and Electronic Case Reporting, are required under the objective; three of the measures, Syndromic Surveillance Reporting, Public Health Registry Reporting and Clinical Data Registry Reporting, are optional bonus measures. MIPS eligible clinicians may receive a total of 5 bonus points for reporting on one or more optional measures.

Measures under the Public Health and Clinical Data Exchange objective promote the exchange of health information for specific public health use cases with PHAs and other entities using CEHRT. However, one difficulty with the electronic exchange of health information for many different public health purposes is that exchange between PHAs and MIPS eligible clinicians requires different processes for each measure under the Public Health and Clinical Data Exchange objective. For instance, health information exchange for the Electronic Case Reporting measure may be based on several point-to-point connections among MIPS eligible clinicians, intermediaries, and PHAs, but these connections and agreements may be different for other use cases such as those associated with the Immunization Registry Reporting measure. TEFCA establishes a common governance and technical framework for nationwide health information exchange. We anticipate that participation in TEFCA could help reduce the difficulty of public health information exchange over time. Facilitating health information exchange with PHAs through the TEFCA framework has the potential to increase standardization of connections to PHAs and reduce reporting burden for MIPS eligible clinicians and PHAs.

(ii) Background on TEFCA

Section 4003(b) of the 21st Century Cures Act, enacted in 2016, amended section 3001(c) of the Public Health Service Act and required HHS to take steps to ensure full network-to-network exchange of health information. Specifically, in section 3001(c)(9)(A) of the Public Health Service Act, the Congress directed the National Coordinator, in collaboration with NIST and other agencies within HHS, to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of the TEFCA framework.

The electronic exchange of health information allows MIPS eligible clinicians, other healthcare providers, and patients to access and securely share a patient's vital medical information electronically.[384] By standardizing health information exchange across many different networks, TEFCA helps to ensure nationwide network-to-network exchange of health information. Standardization across networks simplifies health information exchange by reducing the number of connections that health care providers, MIPS eligible clinicians, PHAs, and other interested parties need to make to send and receive health information. TEFCA supports this standardization by creating baseline governance, legal, and technical requirements that enable secure health information exchange across different networks nationwide, including: a common method for authenticating trusted network participants, a common set of rules for trusted exchange, organizational and operational policies to enable the exchange of health information among networks, and a process for filing and adjudicating noncompliance with the terms of the Common Agreement.[385] We anticipate that TEFCA can help expand the nationwide availability of secure health information exchange capabilities in public health reporting.

CMS, the Centers for Disease Control and Prevention (CDC), and ASTP/ONC have been working closely with PHAs and other interested parties to expand the use of TEFCA for sharing health information for public health purposes. TEFCA is an important part of a shared vision for building a modernized public health infrastructure that connects previously siloed public health and health care systems. Early efforts to enable public health reporting through TEFCA exchange have focused on electronic case reporting, which is likely to be the primary mechanism of public health information exchange supported by entities that are part of TEFCA during CY 2026.

(iii) Proposal To Adopt the Public Health Reporting Using TEFCA Measure as an Optional Bonus Measure Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

We propose to adopt an optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a PHA that occurs using TEFCA (the Public Health Reporting Using TEFCA measure) beginning with the CY 2026 performance period/2028 MIPS payment year. Specifically, we are proposing to adopt the following measure as an optional bonus measure:

- Public Health Reporting Using TEFCA. The MIPS eligible clinician: (1) participates as a signatory to a

[384] For additional information about health information exchange, visit: *https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-hie.*

[385] Additional information on TEFCA can be found on the ASTP website, located at: *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** (89 FR 93309) and on ASTP/ONC's website);[386] (2) is not suspended from participating in TEFCA Exchange; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (Validated Data Production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange with the PHA.

Under our proposal, a MIPS eligible clinician would be able to claim five bonus points under the Public Health and Clinical Data Exchange objective if the MIPS eligible clinician has attested that they are in active engagement Option 2 (Validated Data Production) with a PHA to submit electronic production data for one or more of the measures under the Public Health and Clinical Data Exchange objective using TEFCA. As previously finalized in the CY 2023 PFS rule (87 FR 70071 through 70074), for the measures in the Public Health and Clinical Data Exchange objective, MIPS eligible clinicians are required to report their level of active engagement as either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production), and may only spend one performance period at Option 1 (Pre-production and Validation) level of active engagement before advancing to Option 2 (Validated Data Production) to fulfill measure requirements. Under our proposal, this bonus measure would only be available where the MIPS eligible clinician is in active engagement Option 2 (Validated Data Production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective.

Furthermore, under the proposal, to attest ''Yes'' for the Public Health Reporting Using TEFCA measure, a MIPS eligible clinician must be a signatory to a TEFCA Framework Agreement,[387] meaning either the Common Agreement or an agreement that includes the Participant/Sub-participant Terms of Participation,[388] and is not suspended under the respective agreement. Additionally, to attest ''Yes'' for such bonus measure, a MIPS eligible clinician must transmit electronic health information for at least one measure under the Public Health and Clinic Data Exchange objective using TEFCA.

For more information about exchange of public health data using TEFCA, we refer readers to the TEFCA Public Health Exchange Purpose Implementation Standard Operating Procedure (SOP).[389] The Public Health Exchange Purpose Implementation SOP currently identifies electronic case reporting and electronic laboratory reporting as exchange use cases, but the SOP can also be used for any allowable public health purpose. CMS, CDC, and ASTP/ONC are focused on establishing a foundation for MIPS eligible clinicians to use TEFCA to meet their public health reporting needs for the benefit of both public health and clinical care.

Finally, the MIPS eligible clinician must use the functions of CEHRT to engage in exchange with a PHA. We believe there are numerous certified health IT capabilities that can support exchange under a TEFCA Framework Agreement with a PHA. For instance, MIPS eligible clinicians may exchange information under a TEFCA Framework Agreement by using technology certified to the ONC health IT certification criterion, ''Transmission to public health agencies—electronic case reporting'' at 45 CFR 170.315(f)(5). This criterion is associated with the exchange use cases currently identified under the TEFCA Public Health Exchange Purpose Implementation SOP. We further recognize that MIPS eligible clinicians may connect to entities that connect directly or indirectly to a Qualified Health Information Network™ [390] (QHIN) using certified health IT in a variety of ways. This includes the other ONC health IT certification criterion at 45 CFR 170.315(f) associated with the Public Health and Clinical Data Exchange objective measures, and we believe that we should allow for substantial flexibility in how MIPS eligible clinicians use certified health IT to exchange health information under a TEFCA Framework Agreement. We seek public comment on ONC health IT certification criteria that can support the proposed bonus measure.

We propose that a MIPS eligible clinician may earn a total of five bonus points if the MIPS eligible clinician attests ''Yes'' to one, more than one, or all of the following optional bonus measures: the Public Health Reporting Using TEFCA measure, the Public Health Registry Reporting measure, the Clinical Data Registry Reporting measure, or the Syndromic Surveillance Reporting measure. In the CY 2022 PFS final rule, we previously finalized that, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians may attest ''Yes'' to more than one optional bonus measure in the Public Health and Clinical Data Exchange Objective, but the MIPS eligible clinician can only earn a total of 5 bonus points even if the MIPS eligible clinician attests ''Yes'' to multiple bonus measures (86 FR 65474 and 65475). As set forth in Table 60 in section IV.A.4.d.(4)(h)(i) of this proposed rule, we have specified optional bonus measures for only the Public Health and Clinical Data Exchange Objective. We did not codify such policy in regulation at that time.

Currently, our regulation at § 414.1380(b)(4) sets forth our scoring policy for bonus measures across all objectives in the Promoting Interoperability performance category, but does not clearly reflect the finalized policy as described in the CY 2022 PFS final rule (86 FR 86 FR 65474 and 65475). Specifically, § 414.1380(b)(4)(ii)(C) currently provides that, for the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth five points, as specified by CMS. Such language may imply that we will provide five points for performance of each individual optional measure; this language does not account for the maximum total of 5 bonus points scoring policy that was previously finalized in the CY 2022 PFS final rule (86 FR 65474 and 65475). In the CY 2023 PFS final rule (87 FR 70228), the current regulation codified at § 414.1380(b)(4) inadvertently did not reflect the intent of the allocation of bonus points for optional bonus measures as previously finalized (86 FR 86 FR 65474 and 65475). To rectify such

[386] Agreement located at: *https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf.*

[387] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 2.1 (Nov 2024) located at: *https://www.healthit.gov/sites/default/files/2024–11/Common_Agreement_2.1.pdf.*

[388] Participant/Subparticipant Terms of Participation (Apr. 2024) located at: *https://rce.sequoiaproject.org/wp-content/uploads/2024/05/Common-Agreement-v2.0-Exhibit-1_508.pdf.*

[389] For more information, visit: *https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-Public-Health-PH.pdf.*

[390] A Qualified Health Information Network is a health information network that facilitates TEFCA exchange by undergoing technology and security testing, onboarding, and designation. For more information, visit: *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

incongruency beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing to amend the regulation at § 414.1380(b)(4)(ii)(C) to address our previously finalized scoring policy.

Specifically, we are proposing to amend our regulation by adding a new paragraph at § 414.1380(b)(4)(ii)(C)(*3*) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, the total number bonus points available to be earned when reporting one bonus measure, more than one bonus measure, or all bonus measures is a total of five bonus points. We are not proposing any substantive modifications to the remaining regulation text as currently codified at § 414.1380(b)(4)(ii)(C). we are proposing technical modifications to reorganize the current regulation text as new paragraphs at § 414.1380(b)(4)(ii)(C)(*1*) and (C)(*2*).

Because the Public Health Reporting Using TEFCA measure would be an optional bonus measure, we are not proposing any exclusions. Also, we are proposing that if a MIPS eligible clinician uses TEFCA to fulfill any of the required Public Health and Clinical Data Exchange objective measures, such as Electronic Case Reporting or Immunization Registry Reporting that MIPS eligible clinician would be able to claim the five bonus points if it affirmatively attests ''Yes'' to the Public Health Reporting Using TEFCA measure in addition to earning points for fulfilling the requirements of the required measure(s).

MIPS eligible clinicians can participate in TEFCA as Participants with a QHIN, or as Sub-participants through a regional HIE or Health Information Network (HIN) that is a QHIN participant, through a health system, or through an EHR vendor.

We seek public comment on the proposal to adopt the Public Health Reporting Using TEFCA measure as an optional bonus measure under the Public Health and Clinical Data Exchange objective beginning with the CY 2026 performance period/2028 MIPS payment year.

Also, we seek public comment on the proposal to modify the regulation at § 414.1380(b)(4)(ii)(C) to clarify the scoring of optional bonus measures under the Public Health and Clinical Data Exchange objective beginning with the CY 2026 performance period/2028 MIPS payment year.

(f) Proposal To Adopt Measure Suppression Policy for the MIPS Promoting Interoperability Performance Category Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year and for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) Beginning With the EHR Reporting Period in CY 2026

For MIPS, section 1848(q)(1)(A)(i) and (ii) of the Act provides, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards for a performance period and use such methodology to provide for a composite performance score (that is, MIPS final score) for each such clinician for each performance period. As discussed previously in section IV.A.4.d.(4)(a), section 1848(q)(2)(A)(iv) of the Act requires that we assess a MIPS eligible clinician's performance as a meaningful user of CEHRT to calculate the MIPS final score. Section 1848(q)(2)(B)(iv) of the Act provides that we apply the requirements established for a performance period under section 1848(o)(2) of the Act to determine whether a MIPS eligible clinician is a meaningful user of CEHRT.

For the Medicare Promoting Interoperability Program, sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act (as amended by the Health Information Technology for Economic and Clinical Health Act, Title XII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111–5) authorize downward payment adjustments under Medicare, beginning with FY 2015 for eligible hospitals and Critical Access Hospitals (CAHs) that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for the applicable electronic health record (EHR) reporting period. Section 602 of Title VI, Division O of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) added subsection (d) hospitals in Puerto Rico as eligible hospitals under the Medicare EHR Incentive Program and extended the participation timeline for these hospitals such that downward payment adjustments were authorized beginning in FY 2022 for section (d) Puerto Rico hospitals that do not successfully demonstrate meaningful use of CEHRT for the applicable EHR reporting period.

For both the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, respectively, set forth three substantively similar criteria to determine whether a MIPS eligible clinician or an eligible hospital or CAH is a meaningful user of CEHRT. In addition, sections 1848(o)(2)(B)(i) and 1886(n)(3)(B)(i) of the Act, respectively, provide, in relevant part, that the Secretary shall select measures for purposes of the third criterion for assessing and determining if MIPS eligible clinician, an eligible hospital, or CAH is a meaningful user of CEHRT (sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act, respectively).

We have identified a need for additional flexibility in whether we use a measure to calculate scores or otherwise determine whether MIPS eligible clinicians meet the definition of a meaningful EHR user in the MIPS Promoting Interoperability performance category and eligible hospitals and CAHs meet the definition for the Medicare Promoting Interoperability Program. This would account for the impact of changing conditions that are beyond the control of MIPS eligible clinicians, eligible hospitals, and CAHs, which arise outside of rulemaking for a given performance period or EHR reporting period. Such flexibility would allow us to ensure that MIPS eligible clinicians,[391] eligible hospitals, and CAHs are not impacted negatively by external factors as determined by CMS when they are being assessed for meeting measure requirements or meeting the definition of a meaningful user.

A measure suppression policy would provide CMS with the flexibility to not score a measure for circumstances outside the control of MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category and eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. There may be circumstances that could impede the assessment of

[391] In the CY 2024 PFS final rule (88 FR 79124 through 79132), the Medicare Shared Savings Program aligned its CEHRT use requirements for Accountable Care Organizations (ACOs) with the MIPS Promoting Interoperability performance category's requirements. As codified at § 425.507, beginning with performance years on or after January 1, 2025, unless otherwise excluded, an ACO participant, ACO provider/supplier, and ACO professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial Qualifying APM Participant (Partial QP) (each as defined at § 414.1305) must: (1) report the objectives and measures for MIPS Promoting Interoperability performance category; and (2) earn a performance category score for the MIPS Promoting Interoperability performance category.

performance or a fair comparison of performance across applicable participants, creating the potential to unduly penalize a significant portion of MIPS eligible clinicians, eligible hospitals, and CAHs. We believe that there are certain circumstances that would warrant the necessity to suppress the scoring of a measure.

On this basis, for both the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, beginning with the CY 2026 performance period/2028 MIPS payment year for MIPS eligible clinicians and the EHR reporting period in CY 2026 for eligible hospitals and CAHs, we propose to adopt a measure suppression policy to permit CMS to exclude a measure from scoring or the determination of a meaningful EHR user for an applicable performance period/MIPS payment year or EHR reporting period in an applicable CY. Specifically, we propose that such a measure suppression policy would allow CMS to exclude a measure from scoring due to circumstances that impede the effective measurement of a measure within the measure's applicable objective or to exclude such a measure from the determination of a meaningful EHR user for measures that are not scored. We have previously finalized similar measure suppression policies for the MIPS quality performance category (§ 414.1380(b)(1)(vii)(A)) and MIPS cost performance category (§§ 414.1380(b)(2)(v)(A) and (B)). We have modeled the proposed measure suppression policy we are proposing for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program on such policies, with some substantive differences to reflect more specific requirements of the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program.

For an applicable performance period/MIPS payment year or EHR reporting period, we propose that CMS would determine whether certain circumstances exist warranting suppression of a measure within the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program based on CMS's consideration of one or more of the following factors:

- The nature, breadth, and duration of the circumstance's effect on MIPS eligible clinicians', eligible hospitals', and CAHs' ability to fulfill the measure requirement;
- The availability of certified health IT modules to fulfill the measure;
- The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance;
- Out-of-date or conflicting technical standards;
- Technical or operational capacity of required partners; or
- Other factors as determined by CMS.

The aforementioned factors would provide a basis for CMS to determine when circumstances may warrant CMS to suppress the scoring of a measure, particularly when circumstances arise that may impact a significant portion or all MIPS eligible clinicians, eligible hospitals, and CAHs. We believe that there may be circumstances that affect the ability of MIPS eligible clinicians, eligible hospitals, and CAHs to meet the requirements of a measure that are outside of their control, such as technical or operational limitations experienced by required partners that limit the ability of MIPS eligible clinicians, eligible hospitals, and CAHs to complete specific elements of a measure. Also, there may be circumstances in which the timeline for the availability of certified health IT modules or updated technical standards may be delayed or incongruent with measure implementation requirements and, as a result, we believe that MIPS eligible clinicians, eligible hospitals, and CAHs should not be penalized or unfairly scored on a measure. If we transition to performance-based measures in the future, we may find that the data being reported may not be consistent due to various factors causing the data to not be valid or accurate.

Under the measure suppression policy we are proposing for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, our decision to suppress a measure would still require the measure to be reported. However, regardless of what data, attestation, or other information the MIPS eligible clinician, eligible hospital, or CAH reported for the measure, it would not affect the score for the applicable objective or the determination of a meaningful EHR user for measures that are not scored. For example, for a measure that requires a ''Yes'' or ''No'' response, the MIPS eligible clinician's, eligible hospital's, or CAH's score for the objective in which the measure is found would not be negatively impacted, regardless of whether it reported a ''Yes'' or a ''No,'' as long as they reported a response.

Establishing a measure suppression policy would allow us to identify measures affected by one or more of the aforementioned factors outside of rulemaking to timely address such a situation. For any measure for which we determine it must be suppressed based on one of more of the factors we have identified, we would notify MIPS eligible clinicians, eligible hospitals, and CAHs of the suppression via existing communication channels. This proposal would allow us to disseminate via a listserv announcement (MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program) and publish on a CMS website (MIPS Promoting Interoperability performance category) measures identified as being suppressed for an applicable CY performance period/MIPS payment year and EHR reporting period in an applicable CY, no later than the beginning of the applicable data submission period when technically feasible, which starts in January of the CY following the applicable performance period/EHR reporting period.

We are proposing to adopt this measure suppression policy for the MIPS Promoting Interoperability performance category beginning with the CY 2026 performance period/2028 MIPS payment year and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs beginning with the EHR reporting period in CY 2026.

We propose to codify the proposed measure suppression policy at § 414.1380(b)(4)(iii) for the MIPS Promoting Interoperability performance category and § 495.24(f)(3) for the Medicare Promoting Interoperability Program. Specifically, we propose to codify at § 414.1380(b)(4)(iii) that, beginning with the CY 2026 performance period/2028 MIPS payment year, if certain circumstances occur impacting CMS's assessment of performance of MIPS eligible clinicians on a measure specified for the Promoting Interoperability performance category under § 414.1375, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS's calculation of the MIPS Promoting Interoperability performance category objective score under § 414.1380(b)(4) or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. In addition, we propose to codify at § 495.24(f)(3) that beginning with the EHR reporting period in CY 2026, if certain circumstances occur impacting CMS's assessment of performance of eligible hospitals and CAHs on a measure specified for the Medicare Promoting Interoperability Program, CMS may, in

its sole discretion, suppress the affected measure by excluding it from CMS's calculation of the Medicare Promoting Interoperability Program objective score or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. Also, we are proposing to codify at both § 414.1380(b)(4)(iii) and § 495.24(f)(3) that CMS would determine whether certain circumstances exist warranting suppression of a measure based on one or more of the following factors::

- The nature, breadth, and duration of the circumstance's effect on MIPS eligible clinicians', eligible hospitals', and CAHs' ability to fulfill the measure requirement;
- The availability of certified health IT modules to fulfill the measure;
- The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance;
- Out-of-date or conflicting technical standards;
- Technical and operational capacity of required partners; or
- Other factors as determined by CMS.

We seek public comment on our proposals to adopt and codify a measure suppression policy for the MIPS Promoting Interoperability performance category beginning with the CY 2026 performance period/2028 MIPS payment year at § 414.1380(b)(4)(iii), and the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 at § 495.24(f)(3).

(g) Proposal To Suppress the Electronic Case Reporting Measure by Excluding the Measure From Scoring for the MIPS Promoting Interoperability Performance Category for the CY 2025 Performance Period/2027 MIPS Payment Year and the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2025

(i) Background: Public Health and Clinical Data Exchange Objective

The Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category for MIPS eligible clinicians and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs has been an important mechanism for encouraging healthcare data exchange for public health purposes. Effective responses to public health events require fast, accurate exchange of data between health care providers and Federal, State, and local public health agencies (PHAs). MIPS eligible clinicians, eligible hospitals, and CAHs collect these data for patient care, and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

For the MIPS Promoting Interoperability performance category, there are two required measures and three optional measures under the Public Health and Clinical Data Exchange objective: Immunization Registry Reporting; Electronic Case Reporting; Syndromic Surveillance Reporting (optional); Public Health Registry Reporting (optional); and Clinical Data Registry Reporting (optional). For background on this objective and its associated measures, we refer readers to the CY 2019 PFS final rule (83 FR 59795, 59815 through 59817). In the CY 2022 PFS final rule (86 FR 65469 through 65475), we finalized the requirement for MIPS eligible clinicians to report two of the 5 measures associated with the Public Health and Clinical Data Exchange objective, beginning with the performance period in CY 2022: Immunization Registry Reporting and Electronic Case Reporting. For background on this objective and its associated measures for MIPS eligible clinicians, we refer readers to the CY 2023 PFS final rule (87 FR 70071 through 70074).

For the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, there are eight measures under the Public Health and Clinical Data Exchange objective: Immunization Registry Reporting; Electronic Case Reporting; Syndromic Surveillance Reporting; Electronic Laboratory Reporting; Antimicrobial Use Surveillance; Antimicrobial Resistance Surveillance; Public Health Registry Reporting (optional); and Clinical Data Registry Reporting (optional). In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes proposed rule, we proposed a ninth measure, which would be optional if finalized: Public Health Reporting Using TEFCA (90 FR 18360). In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program (FY 2022 IPPS/LTCH PPS) final rule (86 FR 45470 through 45478), we finalized the requirement for eligible hospitals and CAHs to report four measures associated with the Public Health and Clinical Data Exchange objective, beginning with the EHR reporting period in CY 2022: Immunization Registry Reporting; Electronic Case Reporting; Syndromic Surveillance Reporting; Electronic Laboratory Reporting. We subsequently finalized the requirement for eligible hospitals and CAHs to report Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance in the FY 2024 IPPS/LTCH PPS final rule (87 FR 49335 through 49337).

The Public Health and Clinical Data Exchange objective of the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program has been an important mechanism for encouraging data exchange between MIPS eligible clinicians, eligible hospitals, CAHs, and PHAs. Requiring MIPS eligible clinicians, eligible hospitals, and CAHs to report on required measures provides ongoing incentive for EHR vendors to implement the necessary capabilities in their products and encourages MIPS eligible clinicians, eligible hospitals, and CAHs to engage in the reporting activities described in the measures.

As noted previously, MIPS eligible clinicians, eligible hospitals, and CAHs are required to report the Electronic Case Reporting measure for the Public Health and Clinical Data Exchange objective as specified for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, respectively. The Electronic Case Reporting measure currently requires that the MIPS eligible clinician, eligible hospital, or CAH be in active engagement with a PHA to submit electronic case reporting of reportable conditions. A MIPS eligible clinician, eligible hospital, or CAH is required to report their level of active engagement as either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production).

As described in the CY 2023 PFS final rule (87 FR 70072) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49338), we currently define ''active engagement'' as when the MIPS eligible clinician, eligible hospital, or CAH is in the process of moving towards sending ''production data'' to a PHA or clinical data registry (CDR), or is sending production data to a PHA or CDR. We further noted that the term ''production

data'' refers to data generated through clinical processes involving patient care; the term is used to distinguish between this data and ''test data'' which may be submitted for the purposes of enrolling in and testing electronic data transfers (87 FR 70072; 87 FR 49337 through 49340).

In the CY 2023 PFS final rule (70071 through 70074) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337 through 49340), we finalized that, beginning with the CY 2023 performance period/2025 MIPS payment year and the EHR reporting period in CY 2023, respectively, a MIPS eligible clinician, eligible hospital, or CAH must indicate its level of active engagement at either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production) to fulfill the Electronic Case Reporting measure and other measures specified for the Public Health and Clinical Data Exchange objective. We further finalized that generally, beginning with the CY 2024 performance period/2026 MIPS payment system and the EHR reporting period in CY 2024, MIPS eligible clinicians, eligible hospitals, and CAHs may spend only one performance period at the Option 1 (Pre-production and Validation) level of active engagement for the Electronic Case Reporting measure and other measures specified for the Public Health and Clinical Data Exchange objective, and MIPS eligible clinicians, eligible hospitals and CAHs must progress to the Option 2 (Validated Data Production) level of active engagement in the next EHR reporting period for which they report the measure (87 FR 70071 through 70074; 87 FR 49340 through 49342). The only exception to this requirement that we finalized is that, in the event a MIPS eligible clinician, eligible hospital, or CAH chooses to switch between one or more PHAs or CDRs, they will be permitted to spend on additional performance period at Option 1 (Pre-production and Validation) to assist with onboarding to the new CDR or PHA (87 FR 70071 through 70074; 87 FR 49340 through 49342).

Additional information on the history of the Electronic Case Reporting measure can be found in prior rulemakings for the predecessor Medicare EHR Incentive Programs for Eligible Professionals and for Eligible Hospitals and Critical Access Hospitals,[392] the MIPS Promoting Interoperability performance category,[393] and the Medicare Promoting Interoperability Program.[394]

For both the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, the Electronic Case Reporting measure also includes three exclusions. A MIPS eligible clinician, eligible hospital, or CAH meeting one or more of the three established criteria may claim an exclusion from performing and reporting the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, respectively. The first exclusion criterion is that the MIPS eligible clinician, eligible hospital, or CAH does not treat or diagnose any reportable diseases for which data are collected by its jurisdiction's reportable disease system during the performance period or EHR reporting period (Exclusion 1). The second exclusion criterion is that the MIPS eligible clinician, eligible hospital, or CAH operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period (Exclusion 2). The third exclusion criterion is that the MIPS eligible clinician, eligible hospital, or CAH operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of six months prior to the start of the performance period (Exclusion 3). We interpret ''capable of receiving electronic case reporting data in the specific standards required'' in Exclusion 2 to mean that there is not a PHA in a MIPS eligible clinician's, eligible hospital's, or CAH's jurisdiction that has the ability to advance, and has advanced, a MIPS eligible clinician, eligible hospital, or CAH registered with the PHA to Active Engagement Option 2: Validated Data Production in the timeframe required for the MIPS eligible clinician, eligible hospital, or CAH to achieve Validated Data Production under the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program. For information regarding the 2025 measure specifications for the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, we refer readers to: *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2025-MIPS-Promoting-Interoperability-Measure-Electronic-Case-Reporting-Updated-April-2025.pdf* and *https://www.cms.gov/files/document/cms-specifications-manual-ehr-period-cy-2025.pdf.*

We note that the policy proposals for the Medicare Promoting Interoperability Program appeared in the **Federal Register** on April 30, 2025 (90 FR 18002) as part of the FY 2026 IPPS/LTCH PPS proposed rule. The proposed rule contains proposals for program scoring (90 FR 18361) that are unchanged with respect to Electronic Case Reporting measure; scoring changes to the measure are outlined in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69604).

(ii) Proposal To Suppress the Electronic Case Reporting Measure for the CY 2025 Performance Period and the EHR Reporting Period in CY 2025

As discussed previously in section IV.A.4.d.(4)(g)(i), MIPS eligible clinicians, eligible hospitals, and CAHs have been required to register with a PHA and send testing files (Pre-production and Data Validation files) to report the Electronic Case Reporting measure at the Option 1 level of active engagement (87 FR 70071 through 70074; 87 FR 49338 through 87 FR 49342). Beginning with the CY 2024 performance period/2026 MIPS payment system and the EHR reporting period in CY 2024, MIPS eligible clinicians, eligible hospitals, and CAHs may spend only one performance period at the Option 1 (Pre-production and Validation) level of active engagement for the Electronic Case Reporting measure, and they must progress to the Option 2 (Validated Data Production) level of active engagement in the next performance period or EHR reporting period for which they report the measure (87 FR 70071 through 70074; 87 FR 49338 through 87 FR 49342). Therefore, beginning with the CY 2025 performance period and EHR reporting period in CY 2025, many MIPS eligible clinicians, eligible hospitals, and CAHs may need to submit case files (that is, production data) using CEHRT to their PHA to report that they have progressed to Option 2 level of active engagement for the Electronic Case Reporting measure.

In regard to the level of engagement pertaining to Option 1 and Option 2 for

[392] We refer readers to Stage 1 final rule (75 FR 1844), Stage 2 final rule (77 FR 13698), and Stage 3 final rule (80 FR 62762).

[393] We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77008), CY 2018 Quality Payment Program final rule (82 FR 53568), the CY 2019 PFS final rule (83 FR 59815), the CY 2022 PFS final rule (86 FR 65469 through 65475), and the CY 2023 PFS final rule (87 FR 70071 through 70082).

[394] We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45478).

the CY 2025 performance period and EHR reporting period in CY 2025, we have recently been informed by the Centers for Disease Control and Prevention (CDC) that it has temporarily paused electronic case reporting registration and onboarding of new health care organizations (HCOs) to establish a more efficient and automated process. During such time, the CDC will evaluate the onboarding process for HCOs and their EHR vendors and establish a more sustainable long-term path for broadscale adoption and integration of healthcare and electronic case reporting data. On June 6, 2025, we shared this information through the Quality Payment Program (QPP) and Medicare Promoting Interoperability Program listserv announcements and published this information on the QPP Resource Library webpage (located at: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3268/2025-MIPS-Promoting-Interoperability-CDC-Pause-In-eCR-Onboarding.pdf*) and CMS QualityNet Hospital Inpatient Notifications webpage (located at: *https://qualitynet.cms.gov/files/68437ab1416b533f04e5f5f0?filename=2025-59-IP.pdf*). Due to this temporary pause, some MIPS eligible clinicians, eligible hospitals, and CAHs may not meet the electronic case reporting registration and onboarding requirements by the end of the CY 2025 performance period and EHR reporting period in CY 2025. The onboarding process includes a timeframe that accounts for connecting to intermediaries to send electronic case reporting data to PHAs with HCOs and EHR vendors. This temporary pause will enable the CDC to evaluate the onboarding process for HCOs and their EHR vendors. The CDC is enhancing its electronic case reporting modernization initiatives and creating a sustainable long-term strategy for the widespread adoption and integration of healthcare and electronic case reporting data.

To avoid undue adverse consequences for MIPS eligible clinicians, eligible hospitals, and CAHs as a result of such circumstances, which are outside of their control, we are proposing to suppress the Electronic Case Reporting measure. Specifically, we propose to exclude the Electronic Case Reporting measure from scoring under the MIPS Promoting Interoperability performance category for the CY 2025 performance period and the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025.

Specifically, we propose that we would suppress the Electronic Case Reporting measure by excluding it from calculations for scoring purposes, but MIPS eligible clinicians, eligible hospitals, and CAHs would continue to be required to report the measure, in which they would either attest ''Yes'' or ''No'' to meeting the requirements pertaining to Option 1 and Option 2, or claim an applicable exclusion. As long as the MIPS eligible clinicians, eligible hospitals, and CAHs report responses, their score for the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category or the Medicare Promoting Interoperability Program, as applicable, would not be adversely affected irrespective of the responses reported for this measure.

If this proposal is finalized as proposed, MIPS eligible clinicians, eligible hospitals, and CAHs should report the Electronic Case Reporting measure in accordance with the applicable specifications. However, if this proposal is not finalized, we encourage MIPS eligible clinicians, eligible hospitals, and CAHs to claim an exclusion, if applicable.

Please note that we are proposing to suppress the Electronic Case Reporting measure through rulemaking in order to notify MIPS eligible clinicians, eligible hospitals, and CAHs of how we intend to address the issues related to CDC's pause on onboarding, which may affect MIPS eligible clinicians', eligible hospitals', and CAHs' ability to meet requirements of the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category for the CY 2025 performance period and the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025. In the absence of a measure suppression policy currently in effect for the CY 2025 performance period and the EHR reporting period in CY 2025, we are utilizing this proposed rule and subsequently, the upcoming CY 2026 PFS final rule that will be published by November 1, 2025, to communicate and seek public comment on our proposed approach to address scoring of the Electronic Case Reporting measure due to the CDC's pause on onboarding.

We note that the Public Health and Clinical Data Exchange objective requirements and the 25 points attributed to the objective under the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program would remain the same if we finalize this proposal. The Electronic Case Reporting measure would continue to be a required measure even though we are proposing to suppress it by excluding it from our scoring calculations. If this proposal is finalized as proposed, the 25 points attributed to the Public Health and Clinical Data Exchange objective the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program would apply to the measure(s) in the objective that are required and not suppressed. Moreover, we note that this proposal does not affect the measure specifications nor the required reporting of the measure but merely affects whether the measure is scored for purposes of the applicable objective.

We seek public comment on the proposals to suppress the Electronic Case Reporting measure by excluding the measure from scoring for MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category, and eligible hospitals, and CAHs participating in the Medicare Promoting Interoperability Program for the CY 2025 performance period and the EHR reporting period in CY 2025.

(h) Proposed Requirements for the Promoting Interoperability Performance Category for the CY 2026 Performance Period/2028 MIPS Payment Year

(i) Proposed Objectives and Measures for the CY 2026 Performance Period/2028 MIPS Payment Year

For reference, Table 59 sets forth the objectives and measures for the Promoting Interoperability performance category that would be required for the CY 2026 performance period/2028 MIPS payment year. Table 59 reflects proposed modifications to previously established objectives and measures, including the proposal to establish a new optional bonus measure, under the Promoting Interoperability performance category.

TABLE 59: PROPOSED OBJECTIVES AND MEASURES FOR THE PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of	Support Electronic Referral Loops by Sending Health Information: For at	Number of transitions of care and referrals in the denominator where	Number of transitions of care and referrals during the performance period	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times

Objective	Measure	Numerator	Denominator	Exclusion
care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other healthcare providers into their EHR using the functions of CEHRT	least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or healthcare provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	the summary of care record was created using CEHRT and exchanged electronically	for which the MIPS eligible clinician was the transferring or referring clinician	during the performance period.
Health Information Exchange (HIE)	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: ● Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ASTP/ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. ● Using the functions	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.			
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT

Objective	Measure	Numerator	Denominator	Exclusion
				definition at the start of the performance period; OR 3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a PHA to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2. Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Public Health Registry Reporting (Optional Bonus): The MIPS eligible clinician is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting (Optional Bonus): The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting (Optional Bonus): The MIPS eligible clinician is in active engagement with a PHA to submit syndromic surveillance data from an urgent care setting.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

Objective	Measure	Numerator	Denominator	Exclusion
Public Health and Clinical Data Exchange	Public Health Reporting Using TEFCA (Optional Bonus):* The MIPS eligible clinician is (1) participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ASTP/ONC's website); (2) is not suspended from participating in TEFCA exchange; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange with the PHA.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	Security Risk Analysis:* First, conduct or review a security risk analysis; and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include addressing the	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

Objective	Measure	Numerator	Denominator	Exclusion
	security of data created or maintained by CEHRT (to include encryption), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the MIPS eligible clinician would adopt an equivalent alternative measure if it is reasonable and appropriate to do so.			
Protect Patient Health Information	High Priority Practices SAFER Guide:* Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the High Priority Practices SAFER Guide measure using the 2025 High Priority Practices SAFER Guide during the year in which the performance period occurs.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

*The proposed bonus measure, Public Health Reporting Using TEFCA, and the proposed modifications to the Security Risk Analysis measure and the High Priority Practices SAFER Guide measure would be effective beginning with the CY 2026 performance period.

(ii) Proposed Scoring Methodology for the CY 2026 Performance Period/2028 MIPS Payment Year

For reference, Table 60 sets forth the scoring methodology for the Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, which includes the proposed new optional bonus measure, Public Health Reporting Using TEFCA. When earning bonus points, a MIPS eligible clinician can receive a maximum of 5 points regardless of the number of bonus measures reported.

TABLE 60: PROPOSED SCORING METHODOLOGY FOR THE CY 2026 PERFORMANCE PERIOD/ 2028 MIPS PAYMENT YEAR

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting****	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA*	5 points (*bonus*)	Optional
Protect Patient Health Information	Security Risk Analysis*	Not scored**	Required
	High Priority Practices SAFER Guide*	Not scored**	Required
No Associated Objective: Attestation Requirements***	ONC Direct Review Attestation	Not scored	Required
	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored	Required
	ONC-ACB Surveillance Attestation	Not scored	Optional

*The proposed optional bonus measure, Public Health Reporting Using TEFCA, and the proposed modifications to the Security Risk Analysis measure and the High Priority Practices SAFER Guide measure would be effective beginning with the CY 2026 performance period.
**MIPS eligible clinicians must submit an affirmative attestation regarding the Security Risk Analysis measure and the High Priority Practices SAFER Guide measure. Failure to submit an affirmative ("Yes") attestation to fulfill such requirements will result in a zero score for the Promoting Interoperability performance category.
***Attestation Requirements: MIPS eligible clinicians must submit an attestation regarding the ONC Direct Review and that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3). Failure to submit an attestation or an affirmative ("Yes") attestation to fulfill such requirements will result in a zero score for the Promoting Interoperability performance category.
****We note that the proposal pertaining to the suppression of this measure, which excludes the measure from scoring is for the CY 2025 performance period/2028 MIPS payment year outlined in section (g) of this proposed rule. The proposed suppression of this measure does not include the CY 2026 performance period/2028 MIPS payment year.

(iii) Exclusion Redistribution

Many required measures would have exclusions associated with them as set forth in Table 59. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available in Table 60 do not include the points that would be redistributed if a MIPS eligible clinician claims an exclusion for a specific measure. Table 61 sets forth how points would be redistributed among the objectives and measures specified for the Promoting

Interoperability performance category for the CY 2026 performance period/ 2028 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

TABLE 61: PROPOSED EXCLUSION REDISTRIBUTION FOR CY 2026 PERFORMANCE PERIOD/ 2028 MIPS PAYMENT YEAR

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange Under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

(iv) ONC Health IT Certification Criteria

Table 62 sets forth the objectives and measures for the Promoting Interoperability performance category for the CY 2026 performance period/ 2028 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. We refer readers to the CY 2024 PFS final rule (88 FR 79307 through 79312) for discussion of and amendments to the definition of CEHRT at § 414.1305.

TABLE 62: PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION CRITERIA

Objective	Measure	Certification Criteria (CY 2026 Performance Period/2028 MIPS Payment Year) in Title 45 of the CFR
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	§ 170.315(b)(1) Transitions of care
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange Under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Standardized API for patient and population services
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization Registry Reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic Surveillance Reporting (Optional)	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic Case Reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting

Objective	Measure	Certification Criteria (CY 2026 Performance Period/2028 MIPS Payment Year) in Title 45 of the CFR
	Public Health Registry Reporting (Optional)	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical Data Registry Reporting (Optional)	No health IT certification criteria at this time.
	Public Health Reporting Using TEFCA (Optional)	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	High Priority Practices SAFER Guide	No health IT certification criteria at this time.

(i) Requests for Information (RFI) Regarding the Query of Prescription Drug Monitoring Program (PDMP) Measure

(i) Background on PDMPs and the Query of PDMP Measure

PDMPs are electronic databases that monitor the use of controlled substances, including prescription drug usage and prescription drug history. PDMPs are critical decision support tools for addressing prescription drug use, misuse, and diversion. Recent legislation has continued to advance the use of PDMPs, including the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115–271), enacted in 2018, that authorizes important investments in combating the opioid epidemic. Among other provisions, the SUPPORT for Patients and Communities Act included new requirements and Federal funding for the enhancement, integration, and interoperability of PDMPs to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorders.

Currently, all 50 states, the District of Columbia, Guam, Puerto Rico, and the Northern Mariana Islands host PDMPs.[395] PDMPs play an important role in patient safety by enabling clinicians to check PDMP data for prescription opioids and other controlled medications received by a patient from other clinicians to determine whether a patient is put at high risk for overdose. A literature review of recent studies on PDMP effectiveness compiled by the PDMP Training and Technical Assistance Center (TTAC) at the Institute for Intergovernmental Research and published in the *PDMP Administrators' Orientation Guide of PDMPs* highlights the role of PDMPs in reducing the following: high-risk opioid prescribing and dispensing behaviors; overall supply of opioid prescriptions; multiple provider episodes (for example, doctor or pharmacy shopping); opioid-related overdose rates; and admissions to treatment facilities for prescription drug misuse.[396]

Increased integration of PDMP data into health IT systems such as EHRs, pharmacy dispensing software systems (PDS), and HIEs continues to reduce barriers to and burden of PDMP review by incorporating PDMP queries into the provider workflow. A PDMP TTAC assessment of PDMP Policies and Capabilities[397] published in December 2024 found that 49 of the 54 PDMPs have taken steps to integrate PDMP data into EHRs, HIEs, and PDS systems. We refer readers to Table 63 for more information.

TABLE 63 PDMP INTEGRATION AS OF 2024[398]

Type of Integration	Number of PDMPs
EHR, HIE, and PDS	18
EHR and PDS	24
EHR and HIE	1
EHR only	5
HIE only	1

[395] PDMP TTAC, PDMP Policies and Capabilities: 2023 Assessment Results, January 2024, located at: *https://www.pdmpassist.org/Content/Documents/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf.*

[396] PDMP TTAC, PDMP Administrators Orientation Package, November 2024, located at: *https://www.pdmpassist.org/Content/Documents/pdf/PDMP_admin/PDMP_Administrators_Orientation_Package_revision_20241105.pdf.*

[397] PDMP TTAC, PDMP Policies and Capabilities: 2024 Assessment Results, December 2024, located at: *https://www.pdmpassist.org/Content/Documents/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf.*

[398] PDMP TTAC, PDMP Policies and Capabilities: 2024 Assessment Results, December 2024, located at: *https://www.pdmpassist.org/Content/Documents/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf.*

We continue to work with Federal partners and industry stakeholders to advance common standards for the exchange of information between PDMPs, EHRs, PDS systems, HIEs, and exchange networks. ONC and CDC convened the PDMP and health IT system communities to standardize data format and transport protocols to exchange controlled substances prescription data between PDMP and health IT systems, which produced a PDMP–EHR Integration Toolkit.[399] ONC and CDC jointly developed the Integration Framework to provide guidance to health care systems, states, and health IT vendors to support successful project execution, management and communications for implementing health IT integrations, such as PDMP data integration into clinical workflow.[400] Moreover, ASTP/ONC continues to collaborate with industry partners furthering the development of a Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (FHIR) Implementation Guide that allows EHRs and other health IT systems to support more seamless exchange of prescription data with PDMP systems.[401] We refer readers to the ASTP/ONC website for additional information and resources regarding PDMPs.[402]

[399] PDMP–EHR Integration Toolkit located at: *https://www.healthit.gov/topic/health-it-health-care-settings/prescription-drug-monitoring-programs.*

[400] Integration Framework located at: *https://www.healthit.gov/sites/default/files/page/2024-09/Integration%20Framework_final%20for%20posting.pdf.*

[401] HL7 FHIR PDMP Implementation Guide located at: *https://build.fhir.org/ig/HL7/fhir-pdmp/.*

[402] For more information on Prescription Drug Monitoring Programs, visit: *https://www.healthit.gov/topic/health-it-health-care-settings/prescription-drug-monitoring-programs.*

On August 5, 2024, the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI–2) proposed rule appeared in the **Federal Register** (89 FR 63498). The HTI–2 proposed rule includes a proposal for a PDMP certification criterion at 45 CFR 170.315(f)(9) entitled ''Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter'' that would enable the bi-directional interaction and electronic health information exchange between certified Health IT Modules and PDMP databases using a consistent approach to querying PDMP data (89 FR 63547). Specifically, the proposed certification criterion would enable the query of prescription drug monitoring systems and the receipt, validation, parsing, and filtering of medication information from PDMPs. The proposed criterion would be a functional criterion agnostic to a specific PDMP standard, but would include transport, content, and vocabulary standards where appropriate. ONC has not finalized the proposal to date.

In the CY 2019 PFS final rule, CMS adopted the Query of PDMP measure under the e-Prescribing objective of the Promoting Interoperability performance category to support HHS initiatives aimed at improving the treatment of opioid and substance use disorders by helping MIPS eligible clinicians avoid inappropriate prescriptions (83 FR 59795). The Query of PDMP measure provides that, for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history as described in the CY 2024 PFS final rule (88 FR 79353 and 79354).

We are interested in continuing to make improvements to the Promoting Interoperability performance category that promote patient safety and encourage appropriate prescribing of controlled substances while minimizing provider burden. We further believe improved technology approaches and increased PDMP integration into EHR systems can enable increased utilization of PDMPs and associated positive outcomes for patients.

Therefore, we are seeking public comment through this RFI to potentially inform future rulemaking for the Query of PDMP measure related to the following policy considerations: (1) changing the Query of PDMP measure from an attestation-based measure (''Yes'' or ''No'') to a performance-based measure (numerator and denominator), as well as alternative measures designed to more effectively assess the degree to which participants are utilizing PDMPs; and (2) expanding the types of drugs to which the Query of PDMP measure could apply.

(ii) RFI on Changing the Query of PDMP Measure From an Attestation-Based Measure to a Performance-Based Measure

The Query of PDMP measure was initially finalized in the CY 2019 PFS final rule (83 FR 59800 through 598045) as a performance-based measure with a numerator and denominator described as follows:

- Denominator: Number of Schedule II opioids [403] electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.
- Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.

In the CY 2020 and CY 2021 PFS final rules (84 FR 62992 through 62994 and 85 FR 84887 through 84888), we described the concerns expressed by interested parties that they believed it was premature for the Promoting Interoperability performance category to require the Query of PDMP measure and score it based on performance. In the CY 2022 PFS proposed rule (86 FR 39410), we discussed our support of efforts to expand the use of PDMPs, describing federally supported activities aimed at developing a more robust and standardized approach to EHR–PDMP integration, and additional discussions on the feedback we have received from health IT vendors and MIPS eligible clinicians thus far. In the CY 2023 PFS final rule (87 FR 70062 through 70067), we finalized the Query of PDMP measure to require a ''Yes'' or a ''No'' attestation from MIPS eligible clinicians participating in the Quality Payment Program beginning with the CY 2023 performance period/2025 MIPS payment year. A ''Yes'' response would indicate that, for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for a prescription drug history.

Given recent progress in a variety of areas, there is now a clearer trajectory moving forward to enhance the Promoting Interoperability performance category's capacity to incentivize use of PDMPs, and thereby, to improve the quality of health care and promote care coordination. Notably, PDMPs are now widely available across all 50 States and several localities, and PDMP integration with HIEs, EHRs, and PDSs has increased since the Query of PDMP measure was finalized as an attestation measure. Therefore, to further promote the utilization of PDMPs and to support appropriate prescribing for controlled substances, we are inviting public comment and feedback on the potential modification or replacement of the Query of PMDP measure from an attestation measure to a performance-based measure to inform potential future rulemaking and include the following questions:

- Should CMS propose to adopt a performance-based (numerator/denominator) reporting requirement for the Query of PDMP measure? If so, how should the numerator and denominator be defined?

For example, one approach we are considering to potentially inform future rulemaking is the following description of a numerator and a denominator, which is updated from the numerator and denominator established in the CY 2019 PFS final rule (83 FR 59800 through 59804), when the Query of PDMP measure was initially finalized as a performance-based measure and only included Schedule II opioids:

++ Denominator: Number of Schedule II opioid or Schedule III or IV drugs electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.

++ Numerator: The number of prescriptions of Schedule II opioid or Schedule III or IV drugs in the denominator for which data from CEHRT is used at the time of prescribing to conduct a query of a PDMP for prescription drug history.

- What are potential barriers for MIPS eligible clinicians meeting the Query of PDMP measure as a performance-based measure?
- How should CMS account for varying levels of readiness and capacity for performance-based reporting, particularly for small and rural providers, including MIPS eligible clinicians?

[403] In the CY 2019 PFS final rule, the Query of PDMP only included Schedule II opioids (83 FR 59800 through 59804). We finalized the expansion of the Query of PDMP measure to include Schedule II opioids and Schedule III and IV drugs beginning with the CY 2023 performance period in the CY 2023 PFS final rule (87 FR 70062 through 70067).

- Are there specific exclusions that we should consider for performance-based reporting?
- What timeframe would allow for systems and process changes to account for a change of the Query of PDMP measure from an attestation measure to a performance-based measure while minimizing burden?
- Would adoption and use of Health IT Modules certified to the ''Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter'' certification criterion proposed by ONC in the HTI–2 proposed rule (89 FR 63547), if this criterion were to be finalized, help to mitigate previously identified burden associated with implementing and reporting on a performance-based ''Query of PDMP'' measure?
- How would the adoption and use of Health IT Modules certified to the proposed ''Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter'' certification criterion, if it were finalized, impact the numerator and denominator of a potential performance-based PDMP measure?

We are also requesting feedback on a broader set of performance-based measurement concepts that could help to advance our priorities with respect to the use of PDMPs to support the prevention and treatment of opioid use disorders. We are specifically interested in creating performance-based measures that allow MIPS eligible clinicians to leverage technology to improve care and reduce burden.

- What are other measure concepts we should consider that would allow us to focus on outcomes related to overdose prevention?
- Should we explore measures related to monitoring data from PDMPs that could assess multiple opioid prescriptions, opioid prescriptions from multiple prescribers, combined opioid and benzodiazepine prescriptions, or very high standardized dosage of opioids prescribed?
- What measure concepts related to the use of PDMPs are likely to involve the lowest effort and provide the highest value to the health care community?

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

(iii) RFI on the Modification of the Query of PDMP Measure To Include All Schedule II Drugs

Under the Controlled Substances Act (CSA),[404] the Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A drug's abuse rate is a factor used to determine its classification; for example, Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential.[405] We refer readers to Table 64 for information on each Schedule, including abuse potential, medicinal use, if any, and drug examples. For additional information, we refer readers to the listing of drugs and their schedule located at CSA Scheduling at: *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

TABLE 64: CONTROLLED SUBSTANCE SCHEDULES, DESCRIPTIONS, AND EXAMPLES[406]

Schedule	Description	Examples
Schedule I	No accepted medical use, are unsafe, and hold a high potential for abuse.	Heroin and LSD
Schedule II	Accepted medical use, high potential for abuse, abuse could lead to severe psychological or physical dependence.	Hydrocodone, methadone, meperidine, oxycodone, morphine, codeine, and amphetamine
Schedule III	Accepted medical use, less potential for abuse than schedule I or II substances, abuse may lead to moderate or low physical dependence or high psychological dependence.	Ketamine and anabolic steroids
Schedule IV	Accepted medical use, low potential for abuse relative to schedule III substances, abuse may lead to limited physical or psychological dependence relative to schedule III substances.	Alprazolam, clonazepam, diazepam, and tramadol
Schedule V	Accepted medical use, low potential for abuse relative to schedule IV substances, abuse may lead to limited physical or psychological dependence relative to schedule IV substances.	Pregabalin, cough preparations containing less than 200 mg per 100 mL or 100 g of codeine

[404] Public Law 91–513, tit. II, 84 Stat. 1236, 1242–84 (1970); codified, as amended, at 21 U.S.C. 801 *et seq.*

[405] United States Drug Enforcement Administration website located at: *https://www.dea.gov/drug-information/drug-scheduling.*

PDMPs are operated at the state level, and individual state requirements for reporting and use differ from state to state.[407] Currently, almost every state collects data on Schedules II, III, and IV drugs that are prescribed.[408]

In the CY 2023 PFS final rule, we finalized the expansion of the Query of PDMP measure to not only include Schedule II opioids, but also include Schedule III and IV drugs, beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70061 through 70068). We also finalized the measure description: for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history. We noted that expanding the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids would offer MIPS eligible clinicians a broader clinical picture aimed at overall patient safety efforts and would reduce burden by minimizing the need to create specialty reports within the EHR specific to capturing one class of drugs. For additional information on the Query of PDMP measure policies, we refer readers to the CY 2023 PFS final rule (87 FR 70061 through 70068) and the CY 2024 PFS final rule (88 FR 79353 through 79354).

To further promote the MIPS Promoting Interoperability performance category's capacity to incentivize the electronic exchange of health information through the use of PDMPs and thereby improve the quality of care by supporting appropriate prescribing of controlled substances, we are considering proposing in future rulemaking to expand the Query of PDMP measure to include all Schedule II drugs, rather than only including Schedule II opioids. Notably, this would expand the Query of PDMP measure to include controlled substances that are categorized as Schedule II drugs that are not opioids, such as central nervous system stimulants that can be prescribed for Attention-Deficit Hyperactivity Disorder (ADHD). We refer readers to Table 65 for examples of Schedule II opioid drugs and other Schedule II drugs.

TABLE 65: EXAMPLES OF SCHEDULE II OPIOID DRUGS AND OTHER SCHEDULE II DRUGS[409]

Schedule II Opioid Drugs	Other Schedule II Drugs
• Codeine • Fentanyl • Hydrocodone • Meperidine • Methadone • Morphine • Oxycodone	• Amphetamine • Lisdexamfetamine • Methamphetamine • Methylphenidate • Pentobarbital

For this RFI, we are inviting public comment and feedback on possible future expansion of the Query of PDMP measure to include all Schedule II (Schedule II opioids and other Schedule II drugs), Schedule III, and Schedule IV drugs in future rulemaking. We are also seeking responses to the following specific questions:

- What challenges exist, if any, around expanding the Query of PDMP measure to include all Schedule II drugs?
- What are the potential benefits versus risks of expanding the Query of PDMP measure to include all Schedule II drugs?
- Would expanding the Query of PDMP measure to Schedule II non-opioid drugs create barriers for patients appropriately prescribed Schedule II non-opioid drugs (for example, central nervous stimulants appropriately prescribed for ADHD)?
- How should CMS account for varying levels of readiness and capacity for MIPS eligible clinicians to meet an expanded scope of the measure, particularly for small and rural providers?
- What exclusions should be considered, if any?

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(j) RFI Regarding Performance-Based Measures

As finalized in the CY 2023 PFS final rule (87 FR 70071 through 70074), the measures under the Public Health and Clinical Data Exchange objective require MIPS eligible clinicians to indicate their level of active engagement with a PHA (Option 1 or Option 2), but do not measure the degree to which MIPS eligible clinicians are exchanging the data specified under each measure. Historically, the Public Health and Clinical Data Exchange objective has included measures that required reporting via attestation to account for factors such as the ongoing development of connections between MIPS eligible clinicians and PHAs, as well as variation across state and local requirements which govern reporting requirements for MIPS eligible clinicians, as established by the Stage 2 final rule for the Medicare EHR Incentive Program for Eligible Professionals (77 FR 54022). However,

[406] GAO–21–22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs; 21 U.S.C. 812; and the U.S. Drug Enforcement Administration website located at: *https://www.dea.gov/drug-information/drug-scheduling.*

[407] PDMP TTAC website located at: *https://www.pdmpassist.org/State.*

[408] PDMP TTAC website located at: *https://www.pdmpassist.org/Policies/Maps/PDMPPolicies.*

[409] For additional information on drug scheduling, we refer readers to the U.S. Drug Enforcement Administration website located at: *https://www.dea.gov/drug-information/drug-scheduling.*

given the ongoing advancements in public health reporting infrastructure across the nation, we are exploring whether alternatives to the current attestation-based measures can drive further improvements in the quality and consistency of reporting to PHAs and associated public health outcomes. This approach would align with the meaningful use of CEHRT criteria set forth in section 1848(o)(2)(A) of the Act, as previously discussed, which seek to improve the use of EHRs and health care quality over time.

In the CY 2025 PFS proposed rule (89 FR 62072 through 620750), we included an RFI regarding the Public Health and Clinical Data Exchange objective, including questions that sought feedback on replacing current attestation-based measures with measures that would require reporting of a numerator and denominator to better assess performance on measures included under the Public Health and Clinical Data Exchange objective. Because we only require that a MIPS eligible clinician indicate their level of active engagement (Option 1 or Option 2), attestation-based reporting does not capture aspects of the health information shared with PHAs that we are seeking to improve, such as comprehensiveness, quality, or timeliness.

We appreciate the responses received on our RFI in the CY 2025 PFS proposed rule, and we are seeking additional feedback from commenters through another RFI in this proposed rule. For this RFI, we are seeking to further refine our discussion of possible future measures to address commenter concerns and seek information to ensure any future proposals align with our goals of ultimately improving public health outcomes. Specifically, we are interested in new measure concepts for public health that would allow us to better focus on aspects of the data quality of public health reporting. We are seeking public comment on the following questions:

- What aspects of data quality and usability are most appropriate and valuable to measure in the context of the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category (for example, timeliness and completeness of reporting)?
- How could data completeness be defined? For instance, how should we define ''complete data?'' Should we consider a threshold approach, under which MIPS eligible clinicians would attest that they are successfully sending complete data for a minimum set of data elements to a PHA?

++ For example, for the Electronic Case Reporting measure, should we define a minimum threshold for completeness of certain data elements that are critical to public health and are supported in CEHRT (for example, data elements included in a specific version of the USCDI such as medications or medication dose)? If so, how should we define or set such thresholds?

- Are there other metrics available that we should consider in the Promoting Interoperability performance category that more directly relate to actions and outcomes that public health reporting is intended to enable (for example, overdose prevention)?
- Of the current types of public health data exchange reflected in the Public Health and Clinical Data Exchange objective measures, what use cases should we prioritize for a focus on data quality that would provide the highest value to the health care community while resulting in the least burden?

As part of our exploration of alternative measure concepts to assess performance on different aspects of the Public Health and Clinical Data Exchange objective measures, we are considering revising our approach to scoring the measures under the objective. Currently, MIPS eligible clinicians can earn 25 points for reporting on the 2 required measures and can earn an additional five bonus points for reporting any of 3 optional bonus measures.

We are seeking public comment on the following questions.

- Under a revised scoring approach, should we specify that MIPS eligible clinicians could earn 10 points for each required measure and five points for each bonus measure, with a maximum of 10 bonus points for a total of 30 points for the objective? Are there other scoring approaches for the Public Health and Clinical Data Exchange objective we should consider?
- Should we score all public health measures for which we finalize a numerator and denominator based on performance? Or should we only score a subset of measures based on performance?

In recent years, ONC has finalized updates to ONC Health IT Certification Program's certification criteria that are included in CEHRT to provide technical capabilities based on FHIR, an advanced, modern interoperability standard developed by HL7 to facilitate efficient, scalable and standardized health information exchange. [410] For instance, technology certified to the ''Standardized API for patient and population services'' criterion at 45 CFR 170.315(g)(10) provides that health IT modules certified to that criteria use FHIR API in Health IT Modules for data in a version or versions of the USCDI. In the HTI–1 final rule, ONC finalized that Health IT Modules certified to the ''Electronic case reporting'' criterion at 45 CFR 170.315(f)(5) may meet the requirements of the criterion by certifying to the HL7 FHIR Implementation Guide: Electronic Case Reporting—US Realm 2.1.0—STU 2 US to support electronic case reporting (89 FR 1231). In the HTI-2 proposed rule, ONC also proposed several updates to public health certification criteria that include reference to FHIR implementation specifications (89 FR 63537 through 63558). In 2024, ASTP/ONC released the Draft FHIR Federal Action Plan with a goal of building an ecosystem for innovation that strengthens consistent use of the FHIR standard.[411] ASTP/ONC, CMS, and CDC plan to continue to explore opportunities to leverage FHIR-based capabilities within certified health IT to support public health reporting, and we are seeking comment on how such future updates could impact the potential measure strategies discussed in this section. Specifically, we are seeking public comment on the following questions:

- What are the most promising uses of FHIR approaches to the public health reporting requirements under the Promoting Interoperability performance category? What approaches have the most potential to reduce the burden of reporting on MIPS eligible clinicians and increase the quality and timeliness of data submitted to PHAs?
- Approaches to public health reporting using FHIR have focused on greater automation of the interactions between health care providers and PHAs to reduce burden on providers and increase PHAs' ability to obtain the information they need. How might FHIR approaches to the exchange of public health data impact measurement of MIPS eligible clinicians' performance?
- Use of FHIR APIs could ultimately result in consolidation of disparate functions in EHRs that are currently being used to support different types of public health data exchange, for instance, through availability of an API

[410] Additional resources regarding FHIR are located at: *https://www.healthit.gov/topic/standards-technology/standards/fhir.*

[411] The Draft FHIR Federal Action Plan is located at: *https://www.healthit.gov/isp/about-fhir-action-plan.*

that makes data available for a range of public health use cases. If these approaches are implemented in certified health IT in the future, should we consider streamlining or reduce the number of measures required in the Promoting Interoperability performance category?

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(k) RFI Regarding Data Quality

Gaps and discrepancies in data accuracy, completeness, reliability, and consistency undermine the integrity of health information exchange. We believe MIPS eligible clinicians should be able to seamlessly exchange high-quality health information with patients, providers, and payers across systems. For the purposes of this discussion, we define data quality as the degree to which health information is accurate, complete, timely, consistent, and reliable. These factors increase the overall quality of health information that touches several aspects of the health care continuum: clinical information, patient safety, claims, provider data, eligibility, benefits, and administrative data.[412] Poor data quality poses direct threats to patient safety, especially when providers, including MIPS eligible clinicians, treat patients based on inaccurate or incomplete information.[413] Accountability, transparency, and improvement efforts also suffer when health care actors evaluate—or are evaluated based on—care quality and outcomes that do not reflect true performance due to unreliable or low quality data.[414] Poor quality data also poses risks beyond health care delivery and administration. Because health care data captured by EHRs serve as the foundation for public health reporting and clinical research using real world evidence, widespread deficits in data quality can adversely affect clinical innovation and public health decision-making.[415]

We encourage MIPS eligible clinicians to work with their health IT vendors to ensure the richest, highest quality data are sent to their exchange partners. This partnership can help ensure data validation; reduce burden between MIPS eligible clinicians and their exchange partners; and reduce unintended consequences and risks that come with low-quality data. For example, timely, complete data are needed for monitoring adverse events such as antimicrobial resistance. When providers send accurate data the first time, this reduces the need for prolonged testing and email exchanges between providers, PHAs, payers, and patients.

As the prevalence of electronic health information continues to grow, and as providers and payers continue to move to a value-based care model, the need for high-quality data will become increasingly important.[416] We want to both encourage and support MIPS eligible clinicians use of modern technologies and standards to ensure data are usable, complete, accurate, timely, and consistent. We are seeking public comment on the following questions:

- What data quality challenges does your health care organization experience (for example, discrepancies in data accuracy, completeness, reliability, and consistency)? How are you working to address data quality challenges? What data quality challenges persist longitudinally across your patient population(s)?
- What are the primary barriers to collecting high-quality data? What resources do you believe could help your organization address these challenges?
- What solutions have MIPS eligible clinicians found most effective to address data quality?
- What steps should CMS consider to drive further improvement in the quality and usability of health information being exchanged? How can CMS partner with MIPS eligible clinicians, industry, and Federal agencies to drive further improvements in the quality and usability of health information being exchanged? What methods should CMS and other partners explore to further rectify data quality issues in the health care community?

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B. Additional CY 2026 Modifications to the Quality Payment Program

1. MIPS Final Score Methodology

a. Performance Category Scores

(1) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, provide for a final score for each MIPS eligible clinician. Section 1848(q)(6)(A) of the Act specifies that, to then determine a MIPS payment adjustment factor for each MIPS eligible clinician for an applicable MIPS payment year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. We refer readers to section IV.B.2. of this proposed rule for further discussion of the performance threshold, and our calculation of MIPS payment adjustment factors, and our proposals with respect thereto.

[412] Schneider EC, Squires D. From last to first—Could the US health care system become the best in the world? New England Journal of Medicine. 2017 Sep 7;377(10):901–3. Located at: *https://www.nejm.org/doi/full/10.1056/nejmp1708704.*

[413] How to Use Digital Health Data to Improve Outcomes. Located at: *https://hbr.org/2022/09/how-to-use-digital-health-data-to-improve-outcomes.*

[414] Fukami T. Enhancing Healthcare Accountability for Administrators: Fostering Transparency for Patient Safety and Quality Enhancement. Cureus. 2024 Aug 2;16(8):e66007. Located at: *https://pubmed.ncbi.nlm.nih.gov/39221336.*

[415] Weng C. Clinical data quality: a data life cycle perspective. Biostat Epidemiol. 2020;4(1):6–14. Located at: *https://pubmed.ncbi.nlm.nih.gov/32258941.*

[416] For more information on EHR adoption over time, visit: *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

Section 1848(q)(2)(A) of the Act provides that the Secretary must assess each MIPS eligible clinician with respect to four performance categories in determining each MIPS eligible clinician's final score: quality, resource use (referred to as ''cost''), clinical practice improvement activities (referred to as ''improvement activities''), and meaningful use of certified EHR technology (referred to as ''Promoting Interoperability''). Section 1848(q)(2)(B) of the Act describes the measures and activities that must be specified under each performance category. Section 1848(q)(3) of the Act provides that we must establish performance standards with respect to the measures and activities specified under the four performance categories for a performance period, considering historical performance standards, improvement, and the opportunity for continued improvement. To calculate a final score for each MIPS eligible clinician for the performance period of an applicable MIPS payment year, section 1848(q)(5)(A) of the Act provides that we must develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards we have established with respect to applicable measures and activities specified for each performance category, using a scoring scale of 0 to 100.

In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for the CY 2026 performance period/2028 MIPS payment year, the scoring weights for each performance category are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

For the CY 2026 performance period/2028 MIPS payment year, we propose to update our scoring methodologies to respond to statutory requirements and impacts observed in performance data. Specifically, we propose to—

- Modify the existing approach for identifying measures impacted by limited measure choice and subject to topped out measure benchmarks by applying the existing analysis to MVPs;
- Apply defined topped out benchmarks for certain topped out measures for clinicians impacted by limited measure choice; and
- Modify the benchmarking methodology for scoring administrative claims-based measures in the quality performance category.

The policies proposed in this section of the proposed rule for scoring the quality performance category within traditional MIPS would apply to MVP scoring under § 414.1365(d)(3)(i) since a quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

We are not proposing any changes to our scoring policies for the cost, improvement activities, or Promoting Interoperability performance categories.

(2) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure, and Administrative Claims Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules, and § 414.1380(b)(1) for our current policies regarding, among other things, quality measure benchmarks, calculating total measure achievement points, calculating the quality performance category score, including achievement and improvement points, the small practice bonus, and scoring flexibilities (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, 87 FR 70088 through 70091, and 88 FR 79368 and 79369). In the CY 2025 PFS final rule (89 FR 98427 through 98439), we finalized policies for scoring topped out measures in specialty measure sets with limited measure choice at § 414.1380(b)(1)(iv)(C) and § 414.1380(b)(1)(ii)(E) and a Complex Organization Adjustment for virtual groups and APM Entities at § 414.1380(b)(1)(vii)(C).

(a) Scoring for Topped Out Measures With Limited Measure Choice

(i) Background on Scoring Topped Out Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2023 and 2025 PFS final rules (81 FR 77282 through 77287, 82 FR 53721 through 53727, 83 FR 59761 through 59765, 88 FR 70090 and 70091, and 89 FR 98429 through 98435), and § 414.1380(b)(1)(iv) for established topped out measure scoring policies.

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (81 FR 77136). Section 1848(q)(3)(B) of the Act requires that in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. Topped out measures do not provide an opportunity for continued improvement, nor do payment adjustments based on topped out measures incentivize clinicians to improve their care. As a result, we finalized policies in the CY 2018 Quality Payment Program final rule (82 FR 53723 through 53727) to identify and cap the scoring potential of such measures. Additionally, we established practices for the removal of such measures, such as establishing the topped out measure lifecycle, to continue to drive quality improvement in areas where such improvement is possible and necessary. The topped out measure lifecycle is described in the CY 2018 Quality Payment Program final rule (82 FR 53721 and 53727). We established at § 414.1380(b)(1)(iv)(B) that we would cap scoring for topped out measures at 7 measure achievement points in the second consecutive year that the measure benchmark is identified as topped out. If a measure has been identified as topped out for 3 consecutive years after being originally identified through the benchmarks, such measure may then be proposed for removal through notice-and-comment rulemaking (83 FR 59761). This timeline, however, is not fixed. We noted our concern that removal of topped out measures would leave clinicians with fewer than 6 applicable measures to report and that such removal in those instances would impact some specialties more than others (82 FR 53721). We stated that consideration for ensuring available applicable measures would be made when considering measure removals (83 FR 59763).

Although in the CY 2018 Quality Payment Program final rule (82 FR 53727), we established the topped out scoring cap to encourage MIPS eligible clinicians to submit measures that are not topped out, we created an exemption to this policy in the CY 2025 PFS final rule (89 FR 98430) for certain measures, which are frequently used by certain specialties impacted by limited measure choice. To address scoring

scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps, we finalized in the CY 2025 PFS final rule (89 FR 98429 through 98432) at § 414.1380(b)(1)(iv)(C) that beginning with the CY 2025 performance period/2027 MIPS payment year, topped out measures frequently used by certain specialties reporting specialty measure sets that are impacted by limited measure choice (specified in accordance with § 414.1380(b)(1)(ii)(E)) are not subject to the 7-point scoring cap. As part of the CY 2025 PFS final rule, we finalized at § 414.1380(b)(1)(ii)(E) that beginning with the CY 2025 performance period/2027 MIPS payment year, we will annually publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice (89 FR 98432). Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period, in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

In the CY 2025 PFS final rule (89 FR 98432 through 98435), we also finalized our approach for identifying the list of measures impacted by limited measure choice and subject to defined topped out measure benchmarks. Specifically, we finalized that each specialty measure set is reviewed by collection type to identify if the prevalence of topped out measures within such a set hinders a clinician's ability to successfully participate in the MIPS quality performance category. To make such a determination, we finalized that we analyze the ability of clinicians reporting the specialty measure sets under review to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements. Specifically, at the collection type level, each measure is assigned points based upon the current benchmarking data: new measures receive 7 or 5 points based on year in the program, measures with benchmarks are given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark are given 0 points. All measure set points are added together to get an output of scoring potential; the Medicare Part B claims collection type measure sets have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each measure set are then compared to the analysis threshold, which is currently 75 percent of available quality achievement points, based upon the number of available measures. Any measure sets that are not able to meet or exceed the threshold are flagged as 'at-risk.' Additional factors that we take into consideration include whether the topped out measure within the specialty measure set under review is considered a cross-cutting measure or is a broadly applicable measure, which we consider to be a measure included in three or more specialty sets. We also consider in reviewing topped out measures within a specialty measure set whether the specialty measure set contains more than ten measures, by collection type (89 FR 98432 through 98435).

(ii) Proposed Measures To Be Subject to the Defined Topped Out Measure Benchmark for the CY 2026 Performance Period/2028 MIPS Payment Year

Beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing to modify this previously finalized approach for identifying measures impacted by limited measure choice (89 FR 98432 through 98435) by applying the analysis and criteria to MVPs, in addition to the analysis of specialty measure sets. For the CY 2026 performance period/2028 MIPS payment year, we are also proposing to continue to use an analysis threshold of 75 percent of available quality achievement points in our determination of which measures would not be subject to the 7-measure achievement point cap. We refer readers to section IV.B.2.b.(2) of this proposed rule where we are proposing a performance threshold of 75 points for the CY 2026 through CY 2028 performance periods/2028 through 2030 MIPS payment years.

MVPs, like specialty measure sets, contain a limited set of quality measures for a clinician to choose from. We have received feedback from interested parties and independently verified that clinicians reporting MVPs in which there is high presence of topped out measures receiving the 7-point cap are often facing both limited measure choice and limited scoring opportunities. Given the limited number of available measures, the prevalence of topped out measures within an MVP may similarly hinder a clinician's ability to successfully participate in the MIPS quality performance category. Using the same methodology applicable to topped out measures within specialty measure sets, we propose to conduct an analysis of each MVP to identify if the prevalence of topped out measures within such MVP hinders a clinician's ability to successfully participate in the MIPS quality performance category. According to the approach finalized in the CY 2025 PFS final rule for specialty measure sets (89 FR 98432 through 98435), at the collection type level, each quality measure in an MVP would be assigned points based upon the current benchmarking data: new measures would receive 7 or 5 points based on year in the program, measures with benchmarks would be given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark would be given 0 points. All points would be added together to get an output of scoring potential; the Medicare Part B claims collection type measures would have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each MVP would be compared to the analysis threshold, which is currently 75 percent of available quality achievement points, based upon the number of available measures. Any MVPs that are not able to meet or exceed the threshold would be flagged as 'at-risk.' Additional factors that we would take into consideration would include whether the topped out measure within the MVP under review is considered a cross -cutting measure or is a broadly applicable measure, which we would consider to be a measure included in three or more MVPs or specialty sets. We would also consider in reviewing topped out measures within an MVP whether the MVP contains more than ten measures, by collection type.

Table 66 contains the list of measures that meet the criteria for topped out measures impacted by limited measure choice in specialty measure sets and MVPs, and for which we are proposing to apply the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year. We had considered proposing MIPS CQM 424: Perioperative Temperature Management to be subject to the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year since it met the criteria for topped out measures in specialty measure sets impacted by limited measure choice, according to the methodology finalized in the CY 2025

PFS final rule (89 FR 98432 through 98435). However, we are not proposing that measure for the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year because it is being proposed for removal for the CY 2026 performance period/2028 MIPS payment year in section IV.A.4.d.(1)(c)(ii) of this proposed rule.

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TABLE 66: PROPOSED TOPPED OUT MEASURES IMPACTED BY LIMITED MEASURE CHOICE AND SUBJECT TO DEFINED TOPPED OUT MEASURE BENCHMARKS FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Measure ID	Collection Type	Measure Title
141	Medicare Part B Claims	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care
143	eCQM, MIPS CQM	Oncology: Medical and Radiation - Pain Intensity Quantified
144	MIPS CQM	Oncology: Medical and Radiation - Plan of Care for Pain
249	Medicare Part B Claims, MIPS CQM	Barrett's Esophagus
250	Medicare Part B Claims, MIPS CQM	Radical Prostatectomy Pathology Reporting
320	Medicare Part B Claims	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
350	MIPS CQM	Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy
351	MIPS CQM	Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation

Measure ID	Collection Type	Measure Title
360	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
364	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
395	Medicare Part B Claims, MIPS CQM	Lung Cancer Reporting (Biopsy/Cytology Specimens)
396	MIPS CQM	Lung Cancer Reporting (Resection Specimens)
397	Medicare Part B Claims, MIPS CQM	Melanoma Reporting
405	MIPS CQM	Appropriate Follow-up Imaging for Incidental Abdominal Lesions
406	Medicare Part B Claims, MIPS CQM	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients
430	MIPS CQM	Prevention of Post-Operative Nausea and Vomiting (PONV) - Combination Therapy
440	MIPS CQM	Skin Cancer: Biopsy Reporting Time - Pathologist to Clinician
463	MIPS CQM	Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics)
477	MIPS CQM	Multimodal Pain Management

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We request comments on the proposal to include MVPs in the analysis used to identify the list of topped out measures impacted by limited measure choice beginning with the CY 2026 performance period/2028 MIPS payment year.

We also request comments on the proposal to continue using an analysis threshold of 75 percent of available quality achievement points in our determination of which measures would be subject to the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

We also request comments on the proposed list of topped out measures impacted by limited measure choice and subject to the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

(b) Benchmark Methodology for Scoring Administrative Claims-Based Quality Measures in the Quality Performance Category

(i) Background on Scoring Administrative Claims Measures in the Quality Performance Category

Under § 414.1325, we specify that there is no data submission requirement for cost measures or administrative claims measures in the quality performance category as these measures are calculated on behalf of participants by CMS using administrative claims data. CMS calculates MIPS eligible clinicians' performance on these measures using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period. In the CY 2017 Quality Payment Program final rule (81 FR 77130), we finalized a policy that clinicians would be scored on applicable administrative claims-based global or population health (henceforth referred to only as population health measures) in addition to the six required submitted quality measures. We refer readers to the CY 2017 Quality Payment Program final rule and the CY 2021 PFS final rule (81 FR 77130 through 77136 and 85 FR 84871 through 84873, respectively) and § 414.1325(a)(2)(i) for our previously established policies regarding administrative claims measures in the quality performance category.

We have codified our quality performance category scoring policies at § 414.1380(b)(1). Under § 414.1380(b)(1)(i), except as provided under paragraph (b)(1)(i)(C) beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) based on their performance on each measure. At § 414.1380(b)(1)(i)(A)(*2*)(*ii*), each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points.

We also refer readers to the CY 2017, CY 2018, CY 2019 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through

53718, and 83 FR 59841 through 59842, respectively) and CY 2020, CY 2021, and CY 2023 PFS final rules (84 FR 63014 through 63016, 85 FR 84901 through 84904, and 87 FR 70088 through 70090, respectively) for our previously established benchmarking policies.

In the CY 2017 Quality Payment Program final rule (81 FR 77276 through 77282), we finalized that we will use MIPS eligible clinicians' performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or quality measures where we do not have comparable data from the baseline period. In these cases, we will calculate benchmarks using data submitted during the applicable performance period. We defined the baseline period to be the 12-month Calendar Year that is 2 years prior to the performance period for the MIPS payment year.

Moreover, in the CY 2023 PFS final rule (87 FR 70088 through 70090), we finalized beginning with the CY 2023 performance period/2025 MIPS payment year, that we would score administrative claims measures using performance period benchmarks (§ 414.1380(b)(1)(ii)(D)). We stated that we believe that using a performance period benchmark to score these measures would allow for scores that are more reflective of current performance, while adding no additional burden to clinicians.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77282), we establish benchmarks as a standardized method to evaluate and compare the performance of quality measures relative to the performance of peers. We use a decile-based approach to create benchmarks, which is done by dividing measure performance rates into deciles, with each decile containing a range of performance rates. CMS assigns measure achievement points based on which benchmark decile range the measure performance rate falls between. CMS assigns partial points to prevent performance cliffs for performance rates near the decile breaks. Additionally, the four administrative claims-based quality measures currently available to MIPS eligible clinicians are inverse measures, meaning the lower the measure performance rate, the higher the measure achievement points. Therefore, lower benchmark deciles are associated with higher performance rates. MIPS eligible clinicians with higher performance rates of administrative claims-based measures (for example, the number of acute unplanned cardiovascular-related admissions per 100 person-years at risk for admission during the measurement period) will have rates that fall into lower benchmark deciles and will score fewer measure points than MIPS eligible clinicians with lower measure performance rates.

TABLE 67: EXAMPLE OF USING DECILE-BASED BENCHMARK AND PARTIAL POINTS TO ASSIGN ACHIEVEMENT POINTS FOR PERFORMANCE ON THE RISK-STANDARDIZED ACUTE CARDIOVASCULAR-RATED HOSPITAL ADMISSION RATES FOR PATIENTS WITH HEART FAILURE UNDER THE MERIT-BASED INCENTIVE PAYMENT SYSTEM ADMINISTRATIVE CLAIMS-BASED QUALITY MEASURE

Benchmark Decile	Example Benchmark Ranges (Performance Rate)	Possible Points
Benchmark Decile 1	81.68-75.77	1.0–1.9
Benchmark Decile 2	75.76-73.44	2.0-2.9
Benchmark Decile 3	73.43-71.92	3.0-3.9
Benchmark Decile 4	71.91-70.81	4.0-4.9
Benchmark Decile 5	70.80-69.72	5.0-5.9
Benchmark Decile 6	69.71-68.79	6.0-6.9
Benchmark Decile 7	68.78-67.72	7.0-7.9
Benchmark Decile 8	67.71-66.51	8.0-8.9
Benchmark Decile 9	66.50-64.97	9.0-9.9
Benchmark Decile 10	64.96 and below	10

Table 67 provides an example of using benchmark deciles along with partial achievement points to assign achievement points for the Risk-standardized Acute Cardiovascular-rated Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System administrative claims-based quality measure under our current methodology. For this measure, that outcome is the number of acute unplanned cardiovascular-related admissions per 100 person-years at risk for admission during the measurement period. Additionally, this measure is an inverse measure. The following formula is used to determine the number of partial points awarded to the MIPS eligible clinician:

Benchmark Decile # + [(performance rate − bottom of benchmark decile range)/(top of benchmark decile range − bottom of benchmark decile range)] = Quality Measure Achievement Points.

For the example measure presented in Table 67, the median performance rate is 69.71, which falls within Benchmark Decile 6. If a MIPS eligible clinician's performance rate for the measure is 73.82, the MIPS eligible clinician's performance rate falls within Benchmark Decile 2, for which the MIPS eligible clinician may receive between 2.0 and 2.9 achievement points. Based on the partial points calculation formula, the clinician would receive 0.83 partial points, resulting in a quality measure score of 2.83 out of 10 achievement points for the administrative claims-based quality measure under this example.

Based on our analysis of quality measure scores for the CY 2022 performance period/2024 MIPS payment year, we observed lower scores for the administrative claims-based quality measures than for the non-administrative claims-based quality measures. Means for administrative claims-based quality measure achievement scores tend to be around 5 to 6 points out of 10, whereas means for non-administrative claims-based measures tend to be around 7 to 9 points out of 10.

There are key factors that may contribute to lower measure scores for the administrative claims-based measures, compared to the other quality measures. First, administrative claims-based quality measures are scored against a performance period benchmark, rather than a benchmark determined based on historical data, which is used, wherever possible, for non-administrative claims-based quality measures. Benchmarks established based on historical data provide MIPS eligible clinicians with helpful performance targets in advance of or during the performance period. Meanwhile, the performance period benchmarks for the administrative claims-based quality measures do not provide information about performance targets before or during the performance period. However, since these measures require no data submission, using performance period benchmarks allows for the calculation of more current and representative measure scores that better track clinician performance and progress over time. We are concerned that the current decile-based, performance period benchmark is a key contributor to lower scores for the administrative claims-based quality measures. Specifically, the current quality benchmark methodology uses a decile range based on linear percentile distributions and assigns 5.0 to 6.9 achievement points to clinicians with measure performance rates within the 50th to 60th percentiles. As a result, clinicians who perform around the median on administrative claims-based measures will receive achievement points below 7.5 points, the equivalent of the performance threshold.

Second, in traditional MIPS, MIPS eligible clinicians are scored on each administrative claims-based quality measure for which the established case minimum is met, and a benchmark can be calculated. Further, not all MIPS eligible clinicians are scored on administrative claims-based quality measures. Therefore, if a clinician is scored on one or multiple administrative claims-based quality measures with measure achievement scores around 5 to 6 points out of 10, these measure scores may have the effect of lowering the MIPS eligible clinician's quality performance category score, especially in comparison to a clinician who is not scored on any administrative claims-based quality measure.

(ii) Background on Scoring Measures in the Cost Performance Category

In the CY 2025 PFS final rule (89 FR 98438 through 98446), we addressed concerns raised by MIPS eligible clinicians about cost performance category scoring having a negative impact on their final MIPS score. We noted how, under the cost scoring methodology for the CY 2017 performance period/2019 MIPS payment year through the CY 2023 performance period/2025 MIPS payment year, a MIPS eligible clinician scoring near the median on a cost measure would need to score perfectly (or nearly perfectly) within the other three performance categories to receive a final score slightly above the performance threshold and to avoid a negative payment adjustment (89 FR 98439 through 98442). To address this concern, we modified the methodology for scoring the cost performance category, as set forth in § 414.1380(b)(2), beginning with the CY 2024 performance period/2026 MIPS payment year (89 FR 98441 through 98446; 89 FR 98563).

The cost scoring methodology we finalized at § 414.1380(b)(2) is now based on standard deviation, median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose average costs attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians that had the measure attributed them, we assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2024 performance period/2026 MIPS payment year, if a MIPS eligible clinician's average costs under the measure is equal to the median costs of all MIPS eligible clinicians attributed the same measure, then we assign the MIPS eligible clinician 7.5 achievement points, based on a performance threshold of 75 as finalized at § 414.1405(b)(9)(iii). For each cost measure, the cut-offs for benchmark ranges are calculated based on standard deviations, expressed in dollars, from the median. We refer readers to Table 68 for an example of how the cost scoring methodology could be implemented for a specific cost measure when the performance threshold is set to 75 points, which is the same example we provided in the CY 2025 PFS final rule (89 FR 98441 and 98442).

TABLE 68: EXAMPLE OF IMPLEMENTATION OF THE PROPOSED COST SCORING METHODOLOGY FOR ASSIGNMENT OF ACHIEVEMENT POINTS FOR PERFORMANCE ON THE SCREENING/SURVEILLANCE COLONOSCOPY COST MEASURE

Benchmark Range	Points	Proposed Methodology for Bottom of Benchmark Range ($)	Example Benchmark Ranges
Benchmark Range 1	1 - 1.9	Median cost + (2.75 x standard deviation)	$1341.93 - $1308.10
Benchmark Range 2	2 - 2.9	Median cost + (2.5 x standard deviation)	$1308.09 - $1.274.26
Benchmark Range 3	3 - 3.9	Median cost + (2.25 x standard deviation)	$1274.25 - $1240.43
Benchmark Range 4	4 - 4.9	Median cost + (2 x standard deviation)	$1240.42 - $1172.75
Benchmark Range 5	5 - 5.9	Median cost + (1.5 x standard deviation)	$1172.74 - $1105.08
Benchmark Range 6	6 – 6.9	Median cost + (1 standard deviation)	$1105.07 - $1037.40
Benchmark Range 7	7 - 7.9	Median cost + (0.5 x standard deviation)	$1037.39 - $902.05
Benchmark Range 8	8 - 8.9	Median cost - (0.5 x standard deviation)	$902.04 - $834.38
Benchmark Range 9	9 - 9.9	Median cost - (1 x standard deviation)	$834.37 - $766.70
Benchmark Range 10	10	Median cost - (1.5 x standard deviation)	$766.69 and below

This modification in our scoring methodology for cost measures aligns the assignment of achievement points for cost measures so that clinicians with costs near the measure's 50th percentile (median) do not receive a disproportionately low score. Our intended goal for this modification to the scoring methodology was to ensure that MIPS eligible clinicians who deliver care at an average cost near the median costs for all MIPS eligible clinicians attributed the measure receive scores at, or very close to, the performance threshold-derived score (89 FR 98442 and 98443). Additionally, this modification addressed MIPS eligible clinicians' concerns that cost measure scoring negatively impacts their final scores more than other performance categories, including disparate negative effects for MIPS eligible clinicians who are scored on the cost performance category compared to clinicians not scored on the cost performance category (89 FR 98443).

(iii) Proposed Modification to Scoring Methodology for Administrative Claims-Based Quality Measures in the Quality Performance Category Beginning With CY 2025 Performance Period/2027 MIPS Payment Year

Given the similarities between scoring cost measures and administrative claims-based quality measures, we are proposing to modify the methodology for scoring the administrative claims-based measures within the quality performance category beginning with the CY 2025 performance period/2027 MIPS payment year. The proposed administrative claims-based quality measure scoring methodology would be based on standard deviation, median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose performance rate under an administrative claims-based measure would be equal to the median performance rate for all MIPS eligible clinicians that are scored on that measure, we would assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2026 performance period/2028 MIPS payment year, the median would have an achievement point value of 7.5, based on a performance threshold of 75 points as proposed in section IV.B.2.b.(2) of this proposed rule. For each administrative claims-based quality measure, the cut-offs for benchmark ranges would be calculated based on standard deviations from the median.

The benchmark ranges, the median, and the performance threshold-derived achievement point values aligned with the median would be dynamic and responsive to changes in performance rates assessed by administrative claims-based quality measures and performance thresholds for each CY performance period/MIPS payment year. The performance threshold-derived point values could change based on the performance threshold established for each performance period/MIPS payment year. The standard deviations from the median used to determine cutoffs for benchmark ranges for each year would be reviewed for any necessary updates on an annual basis based on performance across MIPS eligible clinicians and the performance threshold established for the performance period/MIPS payment year. We would perform analyses when the performance threshold changes to set the benchmark ranges. To determine the benchmark ranges, we would adhere to the following principles: (1) center the majority of performance rates around the performance threshold-derived point value; (2) determine benchmark ranges according to the statistical distribution curve of the performance rate; and (3) distribution of achievement points for administrative claims-based quality measures should be reflective of overall program performance. We refer readers to Table 69 for an example of how the proposed administrative claims-based quality measure scoring methodology could be implemented for a specific quality measure when the performance threshold is set to 75 points.

TABLE 69: EXAMPLE OF IMPLEMENTATION OF THE PROPOSED SCORING METHODOLOGY FOR ASSIGNMENT OF ACHIEVEMENT POINTS FOR PERFORMANCE ON THE RISK-STANDARDIZED ACUTE CARDIOVASCULAR-RATED HOSPITAL ADMISSION RATES FOR PATIENTS WITH HEART FAILURE UNDER THE MERIT-BASED INCENTIVE PAYMENT SYSTEM ADMINISTRATIVE CLAIMS-BASED QUALITY MEASURE

Benchmark Range	Points	Proposed Methodology for Bottom of Benchmark Range	Example Benchmark Ranges (Performance Rate)
Benchmark Range 1	1 - 1.9	Median Performance Rate + (2.75 x standard deviation)	81.77-80.69
Benchmark Range 2	2 - 2.9	Median Performance Rate + (2.5 x standard deviation)	80.68-79.59
Benchmark Range 3	3 - 3.9	Median Performance Rate + (2.25 x standard deviation)	79.58-78.49
Benchmark Range 4	4 - 4.9	Median Performance Rate + (2 x standard deviation)	78.48-76.30
Benchmark Range 5	5 - 5.9	Median Performance Rate + (1.5 x standard deviation)	76.29-74.10
Benchmark Range 6	6 – 6.9	Median Performance Rate + (1 standard deviation)	74.09-71.92
Benchmark Range 7	7 - 7.9	Median Performance Rate + (0.5 x standard deviation)	71.91-67.53
Benchmark Range 8	8 - 8.9	Median Performance Rate - (0.5 x standard deviation)	67.52-65.34
Benchmark Range 9	9 - 9.9	Median Performance Rate - (1 x standard deviation)	65.33-63.15
Benchmark Range 10	10	Median Performance Rate - (1.5 x standard deviation)	63.14 and below

Continuing with the Risk-standardized Acute Cardiovascular-rated Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System administrative claims-based quality measure example, now presented in Table 69 as an example of implementation of the proposed scoring methodology, the median (50th percentile) performance rate would remain 69.71. Under the proposed scoring methodology, for the CY 2025 performance period/2027 MIPS payment year, a MIPS eligible clinician with a performance rate equal to the median performance rate of all MIPS eligible clinicians scored on that measure would receive 7.5 achievement points out of 10 possible achievement points, which falls within the Benchmark Rage 7 in Table 69.

Using the same example as previously presented in section IV.B.1.a.(2)(b)(i) of this proposed rule, we would apply the proposed scoring benchmark methodology as shown in Table 69 to a MIPS eligible clinician with a performance rate for this measure that is 73.82 (a rate of 4.11 above the median rate). Based on the analysis of data in this example, the standard deviation for the example administrative claims-based quality measure would be 4.38. This value for the standard deviation would then be used to calculate the benchmark ranges in Table 69 by plugging in this value for the standard deviation for each benchmark range. For example, ''69.71 + (1 × 4.38)'' would be calculated for ''Median performance rate + (1 standard deviation)'' for the bottom of Benchmark range 6. As shown with the example in Table 69, under our proposed scoring methodology, the MIPS eligible clinician's average performance rate of 73.82 percent would fall within Benchmark Range 6 for the example administrative claims-based quality measure, for which the MIPS eligible clinician may receive between 6.0 and 6.9 achievement points.

In alignment with the cost measure scoring methodology finalized last year (89 FR 98563), this proposed scoring methodology for administrative claims-based quality measures would be based on standard deviation, median, and an achievement point value derived from the performance threshold. For each administrative claims-based quality measure, standard deviations would be used to calculate the benchmark ranges which are then used to determine the measure scores for each MIPS eligible clinician scored on that measure based on their measure performance rate.

Under our proposal to modify the administrative claims-based quality measure scoring methodology for individual measures, we would continue to use our established formula to assign partial achievement points:

Benchmark Range # + [(performance rate − bottom of benchmark range)/(top of benchmark range − bottom of benchmark range)] = Administrative Claims-based Quality Measure Achievement Points.

As a result, using the example shown in Table 69, under our proposed administrative claims-based scoring methodology, the MIPS clinician would receive 6.12 quality measure achievement points (6 + [(73.82 − 74.09)/71.92 − 74.09)] = 6.12). The assignment of 6.12 achievement points under the proposed administrative claims-based quality measure scoring methodology would be closer to the performance threshold equivalent of 7.5 than the assignment of 2.83 achievement points under the current scoring methodology, as discussed in our previous example in section IV.B.1.a.(2)(b)(i) of this proposed rule.

This proposed modification in our scoring methodology for administrative claims-based quality measures would align the assignment of achievement points for such measures so that clinicians with performance rates near the measure's 50th percentile (median) would not receive a disproportionately low score. Based on our analyses utilizing data from the CY 2024 performance period/2026 MIPS payment year, this proposed methodology would increase the mean quality performance category score from 76.75 out of 100 to 80.42 out of 100 (an increase of 3.67 points). Further, this proposed scoring methodology would increase the means for each administrative claims-based quality measure score by amounts ranging from 1.46 to 1.96 points. For example, the mean measure score for the Risk-

Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System administrative claims-based quality measure would increase from 5.59 points out of 10 to 7.05 points out of 10. Our analyses showed that, under our proposed methodology, the mean final score would increase by 1.63 points for MIPS eligible clinicians assessed on at least one administrative claims-based quality measure and receiving a quality performance category score.

Specifically, our analyses support the intended goal for the proposed modification to the scoring methodology: MIPS eligible clinicians who perform near the median performance rate for all MIPS eligible clinicians scored on the administrative claims-based measure would receive scores at, or very close to, the performance threshold-derived score. Additionally, this proposed modification would align the scoring methodologies for administrative claims-based measures in the quality and cost performance categories.

We are also proposing to modify § 414.1380(b)(1)(i) to specify that, except as specified otherwise under paragraph (b)(1)(ii), the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. We did not propose any modifications to the remainder of the language currently at § 414.1380(b)(1)(i).

We also propose to codify our proposed benchmarking methodology at § 414.1380(b)(1)(ii)(D) to specify that beginning with the CY 2025 performance period/2027 MIPS payment year, for each administrative claims-based quality measure, CMS determines 10 benchmark ranges based on the median performance rate of all MIPS eligible clinicians scored on the measure, plus or minus standard deviations and that CMS awards achievement points based on which benchmark range a MIPS eligible clinician's performance rate for an administrative claims-based quality measure corresponds. We also propose to codify at § 414.1380(b)(1)(ii)(D) that, beginning with the CY 2025 performance period/2027 MIPS payment year, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose performance rate is equal to the median performance for all MIPS eligible clinicians scored on the measure.

We seek comments on our proposals to modify our scoring methodology for administrative claims-based quality measures. We also request comments on our proposal to codify the scoring methodology for administrative claims-based quality measures in the quality performance category at §§ 414.1380(b)(1)(i) and 414.1380(b)(1)(ii)(D).

2. MIPS Payment Adjustments

a. Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), CY 2023 PFS final rule (87 FR 70096 through 70102), CY 2024 PFS final rule (88 FR 79373 through 79380), and CY 2025 PFS final rule (89 FR 98448 through 98455).

b. Establishing the Performance Threshold

(1) Statutory Authority and Background

As discussed in this section of the proposed rule, to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. These special rules are no longer applicable for establishing the performance threshold beginning with the CY 2022 performance period/2024 MIPS payment year. We refer readers to the CY 2024 PFS proposed rule (88 FR 52596) for further information on these previously applicable requirements as they explain our prior computations of the performance threshold.

In the CY 2025 PFS final rule (89 FR 98448 through 98451), we selected the mean as the methodology for determining the performance threshold for the CY 2025 performance period/2027 MIPS payment year through CY 2027 performance period/2029 MIPS payment year. We codified this policy in our regulation at § 414.1405(g)(2), providing that, for each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b)(10) (89 FR 98448 through 98451; 89 FR 98564). In the CY 2025 PFS final rule, we established the performance threshold for the CY 2025 performance period/2027 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data (89 FR 98451 through 98455). We also codified this performance threshold in our regulation at § 414.1405(b)(10)(i) (89 FR 98451 through 98455; 89 FR 98564).

We note that, in previous years, we have established the performance threshold for each performance period during the rulemaking cycle immediately preceding the performance period. However, section 1848(q)(6)(D)(i) of the Act does not specify when the Secretary shall compute a performance threshold that would apply for each MIPS payment year. Instead, section 1848(q)(6)(D)(i) of the Act provides the Secretary shall compute a performance threshold for each MIPS payment year based on the

mean or median (selected once every 3 years) of the MIPS final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. We have determined that the performance threshold may be established with respect to the applicable year at any time as long as the performance threshold continues to be based on a prior period specified by the Secretary. In other words, we could establish a performance threshold that would apply to multiple MIPS payment years. We note that we may not always establish the performance threshold for multiple MIPS payment years, but we will consider this as an option as we continue to ensure that the performance threshold is truly reflective of MIPS eligible clinicians' performance in MIPS. Due to several large programmatic changes (such as, transitioning to reporting MVPs and digital quality measures and potential introduction of ''Core Elements'' for selection of quality measures in MVPs) discussed further in sections IV.A.3.b. and IV.A.4.c. of this proposed rule, establishing the same performance threshold for the 2028, 2029, and 2030 payment years would allow us to provide stability and predictability to MIPS eligible clinicians as they adapt to and implement our policy changes for MIPS.

As further discussed under section IV.B.2.b.(2) of this proposed rule, we are proposing to continue using the mean of the final scores for all MIPS eligible clinicians from the CY 2017 performance period/2019 MIPS payment year to establish the performance threshold as 75 points for the CY 2026 performance period/2028 MIPS payment year through the CY 2028 performance period/2030 MIPS payment year. We recognize that our proposal to establish the performance threshold for MIPS payment years 2028, 2029, and 2030 extends beyond the period for which we have established the mean methodology to determine the performance threshold. However, given the current statutory requirement, which allows us to reassess the methodology every three years, there is no requirement that prevents us from setting the methodology for a longer time frame. We plan to reassess the methodology in future rulemaking.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), CY 2023 PFS final rule (87 FR 70096 through 70100), CY 2024 PFS final rule (88 FR 79373 through 79380), and CY 2025 PFS final rule (89 FR 98448 through 98455).

We codified the performance thresholds for each of the first 9 years of MIPS at § 414.1405(b)(4) through (10). These performance thresholds are shown in Table 70.

TABLE 70: PERFORMANCE THRESHOLDS FOR THE CY 2017 PERFORMANCE PERIOD/2019 MIPS PAYMENT YEAR THROUGH THE CY 2025 PERFORMANCE PERIOD/ 2027 MIPS PAYMENT YEARS

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period	2024 MIPS Performance Period	2025 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 points	75 points	75 points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points	0 points	0 points

(2) Proposed Performance Threshold for the CY 2026 Performance Period/2028 MIPS Payment Year Through the CY 2028 Performance Period/2030 MIPS Payment Year

We are proposing to use the mean of 75 points from the CY 2017 performance period/2019 MIPS payment year as it continues to be the most appropriate for establishing the performance threshold for the 2028, 2029, and 2030 MIPS payment years for several reasons. As further described in this section of the proposed rule, these reasons include providing stability and predictability for MIPS eligible clinicians, allowing MIPS eligible clinicians to gain experience with MVPs and other new MIPS policies, and continuing to support solo, small, and rural practices.

TABLE 71: POSSIBLE VALUES FOR THE PERFORMANCE THRESHOLD FOR THE 2028, 2029, AND 2030 MIPS PAYMENT YEARS

MIPS Payment Years	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	2024 MIPS Payment Year	2025 MIPS Payment Year
Mean	74.65	87.00	85.65	89.47	89.22	82.71	83.18

At the time of this proposed rule, we have data available on MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year through CY 2023 performance period/2025 MIPS payment year. As shown in Table 72, we calculated the mean values of MIPS eligible clinicians' final scores for each year from the CY 2017 performance period/2019 MIPS payment year through the CY 2023 performance period/2025 MIPS payment year. The final scores for the CY 2024 performance period/2026 MIPS payment year were not finalized in time for this proposed rule and, therefore, the mean final score for the CY 2024 performance period/2026 MIPS payment year was not included for consideration as a potential performance threshold value for the 2028, 2029, and 2030 MIPS payment years. As discussed further in this section of the proposed rule, we believe that the mean of 75 points from the CY 2017 performance period/CY 2019 MIPS payment year continues to be the most appropriate option that would provide stability and predictability for MIPS eligible clinicians while still encouraging high quality of care.

First, when looking at the data for purposes of establishing a performance threshold for the 2028 through 2030 MIPS payment years, we did not consider any data from the CY 2019 performance period/2021 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year, as they were impacted by the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19), which we discussed in further detail in the CY 2025 PFS final rule (89 FR 98451 through 98453). The geographic differences of COVID–19 incidence rates along with different impacts resulting from Federal, State, and local laws and policy changes implemented in response to the PHE for COVID–19 may have affected which MIPS eligible clinicians were able to submit data for the CY 2019 performance period. This may have led to final scores that were not wholly representative of performance for all MIPS eligible clinicians. Also, for the CY 2020 performance period/2022 MIPS payment year and the CY 2021 performance period/2023 MIPS payment year, we extensively applied our reweighting policies, described under § 414.1380(c)(2)(i), to MIPS eligible clinicians nationwide due to the PHE for COVID–19.

Inherently, these actions, particularly re-weighting the performance categories, skewed the final scores from those years such that they are not an appropriate indicator for future performance of MIPS eligible clinicians. Specifically, we are concerned that the final scores during the PHE for COVID–19 reflect the performance of only MIPS eligible clinicians that may have been less impacted by the pandemic, and do not accurately represent MIPS eligible clinician performance overall during this period. Since the Federal PHE for COVID–19 expired on May 11, 2023,[417] many of the flexibilities and exceptions applied during the PHE for COVID–19, such as the extreme and uncontrollable circumstances reweighting policies described under § 414.1380(c)(2)(i), are no longer being applied in the context of the pandemic. In the interest of establishing a performance threshold using data that is reflective of clinician performance that is not affected by the-PHE for COVID–19, continuing to use data from the CY 2017 performance period/2019 MIPS payment year to establish a performance threshold for the 2028, 2029 and 2030 MIPS payment years will allow us time to gather additional data that is more reflective of clinician performance outside of the PHE for COVID–19. We acknowledge more recent data will be available between CY 2026 performance period/2028 MIPS payment year through CY 2028 performance period/2030 MIPS payment year; however, with the various programmatic changes discussed in this section of the proposed rule, we aim to provide stability and predictability to MIPS eligible clinicians as they transition, implement, and adapt to these changes.

As new MVPs and their related changes are being introduced into the program, and as more MIPS eligible clinicians transition to MVP reporting, we want to provide some stability for MIPS eligible clinicians and allow time for more MVP data to become available. Specifically, in section IV.A.3. of this proposed rule, we discuss several policies to support our goal of phasing out traditional MIPS and fully transitioning to MVP reporting. As stated in the CY 2025 PFS proposed rule, we discussed that we anticipate to fully transition to MVPs by the CY 2029 performance period/2031 MIPS payment year (89 FR 62012). In section IV.A.3.b. of this proposed rule, we are seeking comments in an RFI for a potential policy wherein MVP Participants would select one quality measure from a subset of quality measures in each MVP, referred to as ''Core Elements'' and MVP Participants would select the other three required quality measures and would still have to meet existing MVP reporting requirements. We are considering proposing the Core Elements policy in the CY 2027 PFS proposed rule and proposing the policy for implementation prior to sunsetting traditional MIPS. Further, as discussed in section IV.A.4.c. of this proposed rule, we aim to fully transition to a digital quality measure (dQM) landscape that promotes interoperability and increases the value of reporting quality measure data. As we continue to consider these potential policy changes over the next several years, we aim to provide consistency to MIPS eligible clinicians by maintaining the performance threshold at 75 points for the 2028, 2029, and 2030 MIPS payment years. Meanwhile, we will continue to evaluate how the performance threshold can best reflect clinicians' performance in MIPS.

While the CY 2018 performance period/2020 MIPS payment year's data predate the PHE for COVID–19, we continue to be concerned that an

[417] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

increase in the performance threshold will inadvertently harm certain clinician types, specifically small practices and solo practitioners. As we stated in the CY 2024 PFS final rule, we want to consider the impacts of the performance threshold and its related policies on small practices (88 FR 79377). As discussed in the CY 2025 PFS final rule, we have received feedback that many small practices and solo practitioners face challenges in their ability to participate in MIPS, including the costs to implement and maintain certified electronic health record (EHR) technology (CEHRT), staff and training costs, and limited staff capacity to manage the complexity of the program (89 FR 98451 through 98453). As discussed in the CY 2025 PFS final rule, we also learned that increases in the performance threshold add administrative and financial burden for small practices that discourage their participation in MIPS (89 FR 98451 through 98454).

Further, in a survey distributed during the summer of CY 2024, we learned that, of the small practices and solo practitioners that participated in the survey, the three major barriers for submitting MIPS data included: the burden of data collection and submission, lack of administrative support, and high costs associated with participating in the program. The small practices and solo practitioners that responded to the survey indicated that simplified reporting requirements, free technical assistance, and better informational resources may improve their participation in MIPS.

Though we have several policies within MIPS that continue to support small and solo practices, including scoring and reweighting policies, we are interested in understanding how to best support small practices and enhance their ability to successfully participate in MIPS as MIPS continues to evolve (89 FR 98451 through 98453). As such, we continue to perform qualitative analysis through engagement with small practices, third party intermediaries, and other interested parties to gather information about the experience of small practices participating in the program. Maintaining a performance threshold of 75 points for the 2028, 2029, and 2030 MIPS payment years would allow us to continue developing strategies to reduce barriers for small practices and solo practitioners participating in MIPS.

Finally, as discussed in section IV.B.1.a.(2) of this proposed rule, we are continuing to assess how to best address our topped out scoring policy within the quality performance category. Historically, there have been concerns that certain specialties only have topped out measures to report which would make it difficult for them to meet an increased performance threshold even if they perform very well on those measures. Hence, as we continue to evaluate these programs scoring policies, establishing the performance threshold at 75 points will avoid inadvertently harming these clinician types.

Alternatively, we have considered maintaining the performance threshold at 75 points for either: (1) the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year (excluding the CY 2028 performance period/2030 MIPS payment year, which is currently proposed); or (2) only the CY 2026 performance period/2028 MIPS payment year. We also considered raising the performance threshold. However, as previously discussed, based on the data that we have available, we believe that our proposal to set the performance threshold at 75 points for the 2028, 2029, and 2030 payment years provides stability as MIPS enters a period of transition agnostic of our discretion to reassess the performance threshold methodology for the CY 2028 performance period/2030 MIPS payment year. We will reassess the use of the median or mean methodology in future rulemaking in accordance with section 1848(q)(6)(D)(i) of the Act. We refer readers to section IV.B.2.b.(3) of this proposed rule for Request for Information (RFI) on Future MIPS Performance Thresholds for more discussion on establishing the performance threshold for singe versus multiple years and the potentially increasing the performance threshold in future rulemaking.

We refer readers to the section VII.I.5.d.(4)(c) of this proposed rule for an estimate of the percent of MIPS eligible clinicians that would receive a negative payment adjustment for the CY 2026 performance period/2028 MIPS payment year if the performance threshold is set at 75 points as proposed.

Maintaining a performance threshold of 75 points allows additional time for more MVP data to become available, continues to provide opportunities for clinicians to become familiar with the transition to MVPs, and ensures that we continue to support certain clinician types, such as small practices, solo practitioners, rural providers, and clinicians who have several topped out measures. Therefore, we are proposing to establish a performance threshold of 75 points for the 2028, 2029, and 2030 MIPS payment years based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year. We also propose to codify this performance threshold in our regulation by adding § 414.1405(b)(10)(ii).

We request public comments on our proposal to establish a performance threshold of 75 points for the 2028, 2029, and 2030 MIPS payment years based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year. We also request comments on our proposal to codify this performance threshold by adding § 414.1405(b)(10)(ii).

(3) Request for Information on Future MIPS Performance Thresholds

As we consider the potential changes within MIPS while aiming to ensure that the performance threshold reflects clinician performance, we also request public feedback on the following issues:

- Establishing the performance threshold for single versus multiple years (for example, 1, 2, or 3 years at a time) via rulemaking; and
- As we approach later years in MIPS, increasing the performance threshold based on data from a prior period which potentially would provide larger positive MIPS payment adjustments for MIPS eligible clinicians with MIPS final scores higher than such performance threshold.

c. Example of Adjustment Factors

Figure 5 provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2026 performance period/2028 MIPS payment year. In Figure 5, the performance threshold is set at 75 points, as we have proposed in section IV.B.2.b.(2) of this proposed rule.

For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2026 performance period/2028 MIPS payment year. We calculate the MIPS payment adjustment factor using a linear sliding scale in accordance with section 1848(q)(6)(F)(i) of the Act. This linear sliding scale is calculated based on MIPS final scores from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the

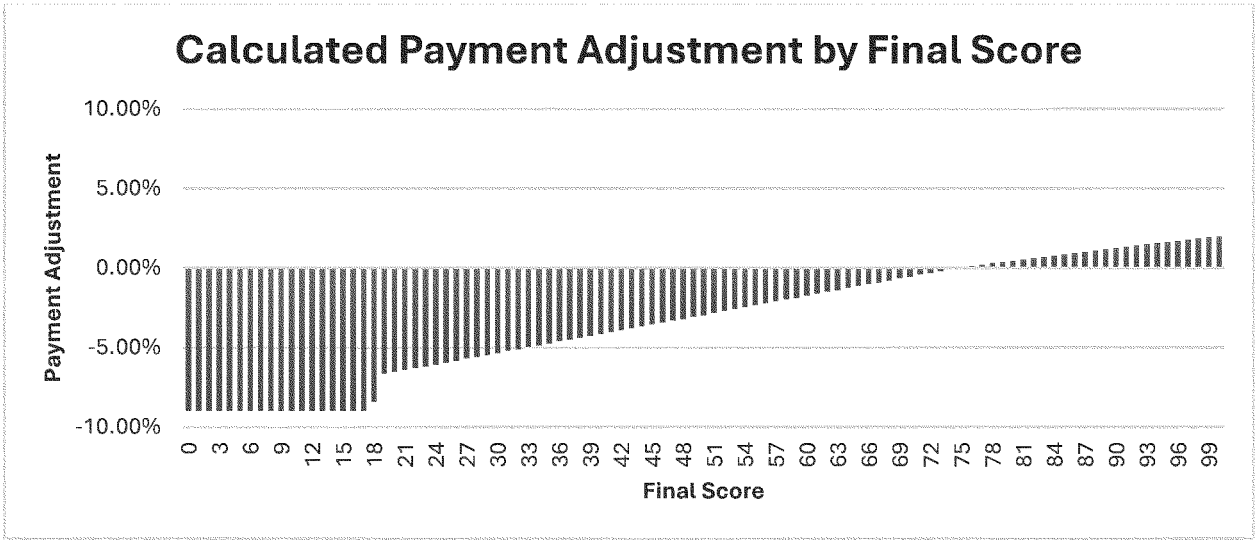
highest positive applicable percentage and resulting in the highest payment adjustment.

However, there are two modifications to this linear sliding scale. First, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the proposed performance threshold of 75 points for the CY 2026 performance period/2028 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent (the applicable percentage). If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 75 points (the performance threshold proposed for the CY 2026 performance period/2028 MIPS payment year) will receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 5 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 5: ILLUSTRATIVE EXAMPLE OF MIPS PAYMENT ADJUSTMENT FACTORS BASED ON FINAL SCORES AND PERFORMANCE THRESHOLD FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 72 illustrates the changes in payment adjustment based on the final policies from the CY 2025 PFS final rule (89 FR 98448 through 98455) for the CY 2025 performance period/2027 MIPS payment year and the proposed policies for the CY 2026 performance period/2028 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 72: ILLUSTRATION OF POINT SYSTEM AND ASSOCIATED ADJUSTMENTS COMPARISON BETWEEN THE CY 2025 PERFORMANCE PERIOD/2027 MIPS PAYMENT YEAR AND THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

2025 Performance Period Final Score Points	MIPS Adjustment for 2025 Performance Period	2026 Performance Period Final Score Points	MIPS Adjustment for 2026 Performance Period
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.00	0% adjustment	75.00	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

3. Review and Correction of MIPS Final Score—Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are required to provide MIPS eligible clinicians with timely confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule, we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories (82 FR 53799 through 53801).

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; for the CY 2021 performance period/2023 MIPS payment year on August 22, 2022; for the CY 2022 performance period/2024 MIPS payment year on August 10, 2023; and for the CY 2023 performance period/2025 MIPS payment year on August 12, 2024. Although we aim to provide feedback for the CY 2024 performance period/2026 MIPS payment year on or around July 1, 2025, it is possible the release date could be later depending on circumstances. We direct readers to *qpp.cms.gov* for more information.

4. Third Party Intermediaries General Requirements

a. Requirements for CMS-Approved Survey Vendors

(1) Background

The CAHPS for MIPS survey evaluates patients' experiences of care within a group, subgroup, virtual group, or Alternative Payment Model (APM) Entity. The CAHPS for MIPS survey must be administered by a CMS-approved survey vendor for the purposes of reporting (81 FR 28285). CMS-approved survey vendors must undergo the CMS approval process annually, which includes completing the Vendor Participation Form and complying with the Minimum Survey Vendor Business Requirements (81 FR 28288).

We have codified definitions of key terms for the Quality Payment Program, including third party intermediaries such as CMS-approved survey vendors, at § 414.1305. First, we have defined a third party intermediary as meaning an entity that CMS has approved at § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. Then, we also defined a CMS-approved survey vendor as meaning a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and to transmit survey measures data to CMS.

We refer readers to § 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77386), the CY 2018 Quality Payment Program final rule (82 FR 53818 and 53819), the CY 2019 PFS final rule (83 FR 59907 and 59908), the CY 2022 PFS final rule (86 FR 65538 and 65539), and the CY 2025 PFS final rule (89 FR 98459 and 98460) for previously finalized standards and criteria for third party intermediaries including CMS-approved survey vendors.

(2) Proposals To Codify Two Previously Finalized Policies

In the CY 2025 PFS final rule, we finalized a policy to require CMS-approved survey vendors to submit a range of the cost of their services with their application beginning with the CY 2026 performance period/2028 MIPS payment year (89 FR 98459 and 98460). While this policy was finalized as proposed in the CY 2025 PFS final rule, it was not codified in our regulations governing third party intermediaries. To ensure program requirements are clear, we propose to codify this previously finalized policy at § 414.1400(d)(9), with a technical modification to indicate that this requirement begins on January 1, 2026, rather than with the CY 2026 performance period/2028 MIPS payment year. We specifically propose to codify at § 414.1400(d)(9) to provide that, beginning with January 1, 2026, the entity seeking to be a CMS-approved survey vendor must include on its application the range of costs of its third party intermediary services.

In the CY 2024 PFS final rule, we finalized a policy to require organizations to contract with a CMS-approved survey vendor that would administer the CAHPS for MIPS Survey in the Spanish language translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines (88 FR 79332 through 79334). While this policy was finalized as proposed in the CY 2024 PFS final rule, it was not codified in our regulations governing third party intermediaries. To ensure program requirements are clear, we propose to codify this previously finalized provision at § 414.1400(d)(3)(iv)(A), with technical modifications to refer more broadly to sub-regulatory guidance that details procedures for administering the CAHPS for MIPS Survey. Specifically, we propose to codify at § 414.1400(d)(3)(iv)(A) to provide that, beginning on January 1, 2024, in addition to administering the survey in English, entities will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in sub-regulatory guidance to standardize the CAHPS data collection process for MIPS and to make sure the survey data collected across survey vendors are comparable within the program or model.

We request public comments on these proposals.

(3) Technical Changes

While reviewing the regulations for CMS-approved survey vendors, we identified an area in which language was used to describe survey protocols that is no longer consistent with current practice. We propose to modify § 414.1400(d)(3)(i) by removing the reference to 'mixed -modes' to better align with language typically used in current practice. Specifically, we propose to modify § 414.1400(d)(3)(i) to provide that an entity must have at least 3 years of experience administering surveys in which mail survey administration is followed by survey administration via Computer Assisted Telephone Interview (CATI). We note that this terminology change does not reflect a change in requirements for CMS-approved survey vendors.

We request public comments on this proposal.

(4) CAHPS for MIPS Survey

For the MIPS quality performance category, the CAHPS for MIPS Survey measures patients' experience of care and is administered first through the mail and then by phone interview with non-respondents. The survey is administered in English and Spanish, with additional translations available. The CAHPS for MIPS Survey may only be administered by CMS-approved survey vendors. (81 FR 77116). More details on the CAHPS for MIPS survey can be found here: *https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/cahps-mips*.

(5) Proposal To Require Web-Mail-Phone Protocol for Administration of the CAHPS for MIPS Survey

In the CY 2025 PFS proposed rule (89 FR 61869, 62042, and 62043), we included a request for information (RFI) on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. We solicited public comment on this new protocol given positive results found from our 2023 CAHPS for MIPS Web Mode Field Test.[418]

The field test added the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration, and we found that the addition resulted in a 43 percent response rate compared to 28 percent for the mail-phone protocol from the CY 2022 performance period CAHPS for MIPS Survey (89 FR 62043). In the CY 2025 proposed rule, we outlined details of the field test, including that surveys were administered to a random sample of survey-eligible patients from 20 Medicare Shared Savings Program ACOs between March 6, 2023 and May 31, 2023. These results were compared to survey data collected from the CY 2022 performance period CAHPS for MIPS Survey for the same Medicare Shared Savings Program ACOs.

Although comments in response to the RFI were not included in the 2025 PFS final rule, commenters widely supported an expansion of CAHPS for MIPS survey modes to include a web-based survey protocol, emphasizing that this could help increase response rates. One commenter noted that this is a long overdue update. The CAHPS for MIPS Survey RFI received input from 16 commenters, including medical societies, professional trade associations, Accountable Care Organizations, health care systems, an academic/research institution, and a consumer/patient advocacy organization. Key commenter takeaways included encouraging CMS to:

- Expand the CAHPS for MIPS survey modes to include a web-based option.
- Examine and implement additional changes to improve response rates and reduce burden associated with CAHPS surveys.
- Create additional approaches to assess and reduce any increased costs of survey administration for health care practices.
- Consider the potential impacts of sharing email addresses with vendors on patient privacy and administration burden.

The field test showed an increase in the survey response rate due to the addition of the web-based survey protocol which may lead to more groups meeting case minimum requirements for CAHPS. Additionally, adding a web survey mode increased flexibility for survey respondents, and commenters responded positively to the addition of a web-based survey protocol.

On these bases, we propose to require that, beginning with the CY 2027 performance period/2029 MIPS

[418] Centers for Medicare & Medicaid Services. (June 2024). 2023 CAHPS for MIPS Web Mode Field Test. Available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2893/2023_CAHPS_for_MIPS_WebMode_Field_Test.pdf*.

payment year, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. We propose to codify this requirement at § 414.1400(d)(10).

In addition, we propose to codify new requirements at §§ 414.1400(d)(3)(v)(A), 414.1400(d)(3)(vi)(A), and 414.1400(d)(3)(vii) to ensure an entity applying to become a CMS-approved survey vendor is capable of administering a web-mail-phone protocol prior to CMS approval. We note that, currently, an entity must apply to be a CMS-approved vendor on an annual basis, demonstrating they meet applicable requirements at § 414.1400. We propose to modify our requirements at § 414.1400(d)(3) to ensure an entity is prepared to administer the web-mail-phone protocol prior to CMS approval. Specifically, we propose that, beginning January 1, 2027, to be a CMS-approved survey vendor an entity must have sufficient experience, capability, and capacity to accurately report CAHPS data by demonstrating that they: (1) use equipment, software, computer programs, systems, and facilities that can send survey invitations via email that include a patient-specific hyperlink to a web survey, collect data via web, and track cases from web surveys through telephone follow-up activities (§ 414.1400(d)(3)(v)(A)); (2) employ a web survey administrator (§ 414.1400(d)(3)(vi)(A)); and (3) have at least 3 years of experience administering surveys in which web survey administration is followed by survey administration via mail survey or Computer Assisted Telephone Interview (CATI) (§ 414.1400(d)(3)(vii)).

If this proposal is finalized, CMS would update the survey administration requirements and associated materials, including the survey vendor application, during the 1-year implementation delay. We note that entities seeking to, or that do, become a CMS-approved survey vendor would need to meet other applicable requirements in § 414.1400, including successfully completing CMS' vendor training(s) as provided at § 414.1400(d)(5).

We refer readers to section V.B.5.b. of this proposed rule for discussion on the burden estimates for this proposal.

We request public comments on this proposal.

(6) Proposal To Sunset Application Requirement at § 414.1400(d)(8)

We propose to modify § 414.1400(d)(8) to sunset its requirement that, to apply to become a CMS-approved survey vendor, the entity must send an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data. Though this requirement was established to ensure accurate reporting, it is ultimately not feasible to implement because an entity cannot collect data until it is approved by CMS, and thus, the entity does not have any data to send to CMS prior to approval. Therefore, submission of a survey data file has not been used as a requirement for approval. We propose to sunset the requirement at § 414.1400(d)(8) so it is only effective from January 1, 2019 (when it was first finalized in the CY 2019 PFS final rule) through December 31, 2025. We propose that this requirement would no longer be in effect beginning with January 1, 2026.

We request public comments on this proposal.

5. Advanced APMs

a. Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. Our vision for increased clinician participation in Advanced APMs is aimed at integrating individuals' clinical needs across a spectrum of providers and settings to improve patient care and population health. As we continue to make improvements to the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs.

In the CY 2025 PFS final rule, we anticipated that we would propose a comprehensive approach to QP determination in future rulemaking (89 FR 98464). In this section, we are proposing such a comprehensive approach, which includes two parts. First, we propose to add an individual level calculation to Qualifying APM Participant (QP) determinations, as set forth in proposed regulation text at §§ 414.1425(b)(3 and (c)(3), for all eligible clinicians participating in an Advanced APM, such that each eligible clinician would receive both APM Entity level calculation and an individual level calculation. Second, we are re-proposing to expand the scope of the services in the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to use covered professional services (section 1848(k)(3)(A) of the Act). We believe that, together, these proposals would modernize and improve the QP determination approach across Advanced APMs.

In addition to the above proposals, we further propose to sunset our Advanced APM criterion at § 414.1415(c)(7), which currently limits Medical Home Model participants to 50 clinicians.

Lastly, we propose to modify §§ 414.1455(a)(b)(3)(ii) and (b)(3)(vi) pertaining to the QP Targeted Review process to align with MIPS Targeted Review process set forth at § 414.1385 to ensure that the QP and MIPS Targeted Reviews occur concurrently.

b. QP Determinations

(1) General

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy for QP determinations at § 414.1425. Currently, § 414.1425(b)(1) provides that, for the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any such snapshot date is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for eligible clinicians in an APM Entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List for more than one APM Entity, but who do not achieve QP status based on any APM Entity-level determinations, we make QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual-level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77440) we established a process to calculate Partial QP status at § 414.1425(d). While to date our Partial QP policies have impacted a small number of eligible clinicians, and thus we have not focused our discussion on this specific policy, we note that any change to QP determinations would likely require conforming changes to the policies for Partial QPs for consistency across the program.

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457), we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''Attributed beneficiaries'' to ''Attribution-eligible beneficiaries,'' as these terms are defined at § 414.1305, as shown in Figure 6 below.

FIGURE 6: QP DETERMINATION CALCULATION

$$\frac{\text{Attributed beneficiaries}}{\text{Attribution-eligible beneficiaries}}$$

If the Threshold Score (using either the payment amount or patient count method) calculated at the APM Entity or individual eligible clinician level, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinician or clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) achieve QP status for such year.

Regulation at § 414.1435(b)(3) provides that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) provides that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period are excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be attribution-eligible beneficiaries because the QP performance period does not align with the Advanced APM's performance period or attribution period, or for other reasons. There may also be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. As described in the CY 2017 Quality Payment Program final rule (81 FR 77451), attributed beneficiaries are a subset of attribution-eligible beneficiaries. Therefore, when calculating Threshold Scores for QP determinations, we exclude from the list of attributed beneficiaries any beneficiaries who do not meet the criteria to be attribution-eligible beneficiaries at that point in time.

In the 414.1425(d).

(2) Individual QP Determination

When we initially established our policy in the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445) to make most QP determinations at the APM Entity level, we believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for an APM Entity between the goal for its eligible clinicians to achieve QP status under the Quality Payment Program and the goals of the Advanced APM(s) in which the APM Entity participates.

In the CY 2024 proposed rule (88 FR 52618), we had proposed to address this issue by conducting all QP determinations at the individual level. However, commenters opposed this proposal, citing issues such as administrative burden for APM Entities tracking QP status and Partial QP status and elections at the individual level because of the implications for MIPS reporting. Many further believed that the change may have negative consequences for specialists, the opposite of our intent in making our proposal. In light of comments received, we did not finalize our proposal (88 FR 79403). Since that time, we have continued to examine QP determinations with a desire to right-size the methodology to current and future Advanced APM design, remove barriers to participation, and conduct calculations fairly.

Some commenters on our CY 2024 proposal recommended that we conduct QP determinations at both the APM Entity and individual levels (88 FR 79403). At the time, we indicated that we did not believe that this approach would sufficiently encourage more intensive Advanced APM participation by individual eligible clinicians. However, based on continued examination of QP determinations, including in the time since the publishing of the CY 2025 PFS final rule, we have recognized the importance of individual contribution, particularly for models that are condition-specific or focused on an episode of care. Clinicians in these models are particularly disadvantaged when, as is frequently the case, their APM Entity fails to achieve QP status.

Under our current policy, there is the potential that an eligible clinician who has fully engaged with an Advanced APM may still be unable to earn QP status because it is calculated at the APM Entity level as described at § 414.1425(c)(3). As we have noted earlier, under our current policy we conduct individual determinations, but we only do so in the following specific circumstances: For eligible clinicians who appear on a Participation List for more than one APM Entity, but who do not to achieve QP status based on any APM Entity-level determinations, we make QP determinations at the

individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual-level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2). While these methods exist, individual calculations are not the norm and for an eligible clinician in only a single APM Entity our current policy does not provide for an individual determination.

As such, we are proposing to add a new provision at § 414.1425(b)(3) to add a QP determination at the individual level for all Advanced APM participants, beginning with the 2026 QP Performance Period. Our proposal would not impact our policy at § 414.1425(b)(1) for APM Entity level determinations or our policy at § 414.1425(b)(2) determinations for Affiliated Practitioners as CMS is envisioning that these policies would also remain in effect for 2026 and future QP Performance Periods. Under our proposal, we would amend § 414.1425(b)(3) to add a calculation of Threshold Scores for QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM based on services furnished across all Tax Identification Numbers (TINs) to which the eligible clinician has reassigned their billing rights. This individual Threshold Score would provide a more specific measurement of each eligible clinician's participation in an Advanced APM. Under our proposal, we would calculate at the APM Entity level as provided in § 414.1425(b)(1) and (2) and the individual level for each eligible clinician as provided in proposed § 414.1425(b)(3) at each of the snapshot dates throughout the QP Performance Period. Under our proposal, an eligible clinician is a QP for a year under the Medicare option if they meet or exceed the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described at § 414.1430(a)(1) and (3) at the APM Entity level, or as an individual eligible clinician as stated at § 414.1425(c)(3) or § 414.1425(c)(4) respectively.

We are proposing a conforming revisions at § 414.1425(c)(3)(i) to ensure that an eligible clinician is a QP for a year under the Medicare Option if beginning with the CY 2026 QP Performance Period, the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(1) and (3). Likewise, an eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(1) and (3).

We are proposing a conforming revision to sunset § 414.1425(c)(4) to make clear that the existing policy started with the CY 2017 QP Performance Period and would end with the CY 2025 QP Performance Period, and to preserve in the regulations the history of the applicable policies for specific QP Performance Periods.

We are proposing a revision at § 414.1425(d)(1) and (2) such that an eligible clinician is a partial QP for a year under the Medicare option if they meet or exceed the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(2) and (4) at the APM Entity level or as an individual eligible clinician as stated at § 414.1425(d)(1) or § 414.1425(d)(2) respectively.

We seek public comments on this proposal.

(3) Attribution-Eligible Definition

At § 414.1305, we define an attribution-eligible beneficiary as a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base beneficiary attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

When we finalized the definition of attribution-eligible beneficiary in the CY 2017 Quality Payment Program final rule, (81 FR 77451 through 77452), we intended that this definition would, for purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define attribution-eligible beneficiary were aligned with the attribution methodologies and rules for our contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. We chose to refer to E/M services as the primary basis for purposes of attribution-eligibility because many of the Advanced APMs CMS offered at that time used E/M claims to attribute beneficiaries to their APM Entity groups. Over time, we have updated the list of services that are considered to be E/M services for purposes of identifying attribution-eligible beneficiaries and have published this list as part of the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.gov*.

We also included an exception in this sixth criterion to allow us to use an alternative approach for Advanced APMs that do not base beneficiary attribution on any E/M services, and thus for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for an E/M service. To date, we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify attribution-eligible beneficiaries for these Advanced APMs in the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.gov*.

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which beneficiary attribution is based on services other than E/M services, the attributed beneficiary population is truly a subset of such Advanced APMs' attribution-eligible beneficiary populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations would be appropriate for such Advanced APMs. That said, our thought when we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. We believed that, by affording sufficient flexibility within the program, we could both foster innovation in Advanced APMs and simplify our execution of the program. However, with our more narrowly defined default approach to beneficiary attribution (relying on claims for E/M services), we have increasingly needed to exercise the flexibility to identify an alternative approach to attribution eligibility for Advanced APMs that fell into the exception, which meant that we identified several individually tailored ways of performing the beneficiary attribution methodology for specific Advanced APMs. We anticipate that Advanced APMs will continue to evolve and use novel approaches to value-based care that may emphasize a broad range of covered professional services, and in that event the application of our current regulations may result in increased variability among the ways we define attribution-eligible beneficiary when making QP determinations. In the CY 2025 PFS proposed rule (89 FR 62098 through 62101), we proposed to amend the final criterion in the definition of ''attribution-eligible beneficiary'' at § 414.1305 to expand the scope of services used to covered professional services, indicating that we would conduct further analysis. However, as further discussed in the CY 2025 PFS final rule (89 FR 98461 through 98465)-, we did not finalize this proposal.

After continued examination, we are re-proposing to modify the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician for whom we are making the QP determination, beginning with the 2026 QP Performance Period. In the CY 2025 proposed rule, we described how the proposed approach would result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflect eligible clinicians' actual participation in Advanced APMs, improve transparency and predictability of the determinations, be more operationally efficient than the current policy, and better align the QP determination methodology with the universe of services to which the Quality Payment Program (including MIPS and APMs) applies.

In response to comments in the CY 2025 PFS final rule, we explained that changes in the composition of APM Entity Participation Lists, services furnished, and attributed beneficiaries all have significant effects on the number of projected versus actual QPs for a QP performance period, which complicates the ability to assess effects of methodological changes to QP determinations (89 FR 98461 through 98465). We also described how any methodology changes can lead to varied QP Threshold Scores for APM Entities within the same Advanced APM, and noted that because QP status is determined based on specific QP payment amount and QP patient count thresholds, only those changes in scores that result in an eligible clinician crossing over a QP threshold percentage contribute to the net estimated change in QP counts (89 FR 98461 through 98465). We further note that the QP thresholds have increased relative to previous years and, effective with the 2025 QP Performance Period are now at 75 percent for the payment amount and 50 percent for the patient count. We note that this change, which occurs by statute, will be responsible for the largest quantitative effect on our QP predictions, largely by reducing the number of QPs relative to the previous, lower thresholds. As such, while the quantitative effects of our proposals may show small changes in the number of QPs relative to status quo, that status quo itself reflects this threshold level change to QP determinations, which is significant in its own right.

In the CY 2025 PFS final rule (89 FR 98463 and 98464), we stated that we believed that our proposal was a better approach than the status quo, and we believed that it should likely be part of a comprehensive approach to QP determinations that would better reflect the current and future state of Advanced APMs. In response to public comments, we did not finalize at that time its proposal to revise the sixth criterion of the definition of ''attribution-eligible beneficiary at § 414.1305. However, at the time we stated that we anticipated to propose a comprehensive approach to QP determination in future rulemaking, including a strategy to address the needs of condition-specific models, and that this proposal might be included as one element of such future proposals. (89 FR 98463 and 98464). CMS has further explored this issue and has determined that we could appropriately address the challenges we have described in this and prior rulemaking by allowing for the overall expansion of the QP determinations, in terms of both the level of the determination as discussed in section (2), and the services included in the QP determinations as discussed in this section.

As we noted earlier in this proposed rule, in our discussion of the proposal to calculate QP status at the individual NPI level, primary care practitioners generally furnish a higher proportion of E/M services than do specialists with the same beneficiary, and as for the Threshold Score calculations described previously, the emphasis on E/M services in our beneficiary attribution policy may have inadvertently encouraged APM Entities to exclude specialists from their Participation Lists. Under our current policy, if one or more eligible clinicians on the APM Entity's Participation List furnish covered professional services to a beneficiary but none of those services are among the E/M services we use for attribution, that beneficiary would not be attribution-eligible, and therefore, would not be included in our QP determination calculation, even though the beneficiary is actually receiving covered professional services from an eligible clinician on the APM Entity's Participation List.

We are re-proposing to change the definition of ''attribution-eligible beneficiary'' at § 414.1305 so that, beginning with QP Performance Period 2026, a single definition using covered professional services would be applied regardless of the Advanced APMs in which the eligible clinician participates. We believe that this complements our proposal to add individual-level calculations to QP determinations. We are also concerned that retention of the current policy where E/M services are the default basis for attribution, and where special processes are required for Advanced APMs that use a different attribution basis, could result in a complex set of unique attribution approaches for Advanced APMs.

We believe that this change would more appropriately recognize the Advanced APM participation of the eligible clinicians for whom these determinations are being made, particularly when considered in conjunction with the proposal to add an individual-level calculation to QP

determinations. We further believe that this proposal would simplify and streamline QP determinations and address the challenges to Advanced APM participation reportedly faced by specialists who are less likely than primary care practitioners to provide E/M services.

We are proposing to modify the sixth criterion in the definition of ''attribution-eligible beneficiary'' at § 414.1305 to provide that, beginning with the 2026 QP Performance Period, an attribution-eligible beneficiary is a beneficiary who during the QP Performance Period has a minimum of one claim for any covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity at any determination date during the QP Performance Period.

We seek public comments on this proposal.

c. Medical Home Model 50 Eligible Clinician Limit

In the CY 2017 Quality Payment Program final rule (81 FR 77428), we finalized a policy for the Medical Home Model nominal financial risk criterion to set a limit of 50 on the number of eligible clinicians in an organization that participates as an Advanced APM through a Medical Home Model. In the CY 2023 PFS final rule (87 FR 70117), we amended § 414.1415(c)(7) to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity.

Likewise, in the CY 2017 Quality Payment Program final rule (81 FR 77468) we finalized a policy at § 414.1420(d)(2) and (4) for the Medicaid Medical Home Model nominal financial risk criterion to set a limit of 50 on the number of eligible clinicians in an organization that participates as an Advanced APM through a Medical Home Model. In the CY 2020 PFS final rule (84 FR 63095) we finalized a proposed amendment at § 414.1420(d)(2) and (4) to include Aligned Other Payer Medical Home Models with the existing Medicaid Medical Home Model financial risk and nominal amount standards for Medicaid Medical Home Models.

When we established the medical home model 50 eligible clinician limit in the CY 2017 Quality Payment Program final rule our stated intent was to encourage organizations capable of taking on significant downside risk to participate in Advanced Alternative Payment Models that met the ''Generally applicable financial risk standard'' at § 414.1415(c)(1) (81 FR 77430). Based on our experience operating the Quality Payment Program we note that participation in Advanced APMs has increased, and the necessity of the Medical Home Model 50 eligible clinician limit has lessened. Moreover, we expect that this policy could provide a barrier for participation in models that meet the Medical Home Model definition in the future.

We are proposing to amend our policy at § 414.1415(c)(7) to provide that beginning with the 2026 QP Performance Period we would no longer apply the Medical Home Model 50 eligible clinician limit. Specifically, we propose to modify § 414.1415(c)(7) to sunset that provision and provide that it only applies from the 2023 QP performance Period through the 2025 QP Performance Period.

Additionally, we are proposing a conforming amendment to the Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit at § 414.1420(d)(8) beginning in the 2026 performance period we would no longer apply the Medical Home Model 50 eligible clinician limit.

We seek public comments on this proposal.

d. Targeted Review of QP Determinations

In the CY 2021 PFS final rule (85 FR 84952), we finalized a policy to provide an opportunity for eligible clinicians to bring to our attention potential clerical errors we may have made that could have resulted in the omission of an eligible clinician from a Participation List used for purposes of QP determinations, and for us to review and make corrections if warranted. We also finalized that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period (85 FR 84952). We noted that, consistent with section 1833(z)(4) of the Act, and as provided at § 414.1455(a), there is no right to administrative or judicial review at sections 1869 or 1878 of the Act, or otherwise, of the determination that an eligible clinician is a QP or Partial QP at § 414.1425, or of the determination of the amount of the APM Incentive Payment at § 414.1450.

In the CY 2021 PFS final rule (85 FR 84953), we finalized our proposal to align the timing and procedures for this targeted review process with the MIPS targeted review process as codified at § 414.1385. We noted this alignment would reduce the likelihood of confusion and burden on eligible clinicians and APM Entities. In the CY 2024 PFS proposed rule (88 FR 79380 through 79382; 88 FR 79408), we modified the Targeted Review period for both MIPS and QPs such that we could meet our statutory obligation to apply the differentially higher QP conversion factor beginning on January 1 of each payment year beginning with CY 2026. When we made these updates, we also revised the language in § 414.1385 more generally, including a change from 30 days to 15 days between notification and a response at § 414.1385(a)(5), but we did not make corresponding changes to the QP Targeted Review regulation at § 414.1455.

We recognize that the different language in the current versions of these two sections of regulation could make it appear that our intent is for the MIPS and QP Targeted Review periods to operate differently, and that in fact the inconsistencies could mean that the Targeted Review for both QPs and MIPS participants is not guaranteed to be aligned. Our intent for these Targeted Review periods to be aligned has not changed, and we do not want to give the impression that there is a misalignment between them. Accordingly, we are now proposing to modify the langauge at §§ 414.1455(b)(3)(ii) and 414.1455(b)(3)(vi) to make clear that the same timing requirements that for MIPS Targeted Reviews that are currently specified in at §§ 414.1385(a)(2) and 414.1385(a)(5) also apply for purposes of QP Targeted Reviews. We seek comments on our proposal to modify the language at §§ 414.1455(b)(3)(ii) and 414.1455(b)(3)(vi) to the same timing requirements as that of MIPS Targeted Reviews specified at § 414.1385(a)(2) and 414.1385(a)(5).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement (as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations) is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comments (see section VI. of this proposed rule) on each of the aforementioned issues for the following sections of this document that contain information collection requirements (ICRs). Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2024/may/oes_nat.htm*). In this regard, Tables 73 and 74 present BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We note that the May 2024 BLS data does not include median hourly wage rates for multiple physician occupation types listed in Table 74; in these cases, the BLS identifies that the median wage rate is equal to or greater than $115.00/hr or $239,200 per year. BLS data for prior years, such as the May 2022 and May 2023 data, provide similar notes for median wage rates for occupations that are above the same thresholds ($115.00/hr or $239,200 per year for the May 2022 BLS data (*https://www.bls.gov/oes/2022/may/oes_nat.htm*) and May 2023 BLS data (*https://www.bls.gov/oes/2023/may/oes_nat.htm*)). Therefore, for consistency with previous years for estimating physician wage rates, we have continued to use mean hourly wage rates across our wage estimates.

TABLE 74: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES (EXCLUDING PHYSICIANS)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	23.80	23.80	47.60
Business Operations Specialists	13-1000	43.76	43.76	87.52
Computer System Analysts	15-1211	53.83	53.83	107.66
General and Operations Managers	11-1021	64.00	64.00	128.00
Licensed Practical and Licensed Vocational Nurses	29-2061	30.84	30.84	61.68
Medical and Health Services Managers	11-9111	66.22	66.22	132.44
Secretary/Administrative Assistant	43-6000	22.90	22.90	45.80
Software Quality Assurance Analysts and Testers	15-1253	53.01	53.01	106.02
Training and Development Managers	11-3131	67.59	67.59	135.18

For our purposes, BLS' May 2024 National Occupational Employment and Wage Estimates do not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we used an average conglomerate wage of $299.32/hr as demonstrated below in Table 74.

TABLE 75: National Occupational Employment and Wage Estimates (Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Anesthesiologists	29-1211	161.85	161.85	323.70
Family Medicine Physicians	29-1215	123.47	123.47	246.94
General Internal Medicine Physicians	29-1216	126.31	126.31	252.62
Obstetricians and Gynecologists	29-1218	135.16	135.16	270.32
Orthopedic Surgeons, Except Pediatric	29-1242	175.51	175.51	351.02
Pediatric Surgeons	29-1243	216.74	216.74	433.48
Pediatricians, General	29-1221	106.89	106.89	213.78
Physicians, All Other	29-1229	121.86	121.86	243.72
Psychiatrists	29-1223	129.39	129.39	258.78
Surgeons	29-1240	170.56	170.56	341.12
Surgeons, All Other	29-1249	178.50	178.50	357.00
Total				3,292.48
Average Physician Wage (3,292.48/11)				299.32

B. Proposed Information Collection Requirements (ICRs)

1. Ambulatory Specialty Model (42 CFR Part 512 and Section X.D of This Proposed Rule)

In section X.D of this proposed rule, we discuss testing the Ambulatory Specialty Model and propose polices for the model under the authority of the Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing, evaluation, and expansion of models under section 1115A of the Act. As a result, the information collection requirements contained in this rule are not subject to the requirements of the PRA. However, the anticipated impact is scored below in section VII.I.5. of the Regulatory Impact Analysis.

2. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program (§§ 410.79, 414.84, and 424.205)

In section § 410.79(b), we are proposing to make changes to our regulation Conditions of Coverage. First, we are proposing to amend § 410.79(b) by revising the definitions of ''Extended flexibilities period'' and ''Online'' and adding definitions for three new terms for MDPP, including ''Live Coach interaction,'' ''Online delivery period,'' and ''Online session.'' The definitions will extend virtual delivery flexibilities through December 31, 2029, describe accepted delivery modes for MDPP, and further align MDPP terminology with CDC DPRP Standards.[419] These proposed changes to the definitions aim to remove access barriers for beneficiaries and provide suppliers with more delivery options in response to comments regarding the increasing demand for virtual participation options.

We are also proposing to amend § 410.79(c)(1)(ii) by clarifying that weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the completion of the MDPP session. Additionally, we propose to amend § 410.79(e)(3)(iii)(C) to revise weight collection requirements for MDPP in response to comments regarding increased flexibility for MDPP participants who may be traveling or unable to obtain weight measurements at home due to mobility and safety considerations. This change allows beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site while maintaining program integrity through existing date-stamp requirements described in § 410.79(e)(3)(iii)(c) which state that the photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scaled on the date associated with the billable MDPP session.

Finally, we propose to amend § 410.79 by adding paragraph (f) to test the addition of coverage of an asynchronous, Online delivery modality during the ''Online delivery period'' (until December 31, 2029), and clarify that MDPP suppliers are not required to maintain in-person delivery capability during the Online delivery period. These changes will allow virtual-only organizations to enroll in Medicare as MDPP suppliers, streamline the process to allow for greater delivery of Online sessions, and promote alignment with the 2024 CDC DPRP Standards. We propose edits throughout § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text to update language to include all accepted MDPP delivery modes for performance goals in which beneficiaries achieve weight loss milestones. We also propose adding paragraph (c)(3) to indicate payment for Online delivery, including the inclusion of a new Healthcare Common Procedure Coding System (HCPCS) G-code for online delivery. Finally, we propose redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively and revising the redesignated paragraph (c)(4)(ii) to include a payment rate for a

[419] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

core session or core maintenance session furnished Online during the Online delivery period.

Lastly, we propose amending § 424.205(c)(10) to allow the minimum number of required MDPP core sessions and core maintenance sessions to be delivered Online during the Online delivery period; § 424.205(f)(2)(i) to include the online modality among acceptable session types for session documentation; and § 424.205(f)(5) to update requirements for achieving 5 and 9 percent weight loss measured in accordance with § 410.79(c)(ii). Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions, including the collection of weights.

3. ICR Regarding the Medicare Prescription Drug Inflation Rebate Program Under Sections 11101 and 11102 of the Inflation Reduction Act (IRA)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10930). At this time the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this rule's proposed collection of information request. We expect to set out that number in our subsequent final rule (CMS–1832–F).

In section III.I of this rule, we are proposing to establish a 340B repository and allow 340B covered entities to optionally begin submitting to the 340B repository data elements from 340B identified claims for covered Part D drugs billed to Medicare Part D. We propose to allow covered entities to begin submitting the fields specified by CMS to the 340B repository beginning in 2026 for Part D 340B-identified claims with dates of service on or after January 1, 2026. This testing period would provide data for CMS to conduct usability testing for the 340B repository and allow covered entities to develop and test processes for submitting data elements to the 340B repository. CMS would not use the data submitted for user testing to remove units from Part D inflation rebates for the applicable period beginning on October 1, 2025. We propose that covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 would submit fields specified by CMS to the 340B repository for Part D 340B-identified claims by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available for covered entities to report data elements related to Part D 340B-identified claims with dates of service from January 1, 2026 onward. CMS will provide a deadline that CMS believes will allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. CMS will provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate ICR is finalized. During the rest of the testing period, CMS anticipates that covered entities will be expected to report data on a quarterly basis to the 340B repository within 3 months of the end of a given calendar quarter. Covered entities would voluntarily submit this data directly to CMS to be included in the 340B repository. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B identified claims; that is, the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data. Under this process, CMS intends to require a certification from covered entities that choose to submit data to the 340B repository that they have submitted data elements for all Part D 340B-identified claims with dates of service during the reporting period and that the data elements from all claims submitted to the 340B repository are from verified 340B claims. CMS would match the stored data elements in the 340B repository to Prescription Drug Event (PDE) transactions for each Part D rebatable drug dispensed during the applicable period. Units associated with PDE transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provided a discount under the 340B Program.

The collection established via the new ''340B Repository Data Elements Instructions and Collection ICR Form'' would provide CMS with the opportunity to assess the usability of the data received and the feasibility of CMS using such data to remove 340B units from the total number of units used to calculate the total rebate amount in the future. This data and information is necessary to implement statutory requirements of the Medicare Part D Drug Inflation Rebate Program at section 1860D–14B(b)(1)(B) of the Act which requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. As stated earlier, we are proposing a testing period for the 340B repository beginning in 2026 on a date announced in the future to allow covered entities to begin submitting the fields specified by CMS to the 340B repository beginning in 2026 for Part D 340B-identified claims with dates of service on or after January 1, 2026.

We estimate that approximately 6,500 covered entities will respond and submit data to the 340B Repository Data Elements Instruction and Collection ICR Form for CY 2026 based on internal CMS analyses of the unique 340B ID numbers in the HRSA OPAIS database that are active (that is, not terminated) with at least one contract pharmacy association listed and based on comments received on the CY 2025 PFS proposed rule from interested parties, including covered entities, requesting and expressing support for the establishment of a 340B repository.

Using the wage rates from Table 73 of this proposed rule, we expect, for a covered entity or its third-party administrator (TPA), a dedicated Software Quality Assurance Analyst and Tester, or team of analysts, 6 hours sampling for each submission and a General and Operations Manager 2 hours reviewing each submission.

In aggregate, we estimate an annual burden of 208,000 hours (26,000 responses × 8 hr/response) at a cost of $23,195,120 (26,000 responses × [(2 hr × $128.00/hr) + (6 hr × $106.02/hr)]).

TABLE 76: SUMMARY OF TOTAL ANNUAL BURDEN FOR ALL COVERED ENTITIES OR TPAs TO COMPLETE 340B REPOSITORY DATA ELEMENTS FORM IN 2026

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act	0938-TBD (CMS-10930)	6,500 Covered Entities or TPAs	26,000 (6,500 x 4 submissions per year)	8	208,000	Varies	23,195,120

4. ICRs Regarding Manufacturers Reporting of Drug Pricing (§§ 414.802, 414.804, and 414.902)

Pending our finalization of the following proposed provisions, the changes will submitted to OMB for review and approval under control number 0938–0921 (CMS–10110) using the standard PRA process. The process includes the publication of 60- and 30-day **Federal Register** notices that will provide the public with additional opportunities to review and comment on the changes. The following proposed changes will be submitted to OMB for review under control number 0938–0921 (CMS–10110).

a. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.902)

In the CY 2022 PFS final rule, it was stated that the new provisions finalized in that rule at §§ 414.802 and 414.804 implemented new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 401''), which requires manufacturers without a Medicaid National Drug Rebate Agreement (NDRA) to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological (86 FR 65560). In that final rule, we estimated that an additional 568 respondents had products for which they would be required to report ASP data to CMS beginning January 1, 2022 (86 FR 65560), some of which are manufacturers of skin substitutes. Following the implementation of section 401, we estimated 500 respondents, 2,000 responses (500 respondents × 4 responses/yr), 26,000 hours (2,000 responses × 13 hr/response).

In section II.K. of this proposed rule, we are proposing that skin substitutes be paid as incident-to supplies, which are not required to be paid under section 1847A of the Act. Accordingly, if this proposal is finalized, manufacturers of skin substitutes will no longer be required to report ASP data to CMS. Instead, ASP data reporting for manufacturers of skin substitutes would become voluntary. The proposal to shift the payment of skin substitute manufactures to incident-to supplies would decrease the number of manufacturers that are required to report ASP data to CMS each quarter, ultimately decreasing the overall burden of ASP data reporting. Based on the most recent ASP data, 65 skin substitute manufacturers are reporting ASP data. Under the proposal to pay for skin substitute products as incident-to supplies, the number of manufacturers required to report ASP data to CMS would decrease manufacturer burden by minus 65 respondents, minus 260 responses (−65 respondents × 4 responses/yr), and minus 3,380 hours (−260 responses × 13 hr/response) and minus $154,804 (−3,380 hr × $45.80/hr).

TABLE 77: SUMMARY OF TOTAL ANNUAL BURDEN OF INFORMATION COLLECTION REQUEST

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	(65)	(260)	13	(3,380)	45.80	(154,804)

b. Average Sales Price: Price Concessions and Bona Fide Service Fees (§§ 414.802 and 414.804)

In section III.A of this proposed rule, we are proposing revisions to § 414.804(a)(5) to add additional submission requirements for the reporting of ASP data. Specifically, the submission requirement is being expanded to include (1) reasonable assumptions for calculating the manufacturer's ASP as described at § 414.804 and (2) warranty or certification letter from the recipient of a fee from a manufacturer as evidence that a fee was not passed on as a price concession in accordance with the proposed revised definition of bona fide service fee at § 414.802 and submission requirements at § 414.804.

Currently, in the absence of specific guidance in the Act or Federal regulations, the manufacturer may make

reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices. The reasonable assumptions explain the methodology used by the manufacturer to calculate ASP. This proposal would make the reasonable assumptions document, which is currently submitted voluntarily by some manufacturers along with ASP data, to a required component of the quarterly ASP data submission.

The warranty or certification from the recipient of a bona fide service fee is a new document that we are proposing to be required as evidence of whether or not a fee was passed on as a discount (that is, price concession).

The burden associated with these new proposed requirements would be the time and effort required by manufacturers of drugs and biologicals to submit ASP data to CMS quarterly under sections 1847A and 1927 of the Act prepare and submit the reasonable assumption document and warrantee/certification letter to CMS.

We anticipate an increase in burden because, in addition to the current requirement for submission of ASP data each quarter to CMS, all manufacturers would also be required to submit reasonable assumptions and warrantee/certification letters to accompany their ASP data submissions. Reasonable assumptions may vary in terms of the exact information that is provided and are generally updated by each manufacturer every 1 to 3 years depending on changes in the product line and various contract terms and conditions with intermediaries or consultants. With this in mind, we are adding mandatory templates for submitting reasonable assumptions and bona fide service fee warrantee/certifications.

As discussed, we anticipate that the number of manufacturers required to report ASP data to CMS will decrease by minus 65 manufacturers (500 active estimate − 435 proposed estimate) and estimate (as described in the following paragraphs) that it will take 77 hours per year for each respondent.

Based on our review of voluntarily submitted reasonable assumption data, we estimate that it would take 19 hours annually at $45.80/hr for a Secretary/Administrative Assistant (consisting of 10 hr to compile and/or update the information and 5 hours to review the information approximately once annually and 1 hour per quarter (or 4 hr annually) to submit the reasonable assumptions to CMS, including signature, to CMS via ASP Data Collection System.

We estimate the disclosure and submission of the warrantee/certification letter from the recipient of a bona fide service fee is 6 hours annually at $45.80/hr for a Secretary/Administrative Assistant (consisting of 2 hr to review the warrantee/certification letter approximately once per year and 1 hour per quarter (or 4 hr annually)) to submit the warrantee/certification letter including signature, to CMS via the ASP Data Collection System. Although a warrantee/certification letter could be renewed up to every three years depending on the specific terms of each contract, we will use a calculation of once annually to accommodate the burden in most circumstances.

This proposed burden is in addition to the current estimated burden of ASP data submission of 52 hours per year per respondent at $45.80/hr for a Secretary/Administrative Assistant (13 hr per quarter).

The proposed requirements would result in an annual burden of 25 hours (19 hr + 6 hr) per response per year. In aggregate, we estimate a burden of 10,875 hours (435 responses × 25 hr/response) at an annual cost of $498,075 (10,875 hr × $45.80/hr).

TABLE 78: ANNUAL REQUIREMENTS AND BURDEN FOR MANUFACTURERS REPORTING DRUG PRICING INFORMATION FOR PART B

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	435	4	4.75	19	45.80	378,537
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	435	4	1.5	6	45.80	119,538.00
TOTAL	n/a	435	4	varies	77	45.80	498,075.00

5. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out Shared Savings Program burden estimates under this section of the rule. Please refer to section VII.E. of this proposed rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.F. of this proposed rule.

6. The Quality Payment Program (42 CFR Part 414 and Section IV. of This Proposed Rule)

The following Quality Payment Program-specific ICRs reflect proposed changes to our currently approved requirements/burden as summarized in section V.B.5.a.(1) in this proposed rule.

Below, we present detailed burden estimates for Quality Payment Program ICRs that are new or revised based on policy proposals in this proposed rule. We also discuss policy proposals for Quality Payment Program ICRs for which we assume there are no burden impacts. Non-rulemaking revisions, due to updated data and assumptions, and the changes due to proposals in this proposed rule, will be submitted to OMB for review under the identified control numbers. This approach for the Quality Payment Program ICRs follows our long-standing process for setting out PRA-related burden in most of our proposed and final rules. It is intended to focus our PRA score on the impact of this rule's proposed policy changes. We refer readers to section VII.I.5. of this proposed rule for the Regulatory Impact Analysis for discussion of this year's proposed policies' impacts to final scores and payment adjustments. For all ICRs, including ICRs where we do not propose any changes to the number of respondents, responses, or time per response, the costs identified in the revised collection of information requests will reflect the updated 2024

wage rate data described in section V.A. of this proposed rule.

For the CY 2026 rulemaking cycle, we simplified our methodology for calculating the total cost of each ICR to be consistent with the approach adopted by other programs. In prior years, we assessed total cost as the number of responses multiplied by cost per response, determining cost per response as the time per wage rate category per response multiplied by the hours per response. For this proposed rule, to calculate the burden, we removed the cost per response measurement from our total cost calculations and, instead, determined cost as a function of hourly wage rates per labor category identified in Tables 73 and 74 of this proposed rule multiplied by the annual hours per labor category. We determine annual hours per labor category by multiplying the annual burden hours per response by the number of annual responses. Accordingly, we have updated our summary calculations of the total change in time and cost of this rulemaking to focus on the estimated incremental burden of this rulemaking.[420]

a. Background

(1) ICRs Regarding the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In section V.B.5.a.(2) of this proposed rule, we discuss changes in the estimated burden for the information collections associated with the Quality Payment Program. The proposed changes to the estimated burden and the information collections for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey, described in section V.B.5.b.(1) of this proposed rule, will be submitted to OMB for review under control number 0938–1222 (CMS–10450). All other changes to burden and information collections for Quality Payment Program ICRs due to proposed policies described in this section of the proposed rule, or the availability of updated data, will be submitted to OMB for review under control number 0938–1314 (CMS–10621). We are not proposing changes to the virtual group election process or burden estimates, currently approved under OMB control number 0938–1343 (CMS–10652).

(a) Summary of Annual Quality Payment Program Burden Estimates

We summarize changes to the Quality Payment Program's estimated burden for ICRs that have related policy proposals in this proposed rule that impact our burden estimates. For only these ICRs with burden implications due to policy proposals in this proposed rule, we also update our burden assumptions based on the most recent data on MIPS participation available at the time of this rulemaking. These updated data sources are described in section V.B 5.a.(4)(b) of this proposed rule.

For ICRs under OMB control number 0938–1314 (CMS–10621), we estimate that the policy proposals in this proposed rule related to five ICRs would result in 2,312 additional responses due to the availability of new MIPS Value Pathways (MVPs). This change reflects the number of historic traditional MIPS submissions we estimate would move to MVP reporting due to the availability of the proposed new MVPs and would need to complete a registration form that is not required with traditional MIPS submissions. Accordingly, we estimate the increase in MVP submissions and registrations, and resulting decrease in traditional MIP submissions would result in an annual decrease of 6,798 hours and $840,757 (see total Policy Change in tables 77, 78, and 79, respectively) beginning with the CY 2026 performance period/2028 MIPS payment year. In addition, we separately estimate changes to annual burden due to the availability of updated MIPS submission data for these five ICRs since our currently approved estimates would result in an additional annual burden decrease of 5,353 responses, 59,372 hours, and $7,119,526 (see total Updated Data in Tables 77, 78, and 79, respectively). Taken together, we estimate a total reduction of 3,041 responses, 66,169 hours, and $7,960,283 (see total of Total Change in Tables 77, 78, and 79, respectively). All time estimates in the referenced tables are rounded to the hour, and all cost estimates are rounded to the dollar. The change in total time and total cost in the referenced tables per ICR are described in section V.B.5.c. of this proposed rule and reflect the sum of changes due to policy proposals and newly available data before this rounding. Accordingly, the total change in time per ICR may not equal the sum of changes due to policy and data adjustments because of this rounding. The Total row estimate per table represents the sum of the *COM007*component ICR rows in that table.

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[420] Due to this approach to estimate the change in cost, annual changes to the hourly wages rates as identified by BLS are not identified as a change in cost due to data adjustments. Any changes in cost due to data adjustments in section V.B.5.a.(1)(a) of this proposed rule reflect changes due to the annual hours based on the availability of updated MIPS submission data since our currently approved estimates.

TABLE 79: ANNUAL RESPONSES BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1314 (CMS-10621)

Requirement	Currently Approved Responses*	Proposed Annual Responses**	Total Change***	Change Due to Policy	Change Due to Updated Data****
Quality Performance Category: Medicare Part B Claims Measure Collection Type (Traditional MIPS)	12,197	8,350	(3,847)	(388)	(3,459)
Quality Performance Category: MIPS CQM and QCDR Measure Collection Type (Traditional MIPS)	17,008	17,407	399	(810)	1,209
Quality Performance Category: eCQM Collection Type (Traditional MIPS)	27,179	23,936	(3,243)	(1,114)	(2,129)
MVP Registration	6,285	8,110	1,825	2,312	(487)
MVP Quality Submission	6,285	8,110	1,825	2,312	(487)
Total	68,954	65,913	(3,041)	2,312	(5,353)

*Currently approved annual estimates for CY 2025 performance period/2027 MIPS payment year under OMB Control Number 0938-1314 (CMS-10621).
** Proposed total annual estimate beginning with the CY 2026 performance period/2028 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy changes and updated data.
*** Total impact of policy proposals described in this proposed rule and the availability of updated MIPS submission data.
**** Change reflects the availability of updated MIPS submission data. The currently approved estimate incorporated MIPS submission estimates from the CY 2022 performance period/2024 MIPS payment year. In this proposed rule, we apply updated MIPS submission data from the CY 2023 performance period/2025 MIPS payment year. For additional information of this data, see section V.B.5.a.(4) of this proposed rule.

TABLE 80: ANNUAL TIME BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1314 (CMS-10621)

Requirement	Currently Approved Total Time (Hours)*	Proposed Total Time (Hours)**	Total Change (Hours)***	Change Due to Policy	Change Due to Updated Data****
Quality Performance Category: Medicare Part B Claims Measure Collection Type (Traditional MIPS)	173,197	118,570	(54,627)	(5,510)	(49,118)
Quality Performance Category: MIPS CQM/QCDR Measure Collection Type (Traditional MIPS)	154,484	158,108	3,624	(7,357)	10,981
Quality Performance Category: eCQM Collection Type (Traditional MIPS)	217,432	191,488	(25,944)	(8,912)	(17,032)
MVP Registration	1,571	2,027	456	578	(122)
MVP Quality Submission	40,193	50,515	10,322	14,403	(4,081)
Total	586,877	520,708	(66,169)	(6,798)	(59,372)

* Currently approved annual estimates for CY 2025 performance period/2027 MIPS payment year under OMB Control Number 0938-1314 (CMS-10621).
** Proposed total annual estimate beginning with the CY 2026 performance period/2028 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy changes and updated data.
*** Total impact of policy proposals described in this proposed rule and the availability of updated MIPS submission data. The estimate per ICR applies the change in policy and change in updated data as calculated in section V.B.5.c. of this proposed rule, before rounding to the full hour as displayed in this table. Thereby, the sum of the "Change Due to Policy" and "Change Due to Updated Data" columns may be one hour different than this estimate due to rounding. The "Total" row is the sum of the preceding rows in this table.
**** This change reflects the change in hours due to the updated number of estimated responses due to the availability of updated MIPS submission data (independent of the proposal of additional MVPs). The currently approved estimate incorporated MIPS submission estimates from the CY 2022 performance period/2024 MIPS payment year. In this proposed rule, we apply updated MIPS submission data from the CY 2023 performance period/2025 MIPS payment year.

TABLE 81: ANNUAL COST BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1314 (CMS-10621)

Requirement	Total Change in Cost*	Change Due to Policy	Change Due to Updated Data**
Quality Performance Category: Medicare Part B Claims Measure Collection Type (Traditional MIPS)	($6,496,552)	($655,228)	($5,841,324)
Quality Performance Category: MIPS CQM/QCDR Collection Type (Traditional MIPS)	$444,109	($901,575)	$1,345,684
Quality Performance Category: eCQM Collection Type (Traditional MIPS)	($3,231,520)	($1,110,056)	($2,121,463)
MVP Registration	$49,120	$62,227	($13,108)
MVP Quality Submission	$1,274,560	$1,763,875	($489,315)
Total	($7,960,283)	($840,757)	($7,119,526)

* This change reflects the change in cost due to the total change in hours (determined as the sum of change in hours multiplied by hourly wages, per labor category). This change incorporates changes due to policy and due to updated data. The estimate per ICR applies the change in policy and change in updated data as calculated in section V.B.5.c. of this proposed rule, before rounding to the full dollar as displayed in this table. Thereby, the sum of the "Change Due to Policy" and "Change Due to Updated Data" columns may be one dollar different than this estimate due to rounding. The "Total" row is the sum of the preceding rows in this table.

**This change reflects the change in dollars due to the updated number of estimated responses due to the availability of updated MIPS submission data (independent of the proposal of additional MVPs). The currently approved estimate incorporated MIPS submission estimates from the CY 2022 performance period/2024 MIPS payment year. In this proposed rule, we apply updated MIPS submission data from the CY 2023 performance period/2025 MIPS payment year.

TABLE 82: ANNUAL RESPONSES BEGINNING WITH THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1222 (CMS-10450)

Requirement	Currently Approved Responses*	Proposed Responses**	Total Change in Responses	Change Due to Policy	Change Due to Updated Data
CAHPS for MIPS Survey Vendor Application	10	10	0	0	0

* Currently approved annual estimates under OMB Control Number OMB control number 0938-1222 (CMS-10450).

** Proposed total annual responses beginning with the CY 2027 performance period/2028 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy adjustments and updated data.

TABLE 83: ANNUAL TIME BEGINNING WITH THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1222 (CMS-10450)

Requirement	Currently Approved Total Time (Hours)*	Proposed Time Per Response**	Proposed Total Time (Hours)***	Total Change in Time (Hours)****	Change in Total Time (Hours) Due to Policy	Change in Total Time (Hours) Due to Updated Data*****
CAHPS for MIPS Survey Vendor Application	100	11	110	10	10	0

* Currently approved annual estimates under OMB Control Number OMB control number 0938-1222 (CMS-10450).

** Proposed total annual time per response beginning with the CY 2027 performance period/2028 MIPS payment year.

*** Proposed total annual estimate beginning with the CY 2027 performance period/2029 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy changes and updated data.

**** Total impact of policy proposals described in this proposed rule and the availability of updated MIPS submission data.

***** We are not proposing a change to our currently approved estimates due to the availability of updated data that is independent of the impacts of proposed policies.

TABLE 84: ANNUAL COST BEGINNING WITH THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1222 (CMS-10450)

Requirement	Total Change in Cost*	Change in Cost Due to Policy	Change in Cost Due to Updated Data
CAHPS for MIPS Survey Vendor Application	$1,077	$1,077	N/A

* This change reflects the change in cost due to the total change in hours (determined as the sum of change in hours multiplied by hourly wages, per labor category). This change incorporates changes due to policy and due to updated data.

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(2) Summary of Changes for the Quality Payment Program: MIPS

(a) MIPS ICRs With Changes Due to Proposed Policy Provisions

For the six ICRs detailed in tables 78 through 84, we detail proposed changes to our most recent estimates for these ICRs under their associated control numbers based on proposed policy provisions as well as revised burden assumptions based on the updated data available at the time of preparation of this proposed rule; these discussions begin in section V.B.5.b. of this proposed rule.

(b) MIPS ICRs With No Changes to Currently Approved Burden Estimates

We are not updating our burden estimates for the following ICRs under OMB control number 0938–1314 (CMS–10621) because there are no proposed changes to related policies that would affect our currently approved burden estimates, and nor do we have updated available data by which we would revise our currently approved burden estimates for respondents or hours from our currently approved estimates: (1) Nomination of Improvement Activities; (2) Nomination of MVPs; (3) Opt-out of Performance Data Display on Compare Tools for Voluntary Participants; (4) Subgroup Registration; (5) Qualified Clinical Data Registry (QCDR) Full Self-Nomination and other Requirements; (6) QCDR Simplified Self-Nomination and other Requirements; (7) Qualified Registry Full Self-Nomination and other Requirements; (8) Qualified Registry Simplified Self-Nomination and other Requirements; and (9) Third Party Intermediary Plan Audits. Additionally, we are not proposing changes to our burden response and hour estimates for the following ICRs under OMB control number 0938–1222 (CMS–10450): (1) Beneficiary Responses to CAHPS for MIPS Survey; and (2) Group Registration for CAHPS for MIPS Survey. Lastly, we are not proposing changes to our burden estimates for Registration for Virtual Groups under OMB control number 0938–1343 (CMS–10652). Where applicable, we discuss related policy proposals and the reasoning for not impacting our burden estimates per ICR, beginning in section V.B.5.b.(2) of this proposed rule.

(c) MIPS ICRs With Changes Due to Available Data

Separate from the policy proposals in section IV. of this proposed rule and ICRs described in tables 77 through 82, we are updating our burden estimates for the following ICRs for the CY 2026 performance period/2028 MIPS payment year due to the availability of updated data. Since the changes are not derived from this rule's proposed provisions, they are not set out in this proposed rule: (1) Call for Quality Measures; (2) Data Submission for the Improvement Activities Performance Category; (3) Data Submission for the Promoting Interoperability Performance Category; (4) Open Authorization (OAuth) Credentialing and Token Request Process; (5) Quality Payment Program Identity Management Application Process; and (6) Reweighting Applications for Promoting Interoperability and Other Performance Categories.

Where applicable, we discuss any related policy proposals and reasoning for not impacting our burden estimates per ICR, beginning in section V.B 5.d.(2) of this proposed rule.

(d) New MIPS ICRs

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We are proposing to add a new ICR to reflect submissions for the Alternative Payment Model Performance Pathway (APP), due to the availability of updated data. The APP is an optional MIPS reporting and scoring pathway for MIPS eligible clinicians who are also participants in MIPS APMs, as defined under § 414.1367. Our burden estimates for the APP will focus on submissions by individuals, groups, or non-Shared Savings Program ACO APMs for the APP quality measure set. As there are no related policy proposals in this proposed rule that would affect these estimates, we do not detail the APP burden estimates in this proposed rule.

We are not estimating burden for Shared Savings Program ACOs under the APP. Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Additionally, we are not establishing an ICR for the APP Plus quality measure set. In the CY 2025 PFS final rule (89 FR 98355 through 98371), we established the APP Plus as a new quality measure set designed for APP participants that expands the existing APP measure set and is mandatory for Shared Savings Program ACOs starting in the CY 2025 performance period/2027 MIPS payment year. We continue our assumption from the CY 2025 PFS final rule (89 FR 98549 and 98550) that MIPS eligible clinicians, groups, and APM Entities (excluding Shared Savings Program ACOs) would not elect to submit the APP Plus quality measure set. This assumption is because the APP Plus quality measure set has greater reporting requirements than the APP quality measure set. The APP Plus quality measure set for CY 2026 performance period/2028 MIPS payment year finalized in the CY 2025 PFS final rule (89 FR 98368) requires that MIPS eligible clinicians, groups, or non-Shared Savings Program ACOs actively report five quality measures (via the eCQM, MIPS CQM, and Part B Claims collection types as available per measure for non-Shared Savings Program ACOs per measure) instead of three quality measures in the APP quality measure set that are actively reported via the MIPS CQM, part B Claims and eCQM collection types, as available per measure for non-Shared Savings Program ACOs. We do not believe MIPS eligible clinicians, groups, and APM Entities who are not required to report the APP Plus quality measure set would elect to report APP Plus over APP quality measure set due to the

increased data collection and submission requirements.

(3) Summary of Changes for the Quality Payment Program: Advanced APMs

We are not proposing changes to the following ICRs due to policy proposals in this proposed rule or the availability of updated submission data beyond the wage rate data described in section V.A. of this proposed rule: (1) Partial Qualifying Advanced APM (QP) Elections; (2) Other Payer Advanced APM Determinations: Payer-Initiated Process; (3) Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process; and (4) Submission of Data for QP Determinations under the All-Payer Combination Option. We discuss related policy proposals and why they do not impact our burden estimates in sections V.B 5.a.(4)(c) and VII.I.5.e.(2)(b) of this proposed rule.

(4) Framework for Understanding the Burden of MIPS Data Submission and Data Considerations

(a) Framework for Understanding the Burden of MIPS Data Submission

Across organizations permitted or required to submit data on behalf of clinicians, there can be variation across the types of data provided, and whether a clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, a MIPS APM participant, or an Advanced APM participant. MIPS eligible clinicians and other clinicians voluntarily submitting data to MIPS for the quality, Promoting Interoperability, and improvement activities performance categories may submit data as the following participation types: individual; group; virtual groups (available only for traditional MIPS); subgroups (available only for MVPs); and APM Entities. Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS. MIPS eligible clinicians are not required to submit any additional data for the cost performance category, as CMS calculates performance on measures specified for this performance category based on claims-data.

Virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted.

For the aforementioned participation types, we assess the same burden per reporting option and assume from our available data that all non-Shared Savings Program ACO APM Entity submissions represent single Taxpayer Identification Number (TIN) APMs. We exclude performance category submissions by Shared Savings Program ACO APM Entities from our MIPS reporting estimates. Per section 1899(e) of the Act, the PRA does not apply to the Shared Savings Program. The regulatory impact analysis in section VII. of this proposed rule discusses impacts to the Shared Savings Program from proposals associated with this proposed rule.

There are three MIPS reporting options: traditional MIPS, MVPs, and the APP. In section V.B.5.c. of this proposed rule, we provide distinct estimates for the traditional MIPS and MVP reporting options for the quality performance category, focusing on changes to our currently approved burden estimates. We do not detail burden estimates for the Promoting Interoperability and improvement activities performance categories because we are not proposing any updates to our burden estimates associated with policy proposals in this proposed rule; for discussion of these proposals relative to burden implications, please see sections V.B.5.d. and V.B.5.e. of this proposed rule. Additionally, we have not separately estimated burden for Traditional MIPS and MVPs for the Promoting Interoperability and improvement activities performance categories. Traditional MIPS and MVPs require reporting on all Promoting Interoperability performance category objectives and measures. Traditional MIPS reporting for the improvement activities performance category typically requires attestation to two improvement activities; however, clinicians, groups, and virtual groups with a special status designation are only required to attest to one improvement activity. MVP participants are required to attest to one improvement activity regardless of special status. For additional details on historic burden assumptions for the improvement activities performance category, we refer readers to the CY 2025 PFS final rule (89 FR 98492). In the related collection of information request (OMB control number 0938–1314 (CMS–10621)), we aggregate submissions across all reporting options. For additional burden historic frameworks, we refer readers to the CY 2024 PFS final rule (88 FR 79422 through 79424) and the CY 2025 PFS proposed rule (89 FR 62111 through 62114).

(b) Summary of Available MIPS Submission Data Sources

Where available, we incorporate updated data into our burden estimates beginning with the CY 2026 performance period/2028 MIPS payment year. These updates include submission data from the CY 2023 performance period/2025 MIPS payment year. To estimate QPs excluded from MIPS reporting requirements, we use the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot for the 2023 QP Performance period.

The available CY 2023 performance period/2025 MIPS payment year data identifies performance category submissions by non-Shared Savings Program ACO APM Entities. We incorporate these estimates alongside our longstanding inclusion of individual, group, and virtual group data.

As detailed in section V.B.5.c.(6) of this proposed rule, we are updating our assessment of estimated MVP quality performance category submissions and registrations, assessing measure level submission trends from the CY 2023 performance period/2025 MIPS payment year (87 FR 70650 through 70701) alongside the MVP inventory finalized in the CY 2025 PFS final rule Appendix 3 (89 FR 98972 through 99057), and the new MVPs proposed in section IV.A.4.a.(1) of this proposed rule. The CY 2023 performance period/2025 MIPS payment year submission data include MVP submissions and registration for the 12 MVPs available at that time for MIPS reporting. Due to the expanded MVP inventory (16 MVPs available for the CY 2024 performance period/2026 MIPS payment year (88 FR 79978 through 80047), 21 MVPs available for the CY 2025 performance period/2027 MIPS payment year (89 FR 98972 through 99057)), and the newly proposed MVPs for the CY 2026 performance period/2028 MIPs payment year, we anticipate increased MVP adoption for the CY 2026 performance period/2028 MIPS payment year and beyond. For this proposed rule, we estimate MVP submissions as a percentage of the total traditional MIPS and MVP submissions from the CY 2023 performance period/2025 MIPS payment year. For details on this analysis, we refer readers to section V.B.5.c.(6) of this proposed rule.

(c) Additional Data Considerations

The accuracy of our estimates of the total burden for data submission for MIPS performance categories may be impacted by several primary factors. First, we are unable to predict with certainty who will be a QP for the CY 2026 performance period/2028 MIPS payment year and later years.

Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2026 performance period/2028 MIPS payment year or later years compared to the CY 2023 performance period/2025 MIPS payment year. Therefore, the actual number of Advanced APM participants and how they elect to submit data may differ from our estimates. However, we believe our estimates are the most appropriate given the available data. We refer readers to section VII.I.5.e.(2)(b) of this proposed rule for a discussion of the potential but unquantifiable burden implications on MIPS-related burden of the proposals to change QP determinations and remove the eligible clinician limit to the Medical Home Model, Aligned Other Payer Medical Home Model, and Medicaid Medical Home Model, presented in section IV.B.5. of this proposed rule.

In section IV.B.5.d. of this proposed rule, we are proposing to make a technical amendment to the language in § 414.1455 that establishes Targeted Review for QPs. This proposal would revise the timeline but not the other established processes for requested a targeted review. We note that information collection requirements, such as targeted reviews, that are imposed after an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2).

b. ICRs Regarding Third Party Intermediaries

(1) CMS-Approved Survey Vendor Requirements

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey. We refer readers to the CY 2024 PFS final rule (88 FR 79433 through 79434) and the CY 2025 PFS final rule (89 FR 98475) for recent burden discussions on this ICR. The following proposed changes (associated with CAHPS survey vendors to submit data for eligible clinicians) will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We will make the revised files available for public review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices, which are expected to publish in the CY 2026 performance period/2028 MIPS payment year.

As discussed in section IV.B.4.a.(5) of this proposed rule, we are proposing to add a web administration mode to the current CAHPS for MIPS Survey administration in addition to the existing mail and phone options. Beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors would administer the CAHPS for MIPS Survey via a web-mail-phone protocol. During the 1-year implementation delay, we would update the survey administration requirements and associated materials.

For the CY 2027 performance period/2029 MIPS payment year, we are proposing to increase the currently approved burden estimate of 10 hours to complete the vendor application by 1 hour for a total of 11 hours per application. The currently approved burden estimate for the vendor application includes completing the Vendor Attestation Statement, the Vendor Participation Form, and compiling documentation, including the quality assurance plan that demonstrates compliance with the Minimum Survey Vendor Business Requirements. We estimate that it would take applicants an additional 0.5 hours to compile documentation related to the web mode and an additional 0.5 hours to develop a quality assurance plan related to web implementation. We assume that our proposal to add a web administration mode to the current CAHPS for MIPS survey administration would not affect our currently approved estimate of 10 survey vendor applicants. We estimate an annual increase of 10 hours due to this proposed requirement (+1 hr/vendor × 10 vendors) at a cost of +$1,077 (10 hr × $107.66/hr for a computer systems analyst or equivalent).

TABLE 85: PROPOSED ANNUAL REQUIREMENT AND BURDEN ESTIMATES FOR CMS-APPROVED SURVEY VENDORS

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1400 Quality Payment Program: CAHPS for MIPS Survey	0938-1222 (CMS-10450)	10	10	1	10	107.66	1,077

(2) Full and Simplified Self Nomination for Qualified Clinical Data Registries and Qualified Registries

In section IV.A.4.a.(3) of this proposed rule, we are proposing to provide additional flexibilities to allow third party intermediaries additional time to fully support finalized MVPs. As this proposal does not alter requirements related to the self-nomination process, we are not proposing revisions to our currently approved responses and time per response for both the Full and Simplified Self Nominations for Qualified Registries and Qualified Clinical Data Registries under OMB control number 0938–1314 (CMS–10621).

c. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Changes to Quality Performance Category Submissions

In this section, we estimate the number of submissions for each collection type that requires active reporting by individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program ACO APM Entities. This includes Medicare Part B claims measures (individual clinicians only), MIPS Clinical Quality Measures (CQM) and QCDR measures, and electronic Clinical Quality Measures (eCQM). Notably, we do not assess burden for the quality administrative claims collection type, as CMS automatically calculates scores for individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program ACO APM Entities that meet requirements to be scored. We assume that the proposal to revise QP determinations in section IV.B.5.b. would not affect MIPS performance category-level data submissions.

Because MIPS eligible clinicians may submit data for multiple collection types for the quality performance category, the estimated numbers of individual clinicians, groups, subgroups (as applicable for MVP reporting), and non-Shared Savings Program ACO APM Entities to collect via the various

collection types are not mutually exclusive and reflect the occurrence of individual clinicians, groups, subgroups (as applicable for MVP reporting) and non-Shared Savings Program ACO APM Entities that collected and submitted data via multiple collection types or reporting options during the CY 2023 performance period/2025 MIPS payment year. We describe our approach for each MIPS reporting option below.

(a) Traditional MIPS

We estimate the number of traditional MIPS submissions for the CY 2026 performance period/2028 MIPS payment year as the sum of estimated traditional MIPS and MVP quality performance submissions from the CY 2023 performance period/2025 MIPS payment year for each actively submitted collection type (Medicare Part B claims measures, MIPS CQMs and QCDR measures, and eCQMs) submitted by individual clinicians, groups, or non-Shared Savings Program APM Entities individual, less the estimated number of submissions we expect to submit MVPs. This analysis is described in section V.B.5.c.(6) of this proposed rule.

(b) MVPs

We estimate the number of MVP submissions for the CY 2026 performance period/2028 MIPS payment year as a percent of the total traditional MIPS and MVP submissions from the CY 2023 performance period/2025 MIPS payment year for each actively submitted collection type (Medicare Part B claims measures, MIPS CQMs and QCDR measures, and eCQMs) by individual clinicians, groups, or non-Shared Savings Program ACO APM Entities, and add our estimate of subgroup submissions described in section V.B.5.c.(6) of this proposed rule. We believe this approach to estimate MVP submissions as a function of historic traditional MIPS and MVP submissions, and not just MVP submissions from a given year, is appropriate to estimate future reporting behaviors because we expect increased adoption due to the annual expansion of and updates to the MVP inventory as summarized in section IV.A.4.a. of this proposed rule. This analysis is described in section V.B.5.c.(6) of this proposed rule.

(c) APM Performance Pathway (APP)

We assume the number of submissions per available collection type that is actively reported by clinicians, groups, or non-Shared Savings Program APM ACO Entities. As we do not expect changes due to policy proposals in this proposed rule, we do not detail these estimates in this proposed rule.

(d) Factors Affecting Quality Performance Category Submission Estimates

Several factors drive our proposed updates to the number of submissions for the Medicare Part B claims measures, MIPS CQMs and QCDR measures, and eCQMs. First, we incorporate updated traditional MIPS and MVP submission data available for the CY 2023 performance period/2025 MIPS payment year. For the CY 2025 PFS final rule (89 FR 98475), our available submission data for the CY 2022 performance period/2024 MIPS payment year included only traditional MIPS submissions. In this proposed rule, we aggregate the submissions for both traditional MIPS and MVPs by collection type and create a new baseline to which we apply our MVP participation estimates for the CY 2026 performance period/2028 MIPS payment year. Please see section V.B 5.a.(4) of this proposed rule for additional details on updates to available data.

Second, we are updating our estimates for MVP participation for the CY 2026 performance period/2028 MIPS payment year. This updated estimate for MVP participation impacts our estimate of the number of estimated clinicians submitting quality data for traditional MIPS using each collection type. As detailed in section V.B.5.c.(6) of this proposed rule, we are updating our estimates to account for the expected increase in MVP participation of 4 percentage points due to the proposed addition of new MVPs in this proposed rule; we associate this incremental effect, all else equal, with proposed policy provisions. With this approach, any increase to our expected MVP participation rate reduces the number of estimated submissions for each quality performance category collection type via traditional MIPS. Similarly, any decrease to our estimated MVP participation rate increases the number of estimated submissions for each quality performance category collection type via traditional MIPS.

(e) Medicare Part B Claims Measure, MIPS CQMs/QCDR Measure, and eCQM Collection Types

Table 84 of this proposed rule identifies our methods to estimate the number of individual clinicians, groups, and non-Shared Savings Program ACO APM Entities that may submit data via each collection type in the CY 2026 performance period/2028 MIPS payment year, separating traditional MIPS and MVP estimates. We identify estimated submissions per collection type from CY 2023 performance period/2025 MIPS payment year data (row a). We estimate that 14 percent of these quality performance category submissions may report via MVPs for the CY 2026 performance period/2028 MIPS payment year (row b). This 14 percent encompasses our estimate that 10 percent of submissions would report the MVPs previously finalized in the CY 2025 PFS final rule (row c), and that 4 percent of submissions would submit the proposed MVPs in this proposed rule (row d). The basis of these assumptions is described in section V.B.5.c.(6) of this proposed rule.

In the following paragraphs, we discuss the impacts to the estimated number of submissions for traditional MIPS, aggregated across individual clinician, group, and non-Shared Savings Program APM Entity submissions where applicable per collection type. We discuss the impacts to the estimated number of submissions for MVPs in section V.B.5.c.(6) of this proposed rule. For each collection type, we assume there is one annual submission or response per respondent.

Medicare Part B Claims Measure Collection Type: In the CY 2025 PFS final rule (89 FR 98479 through 98481), we estimated 12,197 submissions. For the CY 2026 performance period/2028 MIPS payment year we estimate 3,459 fewer submissions for this collection type via traditional MIPS due to the availability of updated submission data and assumptions. Additionally, we estimate that the new MVPs proposed in section IV.A.4.a.(1) of this proposed rule would result in 388 fewer traditional MIPS submissions for this collection type, as the proposed availability of new MVPS could lead clinicians who previously reported via traditional MIPS to report via MVPs. We estimate that there would be approximately 8,350 Medicare Part B claims measure collection type submissions for the CY 2026 performance period/2028 MIPS payment year submitted by individual clinicians. Taken together, we estimate a total decrease of 3,847 submissions (−388 submissions due to proposed policy provisions + −3,459 submissions due to updated data). The net result is 8,350 submissions (12,197 currently approved submissions − 3,847 submissions).

The aforementioned proposed changes apply to OMB control number 0938–1314 (CMS–10621).

MIPS CQM and QCDR Measure Collection Types: In the CY 2025 PFS

final rule (89 FR 98481 through 98483), we estimated 17,008 submissions. For the CY 2026 performance period/2028 MIPS payment year we estimate 1,209 more submissions for collection type via traditional MIPS due to the availability of updated submission data and assumptions. Additionally, we estimate that the new MVPs proposed in section IV.A.4.a.(1) of this proposed rule would result in 810 fewer traditional MIPS submissions for this collection type, as the proposed availability of new MVPS could lead clinicians who previously reported via traditional MIPS to report via MVPs. We estimate that there would be approximately 17,407 MIPS CQM/QCDR measure collection type submissions for the CY 2026 performance period/2028 MIPS payment year (11,266 individual clinicians + 6,132 groups + 9 non-Shared Savings Program ACO APM Entities). This is a total increase of 399 submissions (1,209 submissions due to updated data + −810 submissions due to proposed policy provisions). The net result is 17,407 submissions (17,008 currently approved submissions + 399 submissions). Given the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQMs or QCDR measures.

The aforementioned proposed changes apply to OMB control number 0938–1314 (CMS–10621).

eCQM Collection Type: In the CY 2025 PFS final rule (89 FR 98483 to 98485), we estimated 27,179 submissions. For the CY 2026 performance period/2028 MIPS payment year we estimate 2,129 fewer submissions for this collection type via traditional MIPS due to the availability of updated submission data and assumptions. Additionally, we estimate that that the new MVPs proposed in section IV.A.4.a.(1) of this proposed rule would result in 1,114 fewer traditional MIPS submissions for this collection type, as the proposed availability of new MVPS could lead clinicians who previously reported via traditional MIPS to report via MVP. We estimate that there would be approximately 23,936 eCQM collection type submissions for the CY 2026 performance period/2028 MIPS payment year (approximately 18,282 individual clinicians + 5,647 groups + 7 non-Shared Savings Program ACO APM Entities). This is a total decrease of 3,243 submissions (−2,129 submissions due to updated data + −1,114 submissions due to proposed policy provisions). The net result is 23,936 submissions (27,179 currently approved submissions − 3,243 submissions).

The aforementioned proposed changes apply to OMB control number 0938–1314 (CMS–10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR measure collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 86 are not mutually exclusive. We assume that each response or submission per collection type for traditional MIPS includes six quality measures, and that each response or submission per collection type for MVPs includes four quality measures.

TABLE 86: ESTIMATED NUMBER OF SUBMISSIONS FOR QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

Burden and Submission Description	Medicare Part B Claims Measure	MIPS CQM/QCDR Measure	eCQM
2026 MIPS Performance Period (Excludes QPs) Before Applying Estimated MVP Submission Rate (a)	9,709	20,241	27,833
Total Estimated MVP Submissions (14%) (b) = (a) × - 0.14 or (c) + (d)	(1,359)	(2,834)	(3,897)
Estimate for CY 2025 Approved MVPs (10 percent) (c)= (a) × -0.10	(971)	(2,024)	(2,783)
Estimate for MVPs Proposed in the CY 2026 Proposed Rule (4 percent) (d) = (b) - (c)	(388)	(810)	(1,114)
2026 MIPS Performance Period (Excludes QPs and Estimated MVP Submissions) (e) = (a) + (b)	8,350	17,407	23,936
2025 MIPS Performance Period from CY 2025 PFS Final Rule (Excludes QPs) (f)	12,197	17,008	27,179
Difference in Number of Submissions (g) = (e) − (f)	(3,847)	399	(3,243)
Change Due to Policies Proposed in the CY 2026 Proposed Rule (h) = (d)	(388)	(810)	(1,114)
Change Due to Availability of Updated Data (i) = (g) – (h)	(3,459)	1,209	(2,129)

(2) Additional Burden Assumptions for the Quality Performance Category

For a discussion of the longstanding burden assumptions and any related limitations associated with the submission of quality performance category data, we refer readers to the CY 2025 PFS final rule (89 FR 98478 and 98479). We refer readers to the CY 2022 PFS final rule for details on MVP quality reporting requirements (86 FR 65411 through 65412).

As described in section IV.A.4.d.(1)(c)(iii) of this proposed rule, for the quality performance category, we are proposing to update the MIPS quality measure inventory for the CY 2026 performance period/2028 MIPS payment year; and revise the definition of a high priority measure. As described in section IV.A.4.b.(2) of this proposed rule, we are proposing to incorporate the updated versions of the MIPS quality measures used in the APP quality measure set. As these proposals would not affect the minimum reporting requirements for the quality performance category under traditional MIPS, MVPs, and the APP quality measure set, we do not anticipate burden changes for the Quality Payment Program. We refer readers to Table Group A of Appendix 1 for the proposed new measures; Table Group C of Appendix 1 for the proposed removed measures; and Table Group D of Appendix 1 for the proposed substantive changes to measures.

In sections V.B.5.c.(3), V.B.5.c.(4), and V.B.5.c.(5) of this proposed rule, we

detail our proposed burden changes per collection type for traditional MIPS, and in section V.B.5.c.(6) for MVPs. As noted in section V.B.5.a.(4) of this proposed rule, we are proposing to revise our estimates described in the CY 2025 PFS final rule and submitted to OSORA for each collection type due to: (1) the availability of updated performance category data; (2) the inclusion of data estimates for non-Shared Savings Program ACO APM Entities; and (3) the new MVPs.

(3) Traditional MIPS Quality Data Submission by Clinicians: Medicare Part B Measure Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 70149 through 70151) and the CY 2025 PFS final rule (89 FR 98479 through 98481). As with the CY 2025 PFS final rule (89 FR 98479 through 98481), we acknowledge a range of times for computer system analysts to submit quality measure data (minimum, mean, and maximum burden estimates) for this collection type. We continue to apply the maximum burden in our total burden estimates. All changes to the number of quality performance category submissions described below are relative to our currently approved estimate of 12,197 submissions detailed in the CY 2025 PFS final rule (89 FR 98479 through 98481).

Impact of Policy Proposals: We estimate a change of −388 submissions due to the proposal of additional MVPs in this proposed rule. Multiplying the estimated change in submissions (−388) by the time per submission by labor category, we estimate a maximum total change of minus 5,509.60 hours. All estimates encompass time to review measure specifications unless otherwise noted. This change of −5,509.60 hours incorporates the following estimates:

- Minimum of −446.20 hours for computer system analysts (−388 submissions × 1.15 hr/submission (0.15 hr to submit data and 1 hr to review measure specifications)).
- Mean of −795.40 hours for computer system analysts (−388 submissions × 2.05 hr/submission (1.05 hr to submit data and 1 hr to review measure specifications)).
- Maximum of −3,181.60 hours for computer system analysts (−388 submissions × 8.2 hr/submission (7.2 hr to submit data and 1 hr to review measure specifications)).
- −1,164 hours for medical and health service managers (−388 submissions × 3 hr/submission).
- −388 hours for licensed practical nurses (LPNs) (−388 submissions × 1 hr/submission).
- −388 hours for billing clerks (−388 submissions × 1 hr/submission).
- −388 hours for physicians (−388 submissions × 1 hr/submission).

We estimate a maximum annual change of minus $655,228.02 [(−3,181.602 hr × $107.66/hr = −$342,531.06 for computer system analysts) + (−1,164 hr × $132.44/hr = −$154,160.16 for medical and health service managers) + (−388 hr × $61.68/hr = −$23,931.84 for LPNs) + (−388 hr × $47.60/hr = −$18,468.80 for billing clerks) + (−388 hr × $299.32/hr = −$116,136.16 for physicians)].

Impact of Updated Data: We estimate an additional change of −3,459 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (−3,459) by the time per submission identified by labor category in preceding list, we estimate a maximum total change of −49,117.808 hours. This change incorporates the following estimates:

- Minimum of −3,997.85 hours for computer system analysts (−3,459 submissions × 1.15 hr/submission).
- Mean of −7,090.95 hours for computer system analysts (−3,459 submissions × 2.05 hr/submission).
- Maximum of −28,363.80 hours for computer system analysts (−3,459 submissions × 8.2 hr/submission).
- −10,377 hours for medical and health service managers (−3,459 submissions × 3 hr/submissions).
- −3,459 hours for LPNs (−3,459 submissions × 1 hr/submission).
- −3,459 hours for billing clerks (−3,459 submissions × 1 hr/submission).
- −3,459 hours for physicians (−3,459 submissions × 1 hr/submission).

We estimate a maximum annual change of −$5,841,323.994 [(−28,363.80 hr × $107.66/hr = −$3,053,646.71 for computer system analysts) + (−10,377 hr × $132.44/hr = −$1,374,329.88 for medical and health service managers) + (−3,459 hr × $61.68/hr = −$213,351.12 for LPNs) + (−3,459 hr × $47.60/hr = −$164,648.40 for billing clerks) + (−3,459 hr × $299.32/hr = −$1,035,347.88 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy proposals and newly available data would result in a change of minus 3,847 submissions (−388 due to policy proposals + −3,459 due to updated data), a maximum annual burden change of minus 54,627 hours (−5,509.60 hr due to policy proposals + −49,117.80 hr due to updated data, rounded to the hour) and minus $6,496,552 (−$655,228.02 due to policy proposals + −$5,841,323.994 due to updated data). We estimate a total of 8,350 traditional MIPS submissions under the Medicare Part B collection type for the CY 2026 performance period/2028 MIPS payment year. We invite public comments on our estimates and assumptions.

(4) Traditional MIPS Quality Data Submission: MIPS CQM and QCDR Measure Collection Types

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

These estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians, groups, and non-Shared Savings Program ACO APM Entities. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 70149 through 70151) and the CY 2025 PFS final rule (89 FR 98479 through 98483). All estimates encompass time to review measure specifications unless otherwise noted. All changes to the number of quality performance category submissions described below are relative to our currently approved estimate of 17,008 submissions detailed in the CY 2025 PFS final rule (89 FR 98481 through 98483).

Impact of Policy Proposals: We estimate a change of minus 810 submissions due to our proposal to add new MVPs. Multiplying the estimated change in submissions (−810) by the time per submission by labor category, we estimate a total change of −7,357.23 hours. This change of incorporates the following estimates: −3,307.23 hours for a computer system analyst (−810 submissions × 4.083 hr/submission (3 hr to submit data; 1 hr to review measure specifications, and 5 minutes (0.083 hr) to authorize or instruct the qualified registry or QCDR to submit quality measure data on their behalf), −1,620 hours for medical and health service managers (−810 submissions × 2 hr/submission), −810 hours for LPNs (−810 submissions × 1 hr/submission), −810 hours for billing clerks (−810 submissions × 1 hr/submission), and −810 hours for physicians (−810 submissions × 1 hr/submission). We estimate an annual change of

−$901,575.18 [(−3,307.23 hr × $107.66/hr = −$356,056.38 for computer systems analysts) + (−1,620 hr × $132.44/hr = −$214,552.80 for medical and health service managers) + (−810 hr × $61.68/hr = −$49,960.80 for LPNs) + (−810 hr × $47.60/hr = −$38,556.00 for billing clerks) + (−810 hr × $299.32/hr = −$242,499.20 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of +1,209 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (+1,209) by the time per submission identified in the preceding paragraph by labor category, we estimate a total change of +10,981.35 hours. This change incorporates the following estimates: 4,936.347 hours for computer system analysts (+1,209 submissions × 4.083 hr/submission), 2,418 hours for medical and health service managers (+1,209 submissions × 2 hr/submission), 1,209 hours for LPNs (+1,209 submissions × 1 hr/submission), 1,209 hours for billing clerks (+1,209 submissions × 1 hr/submission), and 1,209 hours for physicians (+1,209 submissions × 1 hr/submission). We estimate an annual change of +$1,345,684.44 [(+4,936.347 hr × $107.66/hr = $531,447.12 for computer system analysts) + (+2,418 hr × $132.44/hr = $320,239.92 for medical and health service managers) + (+1,209 hr × $61.68/hr = $74,571.12 for LPNs) + (+1,209 hr × $47.60/hr = $57,548.40 for billing clerks) + (+1,209 hr × $299.32/hr = $361,877.88 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy proposals and newly available data would result in a change of +399 submissions (−810 submissions due to policy proposals + 1,209 submissions due to updated data), an annual burden change of +3,624 hours (−7,357.23 hr due to policy proposals + 10,981.35 hr due to updated data, rounded to the hour) at a cost of +$444,109 (−$901,575.18 due to policy proposals + $1,345,684.44 due to updated data, rounded to the dollar). We estimate a total of 17,407 traditional MIPS submissions under the MIPS CQM/QCDR measure collection types for the CY 2026 performance period/2028 MIPS payment year (11,266 individual clinicians + 6,132 groups + 9 non-Shared Savings Program ACO APM Entities). We invite public comments on our estimates and assumptions.

(5) Traditional MIPS Quality Data Submission: eCQM Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

These estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians, groups, and non-Shared Savings Program ACO APM Entities. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 79441 through 79442) and the CY 2025 PFS final rule (89 FR 98483 through 98485). All estimates encompass time to review measure specifications unless otherwise noted. All changes to submissions described below are relative to our currently approved estimate of 27,179 submissions detailed in the CY 2025 PFS final rule (89 FR 98483 through 98485).

Impact of Policy Proposals: We estimate a change of −1,114 submissions due to the proposal of additional MVPs in this proposed rule. Multiplying the estimated change in submissions by the time per submission by labor category, we estimate a total change of −8,912 hours. This change incorporates the following estimates: −3,342 hours for computer system analysts (−1,114 submissions × 3 hr/submission (2 hr to submit data file and 1 hr to review measure specifications)), −2,228 hours for medical and health service managers (−1,114 submissions × 2 hr/submission), −1,114 hours for LPNs (−1,114 submissions × 1 hr/submission), −1,114 hours for billing clerks (−1,114 submissions × 1 hr/submission), and −1,114 hours for physicians (−1,114 submissions × 1 hr/submission). We estimate an annual change of −$1,110,056.44 [(−3,342 hr × $107.66/hr = −$359,799.72 for computer system analysts) + (−2,228 hr × $132.44/hr = −$295,076.32 for medical and health service managers) + (−1,114 hr × $61.68/hr = −$68,711.52 for LPNs) + (−1,114 hr × $47.60/hr = −$53,026.40 for billing clerks) + (−1,114 hr × $299.32/hr = −$333,442.48 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of −2,129 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (−2,129) by the time per submission identified in the preceding paragraph by labor category, we estimate a total change of −17,032 hours. This change incorporates the following estimates: −6,387 hours for computer system analysts (−2,129 submissions × 3 hr/submission), −4,258 hours for medical and health service managers (−2,129 submissions × 2 hr/submission), −2,129 hours for LPNs (−2,129 submissions × 1 hr/submission), −2,129 hours for billing clerks (−2,129 submissions × 1 hr/submission), and −2,129 hours for physicians (−2,129 submissions × 1 hr/submission). We estimate an annual change of −$2,121,463.34 [(−6,387 hr × $107.66/hr = −$687,624.42 for computer system analysts) + (−4,258 hr × $132.44/hr = −$563,929.52 for medical and health service managers) + (−2,129 hr × $61.68/hr = −$131,316.72 for LPNs) + (−2,129 hr × $47.60/hr = −$101,340.40 for billing clerks) + (−2,129 hr × $299.32/hr = −$637,252.28 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and the availability of updated data would result in a change of −3,243 submissions (−1,114 due to policy proposals + −2,129 due to updated data), an annual burden change of −25,944 hours (−8,912 hr due to policy proposals + −17,032 hr due to updated data) at a cost of −$3,231,520 (−$1,110,056.44 due to policy proposals + −$2,121,463.34 due to updated data, rounded to the dollar). We estimate a total of 23,936 traditional MIPS submissions under the eCQM collection type for the CY 2026 performance period/2028 MIPS payment year (18,282 individual clinicians + 5,647 groups + 7 non-Shared Savings Program ACO APM Entities). We invite public comments on our estimates and assumptions.

(6) ICRs Regarding Burden for MVP Reporting and Registration

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 PFS final rule (86 FR 65590 through 65592), CY 2023 PFS final rule (87 FR 70155), CY 2024 PFS final rule (88 FR 79443), and CY 2025 PFS final rule (89 FR 98487) for our previously finalized burden assumptions and requirements for submitting quality performance category data for the MVP reporting option.

We refer readers to Appendix 3: MVP Inventory of this proposed rule for updates to the format of the MVP tables. We do not anticipate that the new stratified update to the MVP format would affect reporting burden, as it does not alter the composition of an MVP and

does not affect the general minimum reporting requirements for each MVP.

In section IV.A.4.a. of this proposed rule, we are proposing MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria (85 FR 84849 through 84854). We are also proposing to add new MVPs to the MVP inventory for the CY 2026 performance period/2028 MIPS payment year.

In the CY 2025 PFS final rule (89 FR 98485 and 98486), we estimated that 10 percent of MIPS eligible clinicians from the CY 2022 performance period/2024 MIPS payment year would move from traditional MIPS reporting to MVP reporting for the CY 2025 performance period/2027 MIPS payment year. For details on prior approaches to estimating MVP reporting, we refer readers to the CY 2022 PFS final rule (86 FR 65588 through 65590), CY 2023 PFS final rule (87 FR 70155 and 70156), and CY 2024 PFS final rule (88 FR 79443 and 79444).

To estimate MVP submissions for the CY 2026 performance period/2028 MIPS payment year, we calculated the average quality measure submission rate for each of the newly proposed MVPs for the CY 2026 performance period/2028 MIPS payment year. For these analyses, we assessed measure submissions in the CY 2023 performance period/2025 MIPS payment year for clinicians with relevant clinical specialties for each MVP. We considered quality reporting trends from all quality performance category reporting options (traditional MIPS, MVPs, and the APP), by clinicians, groups, subgroups, and non-Shared Savings Program ACO APM Entities. The total of these average quality measure submissions for all the proposed MVPs was equivalent to about 4 percent of the total quality performance category submissions in the CY 2023 performance period/2025 MIPS payment year. Adding this incremental change of 4 percentage points to the existing estimate of 10 percent for MVPs established in the CY 2025 PFS final rule (89 FR 98485 and 98486), we estimate that MVP reporting will account for 14 percent of MIPS quality performance category submissions for the CY 2026 performance period/2028 MIPS payment year.

Continuing our approach from the CY 2022 PFS final rule (86 FR 65589 and 65590), CY 2023 PFS final rule (87 FR 70155 and 701566), CY 2024 PFS final rule (88 FR 79443 and 79444), and CY 2025 PFS final rule (89 FR 98486), we assume that number of MVP registrations would equal our estimated MVP quality submissions.

(a) Burden for MVP Registration: Individuals, Groups, Subgroups, and APM Entities

In section IV.A.3.a. of this proposed rule, we are proposing to add a new self-attestation requirement to the MVP registration process requiring each group to attest whether it is either a single-specialty group or multispecialty group meeting the requirements of a small practice. We believe the associated impact of this proposal would be minimal, and that this proposal would not require the burden per registration to exceed the currently approved estimate of 15 minutes per registration. Therefore, we are not proposing to revise the burden per MVP registration under OMB control number 0938–1314 (CMS–10621). We refer readers to section IV.A.3.a. of this proposed rule for additional details on the self-attestation requirement.

As described in section V.B.5.c.(6). of this proposed rule, we estimate that approximately 14 percent of the clinicians that participate in MIPS quality performance category reporting would submit data for the measures and activities in an MVP. For the CY 2026 performance period/2028 MIPS payment year, we assume that the total number of individual clinicians, groups, non-Shared Savings Program ACO APM Entities, and subgroups that would complete the MVP registration process is 8,110. All changes to the MVP registrations described below are relative to our currently approved estimate of 6,285 registrations detailed in the CY 2025 PFS final rule (89 FR 98486 and 98487).

We estimate that the proposal of new MVPs, if finalized, would result in an increase of 2,312 MVP registrations. Using the currently approved estimate of 0.25/hr per registration, we estimate an annual burden change of +578.00 hours (+2,312 registrations × 0.25 hr/registration) at a cost of +$62,227.48 (+578 hr × $107.66/hr for a computer system analyst or equivalent). Additionally, we estimate that the availability of updated data would result in a change of −487 submissions. Using the currently approved estimate of 0.25 hr/registration, we estimate an annual change of −121.75 hours (−487 registrations × 0.25 hr/registration) at a cost of −$13,107.61 (−122 hr × $107.66/hr for a computer system analyst or equivalent) due to the availability of updated data.

Taken together, we estimate that the anticipated changes due to policy provisions and the availability of updated data would result in a change of +1,825 registrations (2,312 registrations due to policy proposals + −487 registrations due to updated data), an annual burden change of +456 hr (578.00 hr due to policy proposals + −121.75 hr due to updated data, rounded to the hour) at a cost of +$49,120 (+$62,227.48 due to policy proposals + −$13,107.61 due to updated data, rounded to the dollar). We estimate a total of 8,110 MVP registrations for the CY 2026 performance period/2028 MIPS payment year. We invite public comments on our estimates and assumptions.

(b) Burden for Subgroup Registration

We are not proposing to revise burden for subgroup registration for the CY 2026 performance period/2028 MIPS payment year based on policy proposals in section IV. of this proposed rule. We previously finalized a requirement for subgroup reporting for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). In section IV.A.3.a.(3) of this proposed rule, we are proposing to update the MVP group registration process to add the self-attestation process for groups. If a group does not self-attest as a single specialty group or a multispecialty group meeting the requirements of a small practice during MVP registration, clinicians in the group cannot register as a group. Clinicians in such groups could register as subgroups to participate in MVP reporting. However, we are not revising the subgroups' burden relevant to this proposal because we are operationalizing previously finalized policies that would not impact the utilization of subgroups by groups and hence, would not change the way groups choose to organize clinicians in subgroups.

Additionally, we are proposing to maintain the MVP group reporting option for multispecialty groups with a small practice designation in section IV.A.3.a.(3) of this proposed rule. Maintaining the MVP group reporting option would not impact the currently approved burden for subgroup registration because it would not change any requirements related to subgroup registration. As future performance year data becomes available to reflect subgroup reporting trends amid revisions to the MVP inventory, we would evaluate changes to our currently approved burden estimate under OMB control number 0938–1314 (CMS–10621).

(c) Burden for MVP Quality Performance Category Submission

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). For prior discussions of our related burden estimates, please see the CY 2022 PFS final rule (86 FR 65590 through 65592), CY 2023 PFS final rule (87 FR 70157 through 70159), CY 2024 PFS final rule (88 FR 79444 through 79446), and CY 2025 PFS final rule (89 FR 98487 through 98490).

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621), relative to the currently approved burden estimates detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

We estimate a change to the number of annual MVP quality performance category submissions per collection type from our currently approved burden estimates, beginning with the CY 2026 performance period/2028 MIPS payment year. These estimates include the figures detailed in section V.B.5.c.(1)(e) of this proposed rule plus our currently approved estimate of 20 subgroup submissions (split evenly across the eCQM and MIPS CQM/QCDR measure collection types). These estimates aggregate individual clinician, group, subgroup, and non-Shared Savings Program ACO APM Entity submissions. All estimates encompass time to review measure specifications unless otherwise noted.

(i) Medicare Part B Claims Measure Collection Type

All estimates below presume the maximum submission time. All changes to the estimated number of quality performance category submissions described below are relative to our currently approved estimate of 1,355 submissions detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

Impact of Policy Proposals: We estimate a change of +388 submissions due to the proposal of additional MVPs in this proposed rule. Multiplying the estimated change in submissions (+388) by the time per submission by labor category, we estimate a total change of +3,662.72 hours. This change incorporates the following estimates: 2,118.48 hours for computer system analysts (+388 submissions × 5.46 hr/submission (4.8 hr to submit data + 0.66 hr to review measure specifications), 776 hours for medical and health service managers (+388 submissions × 2 hr/submission), 256.08 hours for LPNs (+388 submissions × 0.66 hr/submission), 256.08 hours for billing clerks (+388 submissions × 0.66 hr/submission), and 256.08 hours for physicians (+388 submissions × 0.66 hr/submission). We estimate an annual change of +$435,483.29 [(2,118.48 hr × $107.66/hr = $228,075.56 for computer system analysts) + (776 hr × $132.44/hr = $102,773.44 for medical and health service managers) + (256.08 hr × $61.68/hr = $15,795.01 for LPNs) + (256.08 hr × $47.60/hr = $12,189.41 for billing clerks) + (256.08 hr × $299.32/hr = $76,649.87 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of −384 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (−384) by the time per submission by labor category, we estimate a total change of −3,624.96 hours. This change incorporates the following estimates, and applies the annual time per labor category identified in the preceding paragraph: −2,096.64 hours for computer system analysts (−384 submissions × 5.46 hr/submission), −768 hours for medical and health service managers (−384 submissions × 2 hr/submission), −253.44 hours for LPNs (−384 submissions × 0.66 hr/submission), −253.44 hours for billing clerks (−384 submissions × 0.66 hr/submission), and −253.44 hours for physicians (−384 submissions × 0.66 hr/submission). We estimate an annual change of −$430,993.76 [(−2,096.64 hr × $107.66/hr = −$225,724.26 for computer system analysts) + (−768 hr × $132.44/hr = −$101,713.92 for medical and health service managers) + (−253.44 hr × $61.68/hr = −$15,632.18 for LPNs) + (−253.44 hr × $47.60/hr = −$12,063.74 for billing clerks) + (−253.44 hr × $299.32/hr = −$75,859.66 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy proposals and newly available data would result in a change of +4 submission (+388 submissions due to policy proposals + −384 submissions due to updated data), an annual burden change of +38 hours (3,662.72 hr due to policy proposals + −3,624.96 hr due to updated data, rounded to the hour) at a cost of +$4,490 ($435,483.29 due to policy proposals + −430,993.76 due to updated data, rounded to the dollar). We estimate a total of 1,359 MVP submissions under the Medicare Part B claims measure collection type for the CY 2026 performance period/2028 MIPS payment year. We invite public comments on our estimates and assumptions.

(ii) MIPS CQM/QCDR Measure Collection Type

All changes to the estimated number of quality performance category submissions described below are relative to our currently approved estimate of 1,900 submissions detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

Impact of Policy Proposals: We estimate a change of +810 submissions due to the proposal of additional MVPs in this proposed rule. Multiplying the estimated change in submissions (+810) by the time per submission by labor category, we estimate a total change of +4,835.70 hours. All estimates encompass time to review measure specifications unless otherwise noted. This change incorporates the following estimates: 2,154.60 hours for computer system analysts (+810 submissions × 2.66 hr/submission (2 hr to submit data and 0.66 hr to review measure specifications)), 1,077.30 hours for medical and health service managers (+810 submissions × 1.33 hr/submission), 534.60 hours for LPNs (+810 submissions × 0.66 hr/submission), 534.60 hours for billing clerks (+810 submissions × 0.66 hr/submission), and 534.60 hours for physicians (+810 submissions × 0.66 hr/submission). We estimate an annual change of $593,079.41 [(2,154.60 hr × $107.66/hr = $231,964.24 for computer system analysts) + (1,077.30 hr × $132.44/hr = $142,677.61 for medical and health service managers) + (534.60 hr × $61.68/hr = $32,974.13 for LPNs) + (534.60 hr × $47.60/hr = $25,446.96 for billing clerks) + (534.60 hr × $299.32/hr = $160,016.47 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of +134 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (+134) by the time per submission by labor category, we estimate a total change of +799.98 hours. This change incorporates the following estimates, and applies the annual time per labor category identified in the preceding paragraph: +356.44 hours for computer system analysts (+134 submissions × 2.66 hr/submission), 178.22 hours for medical and health service managers (+134 submissions × 1.33 hr/submission), 88.44 hours for LPNs (+134 submissions × 0.66 hr/submission), 88.44 hours for billing clerks (+134 submissions × 0.66 hr/submission), and 88.44 hours for physicians (+134 submissions × 0.66 hr/submission). We estimate an annual

change of $98,114.37 [(356.44 hr × $107.66/hr = $38,374.33 for computer system analysts) + (178.22 hr × $132.44/hr = $23,603.46 for medical and health service managers) + (88.44 hr × $61.68/hr = $5,454.98 for LPNs) + (88.44 hr × $47.60/hr = $4,209.74 for billing clerks) + (88.44 hr × $299.32/hr = $26,471.86 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy proposals and newly available data would result in a change of +944 submissions (810 due to policy proposals + 134 due to updated data), an annual burden change of 5,636 hours (4,835.70 hr due to policy proposals + 799.98 hr due to updated data, rounded to the hour) at a cost of +$691,194 ($593,079.41 due to policy proposals + 98,114.37 due to updated data, rounded to the dollar). We estimate a total of 2,844 MVP submissions under the MIPS CQM/QCDR measure collection types for the CY 2026 performance period/2028 MIPS payment year (10 subgroups + 1,834 individuals + 999 groups + 1 non-Shared Savings Program APM ACO entity). We invite public comments on our assumptions and estimates.

(iii) eCQM Collection Type

All changes to the estimated number of quality performance category submissions described below are relative to our currently approved estimate of 3,030 submissions detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

Impact of Policy Proposals: We estimate a change of +1,114 submissions due to the proposal of additional MVPs in this proposed rule. Multiplying the estimated change in submissions (+1,114) by the time per submission by labor category, we estimate a total change of +5,904.20 hours. All estimates incorporate time to review measure specifications unless otherwise noted. This change incorporates the following estimates: 2,216.86 hr for computer system analysts (+1,114 submissions × 1.99 hr/submission (1.33 hr to submit data file and 0.66 hr to review measure specifications)), 1,481.62 hr for medical and health service managers (+1,114 submissions × 1.33 hr/submission), 735.24 hr for LPNs (+1,114 submissions × 0.66 hr/submission), 735.24 hr for billing clerks (+1,114 submissions × 0.66 hr/submission), and 735.24 hr for physicians (1,114 submissions × 0.66 hr/submission). We estimate an annual change of +$735,311.96 [(2,216.86 hr × $107.66/hr = $238,667.15 for computer system analysts) + (1,481.62 hr × $132.44/hr = $196,225.75 for medical and health service managers) + 735.24 hr × $61.68/hr = $45,349.60 for LPNs) + (735.24 hr × $47.60/hr = $34,997.42 for billing clerks) + (735.24 hr × $299.32/hr = $220,072.04 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of −237 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (−237) by the time per submission by labor category, we estimate a total change of −1,256.10 hours. This change incorporates the following estimates, and applies the annual time per labor category identified in the preceding paragraph: −471.63 hr for computer system analysts (−237 submissions × 1.99 hr/submission) + −315.21 hr for medical and health service managers (−237 submissions × 1.33 hr/submission) + −156.42 hr for LPNs (−237 submissions × 0.66 hr/submission) + −156.42 hr for billing clerks (−237 submissions × 0.66 hr/submission) + −156.42 hr for physicians (−237 submissions × 0.66 hr/submission). We estimate an annual change of −$156,435.31 [(−471.63 hr × $107.66/hr = −$50,775.69 for computer systems analysts) + (−315.21 hr × $132.44/hr = −$41,746.41 for medical and health service managers) + (−156.42 hr × $61.68/hr = −$9,647.99 for LPNs) + (−156.42 hr × $47.60/hr = −$7,445.59 for billing clerks) + (−156.42 hr × $299.32/hr = −$46,819.63 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy proposals and newly available data would result in a change of +877 submissions (1,114 due to policy proposals + −237 due to updated data), an annual burden change of +4,648 hours (5,904.20 hr due to policy proposals + −1,256.10 hr due to updated data, rounded to the hour) at a cost of −$578,877 ($735,311.96 due to policy proposals + −$156,435.31 due to updated data, rounded to the hour). We estimate a total of 3,907 MVP submissions using the eCQM collection type for the CY 2026 performance period/2028 MIPS payment year (10 subgroups + 2,977 individuals + 919 groups + 1 non-Shared Savings Program APM ACO entity). We invite public comments on our estimates and assumptions.

(iv) Summation of Medicare Part B Claims Measure, MIPS CQM/QCDR Measure, and eCQM Collection Types

Across the quality performance category collection types for MVPs, we estimate that policy proposals would result in a total change of +2,312 submissions (388 Medicare Part B claims measure submissions + 810 MIPS CQM/QCDR measure submissions + 1,114 eCQM submissions), an annual burden change of +14,402.62 hours (3,662.72 hr for Medicare Part B claims measure submissions + 4,835.70 hr for MIPS CQM/QCDR measure submissions + 5,904.20 hr for eCQM submissions) at a cost of +$1,763,874.66 ($435,483.29 for Medicare Part B claims measure submissions + $593,079.41 for MIPS CQM/QCDR measure submissions + $735,311.96 for eCQM submissions).

Additionally, we estimate that updated data and assumption would result in a total change of −487 submissions (−384 Medicare Part B claims measure submissions + 134 MIPS CQM/QCDR measure submissions + −237 eCQM submissions), an annual burden change of −4,081.08 hours (−3,624.96 hr for Medicare Part B claims measure submissions + 799.98 hr for MIPS CQM/QCDR measure submissions + −1,256.10 hr for eCQM submissions) at a cost of—$489,314.70 (−$430,993.76 for Medicare Part B claims measure submissions + $98,114.37 for MIPS CQM/QCDR measure submissions + −$156,435.31 for eCQM submissions).

Taken together, we estimate that the change in submissions due to proposed policy provisions and newly available data would result in a change of +1,825 submissions (+2,312 submissions due to policy proposals + −487 submissions due to updated data), an annual burden change of +10,322 hours (+14,402.62 hr due to policy proposals + −4,081.08 hr due to updated data, rounded to the hour) at a cost of +$1,274,560 (+$1,763,874.66 due to policy proposals + −$489,314.70 due to updated data, rounded to the dollar). We estimate a total of 8,110 MVP submissions under the Medicare Part B claims measure, MIPS CQM/QCDR measure, and eCQM collection types for the CY 2026 performance period/2028 MIPS payment year (20 subgroups + 6,170 individuals +1,918 groups + 2 non-Shared Savings Program ACO APM entities). We invite public comments on our estimates and assumptions.

(7) Beneficiary Responses to CAHPS for MIPS Survey

In section IV.B.4.a.(5) of this proposed rule, we are proposing to update the CAHPS for MIPS Survey measure by changing from a mail-web protocol to a web-mail-phone protocol. As we are unable to estimate the incremental increase in submissions above our currently approved estimates, we are not proposing to increase our currently approved estimates under OMB control number 0938–1222 (CMS–10450). Additionally, we are proposing to

continue our currently approved estimate of response time per survey of 0.2183 hours (13.1 minutes), as we are not proposing revisions to the survey questions. We invite public comments on these assumptions.

(8) Group Registration for CAHPS for MIPS Survey

In section IV.B.4.a.(5) of this proposed rule, we are proposing to update the CAHPS for MIPS Survey measure by changing from a mail-web protocol to a web-mail-phone protocol. We do not anticipate that this proposal would affect the number of groups registering for the CAHPS for MIPS Survey, nor affect the time to complete each group registration. Therefore, we are not proposing any changes to the requirements and burden estimates that are currently approved by OMB under control number 0938–1222 (CMS–10450).

d. ICRs Regarding Reporting the Promoting Interoperability Performance Category

(1) Background

We refer readers to § 414.1375 for our previously established policies regarding reporting for the Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and §§ 414.1380(b)(4) and 414.1365(d)(3)(iv) for Promoting Interoperability performance category scoring. For historic assumptions on reporting requirements for the Promoting Interoperability performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79449 through 79451). As identified in section V.B.4., we do not estimate MIPS reporting burden due to requirements of the Shared Savings Program in the collection of information pages.

(2) Submitting Promoting Interoperability Data

In the following paragraphs, we outline proposed changes to the MIPS Promoting Interoperability performance category reporting requirements identified in section IV.A.4.d.(4) of this proposed rule and our assumptions as to why such proposals would not affect burden. For the first three policy proposals, there are similar proposed policies for the Medicare Promoting Interoperability Program in the CY 2026 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Systems (IPPS/LTCH PPS) proposed rule (90 FR 18355 through 18361). Our burden assumptions for proposals in this proposed rule affecting the MIPS Promoting Interoperability performance category are consistent with the CY 2026 IPPS/LTCH PPS proposed rule (90 FR 18414 and 18415).

First, beginning with the CY 2026 performance period/2028 MIPS payment year we are proposing to modify the Security Risk Analysis measure to require MIPS eligible clinicians to submit a second attestation (''Yes'' or ''No'') to having conducted security risk management activities as required under the HIPAA Security Rule implementation specification for risk management (codified at 45 CFR 164.308(a)(1)(ii)(B)). This attestation would be in addition to the current requirement under the measure for MIPS eligible clinicians to attest ''Yes'' to having conducted or reviewed a security risk analysis as required under the HIPAA Security Rule. We are not proposing to update the currently approved time per MIPS Promoting Interoperability performance category submission due to the additional attestation, as we believe the currently approved burden of 2.7 hours per MIPS Promoting Interoperability performance category submission is sufficient to absorb the negligible effort of the proposed additional attestation that would be included as a component of the Security Risk Analysis measure.

Second, beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing to modify the High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide measure by specifying that MIPS eligible clinicians use the version of the SAFER Guides published in January 2025. We are not proposing to modify our burden estimates because the proposed modification of the measure does not alter the core requirement to attest ''Yes'' or ''No.''

Third, beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing to establish the new optional bonus measure Public Health Reporting under Trusted Exchange Framework and Common Agreement (TEFCA). We are not proposing to update the burden estimates because the measure submission is optional and we cannot predict which MIPS eligible clinicians would elect to report this measure and how they would participate in MIPS (individual, group, virtual group, subgroup, or APM Entity (excluding Shared Savings Program Accountable Care Organizations (ACOs)) level). For further discussion regarding the three aforementioned policy proposals, we refer readers to section IV.A.4.d.(4) of this proposed rule.

In sections IV.A.4.d.(4)(f) and IV.A.4.d.(4)(g) of this proposed rule, we are also proposing to: (1) establish a measure suppression policy for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, in which an identified suppressed measure would not be included in scoring calculations; and (2) suppress the Electronic Case Reporting measure from scoring calculations for the CY 2025 performance period/2027 MIPS payment year for the MIPS Promoting Interoperability performance category and the EHR reporting period in CY 2025 for the Medicare Promoting Interoperability Program. For further discussion regarding such proposals, we refer readers to sections IV.A.4.d.(4)(f) and IV.A.4.d.(4)(g) of this proposed rule. The exclusion of a measure would only apply to how we score such a measure, and thus MIPS eligible clinicians, eligible hospitals, and CAHs would continue to be required to report the measure. We are not proposing any changes to the burden estimates due to the proposed measure exclusion policy not impacting burden estimates for meeting the requirements of the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

Independent of the aforementioned policy proposals, we are proposing to update the currently approved burden estimates for the number of total submissions for the MIPS Promoting Interoperability performance category due to the availability of updated data from the CY 2023 performance period/2025 MIPS payment year. Additionally, we intend to increase the time per MIPS Promoting Interoperability performance category submission by 30 seconds (0.083 hour) in order to account for the addition of the Electronic Prior Authorization measure under the Health Information Exchange objective for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year. Such measure was established in the CMS Interoperability and Prior Authorization final rule published in the **Federal Register** on February 8, 2024 (89 FR 8758). In this proposed rule, we do not outline the burden estimate updates in this collection of information section due to the burden estimates not being affected by the policy proposals in this proposed rule. The applicable burden changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

e. ICRs Regarding Reporting for the Improvement Activities Performance Category

We refer readers to §§ 414.1355 and 414.1365(c)(3) for our previously established policies regarding reporting for the improvement activities performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1360 for data submission requirements, and §§ 414.1380(b)(3) and 414.1365(d)(3)(iii) for improvement activities performance category scoring. For historic assumptions on reporting requirements for the improvement activities performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79454 and 79455).

In section IV.A.4.d.(3)(b) of this proposed rule, we are proposing changes to the Improvement Activities Inventory for the CY 2026 performance period/2028 MIPS payment year and future years. Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70211), the CY 2024 PFS final rule (88 FR 79519), and the CY 2025 PFS final rule (89 FR 98492), we believe clinicians performing improvement activities, to comply with previously finalized MIPS policies, will continue to perform the same activities because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified via rulemaking (82 FR 54175).

We refer readers to section VII.I.5.e.(2)(a) of this proposed rule for additional discussion. Independent of these policy proposals, we are updating the number of submissions due to the availability of updated submission data from the CY 2023 performance period/2025 MIPS payment year. While not scored in this rule, the non-policy changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

f. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by Compact Disc or hardcopy. The following policy proposals in section IV.A.4.d.(2) of this proposed rule would not result in the need to add or revise or delete any claims data fields: (1) modify the Total Per Capita Cost (TPCC) measure beginning in the CY 2026 performance period/2028 MIPS payment year; (2) update the operational list of care episode and patient condition groups and codes to reflect coding changes identified through annual maintenance of MIPS cost measures; and (3) adopt an informational-only feedback period of 2 years for new MIPS cost measures. Consequently, we are not proposing changes under the aforementioned OMB control number.

C. Summary of Proposed Annual Burden Estimates

Table 85 sets out the burden for this rulemaking's proposed provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of this rule's proposed provisions.

TABLE 87: PROPOSED ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	(65)	(260)	13	(3,380)	45.80	(154,804)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	435	4	varies	77	45.80	498,075
§§ 414.1325, 414.1335, and 414.1365 Quality Payment Program	0938-1314 (CMS-10621)	57,803	65,913	Varies	(6,798)	Varies	(840,757)
§§ 414.1400 Quality Payment Program: CAHPS for MIPS Survey	0938-1222 (CMS-10450	10	10	+1	+10	107.66	+1,077
§ 428.202(h) (Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act)	0938-TBD (CMS-10930	6,835 (335 Manufacturers + 6,500 Covered Entities or TPAs)	26,335 (335 Manufacturers + 26,000 Covered Entities or TPAs)	29 (21 Manufacturers + 8 Covered Entities or TPAs	215,035 (7,035 Manufacturers + 208,000 Covered Entities or TPAs)	Varies	23,949,098 (753,978 Manufacturers + 23,195,120 Covered Entities or TPAs)
TOTAL	n/a	65,018	92,002	varies	204,944	varies	23,452,689

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website

at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1832–P), the ICR's CFR citation, and OMB control number.

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing payment and policy changes under the Medicare PFS. Our proposed policies in this rulemaking specifically address: changes to the PFS; and other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program (MIPS and Advanced APMs); changes to payment policies for drugs and biologicals products paid under Medicare Part B, other changes to Medicare Part B payment policies for Rural Health Clinics and Federally Qualified Health Centers, and changes to the regulations associated with the Ambulance Fee Schedule. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Medicare Prescription Drug Inflation Rebate Program

Section III.I. of this rule proposes regulations to implement provisions of the Inflation Reduction Act of 2022 (IRA) that establish the Medicare Prescription Drug Inflation Rebate Program. Section 11101 of the IRA adds new section 1847A(i) to the Act, which establishes a requirement for manufacturers to pay Medicare Part B rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation, beginning on January 1, 2023. Section 11102 of the IRA adds new section 1860D–14B to the Act, which established a requirement for manufacturers to pay Medicare Part D rebates for certain Part D drugs and biological products with prices that increase faster than the rate of inflation, beginning on October 1, 2022.

b. Quality Payment Program

This proposed rule is also necessary to make changes to the Quality Payment Program to move the program forward to focus more on measurement efforts, refine how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is a value-based payment program that includes two participation tracks: MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We continue to move the Quality Payment Program forward, including focusing more on alignment between the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APM) tracks of participation, alignment with broader CMS initiatives, and new options for clinicians to participate in more meaningful ways. We aim to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the MIPS and Advanced APMs for the CY 2026 performance period/2028 MIPS payment year.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

In section III.A.1. of this proposed rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (IIJA), which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter, refundable drug), we discuss two applications received for increased applicable percentage.

In section III.A.2 of this proposed rule, we are proposing clarifications to two aspects of the calculation of manufacturer's Average Sales Price (ASP), including price concessions and bona fide service fees (BFSFs). Regarding our proposals for price concessions, we are proposing to add a definition of bundled arrangement at § 414.802 to specify how certain financial benefits, including rebates, discounts or price concessions, are conditional upon certain requirements being met and that these arrangements may involve multiple products or performance metrics. We are also proposing to add subparagraphs at § 414.804(a)(2) to provide manufacturers with additional guidance on how to allocate discounts under bundled arrangements. This guidance states that discounts in a bundled arrangement are allocated proportionately to the dollar value of the units of all drugs or products sold under a bundled arrangement. Lastly, we are proposing to add a new subparagraph at § 414.804(a)(2)(i) to specify that when certain fees vary directly with the amount or price of a manufacturer's drugs, they are considered price concessions.

We are also proposing several changes to the definition of BFSFs at § 414.802 and § 414.804. Regarding our proposals at § 414.802, we are proposing to update the definition to describe the methodology manufacturers must use to calculate fair market value (FMV) for a BFSF. Manufacturers must use a market-based approach if the BFSFs do not vary directly with amount or price of a manufacturer's drug. Alternately, if the fees do vary directly, manufacturers must use a cost-plus approach and FMV must be conducted by an independent third-party valuator and this assessment must be submitted to CMS. We are also proposing a requirement that manufacturers conduct periodic updates of any FMV analyses for service arrangements that are ongoing, at a frequency no less than the renewal frequency of the arrangement, whether or not the FMV is conducted using a market-based or cost-plus approach.

For our proposals at § 414.804 for BFSFs, we are proposing several evidence requirements. Specifically, we are proposing to add a new subparagraph under § 414.804(a)(5) that manufacturers are required to provide sufficient evidence that the BFSF is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug by

providing documentation (such as a certification or warranty from the recipient of the fee). In addition, we are proposing to revise § 414.804(a)(5) to add data submission requirements. Under this revision, manufacturers would be required to submit reasonable assumptions for calculations of the manufacturer's ASP. Lastly, we are proposing some specific, non-exhaustive examples of BFSFs and how they should be considered in the calculation of manufacturer's ASP.

In section III.A.3. of this proposed rule, we propose that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself. In addition, we propose that, beginning January 1, 2026 (that is, data reflecting sales beginning on that date), any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that are paid by the manufacturer be included in the calculation of the manufacturer's ASP.

b. RHCs and FQHCs

In section III.B.2. of this proposed rule, we are proposing changes to the furnishing of Advance Primary Care Management (APCM) services in RHCs and FQHCs. We are proposing to adopt add-on codes for APCM that would facilitate billing for Behavioral Health Integration (BHI) and Psychiatric Collaborative Care Model (CoCM) services when RHCs and FQHCs are providing advanced primary care. We are also proposing to require RHCs and FQHCs to report the individual codes that make up the CoCM HCPCS code, G0512. We are also proposing to require RHCs and FQHCs to report the individual codes that make up the communications technology-based services (CTBS), HCPCS code G0071 as well. In addition, we are proposing to revise § 405.2464(c) and (e) to reflect our proposal on payment of CoCM and CTBS services for RHCs and FQHCs. We are also proposing to adopt services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs. We believe this proposal would improve transparency and efficiency for RHCs and FQHCs since their designation as care management services goes through notice and comment rulemaking. In addition, we are seeking comment on whether the proposed process to align the care coordination services with the care management services paid under the PFS is sustainable moving forward or is there a more effective approach for adopting new care coordination codes established under the PFS as care management codes that would improve transparency and efficiency for RHCs and FQHCs.

In section III.B.3. of this proposed rule, we are proposing the to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision permanently for all.

RHC and FQHC services. We are also proposing, on a temporary basis, to facilitate payment for non-behavioral health visits furnished via telecommunication technology using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2026.

c. Ambulatory Specialty Model (ASM)

In section III.D of the preamble of this proposed rule, we discuss the proposed mandatory alternative payment model called the Ambulatory Specialty Model (ASM) which would be tested under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries while reducing program expenditures.

Health care is becoming more fragmented as Medicare beneficiaries are increasingly seeing a greater number of specialists on a more regular basis. We believe there are opportunities to improve coordination between specialists and primary care providers (PCPs) and increase beneficiary engagement in care decisions, particularly with respect to preventing the onset and progression of chronic disease. ASM would test whether rewarding select specialists that furnish a high volume of services related to heart failure or low back pain based on measures of quality, cost, care coordination, and Promoting Interoperability results in enhanced quality of care and reduced costs through more effective upstream chronic condition management for ASM's targeted chronic conditions. We expect that a more targeted approach where clinicians are evaluated: (1) on a set of relevant performance measures they are required to report; and (2) among clinicians furnishing similar sets of services for similar chronic conditions, would produce scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement would also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. We believe this insight is necessary to support and incentivize accountable care, increasing beneficiary access to coordinated specialty care.

We believe that ASM's meaningful comparisons of performance to similar specialists furnishing a substantial volume of services related to ASM's targeted chronic conditions when matched with a payment methodology that creates impactful Medicare Part B payment adjustments would encourage quality improvements in specialty care and meaningful engagement with primary care clinicians to both prevent and manage the onset of chronic conditions, all while achieving net savings to Medicare.

We refer readers to section III.D.1 of this proposed rule for more information on our research and rationale for ASM.

d. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

1. Effects on Beneficiaries

We propose to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) address barriers related to weight collection requirements by clarifying that weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the completion of the MDPP session; (2) allow beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site; (3) extend the flexibilities allowed during the PHE for COVID–19 through December 31, 2029; (4) test the addition of coverage of asynchronous, Online, delivery of MDPP through December 31, 2029; (5) clarify that MDPP suppliers are not required to maintain in-person delivery capability through December 31, 2029; and (6) introduce a new Healthcare Common Procedure Coding System (HCPCS) G-code and payment for Online sessions.

MDPP is a non-pharmacological behavioral intervention consisting of up

to 22 sessions using a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum.[421] CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards, which are updated every 3 years. The 2024 CDC DPRP Standards replaced the 2021 CDC DPRP Standards in June 2024.[422]

The CY 2021 PFS final rule allowed for increased virtual delivery of MDPP during the PHE for COVID–19 (85 FR 84830). Improvements to MDPP in the CY 2024 final rule included a simplified payment structure to allow for fee-for-service (FFS) payments for beneficiary attendance, while retaining the performance-based payments for diabetes risk reduction (that is, weight loss) (88 FR 79241) and an extension of PHE flexibilities to deliver some or all MDPP sessions via distance learning, until December 31, 2027 (88 FR 79241). Another PHE flexibility extended through the CY 2024 PFS Final rule was for MDPP suppliers to obtain weight measurements for beneficiaries using one of the following options through December 31, 2027: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary (88 FR 79243). The CY 2025 PFS expanded this flexibility by allowing beneficiaries with the choice to submit one or two (2) photos for self-reporting weight for an MDPP distance learning session (89 FR 98047). Finally, to align with 2024 CDC DPRP Standards, the CY 2025 PFS Final Rule (89 FR 98045) updated the MDPP definition of ''online'' to align with the 2024 CDC DPRP definition for this delivery modality. However, while the CY 2025 PFS Final Rule updated the MDPP definition for online, only in-person, distance learning (synchronous), and in-person with a distance learning component remained accepted delivery modalities for MDPP in CY 2025.

We are proposing to revise the definitions of ''Extended flexibilities period'' and ''Online'' and add definitions for three new terms for MDPP, including ''Live Coach interaction,'' ''Online delivery period,'' and ''Online session.'' These changes will extend virtual delivery flexibilities through December 31, 2029, describe accepted delivery modes for MDPP by including online (asynchronous) delivery, and further align MDPP terminology with CDC DPRP Standards. These proposed changes aim to remove access barriers for beneficiaries and provide MDPP suppliers with more delivery offerings in response to comments regarding the increasing demand for virtual participation options.

Through the CY 2026 PFS, we are proposing to clarify that weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the completion of the MDPP session. Beneficiaries who participate in MDPP do not currently have the option to submit medical record data as proof of weight. This proposed change is in response to MDPP supplier feedback that the current weight collection requirements discourage individuals with mobility concerns from participating in MDPP due to risk of injury while self-reporting weight from home. For example, some beneficiaries may need to obtain weight at a medical office using a special scale (for example, wheelchair scale) on the same date as their MDPP session. This proposed flexibility may promote safe and consistent collection of weight for MDPP sessions while encouraging model participation.

Additionally, we propose to revise weight collection requirements for MDPP in response to comments regarding increased flexibility for MDPP beneficiaries who may be traveling or unable to obtain weight measurements at home. This change allows beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site while maintaining program integrity through existing date-stamped photo requirements described in 410.79(e)(3)(iii)(c) which state that the photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scaled on the date associated with the billable MDPP session. The current weight collection requirements state that beneficiaries self-report weight by submitting date-stamped photo(s) or video of the beneficiary's weight on the scale with the beneficiary visible in their home. This limits beneficiaries from participating by reporting weight from other reasonable locations outside of an in-person delivery site or home, such as a medical office, or hotel if the beneficiary is on vacation but otherwise able to participate in MDPP sessions. This proposed change is expected to remove barriers to weight collection and provide flexibilities that may increase session attendance.

We propose to test the addition of coverage of an asynchronous, Online delivery modality during the Online delivery period (until December 31, 2029). This change will allow virtual-only organizations to enroll in Medicare as MDPP suppliers, streamline the process to allow for greater delivery of Online sessions, and promote alignment with the 2024 CDC DPRP Standards, which support asynchronous delivery. To date, MDPP suppliers have commented that the exclusion of the asynchronous modality significantly limits program participation among Medicare beneficiaries. Advocacy group members pursued legislation that would require CMS to open the MDPP to suppliers of asynchronous online MDPP programs through the PREVENT DIABETES Act [H.R. 7856] [423] in April 2024. Although this bill was not enacted into law, suppliers continue to encourage CMS to meet the demand for asynchronous delivery of MDPP. To facilitate the ability of MDPP suppliers to deliver the program through an asynchronous, Online delivery modality, we propose to clarify that MDPP suppliers are not required to maintain the ability to deliver the program in-person during the Online delivery period. This will allow for virtual-only organizations to enroll in Medicare as MDPP suppliers and streamline the process to allow for greater asynchronous delivery. Additionally, beneficiary focus groups indicate that among beneficiaries who participate in MDPP via distance learning or in-person with a distance learning component (hybrid), most expressed their satisfaction by citing the flexibility the choices provided when faced with challenges such as inclement weather or travel restrictions that made in-person participation difficult.[424] This extended flexibility is expected to promote beneficiary access to the Set of MDPP services, since suppliers may deliver the Set of MDPP services to beneficiaries across state lines, reaching beneficiaries who do not live near an in-person delivery site.

We propose edits throughout § 414.84 by revising paragraphs (b)(1)

[421] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

[422] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[423] H.R. 7856 (118th): PREVENT DIABETES Act, *https://www.govtrack.us/congress/bills/118/hr7856/text.*

[424] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.*

introductory text and (b)(2) introductory text to update language to include all accepted MDPP delivery modes for performance goals in which beneficiaries achieve weight loss milestones. We also propose adding paragraph (c)(3) to describe the proposed payment for Online delivery, including the inclusion of a new HCPCS G-code for the Set of MDPP services delivered Online. Finally, we propose redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively and revising the redesignated paragraph (c)(4)(ii) to include a payment rate for a core session or core maintenance session furnished Online during the Online delivery period.

Lastly, we propose amending § 424.205(c)(10) to allow the minimum number of required MDPP core sessions and core maintenance sessions to be delivered Online during the Online delivery period; § 424.205(f)(2)(i) to include the online modality among acceptable session types for session documentation; and § 424.205(f)(5) to update requirements for achieving five and nine percent weight loss measured in accordance with § 410.79(c)(ii). Overall, these modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date, feedback from existing MDPP suppliers, and feedback from beneficiary focus groups. The proposed changes are also in response to comments from interested parties made through public comments in response to prior rulemaking. These proposed changes are aimed towards increasing access and participation in this prevention-focused program, empowering beneficiaries, and promoting further alignment between MDPP and the CDC DPRP Standards.

The policy changes proposed for MDPP in the CY 2026 PFS are expected to have a significant impact on beneficiaries' access to MDPP services. Aligning with 2024 CDC DPRP Standards for MDPP delivery modes may help expand beneficiary access and increase the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers. Additionally, the proposed changes to weight collection requirements and the inclusion of online delivery will increase flexibility for both MDPP suppliers and beneficiaries and may help increase access for beneficiaries who lack transportation or live in geographic areas without access to an in-person delivery site.

2. Effects on the Market

We anticipate that the policy changes proposed in this rulemaking are likely to result in a greater number of MDPP suppliers and increased beneficiary access to the Set of MDPP services. We anticipate that our proposal will result in the delayed onset and reduction of the incidence of diabetes among eligible Medicare beneficiaries.

As of May 2025, there are approximately 1,253 nationally recognized in-person organizations that are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes DPRP status.[425] However, only 330 (26 percent) of these eligible in-person organizations are participating in MDPP.[426] Aligning with CDC DPRP delivery modes, particularly allowing asynchronous, Online delivery, is expected to help increase recruitment of new DPRP organizations, MDPP suppliers, and beneficiaries.

3. Payment for MDPP Services

Regulations at § 414.84 specify that MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance targets related to MDPP beneficiary weight loss and attendance.

We anticipate that the inclusion of asynchronous, Online delivery will have minimal impact on total payment for MDPP services, as current performance payments for 5 percent weight loss achieved from baseline weight (G9880) and 9 percent weight loss achieved from baseline weight (G9881) will remain the same regardless of delivery modality for MDPP. For each beneficiary, MDPP suppliers must either bill claims with G9886, G9887, a combination of G9886 and G9887, or GXXXX. The proposed GXXXX for behavioral counseling for diabetes prevention, online, 60 minutes ($18) is for the Set of MDPP services delivered Online, asynchronously. The existing G9886, behavioral counseling for diabetes prevention, in-person, group, 60 minutes, and G9887, behavioral counseling for diabetes prevention, distance learning, 60 minutes are delivered synchronously. Therefore, we are proposing that for each MDPP beneficiary, suppliers may not bill for the Set of MDPP services that were delivered through a combination of synchronous and asynchronous delivery modalities, inclusive of make-up sessions. In order to evaluate the efficacy of the Online delivery modality during the Online Delivery Period, beneficiary outcomes from synchronous (that is, In-person, distance learning, or In-person with a distance learning component) delivery of the Set of MDPP services must be compared to beneficiary outcomes from asynchronous (that is, Online), therefore, these modalities must be delivered separately for individual beneficiaries in order to evaluate whether Online results, including weight loss, are similar to in-person and distance learning delivery modalities.

The total maximum payment per beneficiary for MDPP for in-person or distance learning delivery will remain unchanged by our proposals. The total maximum payment per beneficiary for online delivery of MDPP will be $619.

4. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

The following table shows the estimated impact (in millions) on Medicare spending for allowing asynchronous, online delivery of the MDPP benefit:

[425] Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program Application. Registry of All Recognized Organizations. *https://dprp.cdc.gov/Registry.*

[426] *Medicare Provider Enrollment, Chain, and Ownership System (PECOS), Centers for Medicare & Medicaid Services | CMS (.gov), accessed May 1, 2025).*

TABLE 86: ESTIMATED IMPACT (IN MILLIONS) OF THE PROPOSED CHANGE ON MEDICARE SPENDING

	Year								
	2026	2027	2028	2029	2030	2031	2032	2033	2034
Gross Medicare Impacts	-$1	-$4	-$7	-$9	-$11	-$11	-$11	-$10	-$8
Performance Payments	$6	$11	$2	$2	$0	$0	$0	$0	$0
Total Impact	$5	$6	-$5	-$7	-$11	-$11	-$11	-$10	-$8

(b) Assumptions/Notes

- While we propose several changes to the existing MDPP expanded model for CY 2026, these changes should not lead to significantly different impacts on Medicare spending. The previous table provides projected impacts to Medicare fee for service spending resulting from allowing asynchronous, Online, delivery of MDPP without requiring providers to maintain an in-person delivery option.
- The assumed annual cost of diabetes from the initial certification of MDPP was trended forward using USPCC FFS PMPM spending assumptions included in the 2024 Trustees Report.
- Average per beneficiary MDPP payments for the asynchronous, online, delivery were assumed to be less than the in-person or Distance Learning benefit due to the reduced payment rate for session attendance. In 2025, the maximum total payment for completion of MDPP with weight loss is $795. The proposed maximum payment for the asynchronous, online, delivery of MDPP is $619. Average per beneficiary MDPP payments were trended forward using a projected annual increase of 2.4 percent, consistent with the long-range CPI–U assumption included in the 2024 Trustees Report.
- The above impacts assume that there are 15,000 new beneficiaries in 2026; 25,000 new beneficiaries in 2027; tapering off to 5,000 new beneficiaries in years 2028 and 2029. It is anticipated that the number of new beneficiaries in 2026 and 2027 may be higher due to pent up demand for the Online delivery modality. Additionally, it may take up to 90 days for approval of a Medicare enrollment application for those organizations newly enrolling as MDPP suppliers with an Online organization code, leading to lower uptake of the model in 2026 compared to 2027. There is a high degree of uncertainty with respect to the potential utilization of the asynchronous benefit. The CMS Office of Communications (OC) sends emails to a distribution list made up of potential MDPP participants twice every year. The emails contain a link to a website where more information relating to MDPP is available. OC reviews Medicare fee for service claims data to exclude beneficiaries that would be ineligible to participate in MDPP (ESRD patients or beneficiaries with a diabetes diagnosis) to develop the distribution list. In the last email distribution, approximately 11.8 million emails were sent. Of those receiving the email, about 86,000 recipients followed the link. With little information about the potential interest in the asynchronous benefit from the supplier and beneficiary sides, utilization was assumed to be up to 20 percent in the first year and up to just over half of the number of email recipients who followed the email link during the four years of the asynchronous test.
- To evaluate the reduction in diabetes rates, the effectiveness of the asynchronous, online, benefit is assumed to be equal to that of the in-person benefit. This assumption is revisited in the sensitivity analysis section.

(c) Sensitivity Analysis

The following table shows projected 10-year financial impacts (in millions) of delivering the asynchronous online benefit from 2026–2029 at various levels of effectiveness with respect to the in-person benefit. It also provides the first year in which the accumulated savings is greater than the performance payments.

TABLE 87: 10-YEAR COST IMPACTS (IN MILLIONS) OF ONLINE DELIVERY OF MDPP SERVICES AND BREAK-EVEN POINT

Effectiveness Relative to In-Person	10-Year Impact	Break-Even Year
100%	−$56	2029
75%	−$36	**2030**
50%	−$16	**2031**

As indicated in the table, asynchronous, online, delivery of MDPP services is estimated to produce savings over the next 10 years even when it is 50 percent as effective as the in-person delivery.

As for the Medicare Diabetes Prevention Program, given that we tried to align this rulemaking as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rulemaking impacts only enrolled MDPP suppliers and eligible beneficiaries who have started MDPP or are interested in enrolling in MDPP. We invite public comments on our regulatory impact analysis for our MDPP proposal.

e. Medicare Shared Savings Program

In section III.F. of this proposed rule, we are proposing modifications to the Shared Savings Program regulations to allow for timely improvements to program policies and operations. The proposed changes to the Shared Savings Program include the following.

We are proposing changes to limit participation in a one-sided model to an ACO's first agreement period under the BASIC track's glide path (if eligible), for a maximum of 5 performance years instead of 7 performance years. Under

the proposed modifications, ACOs inexperienced with performance-based risk Medicare ACO initiatives (defined in § 425.20) would progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track (if eligible), compared to existing policies. The proposed changes would apply to agreement periods beginning on or after January 1, 2027.

We are also proposing modifications to the Shared Savings Program eligibility and financial reconciliation requirements in connection with the statutory requirement that ACOs have at least 5,000 assigned Medicare FFS beneficiaries to: (1) require ACOs applying to enter a new agreement period beginning on or after January 1, 2027, to have at least 5,000 assigned beneficiaries in benchmark year (BY) 3, while allowing an ACO to have fewer than 5,000 assigned beneficiaries in BY1, BY2, or both; (2) establish safeguards to reduce the risk that ACOs owe shared losses payments, or are owed shared savings payments by the program, based on normal variation in beneficiary expenditures by (i) requiring that an ACO applying to enter a new agreement period that has fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, may only enter the BASIC track, and (ii) capping shared savings or shared losses at a lesser amount if an ACO, at any time during the agreement period, has fewer than 5,000 assigned beneficiaries in any of the three BYs; as well as (3) exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to leverage existing policies that provide certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings.

We are proposing changes to the Shared Savings Program's quality performance standard and other quality reporting requirements, including to: (1) revise the definition of a beneficiary eligible for Medicare CQMs at § 425.20 for performance year 2025 and subsequent performance years so that the population identified for reporting within the Medicare CQM collection type would have greater overlap with the beneficiaries that are assignable to an ACO; (2) remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 and revise the terminology used to describe the health equity adjustment and other related terms for performance years 2023 and 2024; (3) update the APP Plus quality measure set for Shared Savings Program ACOs including the removal of Quality ID: 487 Screening for Social Drivers of Health; and (4) implement a web-mail-phone protocol and discontinue the mail-phone protocol for the CAHPS for MIPS Survey beginning with 2027.

We are proposing changes to expand the application of the Shared Savings Program's quality and finance extreme and uncontrollable circumstances (EUC) policies to an ACO that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years.

We are proposing changes to other programmatic areas, including: proposed changes to Shared Savings Program eligibility requirements and change request procedures to: (1) require ACOs that experience certain ACO participant CHOWs outside of the change request cycle to update their certified ACO participant list to reflect such ACO participant's CHOW; and (2) require ACOs to submit changes which occur during the performance year to the ACO's SNF affiliate list, if a SNF affiliate undergoes a CHOW resulting in a new TIN. We are proposing updates to the beneficiary assignment methodology to revise the definition of primary care services to align with payment policy changes and include, among other services for the purposes of beneficiary assignment, new behavioral health integration and psychiatric collaborative care model add-on services when these services are furnished with advanced primary care management services. We are proposing changes to the Shared Savings Program's regulations specifying the financial benchmarking methodology applicable for agreement periods beginning on January 1, 2025, and in subsequent years, to rename the ''health equity benchmark adjustment'' (HEBA) the ''population adjustment.'' Finally, we are proposing changes to revise the Shared Savings Program's quality reporting monitoring policies.

f. Changes to the Regulations Associated With the Ambulance Fee Schedule

As outlined in section III.H. of this proposed rule, section 3203 of the American Relief Act of 2025 and most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons sets forth in those subsections through September 30, 2025. The ambulance extender provisions are enacted through legislation that is self-implementing. We are proposing only to revise dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, Regulatory Planning and Review (September 30, 1993), Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354); section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4); and Executive Order 13132, Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. ased on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series).) Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rulemaking will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rulemaking does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this rule; details the costs and benefits of this rulemaking; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this rule, we discussed various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule. The relevant sections of this rulemaking describe significant alternatives we considered, if applicable.

C. Executive Order 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.''

D. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2025 with payment rates for CY 2026 using CY 2024 Medicare utilization. The payment impacts described in this rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

As required by section 1848(d)(1)(A) of the Act, beginning in CY 2026, there will be two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant as defined in section 1833(z)(2) of the Act (referred to as the qualifying APM conversion factor) and another for other items and services (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year (or, for CY 2026, equal to the single conversion factor for CY 2025) multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. As specified by section 1848(d)(20) of the Act, the update to the qualifying APM conversion factor for CY 2026 is 0.75 percent while the update to the nonqualifying APM conversion factor for CY 2026 is 0.25 percent. To calculate the estimated CY 2026 PFS conversion factors, we took the CY 2025 conversion factor and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs, then multiplied by the qualifying APM and nonqualifying APM updates specified by section 1848(d)(20) of the Act, then applied the one-year increase of 2.50 percent for CY 2026 established by statute. We estimate the CY 2026 PFS qualifying APM CF to be 33.5875 which reflects a 0.55 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.75 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2026 PFS nonqualifying APM CF to be 33.4209 which reflects a 0.55 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.25 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2026 anesthesia qualifying APM CF to be 20.6754 and the CY 2026 anesthesia nonqualifying APM CF to be 20.5728, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

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TABLE 88: CALCULATION OF THE CY 2026 PFS QUALIFYING APM CONVERSION FACTOR

CY 2025 Conversion Factor		**32.3465**
CY 2026 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2026 RVU Budget Neutrality Adjustment	0.55 percent (1.0055)	
CY 2026 2.50 Percent Increase	2.50 percent (1.0250)	
CY 2026 Conversion Factor		**33.5875**

TABLE 89: CALCULATION OF THE CY 2026 PFS NON-QUALIFYING APM CONVERSION FACTOR

CY 2025 Conversion Factor		32.3465
CY 2026 Non-Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2026 RVU Budget Neutrality Adjustment	0.55 percent (1.0045)	
CY 2026 2.50 Percent Increase	2.50 percent (1.0250)	
CY 2026 Conversion Factor		**33.4209**

TABLE 90: CALCULATION OF THE CY 2026 ANESTHESIA QUALIFYING APM CONVERSION FACTOR

CY 2026 National Average Anesthesia Conversion Factor		20.3178
CY 2026 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2026 RVU Budget Neutrality Adjustment	0.55 percent (1.0045)	
CY 2026 2.50 Percent Increase	2.50 percent (1.0250)	
CY 2026 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	-2.00 percent (0.9800)	
CY 2026 Conversion Factor		**20.6754**

TABLE 91: CALCULATION OF THE CY 2026 ANESTHESIA NON-QUALIFYING APM CONVERSION FACTOR

CY 2026 National Average Anesthesia Conversion Factor		20.3178
CY 2026 Non-Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2026 RVU Budget Neutrality Adjustment	0.55 percent (1.0045)	
CY 2026 2.50 Percent Increase	2.50 percent (1.0250)	
CY 2026 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	-2.00 percent (0.9800)	
CY 2026 Conversion Factor		**20.5728**

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Table 92 shows the impact on PFS payment for physicians' services based on the proposed policies included in this rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 92 (CY 2026 PFS Estimated Impact on Total Allowed Charges by Specialty).

In recent years, we have received requests from interested parties to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented us with high-level information suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Some of the proposed policies in this rule are estimated to have significant differential effects depending on the site of service, especially the proposed changes to the allocation of indirect PE in the facility setting. Therefore, we are publishing the impact tables including a

facility/non-facility breakout of payment changes, as we believe that displaying the total impact by specialty alone, without the setting of care context, could be misleading for interested parties. The following is an explanation of the information represented in Table 92.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or non-facility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2024 utilization and CY 2025 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Impact of Work RVU Changes): This column shows the estimated CY 2026 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column E (Impact of PE RVU Changes): This column shows the estimated CY 2026 impact on total allowed charges of the changes in the PE RVUs.
- Column F (Impact of MP RVU Changes): This column shows the estimated CY 2026 impact on total allowed charges of the changes in the MP RVUs.
- Column G (Combined Impact): This column shows the estimated CY 2026 combined impact on total allowed charges of all the changes in the previous columns. Column G may not equal the sum of columns D, E, and F due to rounding.

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TABLE 92: CY 2026 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$212	0%	7%	0%	7%
	Non-Facility	$204	0%	8%	0%	8%
	Facility	$8	0%	-11%	0%	-11%
ANESTHESIOLOGY	*TOTAL*	$1,595	0%	-1%	0%	-1%
	Non-Facility	$310	0%	7%	0%	7%
	Facility	$1,285	0%	-3%	0%	-3%
AUDIOLOGIST	*TOTAL*	$75	0%	0%	0%	-1%
	Non-Facility	$72	0%	0%	0%	0%
	Facility	$3	0%	-13%	0%	-14%
CARDIAC SURGERY	*TOTAL*	$150	-1%	-3%	0%	-3%
	Non-Facility	$27	0%	6%	0%	6%
	Facility	$124	-1%	-5%	0%	-5%
CARDIOLOGY	*TOTAL*	$5,995	0%	1%	0%	1%
	Non-Facility	$3,747	0%	5%	0%	5%
	Facility	$2,248	-1%	-6%	0%	-7%
CHIROPRACTIC	*TOTAL*	$626	-1%	-1%	0%	-2%
	Non-Facility	$624	-1%	-1%	0%	-2%
	Facility	$2	-1%	-15%	0%	-17%
CLINICAL PSYCHOLOGIST	*TOTAL*	$727	3%	2%	-1%	3%
	Non-Facility	$589	3%	3%	-1%	5%
	Facility	$138	3%	-5%	-1%	-3%
CLINICAL SOCIAL WORKER	*TOTAL*	$1,011	4%	2%	-1%	4%
	Non-Facility	$871	4%	3%	-1%	6%
	Facility	$140	4%	-5%	-1%	-2%
COLON AND RECTAL SURGERY	*TOTAL*	$146	-1%	-2%	0%	-2%
	Non-Facility	$53	0%	7%	0%	7%
	Facility	$93	-1%	-7%	0%	-7%
CRITICAL CARE	*TOTAL*	$336	0%	-5%	0%	-4%
	Non-Facility	$54	0%	7%	0%	7%
	Facility	$281	0%	-7%	1%	-7%
DERMATOLOGY	*TOTAL*	$3,898	0%	-1%	0%	-2%
	Non-Facility	$3,757	0%	-1%	0%	-1%
	Facility	$142	-1%	-13%	0%	-14%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$913	0%	0%	0%	0%
	Non-Facility	$911	0%	0%	0%	0%
	Facility	$2	-1%	0%	1%	-1%
EMERGENCY MEDICINE	*TOTAL*	$2,408	0%	-3%	1%	-1%
	Non-Facility	$217	0%	7%	0%	7%
	Facility	$2,191	0%	-4%	1%	-2%
ENDOCRINOLOGY	*TOTAL*	$526	0%	2%	0%	3%
	Non-Facility	$425	0%	6%	0%	6%
	Facility	$101	0%	-11%	0%	-10%
FAMILY PRACTICE	*TOTAL*	$5,426	0%	3%	0%	3%
	Non-Facility	$4,367	0%	6%	0%	6%
	Facility	$1,059	0%	-9%	0%	-9%
GASTROENTEROLOGY	*TOTAL*	$1,391	0%	-3%	0%	-4%
	Non-Facility	$504	0%	6%	0%	6%
	Facility	$887	-1%	-9%	0%	-10%
GENERAL PRACTICE	*TOTAL*	$372	0%	3%	0%	3%
	Non-Facility	$298	0%	5%	0%	6%
	Facility	$73	0%	-8%	0%	-7%
GENERAL SURGERY	*TOTAL*	$1,524	0%	-3%	0%	-3%
	Non-Facility	$447	0%	6%	0%	6%
	Facility	$1,078	-1%	-7%	0%	-7%
	TOTAL	$199	1%	1%	0%	1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
GERIATRICS	*Non-Facility*	$127	1%	7%	0%	8%
	Facility	$72	0%	-10%	0%	-9%
HAND SURGERY	*TOTAL*	$260	0%	0%	0%	-1%
	Non-Facility	$141	0%	5%	0%	5%
	Facility	$119	-1%	-7%	0%	-7%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,537	0%	0%	0%	0%
	Non-Facility	$984	0%	6%	0%	6%
	Facility	$552	0%	-11%	0%	-11%
INDEPENDENT LABORATORY	*TOTAL*	$545	0%	-1%	0%	-1%
	Non-Facility	$531	0%	-1%	0%	-1%
	Facility	$14	-1%	-1%	0%	-3%
INFECTIOUS DISEASE	*TOTAL*	$537	0%	-7%	0%	-6%
	Non-Facility	$85	0%	7%	0%	7%
	Facility	$452	0%	-10%	0%	-9%
INTERNAL MEDICINE	*TOTAL*	$9,378	0%	-2%	0%	-1%
	Non-Facility	$4,649	0%	6%	0%	6%
	Facility	$4,729	0%	-9%	0%	-8%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$825	0%	3%	0%	3%
	Non-Facility	$645	0%	7%	0%	6%
	Facility	$180	-1%	-8%	0%	-9%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$437	-1%	2%	0%	2%
	Non-Facility	$259	0%	7%	0%	7%
	Facility	$178	-2%	-6%	1%	-7%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$155	0%	-2%	0%	-2%
	Non-Facility	$77	0%	5%	0%	5%
	Facility	$78	0%	-9%	0%	-9%
NEPHROLOGY	*TOTAL*	$1,623	0%	0%	0%	1%
	Non-Facility	$971	1%	6%	0%	7%
	Facility	$653	0%	-9%	0%	-9%
NEUROLOGY	*TOTAL*	$1,312	0%	1%	0%	1%
	Non-Facility	$833	0%	6%	0%	6%
	Facility	$480	0%	-9%	0%	-9%
NEUROSURGERY	*TOTAL*	$682	-1%	-4%	0%	-5%
	Non-Facility	$115	0%	6%	0%	6%
	Facility	$567	-1%	-6%	0%	-7%
NUCLEAR MEDICINE	*TOTAL*	$47	-1%	0%	0%	-1%
	Non-Facility	$21	0%	2%	0%	1%
	Facility	$27	-1%	-2%	0%	-3%
NURSE ANES / ANES ASST	*TOTAL*	$1,060	0%	-2%	0%	-1%
	Non-Facility	$20	0%	9%	0%	10%
	Facility	$1,040	0%	-2%	0%	-1%
NURSE PRACTITIONER	*TOTAL*	$7,704	0%	0%	0%	1%
	Non-Facility	$5,074	0%	5%	0%	5%
	Facility	$2,630	0%	-9%	0%	-9%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$540	0%	-1%	0%	-1%
	Non-Facility	$369	0%	4%	0%	4%
	Facility	$171	-1%	-10%	1%	-10%
OPHTHALMOLOGY	*TOTAL*	$4,444	0%	-1%	0%	-2%
	Non-Facility	$3,143	0%	3%	0%	3%
	Facility	$1,301	-1%	-12%	0%	-13%
OPTOMETRY	*TOTAL*	$1,356	0%	2%	0%	2%
	Non-Facility	$1,293	0%	3%	0%	3%
	Facility	$62	0%	-13%	0%	-13%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$44	0%	1%	0%	0%
	Non-Facility	$33	0%	4%	0%	4%
	Facility	$11	-1%	-10%	0%	-11%
ORTHOPEDIC SURGERY	*TOTAL*	$3,271	0%	-2%	0%	-3%
	Non-Facility	$1,446	0%	5%	0%	5%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
	Facility	$1,825	-1%	-8%	0%	-9%
OTHER	*TOTAL*	$54	0%	0%	0%	0%
	Non-Facility	$43	0%	3%	0%	3%
	Facility	$11	0%	-9%	0%	-9%
OTOLARNGOLOGY	*TOTAL*	$1,124	0%	0%	0%	0%
	Non-Facility	$892	0%	3%	0%	3%
	Facility	$232	-1%	-11%	0%	-12%
PATHOLOGY	*TOTAL*	$1,169	-1%	-1%	0%	-2%
	Non-Facility	$620	-1%	-1%	0%	-2%
	Facility	$549	-1%	-2%	0%	-3%
PEDIATRICS	*TOTAL*	$53	0%	2%	0%	2%
	Non-Facility	$35	0%	6%	0%	7%
	Facility	$19	0%	-8%	0%	-7%
PHYSICAL MEDICINE	*TOTAL*	$1,136	0%	-2%	0%	-2%
	Non-Facility	$540	0%	6%	0%	6%
	Facility	$596	0%	-9%	0%	-9%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$6,183	0%	-1%	0%	-1%
	Non-Facility	$6,183	0%	-1%	0%	-1%
	Facility	$0	-1%	-6%	0%	-7%
PHYSICIAN ASSISTANT	*TOTAL*	$3,926	0%	0%	0%	1%
	Non-Facility	$2,716	0%	4%	0%	4%
	Facility	$1,211	0%	-8%	0%	-8%
PLASTIC SURGERY	*TOTAL*	$286	-1%	-3%	0%	-4%
	Non-Facility	$127	0%	4%	0%	4%
	Facility	$159	-1%	-9%	0%	-10%
PODIATRY	*TOTAL*	$1,858	0%	2%	0%	2%
	Non-Facility	$1,648	0%	3%	0%	3%
	Facility	$209	0%	-8%	0%	-9%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$79	0%	-1%	0%	-1%
	Non-Facility	$76	0%	-1%	0%	-1%
	Facility	$3	-1%	-1%	0%	-2%
PSYCHIATRY	*TOTAL*	$825	1%	0%	0%	0%
	Non-Facility	$499	1%	6%	0%	6%
	Facility	$326	1%	-9%	0%	-9%
PULMONARY DISEASE	*TOTAL*	$1,227	0%	-2%	0%	-1%
	Non-Facility	$536	0%	7%	0%	7%
	Facility	$691	0%	-8%	0%	-8%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,502	-1%	-1%	0%	-1%
	Non-Facility	$1,006	0%	-1%	0%	-1%
	Facility	$496	-1%	-1%	0%	-2%
RADIOLOGY	*TOTAL*	$4,492	-1%	-1%	0%	-2%
	Non-Facility	$1,964	0%	1%	0%	1%
	Facility	$2,528	-2%	-2%	1%	-3%
RHEUMATOLOGY	*TOTAL*	$523	0%	4%	0%	4%
	Non-Facility	$469	0%	6%	0%	6%
	Facility	$54	0%	-12%	0%	-12%
THORACIC SURGERY	*TOTAL*	$288	-1%	-3%	0%	-3%
	Non-Facility	$55	0%	8%	0%	8%
	Facility	$233	-1%	-5%	0%	-5%
UROLOGY	*TOTAL*	$1,600	0%	1%	0%	0%
	Non-Facility	$1,123	0%	5%	0%	5%
	Facility	$477	-1%	-9%	0%	-10%
VASCULAR SURGERY	*TOTAL*	$929	0%	5%	0%	5%
	Non-Facility	$656	0%	9%	0%	9%
	Facility	$273	0%	-6%	1%	-6%
TOTAL	***TOTAL***	**$90,545**	**0%**	**0%**	**0%**	**0%**
	Non-Facility	$57,482	0%	4%	0%	4%
	Facility	$33,064	0%	-7%	0%	-7%

* Column G may not equal the sum of columns D, E, and F due to rounding.

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2. CY 2026 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for most specialties in the office-based setting, including surgical specialties, primary care specialties, behavioral health specialties, and those who furnish highly technical services outside of the hospital setting reflect significant increases relative to most of those same specialties in the facility setting. These increases can largely be attributed to, the proposed adjustment to indirect PE allocation in the facility setting. To a lesser degree, projected increases for some specialties, especially in primary care and behavioral health are driven by the redistributive effects of the proposed efficiency adjustment to work RVUs and the third year of the behavioral health work update. Increases are also due to proposed increases in valuation for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from supply and equipment pricing updates. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Lab Fee Schedule. Therefore, the estimated 1 percent increase for CY 2026 is only applicable to approximately 17 percent of the Medicare payment to these entities.

The estimated impacts for specialties in the hospital-based setting are driven primarily by the proposed adjustment to indirect PE allocation in the facility setting and the proposed efficiency adjustment. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized supply and equipment pricing updates. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased in over several years.

We note that several specialties appear on the specialty impacts table with both the largest projected increases in payment as well as the largest projected decreases in payment, split across the site of service differential.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 92), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 92 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As discussed previously, we have reviewed our suite of public use files and have worked on new ways to offer interested parties additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2024 utilization data, Total RVUs change between −2 percent and 2 percent for roughly 25 percent of practitioners, representing approximately 32 percent of the changes in Total RVUs for all practitioners, with variation by specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

The specialty impacts displayed in Table 92 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from proposed policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) of the Act (such as the proposed The specialty impacts displayed in Table 92 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from proposed policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) of the Act (such as the proposed efficient adjustment or the proposed changes to indirect PE allocation in the facility setting) but does not include any changes in spending which result from proposed policies that are not subject to the statutory budget neutrality adjustment, and therefore, have a neutral impact across all specialties. The 0.75 percent and 0.25 percent updates to the CY 2026 qualifying APM and APM and nonqualifying APM conversion factors, respectively, as well as the single year increase of 2.50 percent to the conversion factor for CY 2026, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table 92.

b. Impact

Column G of Table 92 displays the estimated CY 2025 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2026 PFS proposed rule website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and non-facility rates are shown. For an explanation of facility and non-facility PE, we refer readers to Addendum A on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts Related to the Proposed Efficiency Adjustment

In section II.E.2.b of this proposed rule, we propose to apply an efficiency adjustment to the work RVU and corresponding intraservice portion of physician time for non-time-based services as we expect these kinds of services to accrue efficiencies over time. As proposed, this would generally apply to all codes except time-based codes, including but not limited to, E/M services, care management services, behavioral health services, services on the CMS telehealth list, and maternity codes with a global period of MMM. This efficiency adjustment policy, as proposed, would apply to all codes that aren't otherwise excluded. Included code families represent the procedures, diagnostic tests, and radiology services that CMS expects to accrue efficiencies over time as changes in medical practice occur, including changes in clinician expertise, workflows, and technology.

The proposed efficiency adjustment for CY 2026 is calculated as the sum of the final productivity adjustments used in the Medicare Economic Index (MEI) for the prior five years (2021 through 2025). The MEI is a measure of input price inflation faced by physicians and practitioners furnishing physicians' services such as physician's own time, non-physician employees' compensation, office rent, medical equipment, and more. The MEI productivity adjustment reflects the most recent historical estimate of the 10-year moving average growth of private nonfarm business total factor productivity, as calculated by the Bureau of Labor Statistics. Every year, the productivity adjustment is calculated by the CMS Office of the Actuary (OACT) based on the most recent historical data published by BLS at the time of the PFS final rule. Beginning in CY 2026, we are proposing a 5-year look-back period to calculate the initial efficiency adjustment. See section II.E.2.b of this rule for more information on the proposed methodology. This calculation results in a proposed efficiency adjustment of 2.5 percent for CY 2026.

Generally, specialties that bill more often for timed codes, such as family practice, clinical psychologists, clinical social workers, geriatrics, and psychiatry would likely see an increase in RVUs; while specialties that bill more often for procedures, diagnostic imaging, and radiology services (such as radiation oncology, radiology, and some surgical specialties), would likely see a decrease in RVUs. This proposed efficiency adjustment will decrease the work RVU for many services across most specialty types to reflect the efficiency gains that have taken place over time. Since this proposal will reduce the work RVU for affected services, we project that there will be a net increase to the conversion factor as required under our budget neutrality provisions. We estimate that almost all specialties will experience no more than +1 or −1 percent change in RVUs as a result of this proposed policy, although the effect on individual services may be greater.

d. Estimated Impacts Related to the Proposed Site of Service Payment Differential

In section II.B. of this proposed rule, we are proposing to, for each service valued in the facility setting, reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs for CY 2026.

Overall, specialties that practice primarily in the non-facility setting will see an increase in PE RVUs as a result of this redistribution. Specialties that perform services primarily in the facility setting will see a decrease in PE RVUs as a result of the proposed reduction to facility indirect PE. Overall, this proposed methodology change to indirect PE allocation would not affect the conversion factor, as all changes in valuation would be contained within the development of PE RVUs and redistribute PE RVUs from the facility to the non-facility setting.

E. Impact of Changes Related to Telehealth Services

We are proposing the addition of several codes to the Medicare Telehealth Services List, including HCPCS codes G0473 and G0545, and CPT codes 90849, 92622, and 92623. We are also proposing to remove HCPCS code G0136 from the Medicare Telehealth Services List. We are proposing certain telecommunications technology-related flexibilities, including that we will continue to use a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using real-time audio and video interactive telecommunications for services without a 010 or 090 global period indicator. We are also proposing to eliminate the telehealth frequency limitations for subsequent nursing facility and inpatient hospital visits. While we note that certain other Medicare telehealth flexibilities related to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19) (PHE for COVID–19)

PHE for COVID–19 are expiring, including the removal of statutory geographic and location limitations for most Medicare telehealth services, the beneficiary's home continues to be a permissible originating site for certain types of services including those furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including a Substance Use Disorder (SUD), and for monthly End Stage Renal Disease (ESRD) related clinical assessments described in section 1881(b)(3)(B). However, expiration of certain flexibilities for Medicare telehealth services is not expected to impact broader utilization of these services because reasonable and necessary services for the diagnosis or treatment of an illness or injury continue to be covered. Despite the fact that some services will no longer be furnished under telehealth, we expect that they will continue to be furnished in-person. We therefore anticipate that our provisions will result in continued utilization of services that can be furnished as Medicare telehealth services during CY 2026 at levels comparable to observed utilization of these services during CY 2025.

F. Other Provisions of the Proposed Rule

1. Impact of Changes Related to Medicare Part B Payment for Skin Substitutes When Used During a Covered Application Procedure Under the PFS in the Non-Facility Setting

As discussed in detail in section II.K.D. of this proposed rule, starting January 1, 2026, we are proposing to pay for the provision of certain groups of skin substitute products used during a covered application procedure (CPT codes 15271 through 15278) as supplies. These skin substitutes will be paid as incident-to supplies under the PFS in the non-facility setting in accordance with section 1861(s)(2)(A) of the Act. While costs associated with supplies are usually bundled into the PE RVUs for particular services in non-facility settings, these products have been paid separately for many years in the non-facility setting, where the majority of these products are currently used.

As discussed in detail in section II.K. of this proposed rule, in light of our careful review of the applicable statutory provisions governing products paid under the ASP methodology under 1847A of the Act, the different FDA regulatory frameworks used for these products, and the skyrocketing increase in Medicare spending for such products, we are proposing to pay separately for specific skin substitute products (other than products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act) that are eligible for Medicare coverage during a covered application procedure in the non-facility setting as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act. To reflect relevant product characteristics, we propose to group skin substitutes that are not drugs or biologicals (that is, biological products licensed under section 351 of the PHS Act) using three CMS payment categories based on FDA regulatory pathways (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. We believe that our proposal to pay for these supplies as incident-to supplies under the PFS, valued in groups by how the products are used, better aligns payment with the resources involved in the provision of these incident-to supplies during a covered application procedure and will generate payment stability over time. We estimate that

under this proposal, which assumes a single rate of approximately $125.38 for CY 2026, there would be an estimated savings of $9.4 billion.

Because the resources involved in provision of these supplies were not previously incorporated into RVUs under the PFS, the costs are not accounted for when we compare the RVUs for physicians' services from 1 year to the next. In other words, changes in payment rates for these particular codes will be incorporated into PFS relativity once we use claims data from 2026, should the policy be finalized. Under the usual methodology, that means that changes in rates for these services between CY 2027 and CY 2028 would have an impact on the development of PE RVUs for other services. Over time, we anticipate that our proposal will continue to result in significant overall price reductions since grouped valuation instead of product-specific pricing should result in downward pricing pressure in the market. Additionally, we do not anticipate an impact to beneficiaries' access to appropriate care.

2. Drugs and Biological Products Paid Under Medicare Part B

a. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023, 2024, and 2025 PFS final rules, we finalized several policies to implement the provision. in December of 2024, CMS sent discarded drug refund reports for CY 2023 ''new refund quarters,'' as defined at § 414.902. The total refunds owed for these quarters in amounts to over $139 million, which was deposited into the Supplementary Medical Insurance (SMI) trust fund, as required by law. In section III.A.1 of this proposed rule, we discuss two applications (CMS 10835, OMB 0938–1435) for increased applicable percentage which will have no impact on Medicare spending.

b. Average Sales Price: Price Concessions and Bona Fide Service Fees (§§ 414.804 and 414.802)

In section III.A.2 of this proposed rule, we are proposing clarifications to two aspects of the calculation of manufacturer's Average Sales Price (ASP), including price concessions and bona fide service fees (BFSFs). Both price concessions and BFSFs have direct implications on the manufacturer's ASP. For example, if a manufacturer currently classifies an amount paid to an entity to be a bona fide service fee but must reclassify the amount as a price concession under these proposed changes, the manufacturer's ASP would theoretically decrease. The resulting payment limit for the drug, typically ASP plus six percent, would also decrease. The opposite would also be true; that is, if a manufacturer considers an amount paid to an entity a price concession but then determines the amount to be a bona fide service fee, the manufacturer's ASP would increase. Therefore, we anticipate that these proposals may have an impact on Medicare spending. The reclassification of certain fees could increase or decrease the ASP for such drugs. We anticipate that the proposed policy would likely result in more amounts to be considered price concessions (instead of BFSFs) resulting in decreases in ASP. If this occurs, there would be decreased spending on affected drugs. However, since details of arrangements and terms that manufacturers have with other entities are often not known to CMS, we are not able to quantify the possible changes in the payment limits for separately paid drugs under Medicare Part B as under these proposals.

c. Impacts Related to Autologous Cell-Based Immunotherapy and Gene Therapy Payment

In section III.A.4. of this proposed rule, we propose that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself. Since the payment for preparatory procedures is an extension of current policy for a subset of these products, Chimeric Antigen Receptor (CAR) T-cell therapies, and these products are furnished to very few beneficiaries, we do not anticipate the proposed policy to have a significant financial impact. In addition, we propose that, beginning January 1, 2026 (that is, data reflecting sales beginning on that date), any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that are paid by the manufacturer be included in the calculation of the manufacturer's ASP. Because we have little information about how manufacturers currently factor in the cost of tissue procurement into pricing these products, we cannot predict the exact financial impact on Medicare payment. However, given that the cost of tissue procurement is typically a very small fraction of the overall cost of the product, we anticipate that any financial impact will not be substantial.

3. Impacts Related to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this proposed rule, to continue alignment with the PFS and goals associated with APCM services, we propose to adopt the add-on codes for APCM that would facilitate billing for BHI and CoCM services when RHCs and FQHCs are providing advanced primary care. We are also proposing to require RHCs and FQHCs to report individual codes that make up HCPCS code G0512. We are also proposing to require RHCs and FQHCs to report the individual codes that make up the communications technology-based services (CTBS), HCPCS code G0071. In addition, we are proposing to revise § 405.2464(c) and (e) to reflect our proposal on payment of CoCM and CTBS services for RHCs and FQHCs. We are also proposing to adopt services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs. In terms of estimated impacts to the Medicare program, we believe that the proposals discussed in section III.B.2 of this proposed rule will have a negligible impact on Medicare spending.

In section III.B.3 of this proposed rule, we are proposing the policy to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision permanently for all RHC and FQHC services. We are also proposing, on a temporary basis, to facilitate payment for non-behavioral health visits furnished via telecommunication technology using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. RHCs and FQHCs would

continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2026. We believe these RHC/FQHC proposals related to telecommunication technology will have a negligible impact on Medicare spending.

4. Ambulatory Specialty Model (ASM)

a. Scale of the Model

As we discuss in sections III.D.2.c.(4) and III.D. l of this proposed rule, there is no one-size-fits-all approach to designing, implementing, and evaluating Innovation Center models. Each payment and service delivery model tested by the Innovation Center is unique in its goals, and thus its design. Models vary in size to accommodate various design features and satisfy a variety of priorities. Decisions made regarding the features and design of the model strongly influence the extent to which the evaluation will be able to accurately assess the effect of a given model test and produce clear and replicable results.

The Innovation Center conducts analyses to determine the ideal number of participants for each model for evaluation purposes. This analysis considers a variety of factors including the target population (for example, Medicare beneficiaries with select chronic conditions), model eligibility (for example, participant eligibility criteria for inclusion in the model), participant enrollment strategy (for example, mandatory versus voluntary) and, the need to test effects on subgroups. Model size can also be influenced by the type and size of hypothesized effect on beneficiary outcomes, such as quality of care, or the target level of model savings. The smaller the expected impact a model is hypothesized to achieve, the larger a model needs to be for CMS to have confidence in the observed impacts.

An insufficient number of participants increases the risk that the evaluation will be imprecise in detecting the true effect of a model, potentially leading, for example, to a false negative or false positive result. The goal is to design a model that is sufficiently large to achieve adequate precision but not so large as to waste CMS's limited resources. These decisions affect the quality of evidence CMS can present regarding the impacts of a model on quality of care, utilization, and spending.

In the case of ASM, in this proposed rule we have determined the sample size necessary for a minimum estimated savings impact of 3.5 percent. While savings higher than 3.5 percent would require a smaller sample size from an evaluation perspective, if we were to reduce the size of ASM and if the actual savings are at or just below the 3.5 percent level, then we would increase the risk of being unable to detect whether ASM resulted in savings.

As proposed, we expect that ASM would include approximately 25 percent of all CBSAs and metropolitan divisions. As proposed at § 512.710(f), a CBSA or metropolitan division must have at least one clinician of the required specialty types who furnished at least 20 eligible episodes between January 1, 2024 and December 31, 2024 to be eligible for selection into ASM. We performed a simulation based on our proposed policies. We simulated the random selection of CBSAs and metropolitan divisions using CY 2023 data based on the methodology proposed at § 512.710(f), which would allow us to detect the minimum estimated savings impact of 3.5 percent described earlier in this section of this proposed rule.

Based on this simulation, we expect to have approximately 3,400 ASM heart failure participants billing under 1,160 TINs and approximately 5,200 ASM low back pain participants billing under 2,400 TINs in the simulated mandated geography areas. Within the ASM heart failure cohort, we expect ASM to include approximately 164,000 unique heart failure episodes, 162,600 unique beneficiaries triggering episodes, and $1.6 billion in total episode FFS spending (Medicare Part A and Part B only) of allowed charges for each ASM performance year. Within the ASM low back pain cohort, we expect ASM to include approximately 441,000 unique low back pain episodes, 398,500 unique beneficiaries triggering episodes, and $1.2 billion in total episode FFS spending of allowed charges for each ASM performance year. To determine the number of ASM participants in each ASM cohort, we counted the number of clinicians in mandatory geographic areas (as described at § 512.710(f)) with the proposed specialty types (as described at § 512.710(d)) that furnished at least 20 episodes related to the ASM's cohort targeted chronic condition in CY 2023 (as described at § 512.710(e)). Similarly, to determine episode count, beneficiary count, and total spending estimates, we drew upon the historical data of ASM participants in the simulated mandatory geographic areas selected for participation.

We welcome public comments on the proposed scale of ASM.

b. Effects on ASM Participants

ASM would not alter the way ASM participants bill Medicare. Therefore, we believe that there will be no additional burden for ASM participants related to billing practices.

We believe the audit and retention policies of ASM are generally consistent with existing policies under Medicare. Additionally, the monitoring requirements for ASM are consistent with the monitoring and evaluation requirements already in place under 42 CFR 405.1110(b) for participants in models tested under section 1115A of the Act. Therefore, we believe the audit and retention policies and the monitoring and evaluation requirements do not add additional regulatory burden on ASM participants.

We do not believe that the model evaluation for ASM would include beneficiaries or clinicians completing surveys.

We estimated the administrative costs of adjusting to and complying with the measure reporting requirements for ASM to be approximately $3,077.36 per ASM participant per year. We believe the burden estimate for submitting data to meet the proposed quality, improvement activities, and Promoting Interoperability measure reporting requirements in sections III.D.2.d.(2), III.D.2.d.(4), and III.D.2.d.(5) of this proposed rule would apply to ASM participants that are and are not considered small entities (see section VI.E.7.b.(1). of this proposed rule for further discussion on the estimated effects of ASM on small businesses). To estimate the costs per ASM participant, we estimate the burden for submitting data in the quality, improvement activities, and Promoting Interoperability ASM performance categories generally using the same assumptions for time and labor categories for the staffing that the Quality Payment Program uses for MVP submissions in section V of this proposed rule. As discussed in section III.D.2.d.(1).(b) of this proposed rule, ASM participants would not need to submit data for the cost ASM performance category and the administrative claims measures in the quality ASM performance category. Therefore, we did not estimate burden for the administrative claims measures in the cost and quality ASM performance categories.

To estimate the burden for submitting quality measure data for an ASM cohort as described in section III.D.2.d.(2) of this proposed rule, we assume 50 percent of the ASM participants would submit data on quality measures using

the eCQM collection type, and the remining 50 percent of the ASM participants would submit data using the MIPS CQM collection type. For an ASM participant to submit a quality measure using the eCQM collection type, we assume it would take a total of 5.3 hours [1.33 hours for a computer system analyst to submit data, 1.33 hours for a Medical and Health Services Manager to review the measure specifications, and 0.66 hours each for a computer system analyst, Licensed Practical Nurse (LPN), billing clerk, and physician to review the measure specifications]. For an ASM participant to submit a quality measure using the MIPS CQM collection type, we assume it would take a total of 5.97 hours [2 hours for a computer system analyst to submit data, 1.33 hours for a Medical and Health Services Manager to review the measure specifications, and 0.66 hours each for a computer system analyst, LPN, billing clerk, and physician to review the measure specifications]. To calculate the estimated cost, we used the May 2024 wage rate data from the U.S. Department of Labor (*https://www.bls.gov/oes/current/oes_nat.htm*) and doubled the mean hourly wage to account for overhead and benefits. Accounting for overhead and benefits, we used salary estimates of $107.66/hr for a computer systems analyst, $132.44/hr for a Medical and Health Services Manager, $61.68/hr for a LPN, $47.60/hr for a billing clerk, and $296.74/hr for a physician. We estimate it would require ASM participants approximately 21.2 hours (4 eCQM measures x 5.3 hours) to submit data using the eCQM collection type or 23.88 hours (4 MIPS CQMs x 5.97 hours) to submit data using the MIPS CQM collection type for the required four quality data measures once annually. We estimate it would cost $658.37 (1.33 hours × $107.66/hr + 1.33 hours × $132.44/hr + 0.66 hours × $61.68/hr + 0.66 hours × $47.60/hr + 0.66 hours × $296.74/hr) per measure to submit quality data using the eCQM collection type and $730.50 (2 hours × $107.66/hr + 1.33 hours × $132.44/hr + 0.66 hours × $61.68/hr + 0.66 hours × $47.60/hr + 0.66 hours × $296.74/hr) per measure to submit quality data using the MIPS CQM collection type. Therefore, we estimate the total annual cost for an ASM participant to submit the required measures in the quality ASM performance category using the eCQM collection type would be $2,633.48 (4 eCQM measures × $658.37) or $2,922 (4 MIPS CQM measures × $730.50) using the MIPS CQM collection type.

We also estimate that data submission of the proposed improvement activities discussed in section III.D.2.d.(4). of this proposed rule would take 0.083 hours (or 5 minutes) and would be required once annually per ASM participant. Data submission for the Promoting Interoperability measures discussed in section III.D.2.d.(5). of this proposed rule would take 2.7 hours and would occur once annually per ASM participant. We used the salary estimate of $107.66/hr for a computer systems analyst to estimate burden for submitting data in the Promoting Interoperability and improvement activities ASM performance categories. For an ASM participant to submit data for the improvement activities ASM performance category, we estimate it would cost $8.94 ($107.66/hr × 0.083 hours × 1 submission). For data submission for the Promoting Interoperability ASM performance category, we estimate it would cost $290.68 ($107.66/hr × 2.7 hours × 1 submission). We estimate that the burden for collecting and reporting quality, improvement activities, and Promoting Interoperability measures for an ASM participant submitting data using the eCQM collection type would be 23.983 hours (21.2 hours + 0.083 hours + 2.7 hours) at a cost of $2,933.10 ($2,633.48 + $8.94 + $290.68) and 26.663 hours (23.88 hours + 0.083 hours + 2.7 hours) at a cost of $3,221.62 ($2,922 + $8.94 + $290.68) for an ASM participate submitting data using the MIPS CQM collection type. We estimate approximately 7,622 ASM participants that would report data, therefore, the total burden estimate for all ASM participants collecting and reporting the measures in the quality, improvement activities, and Promoting Interoperability performance categories would be approximately 193,012 hours (23.983 hours × 3,811 ASM participants + 26.663 hours × 3,811 ASM participants) at a cost of $23,455,621 ($2,933.10 × 3,811 ASM participants + $3,221.62 × 3,811 ASM participants).

Additionally, we assume that approximately 50 percent of ASM participants that are currently not participating in MIPS would need to submit a one-time registration to access the CMS Enterprise Portal User Account (EUA). We estimate that it would take approximately 1 hour for an ASM participant or their representative to submit the registration for EUA. We used the salary estimate of $107.66/hr for a computer systems analyst to submit the registration for EUA access. Therefore, we estimate it would cost $107.66 ($107.66/hr × 1 hour) per registration. We estimate approximately 530 ASM participants would submit the application for EUA access. Therefore, the total burden estimate for ASM participants submitting the registration for EUA access would be approximately 530 hours at a cost of $ 57,059.80 (530 hours × $107.66/hr). We note that we did not include the estimated burden for submitting the registration for EUA access in calculating the total estimated burden per ASM participant as this submission does not occur annually.

We welcome public comments on our proposed estimated burden impacts on ASM participants.

c. Effects on Small Entities

As described in section VI.H of this proposed rule, the RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. HHS uses an RFA threshold of at least a 5 percent impact on the affected entities within an identified industry to determine whether a proposed rule is likely to have ''significant'' impacts on small entities.[427] Approximately 95 percent of practitioners, other suppliers, and providers are considered small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. Although many ASM participants may be small entities as that term is used in the RFA, the proportion of revenue from Medicare Part B covered professional services to which ASM would adjust payments would represent a small fraction of revenue generated by the ASM participant.

Our analysis assumed that ASM would include only Medicare FFS beneficiaries receiving services from ASM participants. During 2024, 53.3 percent of Medicare beneficiaries with both Medicare Part A and Part B coverage on average are estimated to be enrolled in Medicare Advantage plans.[428] ASM participants may also

[427] Office of Advocacy, Small Business Administration. (2012). A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272, Retrieved from *www.sba.gov/sites/default/files/rfaguide_0512_0.pdf* (accessed March 18, 2019).

[428] This figure comes from the 2024 Medicare Trustees Report, Table IV.C1, p157 from the footnote that has the A and B share.

serve patients with other coverage, such as Medicaid or commercial insurance. Given that ASM would only adjust payments to Medicare Part B payments for covered professional services based on performance—not other revenue from other payers like Medicare Advantage and commercial insurance that we expect to be about 50 to 60 percent of total revenue combined—we expect that the anticipated average impact of revenue based solely on Medicare Part B payments for covered professional services to be less than 1 percent. Therefore, we determine that the proposed provisions of ASM would not have a greater than 5 percent impact on total revenues on a substantial number of small entities.

As discussed earlier in section VI.E.b.(1). of this proposed rule, we believe that burden estimate of reporting the required measures and activities for ASM would be the same for ASM participants regardless of their small business status.

We welcome public comments on our analysis that estimates no differential impact of ASM on small entities.

d. Effects on the Medicare Program

(1) Overview

Under the current Medicare FFS payment system, services are paid on a per service basis to clinicians through the PFS. As a proposed mandatory model, ASM would test whether rewarding clinicians based on measures of quality, cost, care coordination, and CEHRT interoperability results in enhanced quality of care and reduced costs through more effective upstream chronic condition management. As proposed, ASM would test adjusting Medicare Part B covered professional services claims of an ASM participant according to a payment adjustment that is determined by an ASM participant's performance on a set of measures they must report (see sections III.D.2.d and III.D.2.f of this proposed rule). For each ASM participant, the payment adjustment amount would be determined as proposed at § 512.750.

ASM is not a total cost of care model. ASM participants would still bill traditional FFS Medicare for services as usual.

(2) Data and Methods

A simulation based on the proposed policies was created to estimate the financial impacts of ASM. The simulation relied upon simulated final scores and ASM payment adjustments, as well as assumptions derived from EBCM episodes related to ASM's targeted chronic conditions from CY 2023 and Medicare FFS claims data. We reviewed these assumptions and determined them to be reasonable for the estimates.

We simulated an ASM final score based on the methodology described in sections III.D.2.d and III.D.2.e of this proposed rule.

For scoring the quality ASM performance category, we first made assumptions on who would report based on whether clinicians were engaged in the CY 2023 MIPS performance period/2025 MIPS payment year and submitted data. We believe that historical engagement and submission of data to MIPS would be an appropriate predictor of an ASM's participant likelihood to submit data to meet ASM's requirements. For clinicians we identified as engaged, we assumed the ASM participants would report all required quality measures (meeting data completeness requirements and case minimum requirements) as discussed in section III.D.2.d.(2). For ASM participants who were eligible for the 2023 MIPS performance period/2025 MIPS payment year, we generally assigned participants as engaged or not engaged based on their 2023 MIPS participation. We carved out an exception for clinicians who were labeled ''not engaged'' in MIPS but had MIPS final scores of 75 as we believe most of these clinicians received extreme and uncontrollable circumstances approval (which would result in a final score of 75 points equal to the MIPS performance threshold).[429] For these participants, we cleared the engaged status flag. For ASM participants who did not have a populated engaged status flag (either because they were not eligible for CY 2023 MIPS performance period/2025 MIPS payment year or because we cleared their engaged status flag as described earlier), we randomly assigned engaged and not engaged flags, based on practice size, to mimic the proportion of ASM participants who were engaged and not engaged in the CY 2023 MIPS performance period/2025 MIPS payment year. This process resulted in all ASM participants receiving an engaged or not engaged assumption for the purpose of simulating a final score and payment adjustment.

In calculating a quality ASM performance category score for engaged participants (and we assumed participants would submit all quality measures meeting data completeness and case minimum requirements), we did not have adequate historical MIPS performance data for the proposed measures in sections III.D.2.d.(2).(b) and III.D.2.d.(2).(c). Therefore, we randomly assigned measure achievement points for each proposed ASM measure. The values ranged from 1 to 10 based on decile benchmarks to simulate performance using benchmarks based on ASM participants only. We recognize that this method may not accurately assign performance for an individual. However, we believe it approximates the relative differences within a benchmark distribution and represents the best available approach given that most ASM participants that previously participated in MIPS did not submit the proposed quality ASM performance category measures in MIPS.

For the ASM participants we identified as not engaged and assumed would not submit quality measures, we assigned a score of zero for the quality ASM performance category. Ultimately, these non-engaged ASM participants received an ASM final score of zero in our model for not meeting the required minimum data submission requirements, as discussed in section III.D.2.e.(2).

For the cost ASM performance category score proposed in section III.D.2.d.(3), we assigned measure achievement points and calculated a cost ASM performance category score using heart failure and low-back pain episode-based cost measure files based on CY 2023 administrative claims data.

To simulate the improvement activity ASM performance category score and scoring adjustment that is proposed in section III.D.2.d.(4).(d), we relied on the same engagement assumptions that we used for the quality ASM performance category. We assumed that engaged ASM participants would also report all the required improvement activities. These ASM participants would have an improvement activities ASM performance category score of 100 percent and would not have any negative ASM improvement activities scoring adjustment. For ASM participants we identified as not engaged, we assigned an ASM performance category score of zero and an improvement activities ASM performance category scoring adjustment of negative 20 points.

For the Promoting Interoperability ASM performance category, we calculated the Promoting Interoperability ASM performance category score and scoring adjustment discussed in section III.D.2.d.(5).(e) using proxies for the Promoting Interoperability ASM performance category score. Our primary proxy for

[429] We also excluded one participant, who was facility-based, who had a score greater than 75.

the Promoting Interoperability ASM performance category score was to use the CY 2023 MIPS performance period/2025 MIPS payment year Promoting Interoperability performance category score where it was available. The Promoting Interoperability ASM performance category scoring adjustment was calculated using the formula discussed in III.D.2.e.(1). of this proposed rule. If an ASM participant was not eligible for the 2023 MIPS performance period/2025 MIPS payment year, we assumed that the Promoting Interoperability ASM performance category score would be 100, as over half of potential ASM participants that were eligible in the CY 2023 MIPS performance period/2025 MPS payment year and reported Promoting Interoperability information had a Promoting Interoperability performance category score of 100. ASM participants with a Promoting Interoperability ASM performance category score of 100 would not have a negative scoring adjustment for the Promoting Interoperability ASM performance category. For ASM participants who were in the CY 2023 MIPS performance period/2025 MIPS payment year but did not have a 2023 MIPS Promoting Interoperability performance category score because the performance category was reweighted, we assumed these participants may not have CEHRT and thus may not be able to report measures for the Promoting Interoperability ASM performance category. For these ASM participants, we assumed a Promoting Interoperability ASM performance category score of 0 which translates into a Promoting Interoperability ASM performance category scoring adjustment of negative 10 points. We anticipate that these clinicians could use CEHRT in the future and that we may be overestimating the number of ASM participants without CEHRT.

Finally, we simulated a final score for each ASM participant using the formula proposed in section III.D.2.e. of this proposed rule. As described in this same section, we utilized scores for the quality and cost ASM performance categories and the scoring adjustments for the improvement activities and Promoting Interoperability ASM performance categories. We also calculated a complex patient scoring adjustment, described in section III.D.2.e.(3). of this proposed rule, and applied a small practice scoring adjustment, described in section III.D.2.e.(4). of this proposed rule, using variables in the Quality Payment Program final eligibility file for the CY 2023 MIPS performance period/2025 MIPS payment year. As described earlier in this section, any ASM participants who we assumed would not be engaged, were assigned a final score of zero points.

Using the simulated final scores for ASM participants, we simulated the resulting payment adjustments using the methods described in section III.D.2.f of this proposed rule. We used Medicare Part B paid amounts from claims for covered professional services in CY 2023 to calculate each ASM incentive pool. For each ASM cohort, we calculated the scaling factor and the resulting ASM payment adjustment factor and ASM payment multiplier for each ASM participant based on their final score and the proposed logistic exchange function with a midpoint at the median final score for the applicable ASM cohort.

We seek comments on our methods to estimate an ASM final score, ASM payment adjustment factor, and ASM payment multiplier for each ASM participant.

(3) Medicare Estimates

In this proposed rule, we summarize the estimated impact of ASM in Table 93. We estimate a net impact of $155.5 million in net savings to the Medicare program due to ASM from January 1, 2029 through December 31, 2033.

The estimated impact reflects the proposed provisions described in this proposed rule. To summarize relevant proposed provisions, we propose a model test period covering five ASM performance years from January 1, 2027 through December 31, 2031 with payment adjustments occurring in corresponding ASM payment years from January 1, 2029 through December 31, 2033. As discussed earlier in this section of this proposed rule, we propose that ASM would operate in 25 percent of all CBSAs and metropolitan divisions. We also propose a payment methodology at § 512.750 under which ASM participants would be subject to a maximum risk level for each ASM payment year, which we propose would range from 9 percent to 12 percent over the ASM test period, and under which an ASM participant would receive an ASM payment adjustment factor based on their final score and the amount of each ASM incentive pool redistributed to each ASM cohort in the form of scaled payment adjustments.

The estimated impact uses Medicare Part B paid amounts for covered professional services attributed to the simulated ASM participants in CY 2023 to determine the baseline spending. We trended the baseline spending in CY 2023 forward to the ASM payment years (CY 2029 through CY 2033) using the trend assumptions underlying the 2024 Medicare Trustees Report. We calculated the financial impact percentage as the downward ASM risk level (that is, the percentage of ASM participant spending at risk for each ASM participant for a given ASM payment year) multiplied by 15 percent (that is, the average amount of the ASM incentive pool that would not be distributed to ASM participants in the form of payment adjustments). We applied this financial impact percentage to the trended baseline spending for each ASM payment year. The estimates in Table 93 do not account for behavioral effects that could occur as a result of implementing ASM. We refer readers to the sensitivity analysis later in this section of this proposed rule for further discussion on potential behavioral effects on spending as a result of ASM.

Thus, we estimate that the Medicare program would save $155.5 million over ASM's model test period. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

TABLE 93: ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR THE AMBULATORY SPECIALTY MODEL (Starting January 1, 2029)

Year	2029	2030	2031	2032	2033	Total
Baseline Spending ($M)	$2,171.3	$2,235.9	$2,302.4	$2,368.5	$2,439.1	$11,517.2
Financial Impact (%)	-1.35%	-1.35%	-1.50%	-1.65%	-1.80%	-1.54%
Financial Impact ($M)	-$29.3	-$30.2	-$34.5	-$39.1	-$43.9	-$177.0

We welcome public comments on our estimated impact of ASM on the Medicare program.

(i) Sensitivity Analysis

ASM participants would receive payment adjustments based on their final scores. We expect these payment adjustments to incentivize participants to improve their ASM performance category scores, which could impact costs. The degree to which the participants would be incentivized to alter their behavior would depend on the magnitude of the payment adjustments, and the magnitude of the payment adjustment, including whether it is positive or negative, depends on the distribution of final scores used in the payment adjustment calculation. Since that distribution is unknown, we have not incorporated behavioral effects into the estimate.

There is evidence that shows that delivering higher-value care could lead to savings for Medicare. For example, better adherence to clinical guidelines for heart failure patients under ASM could reduce the number of hospitalizations that occur among ASM beneficiaries. Since hospitalizations and associated costs comprise a large share of total heart failure patient spending, such changes could reduce spending significantly. Similarly, improved adherence to clinical guidelines for low back pain could lead to lower rates of imaging service use, fewer invasive surgeries, and lower spending among ASM beneficiaries. However, it is unknown how well these changes in care patterns could ultimately be implemented.

Alternatively, some of the quality measures used in determining final scores could motivate ASM participants to deliver more services than they would have absent the model. For example, preventive care and screening metrics for BMI and depression could incentivize participants to provide more care for some patients with low back pain, and metrics on controlling high blood pressure could have a similar effect. Another consideration is that ASM participants could react to negative payment adjustments with adverse behavior (for example, increasing coding intensity) to help offset revenue losses.

To explore the potential financial impacts of these behavioral effects, we adjusted the original impact estimates under several illustrative scenarios using different amounts of behavioral effects, measured in percent change in spending. Table 94 shows estimated financial impacts on total Medicare Parts A and B spending from heart failure and low back pain episodes attributed to our simulated ASM participants based on the estimated behavioral effect levels. The estimated financial impacts presented in Table 94 present one set of assumptions on the behavioral effect on spending; the behavioral impact on spending could be larger in magnitude than the illustrative scenarios here. The resulting financial impact estimates (in millions of dollars) of each scenario in Table 94 represent the total estimated impact across ASM's test period.

TABLE 94: ASM FINANCIAL IMPACT BY ILLUSTRATIVE BEHAVIORAL EFFECTS ON SPENDING, CY 2029 THROUGH CY 2033

Behavioral Effect	Adjusted Financial Impact ($M)
-2%	-$526.7
-1%	-$351.9
0%	**−$177.0***
1%	-$2.2
2%	$172.7

* The adjusted financial impact without any behavioral effects is equal to the total estimated financial impact during ASM's test period included in Table 95.

We welcome public comments on our sensitivity analysis related to the estimated financial impacts of ASM.

d. Effects on the Market

There could be spillover effects in the non-Medicare market, because of the implementation of ASM. Testing changes in Medicare payment policy may have implications for non-Medicare payers. For example, non-Medicare patients may benefit if participating providers and suppliers introduce system-wide changes that improve the coordination and quality of health care. Other payers may also be developing payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS' evaluations of payment models. Because there is uncertainty whether and how this evidence applies to a test of these new payment models, our analyses assume that spillover effects on non-

Medicare payers would not occur, although this assumption is subject to considerable uncertainty. We solicit comments on this assumption and evidence on how this rulemaking would impact non-Medicare payers and patients.

We welcome public comments on our impact of ASM on the market.

5. Impact of Provisions for Medicare Prescription Drug Inflation Rebate Program

In this proposed rule, we are proposing to codify new policies to implement the Medicare Part B Drug Inflation Rebate Program, including CMS' method for calculating the payment amount in the payment amount benchmark quarter if a published payment limit is equal to zero or negative. Additionally, we are proposing to codify revised and new policies to implement the Medicare Part D Drug Inflation Rebate Program, including but not limited to, a claims-based methodology to remove 340B units beginning January 1, 2026 in accordance with § 428.203(b)(2) and the establishment of a Part D claims data 340B repository.

We expect the proposed policies regarding the Medicare Part B Drug Inflation Rebate Program will reduce the amount of rebates collected from Medicare Part B drugs as the proposed policies exclude certain drugs and biologicals and certain billing and payment codes from the definition of a Part B rebatable drug. The magnitude of the reduction cannot be calculated due to a lack of calculated Part B drug inflation rebates. We do not expect the proposed policies regarding the Medicare Part D Drug Inflation Rebate Program to have a material impact on the calculation of total rebates in aggregate, as these proposals are refinements to regulatory requirements and do not otherwise change the scope of rebatable drugs.

In the CY 2025 PFS final rule (89 FR 98593), CMS finalized the proposal at § 428.203(b)(2)(i) to exclude from the total number of units determined under § 428.203(a) units for which a manufacturer provided a discount under the 340B Program (''340B units''), as well as the proposal at § 428.203(b)(2)(ii) to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. However, after consideration of the data limitations of the proposed estimation methodology and public comments, CMS did not finalize the proposed estimation methodology for the applicable period that begins on October 1, 2025. Instead, CMS stated that it would explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a 340B repository. CMS is not reproposing the estimation methodology proposed in the CY 2025 PFS proposed rule, but did consider this estimation percentage as an alternative to the proposal this year, as described in section III.E.3.c.iii. of this proposed rule titled ''Alternative Policy Considered''. CMS therefore is proposing in this rule instead, in accordance with § 428.203(b)(2), a claims-based methodology to remove 340B units beginning January 1, 2026, and is proposing the establishment of a Part D claims data 340B repository. As CMS describes in section III.E.3.c.iv. of this proposed rule a 340B repository will not be operational until after the statutory requirement to remove 340B units goes into effect (that is, January 1, 2026). CMS is therefore proposing a claims-based methodology to remove 340B units from rebate calculations beginning on January 1, 2026.

We do not anticipate our inflation rebate proposed policies will result in an incrementally significant financial impact on the Medicare program relative to a baseline that reflects the status quo in the absence of any modifications to inflation rebate regulations at parts 427 and 428 as these proposed policies are refinements to regulatory requirements.

6. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2025, 11.2 million Medicare beneficiaries receive care from a healthcare provider in one of the 477 ACOs participating in the Shared Savings Program.[430] The policies in this proposed rule are designed, in part, to further improve the quality of care furnished by ACOs by revising the quality performance standard and reporting requirements, encourage more ACOs to move to a two-sided risk model, and promote the continued integrity and fairness of Shared Savings Program financial calculations.

The ACOs in the program in performance year 2023 combined to cover $128 billion in benchmark target spending. Actual ACO spending totaled approximately $123 billion—about $5.2 billion below combined benchmark. After accounting for $3.1 billion in net shared savings to ACOs, the remaining difference of $2.1 billion would represent federal savings from the program if benchmarks proved to be a perfect counterfactual in aggregate. The Regulatory Impact Analysis in the December 2018 final rule (see 83 FR 68044 through 68050) provided evidence that the benchmarks for performance year 2016 combined to represent a lower spending target than the theoretical counterfactual for estimating what spending would have been in the total FFS Medicare Program had ACOs not been present that year. Evidence included all of the following:

- Lower combined market level spending trends observed for cohorts of Hospital Referral Regions (HRRs) with significant ACO formation relative to other HRRs without material ACO activity.
- Spillover effects on spending outside of ACO benchmarks, including non-assigned beneficiaries served by ACO providers and suppliers.
- Program design elements that restrained benchmark levels, including rebasing with agreement periods of only 3 years, feedback of communal ACO effects on national trends used to update benchmarks, and restrictions on risk adjustment.

The Regulatory Impact Analysis in the December 2018 final rule (83 FR 68048) estimated that ACOs may have been responsible for half of the 1.2 percent difference in spending trend observed between national average and the subset of HRRs with minimal ACO activity through 2016. This scaled impact represented about four times the gross savings measured relative to benchmarks, or about 0.5 percent net savings across the entire FFS program after accounting for shared savings payments despite benchmarks only officially showing roughly equivalent overall reductions in spending relative to benchmark compared to total outlays from shared savings payments. Since 2016, changes to the Shared Savings Program have potentially moved the benchmarks closer to what the spending would have been in the absence of the program.

Updating that study to compare more recent trends for markets with varying levels of ACO activity requires updates to the initial study approach, as ACOs have become active in an increasing majority of markets across the nation. There no longer exists a sufficient number of HRRs with nominal ACO

[430] See ''Shared Savings Program Fast Facts—As of January 1, 2025'', available at *https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf.*

penetration in 2023 to construct a de facto counterfactual similar to the study in the December 2018 final rule. An alternate method, however, continues to show spending trends inversely correlated with ACO penetration over time. Roughly five percent of beneficiaries live in HRRs with ACO penetration consistently below the national average by 10 percentage points or more over the 2013 to 2023 time series (''Lagging'') while about 9 percent of beneficiaries live in HRRs with ACO penetration 10 percentage points or more above the national average over the same period (''Leading''). Relative to the 2011 base year immediately preceding the Shared Savings Program's introduction, growth in average unadjusted per capita spending in 2023 for Lagging and Leading markets was 4.3 percent higher and 3.9 percent lower than the national average. The divergence in spending growth was even wider after HCC risk adjustment: 5.3 percent higher for Lagging markets and 4.6 percent lower for Leading markets.

These market trends potentially overstate the impact that ACOs may have had on program spending in 2023. The portion of the difference in spending growth driven by risk adjustment may reflect efforts by ACOs to increase coding intensity. Leading markets may exhibit higher participation rates in CMMI models. ACO participation may naturally flock to markets with lower trend for exogenous reasons. Still, conservatively assuming only 35 percent of the unadjusted trend gap is causally related to Shared Savings Program ACOs would roughly validate the $5.2 billion gross savings indicated by comparing aggregate program benchmarks to actual ACO spending in 2023, and the roughly $2 billion in net savings to FFS Medicare. A more optimistic estimate, assuming Shared Savings Program ACOs were responsible for 50 percent of the risk-adjusted spending growth difference (mirroring assumptions used in the December 2018 final rule), would imply net savings roughly three times greater, or roughly $6 billion net savings for FFS Medicare.

A study of benchmark performance for cohorts of ACOs that participated in both performance year 2022 and performance year 2023 (with related details in Table 95) reveals that the BASIC track is the primary driver of net savings (as measured by program benchmark target spending less actual spending and shared savings payments). Twenty-five ACOs moved from a one-sided model of the BASIC track (Level A or B) to a two-sided model of the BASIC track (Level C, D or E) over performance year 2022 to 2023 and showed the highest rates of net savings to the program at 2.4 percent of benchmark. One hundred six ACOs remained in two-sided models of the BASIC track (Levels C, D or E) over that same two-year period and reached 2.3 percent net savings. Both cohorts showed the lowest average unadjusted per capita spending trend over this two-year period at about 6 percent. One hundred thirty-nine ACOs remained in one-sided models of the BASIC track (Level A or B) over both years and saw net savings grow from 1.4 percent to 1.7 percent by 2023. The 135 ACOs that remained in the ENHANCED track over these 2 years showed 1.3 percent net savings in 2023, up slightly from 1.2 percent for 2022. Findings are compared for each cohort in the study in Table 95.

TABLE 95: WEIGHTED AVERAGE FINANCIAL PERFORMANCE BY ACO COHORT DEFINED BY PATH OF PARTICIPATION OVER PY 2022 TO PY 2023 ($ BILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

Participation Pathway From PY22 to PY23	ACO Count	Benchmark ($B) [A]	Gross Savings % of Benchmark [B]		Shared Savings % of Benchmark [C]		Net Difference % of Benchmark [D]		Unadjusted Per Capita Spending Growth 2022 to 2023 [E]
			2022	2023	2022	2023	2022	2023	
BASIC AB->AB	139	34	-2.2%	-2.7%	0.8%	1.0%	-1.4%	-1.7%	1.08
BASIC AB->CDE	25	5	-4.3%	-4.4%	1.6%	2.1%	-2.7%	-2.4%	1.06
BASIC CDE->CDE	106	26	-3.8%	-4.4%	1.8%	2.2%	-2.0%	-2.3%	1.06
BASIC->ENHANCED	10	5	-5.0%	-6.9%	2.2%	5.1%	-2.8%	-1.8%	1.13
ENHANCED->ENHANCED	135	48	-4.6%	-5.0%	3.4%	3.7%	-1.2%	-1.3%	1.07

Notes: "Participation Pathway" are the following groups of ACOs, identified by the track/level of their participation in PY 2022 and PY 2023: "BASIC AB->AB" are ACOs that remained in a one-sided model of the BASIC track (Level A or B) for PY 2022 and PY 2023; "BASIC AB->CDE" are ACOs that participated in a one-sided model of the BASIC track (Level A or B) for PY 2022, and advanced to a two-sided model of the BASIC track (Level C, D, or E) for PY 2023; "BASIC CDE->CDE" are ACOs that remained in two-sided models of the BASIC track (Levels C, D or E) for PY 2022 and PY 2023; "BASIC->ENHANCED" are ACOs that participated in the BASIC track in PY 2022, and entered a new agreement period to participate in the ENHANCED track for PY 2023; and "ENHANCED->ENHANCED" are ACOs that remained in the ENHANCED track for PY 2022 and PY 2023.

"Benchmark" [A] is the total PY 2023 benchmark spending for each cohort, in billions of dollars.

"Gross Savings % of Benchmark" [B] is the percentage that a cohort's combined spending deviated from their combined benchmark spending (a negative percentage implies savings).

"Shared Savings % of Benchmark" [C] is the cohort's combined shared savings (and losses) paid to (from) ACOs expressed as a percentage of benchmark.

"Net Difference % of Benchmark" [D] is the sum of "Gross Savings % of Benchmark" [B] and "Shared Savings % of Benchmark" [C] and represents the portion of gross savings (as measured by program benchmarks) retained by the program.

"Unadjusted Per Capita Spending Growth 2022 to 2023" [E] is the combined average per capita spending for the cohort in 2023 divided by the corresponding average for the same cohort in 2022.

We will continue to study program data as it emerges, including the extent that new ACOs serving higher spending populations of beneficiaries enter the program and drive down spending in the BASIC track, and whether ACOs with lower relative spending migrating to the ENHANCED track are able to demonstrate materially lower spending trend after multiple years under that higher incentive arrangement.

Two proposed changes to Shared Savings Program policies, described in this proposed rule, are estimated to have a material impact on overall program spending. First, we anticipate that there may be an incremental cost for the proposal to allow only 5 performance years in a one-sided model (down from 7 performance years under the current regulations) for ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, with no prior participation in the Shared Savings Program, applying to enter an agreement period beginning on or after January 1, 2027. The cost would depend on the frequency that the extra two performance years in a one-sided model would have proven essential for certain ACOs serving higher-cost populations of beneficiaries to transition to performance-based risk and remain in the Shared Savings Program for multiple agreement periods. We have already implemented Shared Savings Program changes to increase participation from this general type of ACO, including ending negative regional adjustments to benchmarks, implementing the health equity benchmark adjustment (proposed in this rule to be renamed ''population adjustment''), and providing a prior savings adjustment to the rebased benchmark. However, some ACOs remaining under a one-sided model throughout their first agreement period would likely face significant uncertainty in predicting how these policies may or may not help provide margin for their rebased benchmark at the start of a potential second agreement period. Some such ACOs may find that uncertainty an insurmountable hurdle to renewing their participation in the Shared Savings Program directly into performance-based risk in the first year of their second agreement period. On the other hand, there is a potential for improved care management and increased savings from other ACOs that successfully manage the transition to performance-based risk earlier than they would have, if they had access to 7 performance years instead of 5 performance years of one-sided model participation in the Shared Savings Program. On net, we project the eventual termination of participation by some ACOs will involve a marginally greater reduction in program savings compared to the potential increase in efficiency from earlier transition to performance-based risk from other ACOs, leading to $370 million higher spending over 10 years, ranging from $50 million lower spending to $920 million higher spending at the 10th and 90th percentiles, respectively. The annual and 10-year total projections for this proposal are detailed in Table 96.

TABLE 96: PROJECTED IMPACT OF REDUCING NEW AND RISK INEXPERIENCED ACOS ELIGIBILITY TO 5 YEARS FROM THE CURRENT 7 YEARS ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	Total
Impact Estimate	0	0	0	0	20	40	80	90	70	70	**370**
Estimate Range:											
Low Estimate (10th Percentile)	0	-10	-20	-40	-40	-20	0	0	10	10	**-50**
High Estimate (90th Percentile)	0	10	10	50	80	130	180	200	160	140	**920**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The second area of material impact on program spending is from the proposals to allow ACOs to enter a new agreement period in the BASIC track when an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, in combination with the proposal to cap the shared savings or shared losses at a lesser amount for ACOs with fewer than 5,000 assigned beneficiaries in any of the three benchmark years. These proposals are expected to marginally increase participation by ACOs that would have otherwise been unable to satisfy the 5,000 assigned beneficiary minimum in BY1, BY2, or both, and to do so under an alternative cap that would provide a safeguard against excessive payments if assignment were to grow dramatically during the agreement period despite very low assignment in one or more benchmark years. The alternative cap is also anticipated to generate savings from ACOs that would have otherwise changed composition during the agreement period and exhibited reduced assignment in one or more benchmark years in ways that could have produced excessive shared savings payments due to random variation. The annual and 10-year total projections for this proposal are detailed in Table 97.

TABLE 97: PROJECTED IMPACT FOR ALLOWING ACOS TO ENTER NEW AGREEMENT PERIOD DESPITE EITHER BY1 AND/OR BY2 ASSIGNMENT BELOW 5,000 COMBINED WITH ALTERNATIVE CAP ON SHARED SAVINGS / SHARED LOSSES FOR ACOS WITH FEWER THAN 5,000 ASSIGNED BENEFICIARIES IN ANY BY ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	Total
Impact Estimate	0	0	−10	−10	−30	−50	−70	−80	−70	−70	**−390**
Estimate Range:											
Low Estimate (10th Percentile)	0	−10	−10	−30	−50	−90	−100	−120	−100	−110	**−540**
High Estimate (90th Percentile)	0	0	0	0	−10	−30	−30	−40	−40	−40	**−250**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The remaining proposed changes to the Shared Savings Program regulations, as described in section VII.A.2.e. of this proposed rule, are not estimated to have an impact on program spending at the aggregate level.

The combined impacts for all Shared Savings Program provisions are shown in Table 98. Because estimates are rounded to the nearest $10 million, and because the percentiles are independently sorted for each year and for the 10-year totals, the annual estimates may not sum to exactly match the total 10-year estimates.

TABLE 98: Projected Impact of Medicare Shared Savings Program Provisions (Individually Shown in Tables 96 and 97) ($ Millions; Negative Values Represent Savings to the Program)

	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	Total
Impact Estimate	0	0	-10	-10	-10	-10	10	10	0	0	**-20**
Estimate Range:											
Low Estimate (10th Percentile)	0	−20	−30	−70	−90	−110	−100	−120	−90	−100	**−590**
High Estimate (90th Percentile)	0	10	10	50	70	100	150	160	120	100	**670**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10 year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10 year totals.

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the new proposed policies described in section III.F. of this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposed policies require the use of our authority under section 1899(i) of the Act: the proposal to change the requirements for ACOs' progression to performance-based risk under the program's participation options (described in section III.F.2. of this proposed rule); the proposal to potentially apply an alternative loss recoupment limit, in conducting financial reconciliation for each performance year, for an ACO with fewer than 5,000 assigned beneficiaries in any BY, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c. of this proposed rule); the proposal to exclude ACOs that fall below 5,000 assigned beneficiaries in any BY from being eligible to benefit from the policies providing certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c. of this proposed rule); and the proposal to mitigate shared losses for an ACO determined to be affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years (described in section III.F.7.c. of this proposed rule). When considered together, these changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by hastening the transition to performance-based risk while improving protections against excessive liabilities both for shared losses charged to participants and shared savings paid by the program. These changes are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule, we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that we have enacted relying on section 1899(i)(3) of the Act as authority (*see* 87 FR 70195 and 70196). The marginal impact of the proposed changes in the CY 2024 PFS final rule were estimated to lower net spending by $330 million over the subsequent 10-year period for all new policies combined, including the cap an ACO's regional service area risk score growth, the addition of a new third step to the

beneficiary assignment methodology, and the revised approach to identify the assignable beneficiary population (88 FR 79496). The marginal impact of the changes in the CY 2025 PFS final rule were estimated to lower net spending by an additional $200 million in total through 2034 (89 FR 98527). The marginal impact of the changes in this proposed rule is estimated to be a $20 million reduction in net spending. The cumulative impact of all policies (including those in this proposed rule) is estimated to result in more than $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies we have enacted relying on section 1899(i)(3) of the Act as authority. Therefore, we estimate that program expenditures associated with the implementation of the provisions in this proposed rule would not be greater than those that would result under the statutory payment model, consistent with the requirements of section 1899(i)(3)(B) of the Act.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. Additional Shared Savings Program data beginning to accumulate after the end of the PHE for COVID–19, along with emerging information on the characteristics of, and performance trends for, new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024, and January 1, 2025, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

7. Changes to the Regulations Associated With the Ambulance Fee Schedule

As outlined in section III.H. of this proposed rule, section 3203 of the American Relief Act of 2025 and most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons sets forth in those subsections through September 30, 2025. The ambulance extender provisions are enacted through legislation that is self-implementing. We are proposing only to revise dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions. We have estimated the cost of these provisions to be $20 million in FY 2025 and $10 million in FY 2026 and the Congressional Budget Office (CBO)'s estimated cost of these provisions was $36 million in FY 2025 and $27 million in FY 2025 to 2029 *(https://www.cbo.gov/system/files/2025-03/hr1968.pdf, page 4).*

8. Updates to the Quality Payment Program

In this section of this proposed rule, we estimated the impacts of the Quality Payment Program policies. We estimated participation, final scores, and payment adjustments for eligible clinicians participating through MIPS, and the Advanced APMs, and MVPs. We also presented the impacts on the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our proposed policies, relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall Impact Modeling Approach and Data Assessment

(1) MIPS Impact Modeling Approach

For this proposed rule, we used a similar modeling approach as the CY 2025 PFS final rule (89 FR 97710 through 99057). We created two MIPS impact models: a baseline and a proposed policy model. Our baseline model includes previously finalized policies that are in effect for the CY 2025 performance period/2027 MIPS payment year and in the absence of any of the new policies in this proposed rule. Examples of previously finalized policies included in the baseline model are updated QP and partial QP thresholds and the previously finalized list of MVPs. Please refer to CY2025 PFS final rule for a comprehensive, detailed discussion of finalized policies (89 FR 97710).

The policies model builds on the baseline model and incorporates the new MIPS policies we are proposing for the CY 2026 performance period/2028 MIPS payment year included in this proposed rule. By comparing the baseline model to the proposed policies model, we are able to estimate the impact of the specific policies in this proposed rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This approach enables our model to align as much as possible with actual MIPS scoring and minimize differences between our projections and actual policy implementation. Our model's limitations are outlined later in this impact analysis.

(2) Data Used To Estimate Future MIPS Performance

In the CY 2025 PFS final rule (89 FR 98531), we explained our decision to use CY 2022 performance period submissions data. We noted that using CY 2022 performance data presents the most current data and aligns participation, final scoring, and payment adjustment analysis around the same common data set. For this proposed rule, CY 2023 performance data is the most recently available data for us to construct a model simulation for this proposed rule.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

Beginning with QP Performance Period 2017 (payment year 2019), through the Medicare Option, eligible clinicians who are determined to have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs are QPs for the applicable QP performance period and the corresponding payment year. In payment years 2019 through 2024, these QPs received a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the base year (the calendar year immediately preceding the payment year). In payment year 2025, eligible clinicians who attained QP status for QP Performance Period 2023 will receive a lump-sum APM Incentive Payment equal to 3.5 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. In payment year 2026, eligible clinicians who attained QP status in QP Performance Period 2024 will receive a lump-sum APM Incentive Payment equal to 1.88 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2025.

Beginning with QP Performance Period 2019 (payment year 2021), in addition to the Medicare Option, the All-Payer Combination Option also affords eligible clinicians an opportunity at QP status. The All-Payer Combination Option allows eligible clinicians to become QPs by assessing a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a given QP Performance Period are not subject to MIPS reporting requirements and payment adjustments for the contemporaneous MIPS performance period/payment year. Eligible clinicians who do not become QPs but who meet a lower threshold requirement to become Partial QPs for the year may elect whether or not to report to MIPS. If they elect to report, they are scored in and receive a payment adjustment under MIPS. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Separately from the APM Incentive Payment, beginning in payment year 2026, there are two separate PFS CFs—one for eligible clinicians who are QPs for the year (the qualifying APM CF), and the other for all non-QP eligible clinicians and other suppliers paid under the PFS (the non-qualifying APM CF). The update to the qualifying APM CF for a year is 0.75 percent, whereas the update to the non-qualifying APM CF for a year is 0.25 percent. For payment year 2026, under current law, both an APM Incentive Payment and the qualifying APM CF will apply. This means that eligible clinicians who attained QP status for QP Performance Period 2024 will receive a lump-sum payment of 1.88 percent of their 2025 covered professional services paid claims as described above, and additionally their 2026 covered professional services claims will be paid using the physician fee schedule rates that are established using the 0.75 percent QP APM CF.

In addition, the thresholds to achieve QP status beginning in the 2026 QP Performance Period (2028 payment year) will increase from 50 percent to 75 percent for the payment amount, and from 35 percent to 50 percent for the patient count. Overall, we estimated that for the 2026 QP Performance Period, between 375,000 and 482,200 eligible clinicians will become QPs, and therefore will be excluded from MIPS reporting requirements and payment adjustments.

In addition, the thresholds to achieve QP status beginning in the 2026 QP Performance Period will increase to 75 percent for the payment amount, and 50 percent for the patient count. Overall, we estimated that for the 2026 QP Performance Period, between 375,000 and 482,200 eligible clinicians will become QPs, and therefore be excluded from MIPS reporting requirements and payment adjustments.

In section IV.A.4.m.(2) of the CY2026 PFS proposed rule, we proposed to modify the definition of ''attribution-eligible beneficiary'' to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. However, we are not finalizing this proposal and therefore no impact of this policy is included in the estimated number of QPs provided above.

We projected the number of eligible clinicians who will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2026 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2026 QP Performance Period. The projections also reflect an estimated number of eligible clinicians who will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2026 QP Performance Period:

- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model
- Enhancing Oncology Model (EOM);
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track); and
- Transforming Episode Accountability Model (TEAM)

We used the Participation Lists and Affiliated Practitioner Lists, as applicable (see § 414.1425(a) for information on the APM Participant Lists used for QP determinations) for the 2024 QP performance period third snapshot QP determination date to estimate the number of QPs for the 2026 QP Performance Period. For models starting in the 2026 QP Performance Period we estimated performance based on projected participation. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries were attribution eligible through the APM Entity.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2026 Performance Period/2028 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Proposed Policies Models

For this proposed rule, we applied the same assumptions as in the CY 2025 PFS final rule (89 FR 98532) to estimate our initial population of clinicians using 2023 performance data. Specifically, we used the CY 2023 final reconciled eligibility determination file, same as the 2022 file described in the CY 2025 PFS final rule (88 FR 79505). This file reconciles eligibility from two determination periods and aligns with the CY 2023 performance period submissions data on which we based this model. Our analysis included 1,889,733 clinicians with PFS claims in this initial population. This initial population of clinicians was used to determine eligibility using the methodology described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Eligibility Assumptions

(a) Methods and Assumptions Used To Estimate Eligibility

After identifying the clinician population with PFS claims, we applied the same eligibility assumptions and determination process described in the CY 2025 PFS final rule (89 FR 97710). We are not proposing any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and proposed policies model.

For our impact analysis model, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all 3 criteria (§§ 414.1305 and 414.1310(b)(1)(iii)) and is subject to a MIPS payment adjustment. We based this estimate on the CY 2023 performance period data described in this section of this proposed rule, which includes the 3 low volume criteria. Within the eligible clinicians, we divided them into two groups-

clinicians who report MIPS data and clinicians who do not report MIPS data.

Our next two eligibility assumptions concern clinicians in groups, who may voluntarily participate in MIPS, but are not required to participate. First, we estimate group eligibility. These are the clinicians who have a group submission, and their group exceeds the low-volume threshold in all 3 criteria. Next, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in at least 1 criterion, but not all 3, may elect to opt in. Based on the number of individuals who opted in to MIPS for the CY 2023 performance period/2025 MIPS payment year, our model estimates that these clinicians will continue to opt in to MIPS.

After applying the process outlined in this section of this proposed rule, we then estimate the number of ''Potentially MIPS Eligible'' clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These clinicians are potentially eligible; however, they do not choose to report to MIPS.

Finally, we estimated the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. First, we estimated the number of clinicians who are below all 3 low-volume criteria (both as an individual and as a group) using the CY 2023 performance data as outlined in this section of this proposed rule.

Next, we estimated the number of QPs (not MIPS eligible). Also in this proposed rule, we estimated a range of QPs. For the purposes of our impact analysis, we estimate a specific number of QPs because a specific number of clinicians is needed to simulate the impacts of our proposed policies on participation, final scores, and payment adjustments. Finally, we estimate the number of clinicians who are excluded for other reasons, for example, they are in a clinician type that is not MIPS eligible or newly enrolled in Medicare.

After applying these assumptions to our initial population, we estimate that there will be 607,419 MIPS eligible clinicians with ~$51.84 billion in allowed charges in CY2026.

(b) MIPS Eligibility Estimates

For the impact analysis, we use the estimated population of 607,419 MIPS eligible clinicians described previously in this section of this proposed rule. Table 99 summarizes our eligibility estimates for the policies model after applying our assumptions outlined in this section of this proposed rule.

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TABLE 99: ESTIMATION OF MIPS ELIGIBILITY STATUS FOR CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR USING THE CY 2026 PFS PROPOSED RULE ASSUMPTIONS**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians *	Number of Clinicians	PFS allowed charges ($ in mil)**
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	98,485	$28,689
MIPS eligible	Did not Report to MIPS	38,784	$11,172
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	465,291	$11,705
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	4,812	$275
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**607,419**	**$51,843**
Not MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	176,052	$5,484
Potentially MIPS Eligible	Group Eligible; Did not Report	472,842	$10,966
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	130,002	$810
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	62,084	$549
Qualified Participant (QP)***	Not applicable	441,334	$20,836
Total Number of Clinicians Not MIPS Eligible		1,282,314	**$38,644**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,**889,733**	**$90,487**

* Participation excludes facility-based clinicians who do not have scores in the 2023 MIPS submission data.
** Allowed charges estimated in 2023 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VII.I.5.b. of this proposed rule because, for purposes of establishing the population used in our modeling, we estimate an absolute number of QPs rather than a range.

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d. Modeling Approach and Methods for MIPs Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this proposed rule, we present several proposals that impact the measures and activities, the performance category scores, final scores, and MIPS payment adjustments for MIPS eligible clinicians. In section VII.I.5.d(3). of this proposed rule, we outline these changes in more detail and describe our methodology to estimate MIPS payment adjustments for the CY 2026 performance period/2028 MIPS payment year. We then present the impact of the policies in the CY 2026 performance period/2028 MIPS payment year and compare select metrics to the baseline model. By comparing model outputs in the baseline model to the proposed policies model, we are able to observe the impact of the policies for the CY 2026 performance period/2028 MIPS payment year.

MIPS eligible clinicians' final scores are calculated based on the clinicians' performance on measures and activities specified under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the four MIPS performance categories as an individual, group, virtual group, APM Entity and via traditional MIPS, the APM Performance Pathway (APP), or MVP reporting options. MIPS APM participants can participate in the APP

as an individual, group, virtual group, or APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. Our simulation applies the proposed and baseline policies to the existing MIPS scoring engine.

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MIPS Value Pathways beginning in the CY 2023 performance period/2025 MIPS payment year.

(2) Methodology To Assess Impact for MIPS Value Pathways

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. We assessed whether to use CY 2024 MVP registration data to estimate MVP participation and policy impact, but elected not to simulate the impact for MVP because we do not presently have sufficient MVP scoring data for modeling and simulation, as we only have 1 year of MVP data from the CY 2023 performance period/2025 MIPS payment year. Our model is based on CY 2023 performance data, which contains only one year of MVP scores, and this is insufficient for conducting reconciliation between multiple years, which introduces uncertainty and complexity into our model. As more MVP scoring data becomes available in the future, we will reassess our methodology for estimating MVP participation, final scores, and payment adjustments.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we generally use the CY 2023 performance data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2026 performance period/2028 MIPS payment year for the baseline and policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, improvement activities, and Promoting Interoperability performance categories, and the application of our final scoring policies.

(a) Methodology To Estimate the Quality Performance Category Score

We used the CY 2025 PFS final rule final policies model as the starting point of our baseline model. Since there are no previously finalized policies impacting the quality performance category that were not already included in the CY 2024 PFS final rule policies model, we did not make any modifications to the quality performance category and the baseline model is identical to the CY 2025 PFS final rules policies model with respect to the quality category.

Our policies model incorporates the following policies from this proposed rule as outlined in section IV.B. of this proposed rule:

In section IV.B.1.a.(2)(a) of this proposed rule, to facilitate fairer scoring, we are proposing to remove the scoring cap and change the benchmarking approach for certain topped out measures applicable to clinicians facing both limited measure choice and limited scoring opportunities. We did not simulate the addition of quality measures described in section IV.A.4.d.(1)(c)(i) of this proposed rule since we use existing quality measure data from the CY 2023 performance period, which does not include new measures. We did not simulate the removal of quality measures described in section IV.A.4.d.(1)(c)(ii) of this proposed rule since we cannot predict how clinician behavior and measure selection will change in response.

In section IV.B.1.a.(2(b)(3) of this proposed rule, we are proposing to modify the methodology for scoring the administrative claims-based measures within the quality performance category. The proposed administrative claims-based quality measure scoring methodology would be based on the standard deviation, the median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose performance rate under an administrative claims-based measure would be equal to the median performance rate for all MIPS eligible clinicians that are scored on that measure, we would assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2026 performance period/2028 MIPS payment year, the median would have an achievement point value of 7.5, based on a performance threshold of 75 points as proposed in section IV.B.2.b.(2) of this proposed rule. For each administrative claims-based quality measure, the cut-offs for benchmark ranges would be calculated based on standard deviations from the median. This policy is incorporated into our model based on the specifications explained in section IV.B.1.a.(2(b)(3) of this proposed rule.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2025 PFS final rule (89 FR 98531) for the baseline and the proposed policies RIA models with the modifications described below.

For this proposed rule, the baseline policies RIA model used the same methodology as the final policies RIA model in the CY 2025 PFS final rule (89 FR 98530). The policies RIA model incorporated and implemented the following changes:

- In section IV.A.4.(d).(2).(c). of this proposed rule, we are proposing to modify the Total Per Capita Cost (TPCC) measure. We are also proposing to update the operational list of care episodes and patient condition groups and codes to reflect coding changes identified through our annual maintenance process for MIPS cost measures. We incorporated measure. test data with the specifications for the modified measures.
- In section IV.A.4.(d).(2).(d). of this proposed rule, we are proposing to adopt a 2-year informational-only feedback period for newly implemented MIPS cost measures, which we are also proposing to codify at § 414.1380(b)(2).

(c) Methodology To Estimate the Promoting Interoperability Performance Category Score

In section IV.A.4.d.(4). of this proposed rule, we are proposing modifications to two measures and adoption of one new optional bonus measure: Public Health Reporting Under TEFCA Measure. However, we did not estimate Promoting Interoperability performance category score impacts because, after conducting an assessment of the proposed policies, we determined that there is insufficient data to model the impact of adding a new, optional bonus measure on the Promoting Interoperability performance category scores, and therefore, did not incorporate it into our model.

(d) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline and policies model we used the same method to estimate the improvement activities performance

category score as described in the CY 2025 PFS final rule (89 FR 79508) including alignment with the clarification provided regarding IA automatic weighting for APM participants (89 FR 79366).

In section IV.A.4.d.(3).(b). of this proposed rule, we propose to amend § 414.1355(c)(7) by adding a new subcategory, ''Advancing Health and Wellness'' (AHW), to replace the ''Achieving Health Equity'' subcategory.'' We proposed adding three new Improvement Activities while removing eight existing ones. However, the three new measures were not included in the RIA model because we lack historical benchmark data to estimate their potential impact. Additionally, the eight measures being removed were also excluded from the RIA model, as the models cannot predict how clinicians will alter their behavior once these measures are removed.

(e) Methodology To Estimate the Complex Patient Bonus Points

This proposed rule does not include proposals to modify the complex patient bonus. Therefore, for the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(f) Methodology To Estimate the Final Score

We are not proposing any changes to how we calculate the MIPS final score. Our baseline and proposed policies models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For both models, after adding any applicable complex patient bonus, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a MIPS eligible clinician was approved for reweighting of one or more performance category to zero percent of their final score, and the category's weight redistributed to other performance category(ies), for the CY 2023 performance period/2025 MIPS payment year (which was the data source used in our model) in accordance with our reweighting policies under § 414.1380(c)(2), then we continue to apply that reweighting in our model by assigning them a neutral score equal to the performance threshold if all categories were reweighted or assigning the applicable weights to the categories which were reweighted.

Although it is unlikely (but possible) that the exact same clinicians will apply for and receive reweighting in both the CY 2023 performance period/2025 MIPS payment year (which our data is based on) and the CY 2026 performance period/2028 MIPS payment year (which we are simulating), we believe that this assumption accurately reflects future clinician behavior for two reasons. First, while the exact same MIPS eligible clinicians may not receive reweighting in 2 different years, we believe that this assumption allows us to quantify the impact of the reweighting on a population level. In other words, even if the same clinicians do not apply for and receive reweighting in these 2 different years, the absolute number of reweighting and the characteristics of practices that receive reweighting are likely to remain similar. Secondly, if we were to not assign reweighting to those MIPS eligible clinicians, many of them would receive a very low final score because they did not submit data for one or more performance categories during the year in which they received reweighting. We do not believe that it is a realistic assumption that, in the absence of reweighting, those clinicians will continue not to submit data. For these reasons, we assume that clinicians who received reweighting in the CY 2023 performance period/2025 MIPS payment year are also approved for reweighting in the CY 2026 performance period/2028 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this corresponds with a neutral (0 percent) payment adjustment.

(g) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies models, we applied the hierarchy as finalized in the CY 2023 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculate the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we apply the performance threshold of 75 points finalized in the CY 2025 PFS final rule. In section IV.B.2.b.(2) of this proposed rule, we are proposing to again set the performance threshold at 75. Therefore, for both the baseline and proposed policies models we used a performance threshold of 75 to calculate the exchange function used for MIPS payment adjustments. We note that the results of this exchange are not identical between the baseline and proposed policies models. This is due to the scaling factor used to determine positive adjustments is dependent on the total dollar amount of negative payment adjustments and those adjustments differ as final scores are not identical between both models.

For both the baseline and proposed policies models, we use these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in section VII.I.5.d.(3). of the proposed rule, we create a baseline and proposed policies simulation. Using this simulation, we estimate the impact of the policies of this proposed rule.

(a) Impact on Clinician Eligibility

In section VII.E.17.c.(2). of this proposed rule, we noted that we do not modify clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact on Clinician's Final Scores

Table 100 shows the median final score by practice size and the percentage of MIPS eligible clinicians of each practice size with a positive, neutral, or negative adjustment.

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TABLE 100: CY 2026 FINAL SCORE ESTIMATES BY PRACTICE SIZE

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
1) Solo	17,074	75.00	32.88%	17.98%	49.14%
a) Engaged***	8,131	87.63	68.86%	7.77%	23,37
b) Non-Reporting****	8,934	21.95	0.11%	27.27%	72.62%
2) 2-15	66,808	87.21	66.19%	12.54%	21.27%
3) 16-99	116,647	87.37	76.37%	7.17%	16.45%
4) 100+	406,890	88.46	90.68%	1.19%	8.14%
Overall	607,419	87.96	83.61%	4.06%	12.33%
Proposed Policies					
1) Solo	17,074	75.00	32.85%	17.99%	49.16%
a) Engaged	8,131	87.70	68.92%	7,76%	23.32%
b) Non-Reporting	8,943	21.99	0.11%	27.27	72.62%
2) 2-15	66,808	87.53	66.39%	12.57%	21.04%
3) 16-99	116,647	88.32	77.23%	7.06%	15.71%
4) 100+	406,890	89.89	91.04%	1.18%	7.78%
Overall	607,419	89.47	84.04%	4.03%	11.92%

The median final score includes clinicians who receive reweighting for all MIPS performance categories our policies at § 414.1380(c)(2). These clinicians who have all performance categories reweighted are assigned a score of 75 (neutral payment adjustment) in our model.

*** An engaged clinician refers to a MIPS-eligible clinician who self-reports at least one measure, attestation, or activity.

****A non-reporting clinician was a clinician who was required to report but didn't actively self-report at least one measure, attestation, or activity.

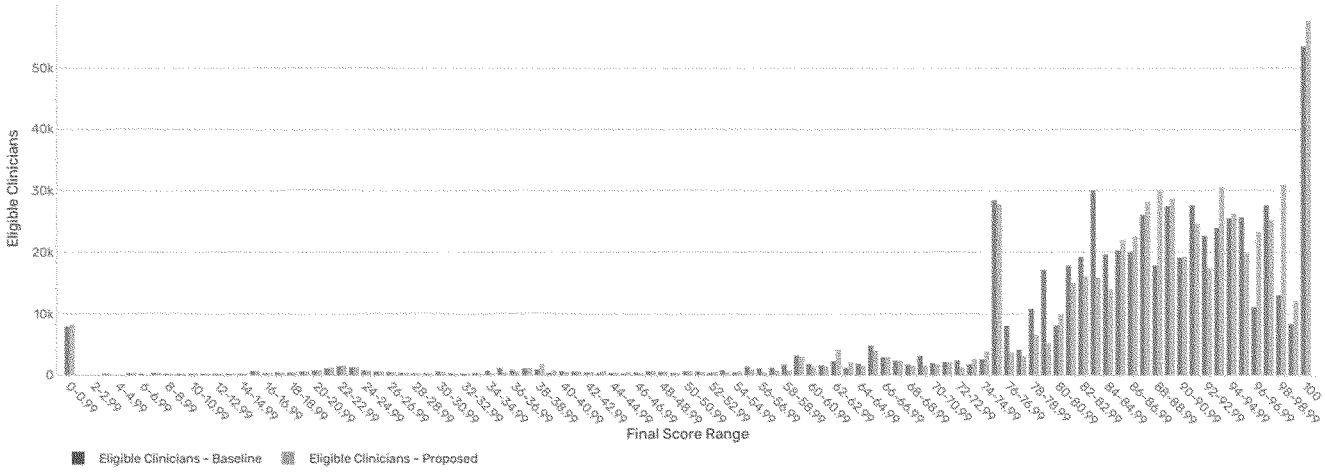
The overall median final score is 87.96 in our baseline model and 89.47 in our proposed policies model, a slight increase for all practice sizes. There is a slight increase in the percentage of clinicians receiving a positive payment adjustment, we project that, overall, 83.61 percent of MIPS eligible clinicians will receive a positive adjustment in our baseline model, and 84.04 percent of MIPS eligible clinicians will receive a positive adjustment in our policies model. This slight increase is largely due to our proposed policies in the quality category, including the change to the administrative claims based quality measure scoring methodology and the updated topped out measure policy discussed in section IV.B.1.a.(2). of this proposed rule. Table 101 shows the median quality category score for MIPS eligible clinicians who are scored on the quality performance category for our baseline and proposed policies model. There is a noticeable difference in median quality category scores between our two models. This is true across almost all practice sizes, except for solo practitioners. The overall median quality category score is 78.78 in our baseline model and 83.76 in our policies model.

TABLE 101: CY 2026 QUALITY SCORE ESTIMATES BY PRACTICE SIZE

Practice Size	MIPS Eligible Clinicians Receiving Quality Score	Total Number of MIPS Eligible Clinicians	Proportion of MIPS Eligible Clinicians Receiving Quality Score	Median Quality Score Estimate
Baseline				
1) Solo	13,862	17,074	81.19%	29.94%
a) Engaged*	7,386	8,131	90.62%	82.59%
b) Non-Reporting**	6,494	8,943	72.62%	0%
2) 2-15	56,708	66,808	84.88%	83.43%
3) 16-99	99,123	116,647	84.98%	80.10%
4) 100+	381,902	406,890	93.86%	78.47%
Overall	551,595	607,419	90.81%	78.78%
Proposed Policies				
1) Solo	13,863	17,074	81.19%	29.96%
a) Engaged	7,369	8,131	90.63%	84.02%
b) Non-Reporting	6,494	8,943	72.62%	0%
2) 2-15	56,713	66,808	84.89%	84.58%
3) 16-99	99,333	116,647	85.16%	82.44%
4) 100+	382,671	406,890	94.05%	84.00%
Overall	552,580	607,419	90.97%	83.76%

Figure 7 shows the distribution of final scores for all MIPS eligible clinicians. Note that there is a noticeable size of MIPS eligible clinicians with a final score of 75. MIPS eligible clinicians whom we approved for reweighting of all MIPS performance categories in accordance with our reweighting policies at § 414.1380(c)(2) are assigned a final score of exactly the performance threshold (75). Overall, the distribution is left skewed, indicating that many more clinicians would receive final scores on the higher side.

FIGURE 7: Count of MIPS Eligible Clinicians by Final Score



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(i) Impact to Small and Solo Practices

Solo practitioners account for 17,074 MIPS eligible clinicians or 2.81 percent of all MIPS eligible clinicians in both the baseline and proposed policies models. The median final score for all solo practitioners is exactly equal to the performance threshold (75) in both the baseline and proposed policies model. The portion of all solo practitioners receiving a positive adjustment are almost the same between the baseline and the proposed policies models (32.85 percent baseline vs 32.88 proposed policies).

Solo practitioners have a lower overall median final score than other practice sizes. This is largely due to the fact that many of these solo practitioners do not actively submit data to MIPS despite being MIPS eligible clinicians. Our 2022 analysis indicates that 49.12 percent of solo practitioners submit data to MIPS compared to 94.07 percent of all clinicians. For solo practitioners who submit data, the median final score is 87.63 in the baseline and 87.70 in the proposed policies model. In contrast,

those who did not report data to MIPS have a median final score of to 21.95 in the baseline model and 21.99 in the proposed model. These findings indicate that the lower final scores among solo practitioners are likely, and largely, due to not reporting data to MIPS.

Table 102 shows that, even among engaged solo practitioners, the percentage receiving a positive payment adjustment is lower than that of clinicians from medium or large practices, while being comparable to those from small practices. Similarly, even for engaged solo practitioners, a higher proportion of them face negative payment adjustments compared to those in other practice sizes Figure 8 shows the distribution of final scores for solo practitioners. Both box plots show similar final score distributions, and both baseline and proposed policies models show a large distance between the lower and upper quartiles. Figure 9 shows the final score distribution for all MIPS eligible clinicians between the baseline and the proposed policies models. These models show similar final score distributions, with the proposed policies model showing slightly higher scores. The upper quartile of is 94.25 in the baseline model and 95.82 in the proposed policies model. The distance between lower and upper quartiles is substantially narrower for all MIPS eligible clinicians than it is for solo practitioners. Figure 10 shows the distribution of final scores for solo practitioners who actively submit data to MIPS. This distribution is similar to the distribution of final scores in all MIPS eligible clinicians.

Additionally, the upper quartile is at 95.86 in the baseline and at 96.07 in the proposed policies model, which are slightly higher than that for all MIPS eligible clinicians. This suggests that, while many solo practitioners do not submit data to MIPS, those who do submit MIPS data tend to perform comparably to all MIPS eligible clinicians. This further supports the idea that the primary reason for low final scores among solo practitioners is the high number of them who do not submit MIPS data.

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FIGURE 8: Distribution of Final Scores for Solo Practitioners

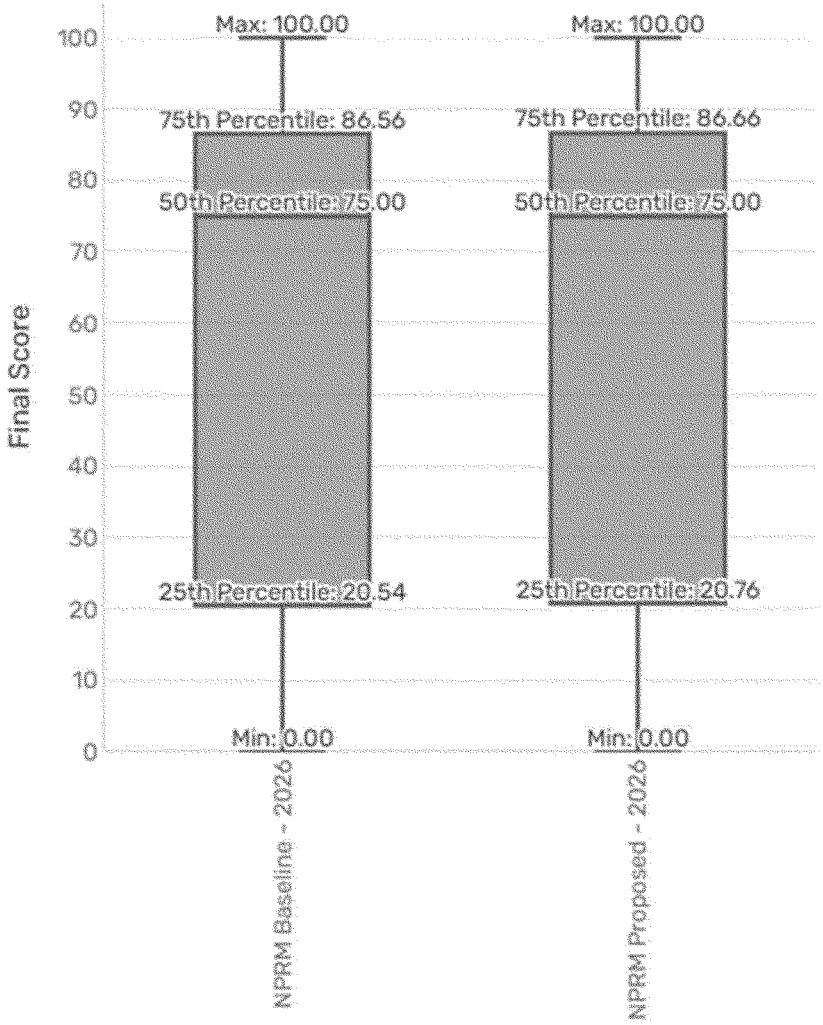


FIGURE 9: Distribution of Final Scores for All MIPS Eligible Clinicians

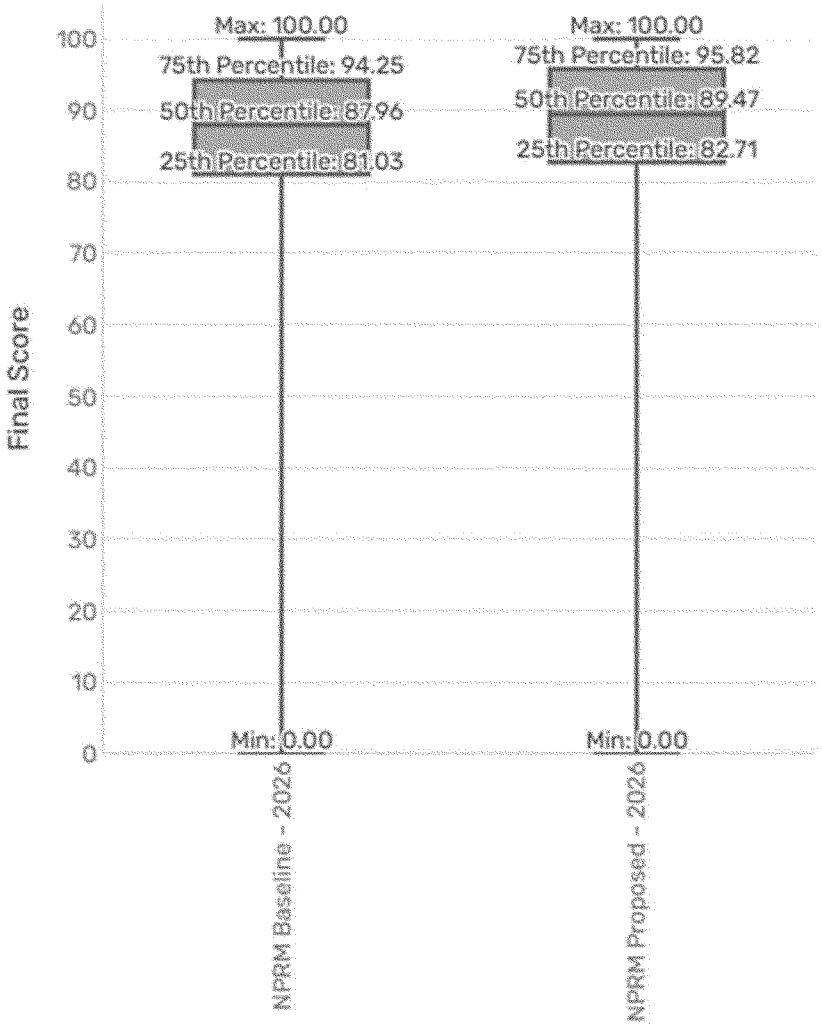
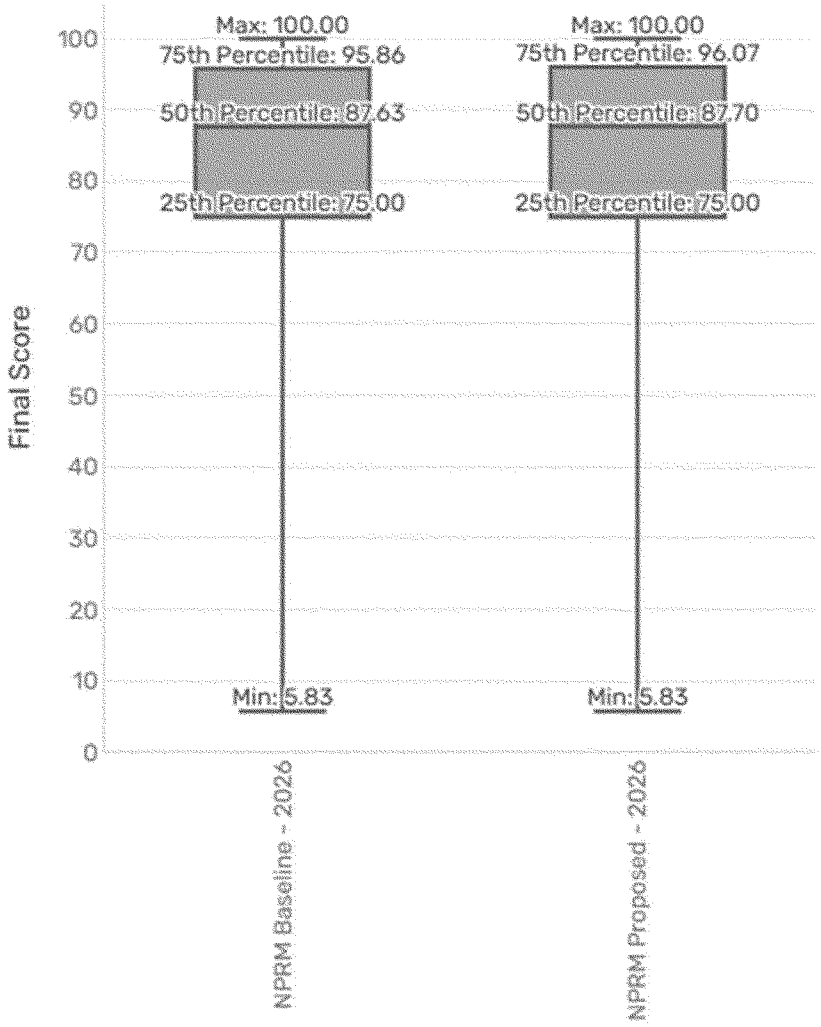


FIGURE 10: Distribution of Final Scores for Solo Practitioners who Submit Data



Small practices, defined at § 414.1305 as groups with 2 to 15 clinicians, have a median final score of 87.21 in the baseline and 87.53 in the policies model. This is slightly lower than the overall median final scores of 87.96 in the baseline model and 89.47 in the proposed policies model. Among small practices that submit data (Table D–B24), the median final score is 91.67 in the proposed policies model and 91.23 in the baseline model. They are higher than the median final score for all MIPS eligible clinicians who submit data, which are 90.10 in the proposed policy model and 89 in the baseline model. This indicates that small practices that submit MIPS data perform slightly better than it is for all MIPS eligible clinicians. Table 102 shows the percentage of clinicians, by practice size, either do or do not submit data to MIPS and their corresponding median final scores. Note that, in the proposed policies model, the median final scores for medium and large practice clinicians who do not submit data are 75. This indicates that many medium or large practice clinicians who do not submit data to MIPS have been approved for reweighting of all of their MIPS performance categories under our policies at § 414.1380(c)(2). In contrast, the median final scores for solo and small practice clinicians, who do not submit data are 21.99 and 27.65, respectively. This indicates that many of them either not being eligible for or not applying for our reweighting policies. Over 90 percent of the medium and large practice clinicians submit data to MIPS. It is possible that the 10 percent or less MIPS eligible clinicians who do not submit data to MIPS are primarily those who have received reweighting under our policies at § 414.1380(c)(2).

TABLE 102: PERCENTAGE OF MIPS ELIGIBLE CLINICIANS WHO SUBMIT DATA AND MEDIAN FINAL SCORE

	Percentage of MIPS Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	Median Final Score of MIPS Eligible Clinicians who Do not submit data.
Baseline			
1) Solo	47.62%	87.63	21.95
2) Small (2-15)	79.31%	91.23	28.21
3) Medium (16-99)	90.14%	89.02	75
4) Large(100+)	98.70%	88.65	75
Overall	93.49%	89.00	75
Proposed Policies			
1) Solo	47.62%	87.70	21.99
2) Small (2-15)	79.31%	91.67	27.65
3) Medium (16-99)	90.34%	89.91	75
4) Large(100+)	98.71%	90.06	75
Overall	93.53%	90.10	75

(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Impact assessment of this group of clinicians indicates that their final scores are similar to the overall MIPS eligible clinicians. Table 103 shows the median final score and the percentage of eligible clinicians with a positive, neutral, or negative adjustment by practice size for rural practitioners.

TABLE 103: CY 2026 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR RURAL PRACTITIONERS ONLY

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
1) Solo	2,306	75.00	37.73%	14.92%	47.35%
a) Engaged*	1,251	86,78	69.54%	5.36%	25.10%
b) Non-Reporting**	1,055	21.44	0.00%	26.26%	73.73%
2) 2-15	10,112	88.61	71.78%	8.24%	19.99%
3) 16-99	20,427	87.31	79.62%	4.04%	16.34%
4) 100+	36,288	86.34	90.66%	0.41%	8.93%
Overall	69,133	86.42	82.87%	3.11%	14.02%
Proposed Policies					
1) Solo	2,306	75.00	37.77%	14.92%	47.31%
a) Engaged	1,251	86.78	69.62%	5.36%	25.02%
b) Non-Reporting	1,055	21.57	0.00%	26.26%	73.74%
2) 2-15	10,112	89.11	71.94%	8.24%	19.82%
3) 16-99	20,430	88.63	81.57%	4.06%	14.37%
4) 100+	36,283	87.74	90.67%	0.40%	8.94%
Overall	69,131	87.80	83.47%	3.11%	13.41%

*An engaged clinician refers to a MIPS-eligible clinician who self-reports at least one measure, attestation, or activity.

**A non-reporting clinician was a clinician who was required to report but didn't actively self-report at least one measure, attestation, or activity.

The overall median final score for rural practitioners is 86.42 in our baseline model and 87.80 in our policies model. This is slightly lower than the median final score for all MIPS eligible clinicians, which is 87.96 in our baseline model and 89.47 in our policies model. According to the results from the proposed policies model, large practice rural clinicians (100+) have a slightly lower median final score (87.74) than it (89.89) is for all MIPS eligible clinicians practicing in large practices.

(iii) Impact to Safety Net Providers

(a) Updated Definition of Safety Net Providers

In the CY 2022 PFS final rule (87 FR 70094), we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

In the 2024 PFS final rule (88 FR 79513), we compared the performance of clinicians who received the complex patient bonus with our overall population. As we further developed our model, we decided to adopt a more precise definition of safety net providers. We believe that by narrowing our definition of safety net providers to clinicians fall in the top 20 percentile for their percent share of patients who are dually eligible for Medicare and Medicaid, we can identify providers who care for a large proportion of socially vulnerable individuals.

Table 104 shows the final score estimates for safety net providers under this new definition. Safety net have higher median final scores (92.43 in the proposed model) than the overall population of MIPS eligible clinicians (89.47 in the proposed model). Safety net solo providers who submit data have a slightly higher median final score (89.66 in the proposed model) than that from the overall solo population who submit data (87.70 in the proposed model). However, only 42.89 percent of safety net solo and 71.14 percent of safety net small practice providers submit data compared to 47.62 percent and 79.31 percent of the overall solo and small practice providers, respectively.

TABLE 104: CY 2026 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR *SAFETY NET PRACTITIONERS ONLY*

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
1) Solo	5,039	57.81	28.70%	16.21%	55.09%
a) Engaged*	2,161	89.39	66.45%	7.45%	26.10%
b) Non-Reporting**	2,878	21.89	0.35%	22.79%	76.86%
2) 2-15	13,412	85.49	58.38%	12.79%	28.83%
3) 16-99	29,166	90.33	77.72%	7.08%	15.20%
4) 100+	81,157	92.06	91.67%	0.95%	7.38%
Overall	128,774	90.96	82.58%	4.17%	13.25%
Proposed Policies					
1) Solo	5,039	57.76	28.72%	16.19%	55.09%
a) Engaged	2,161	89.66	66.50%	7.40%	26.10%
b) Non-Reporting	2,878	21.90	0.35%	22.79%	76.86%
2) 2-15	13,412	85.9	58.64%	12.79%	28.56%
3) 16-99	29,159	91.23	77.66%	7.22%	15.13%
4) 100+	81,136	93.67	92.29%	0.94%	6.77%
Overall	128,746	92.43	82.98%	4.19%	12.82%

*Engaged clinician refers to a MIPS-eligible clinician who self-reports at least one measure, attestation, or activity.

**A non-reporting clinician was a clinician who was required to report but didn't actively self-report at least one measure, attestation, or activity.

TABLE 105: CY 2026 MEDIAN FINAL SCORES FOR *SAFETY NET PRACTITIONERS WHO SUBMIT DATA*

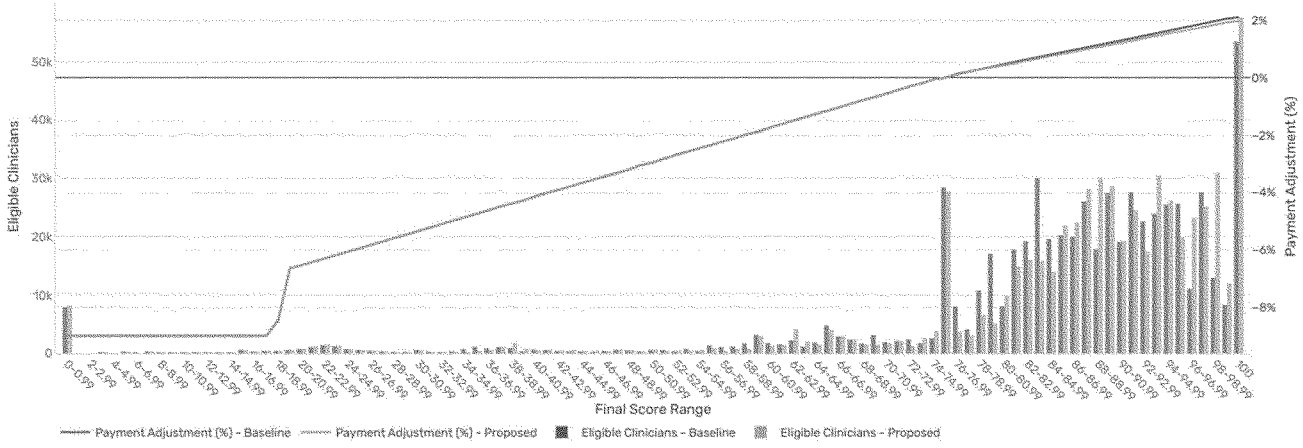
Practice Size	Percent of MIPS Eligible Clinicians who Submit Data	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
1) Solo	42.89%	89.39	66.45%	7.45%	26.10%
2) 2-15	71.14%	93.83	81.95%	3.98%	14.07%
3) 16-99	88.39%	91.63	86.98%	0.43%	12.58%
4) 100+	98.43%	92.38	92.90%	0.00%	7.09%
Overall	91.14%	92.17	90.23%	0.56%	9.22%
Proposed Policies					
1) Solo	42.89%	89.66	66.50%	7.40%	26.10%
2) 2-15	71.14%	94.17	82.32%	3.99%	13.69%
3) 16-99	88.52%	92.73	86.77%	0.72%	12.51%
4) 100+	98.46%	93.99	93.50%	0.00%	6.50%
Overall	91.19%	93.51	90.61%	0.62%	8.77%

(c) Impact to MIPS Eligible Clinicians' Payment Adjustments

We are not proposing to increase the performance threshold in this proposed rule and are proposing to set the performance threshold at 75 points for a period of 3 years. However, as we get consistent and more data as the program evolves, we will continue to gauge whether the performance threshold should be increased in future years.

Figure 106 shows that the payment adjustments are very similar between the baseline and proposed policies model. This is because we made minimal changes to our proposed policies. Although payment adjustments are slightly higher in the baseline model. In the baseline model, we project redistributing $464 million, and in the proposed policies model, we project redistributing $463 million. This decrease is due to the slightly higher proportions of clinicians receiving positive payment adjustments in the proposed policies model (84.05 percent) than it is in the baseline model (83.61 percent). As the proportion of MIPS eligible clinicians receiving a positive payment adjustment increases, the portion of clinicians receiving a negative payment adjustment decreases accordingly (11.92 percent in the proposed policies model vs. 12.33 percent in the baseline model). As the proportion of MIPS eligible clinicians receiving negative payment adjustments decreases, the budget neutral funds available for redistribution also decrease.

FIGURE 11: Final Score Distribution and Payment Adjustment



We also report the median positive and negative payment adjustments by practice size in Table 106.

TABLE 106: CY 2026 MEDIAN POSITIVE AND NEGATIVE PAYMENT ADJUSTMENT ESTIMATES BY PRACTICE SIZE

Practice Size	Median Positive Payment Adjustment*	Median Negative Payment Adjustment*
Baseline		
Solo (1)	1.52%	-6.58%
a) Engaged**	1.52%	-3.02%
b) Non-Reporting***	0.13%	-9.00%
Small (2-15)	1.51%	-5.97%
Medium (16-99)	1.35%	-1.77%
Large (>99)	1.25%	-1.46%
Overall	1.28%	-1.93%
Proposed Policies Model		
Solo (1)	1.44%	-6.55%
a) Engaged	1.45%	-3.04%
b) Non-Reporting	0.09%	-9.00%
Small (2-15)	1.44%	-6.08%
Medium (16-99)	1.32%	-1.78%
Large (>99)	1.27%	-1.44%
Overall	1.30%	-1.88%

Final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal the performance threshold.

**An engaged clinician refers to a MIPS-eligible clinician who self-reports at least one measure, attestation, or activity.

***A non-reporting clinician was a clinician who was required to report but didn't actively self-report at least one measure, attestation, or activity.

The overall median negative payment adjustment in the proposed policies model is slightly lower than it is in the baseline model. That is because the proposed policies model has a higher mean final score than the baseline model (89.47 proposed vs. 87.96 baseline). In Table 107, we report the proportion of MIPS eligible clinicians who either did or did not submit data with the maximum negative adjustment (−9 percent).

e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting payment adjustments, we are proposing several policies that, if finalized, will impact burden. In section V.B.5. of this proposed rule, we separately estimate the burden impacts of policy proposals, and the associated updated data sources. In Table 107, we summarize the incremental burden of the proposed policy provisions for these ICRs by year and OMB control number.

TABLE 107: INCREMENTAL ESTIMATED BURDEN FROM ASSOCIATED PROPOSED POLICIES

PRA Package(s)	Performance Year	Burden Description and Associated Provisions	Burden Hours	Burden Dollars
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for Traditional MIPS Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR due to the proposal of additional MVPs**	(5,510)	($655,228)
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for Traditional MIPS Quality Data Submission by Clinicians: MIPS CQM/QCDR Collection Type ICR due to the proposal of additional MVPs**	(7,357)	($901,575)
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for Traditional MIPS Quality Data Submission by Clinicians: eCQM Collection Type ICR due to the proposal of additional MVPs**	(8,912)	($1,110,056)
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for MVP registration ICR due to the proposal of additional MVPs**	578	$62,227
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for MVP Quality Submission ICR submissions due to the proposal of additional MVPs**	14,403	$1,763,875
	CY 2026 performance period/ 2028 MIPS payment year*	Annual total change in burden due to policy proposals**	(6,798)	($840,757)
	CY 2026 performance period/ 2028 MIPS payment year	Annual total burden for relevant ICRs***	520,708	$63,731,976
0938-1222 (CMS-10450)	CY 2027 performance period/ 2029 MIPS payment year	Annual burden change for CAHPS for MIPS Vendor Registration due to the proposal of the additional web mode**	10	$1,077
0938-1222 (CMS-10450)	CY 2027 performance period/ 2029 MIPS payment year	Annual total burden for relevant ICR***	110	$11,843
	CY 2027 performance period/ 2029 MIPS payment year	Annual total change in burden due to policy proposals**	(6,788)	($839,680)

* Initial performance year affected by this policy. We presume the same annual burden also applies to the CY 2027 performance period/2029 MIPS payment year. Accordingly, these estimates are included in the annual total change in burden for the CY 2027 performance period/2029 MIPS payment year displayed in this table.

** Change in hours relative to estimates for the currently approved under OMB control number 0938-1222 (CMS-10450) and as currently submitted for OMB approval under 0938-1314 (CMS-10621). Change in cost represents change in hours multiplied by the related wage rates.

*** This calculation is the total annual burden estimate for the referenced ICR per control number in this table, inclusive of the currently approved estimates and changes due to both policy and data adjustments.

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(2) Additional Impacts to Clinicians

We provide additional burden discussions for policy proposals that we are unable to quantify.

(a) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.4.d(3)(b)(ii) of this proposed rule, we are proposing changes to the Improvement Activities Inventory beginning with the CY 2026 performance period/2028MIPS payment year. We do not expect these changes to affect our burden estimates for the number of estimated respondents or response time, as most of the improvement activities in the Improvement Activities Inventory remain unchanged for the CY 2026 performance period/2028 MIPS payment year. We refer readers to section IV.A.4.d.(3).(b).(ii). of this proposed rule for details on the proposed changes to the Improvement Activities Inventory.

(b) Qualifying Alternative Payment Model (APM) Participant (QP) Determinations

In section IV.B.5.b. of this proposed rule, we are proposing the following policies related to QP determinations: (1) to add a QP determination at the individual level for all Advanced APM participants; and (2) to update the definition of ''attribution-eligible beneficiary'' at § 414.1305. It is difficult to project the impact of these policy proposals as year-over-year participation changes have historically had outsized impacts on our projections. For example, ACOs frequently add or remove participants as part of their operations. These changes in participation make it difficult to project how these proposals will impact clinicians who are determined to be QPs, Partial QPs, or previously reported MIPS (at the individual, group, subgroup, or APM Entity level), if at all. Accordingly, we have not proposed to adjust our estimates related to performance category submissions due to these policy proposals. For details on these proposals, see section IV.B.5.b. of this proposed rule. Additionally, we are proposing to remove the current 50 clinician limit from the Medical Home Model, the Aligned Other Payer Medical Home Model, and the Medicaid Medical Home model. Where there are no APMs meeting the definition of these three models in the CY 2026 performance period/2028 MIPS payment year, we do not anticipate any reporting impact for these proposals. For details on these proposals, see section IV.B.5.c. of this proposed rule.

(c) Ambulatory Specialty Model

In section III.D. of this proposed rule, the Innovation Center is proposing to test a new mandatory model titled the Ambulatory Specialty Model (ASM). The ASM leverages a framework similar to the MVP framework and shares some quality and cost measures with those in the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVP. Review section III.D of this proposed rule for additional details on the proposed model requirements and correlation to the existing MVP framework.

At this time, we are unable to determine how many clinicians or practices will register for and submit the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVPs for the CY 2026 performance period/2028 MIPS payment year. Similarly, we cannot assess at which participation levels clinicians or practices identified for MVP reporting under the ASM model have reported MIPS in the past (for example, eligibility requirements and special statuses, participation at the individual, group, subgroup, virtual group, or APM Entity level, or reporting via traditional MIPS, the APM Performance Pathway (APP), or MVPs). We refer readers to section VII.G.1. of this proposed rule for a more detailed discussion of impacts of the ASM proposal.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2023 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2026 performance period/2028 MIPS payment year.

As discussed in section V.B.8. of this proposed rule, we are unable to predict which specific MIPS eligible clinicians will receive reweighting for one or more performance categories under policies at § 414.1380(c)(2) in the CY 2026 performance period/2028MIPS payment rear. On this basis, we assumed that those MIPS eligible clinicians for whom we approved reweighting of one or more performance categories under our policies are representative of the number and attributes of MIPS eligible clinicians who will receive reweighting under these policies in the future.

In addition to the limitations described throughout the methodology sections, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 108.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we exercise agency discretion, presents rationale for our policies, and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to the Use of the Relationship Between OPPS APC Payment Rates to Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT codes 77387, 77402, 77407, 77412, and 77417) and Superficial Radiation Treatment (CPT codes 77X05, 77X07, 77X08, and 77X09)

As we discuss in sections II.B and II.E. of this proposed rule, we are proposing to utilize the relationship between OPPS APC payment rates to establish PE RVUs for Radiation Oncology Treatment Delivery and Superficial Radiation Treatment services. As we considered the most accurate approach to developing PE RVUs for these code families, an alternative we considered was the following approach:

Step 1: Estimate the share of direct costs for all services in the radiology-therapeutic cost center using the hospital cost reports.

Step 2: For each service in an APC, calculate the weighted geometric mean of the OPPS total costs. The weights are PFS non-facility volume.

Step 3: Multiply the result of step 2 by the result of step 1.

We did not select this alternative because the use of cost report data to calculate the share of direct costs may reflect an imprecise accounting of direct costs. In addition, the percentage of direct costs is imprecise for a particular service. We are therefore unable to confirm the precision of the estimate of the direct costs for these services, which is a necessary step in this calculation. We refer the reader to the RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html.*[431]

2. Alternatives Considered Related to the Use of the Relationship Between OPPS APC Payment Rates to Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT codes 77387, 77402, 77407, 77412, and 77417) and Superficial Radiation Treatment (CPT codes 77X05, 77X07, 77X08, and 77X09)

As we discuss in sections II.B. and II.E. of this proposed rule, we are proposing to utilize the relationship between OPPS APC payment rates to establish PE RVUs for Radiation Oncology Treatment Delivery and

[431] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

Superficial Radiation Treatment services. As we considered the most accurate approach to developing PE RVUs for these code families, an alternative we considered was the following approach:

Step 1: Estimate the share of direct costs for all services in the radiology-therapeutic cost center using the hospital cost reports.

Step 2: For each service in an APC, calculate the weighted geometric mean of the OPPS total costs. The weights are PFS non-facility volume.

Step 3: Multiply the result of step 2 by the result of step 1.

We did not select this alternative because the use of cost report data to calculate the share of direct costs may reflect an imprecise accounting of direct costs. In addition, the percentage of direct costs is imprecise for a particular service. We are therefore unable to confirm the precision of the estimate of the direct costs for these services, which is a necessary step in this calculation. We refer the reader to the RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html.*[432]

2. Alternatives Considered for Adjusting RVUs To Match PE Share in the American Medical Association's (AMA) Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys

As discussed in section II.B. of this proposed rule, ''(5) PE RVU Methodology,'' Steps 3, 10, and 18, and ''3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)'', we hold the work RVUs constant and adjust the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the Medicare Economic Index (MEI) cost shares are updated, we would typically propose to modify steps 3 and 10 described in section II.B. of this proposed rule to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the updated MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 described in section II.B. of this proposed rule. The most recent recalibration was done for the CY 2014 RVUs. Of note, although we did not propose to for CY 2023, we considered using the rebased and revised 2017-based MEI cost share weights to adjust the aggregate pools of PE RVUs and the relativity adjustment to reflect more recent data, shifting over a 4-year transition to reach the proportions of work, PE, and MP. We refer readers to a detailed discussion of this alternative considered in sections II.B. and V.I. of the CY 2023 PFS final rule (87 FR 69414 through 69415 and 70212 through 70217) for awareness regarding potential future rulemaking.

As an alternative to adjusting the aggregate pools of direct and indirect PE costs and using a relativity adjustment based on the currently used 2006-based MEI, we considered 3 different alternatives related to the weights from the American Medical Association's (AMA) Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys, as discussed in detail in section II.B. of this proposed rule, for purposes of adjusting the RVUs to match PE share from the surveys for CY 2026:

- Full implementation of the updated PPI and CPI Survey PE/HR data, while maintaining the current cost shares (2006-based MEI) (to allow for isolated comparison to the CY 2025 Final Rule impacts).
- Full implementation of the updated shares, as reported by the AMA, while maintaining the current PE/HR data (to allow for isolated comparison to the CY 2025 Final Rule impacts).
- Full implementation of updated shares, weighted by Medicare RVUs, while maintaining the current PE/HR data (to allow for isolated comparison to the CY 2025 Final Rule impacts).

Likely due in part to lower-than-expected response rates, more Medicare specialties were grouped together in the updated PPI and CPI Survey data than the original PPI Survey. The AMA and Mathematica's decision to group together more specialties is a consequential decision alone, therefore, we are displaying the estimated specialty-level impacts that would result from mapping the current PE/HR data to the updated specialty groupings reported in the new PPI and CPI Surveys. To do so, we calculated direct and indirect PE/HR values using the existing data (which primarily come from the 2007–08 PPI Survey) and volume-weighted averages of these existing PE/HR values within each of the new specialty groupings. While this is not an alternative we considered implementing, we believe it is important to display the redistributive impacts of mapping the old PE/HR information to the new specialty groupings for interested parties to consider.

For purposes of displaying impacts for these alternatives considered, we used the estimated impacts from the CY 2025 PFS final rule as a base and comparison rather than the proposed CY 2026 impacts due to the significant redistributive impacts of the policy proposals for CY 2026. We believe that displaying these alternatives considered relative to CY 2025 provides a more stable base to isolate changes related to the alternatives themselves and allows the public to meaningfully comment on the alternatives considered, as opposed to the interaction of these alternatives with the redistributions attributable to the CY 2026 policy proposals.

Table 108 illustrates the estimated specialty-specific impacts under each alternative considered, relative to the CY 2025 PFS final rule estimated impacts as a baseline. The following is an explanation of the information represented in Table 108.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2023 utilization and CY 2024 rates. Reminder: CY 2025 Estimated Impacts are used as a baseline for these alternatives considered, therefore, this column matches Column C of Table 111 in the CY 2025 PFS final rule (89 FR 98503 through 98507).
- Column D (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges of all the changes finalized for CY 2025. Reminder: this column matches Column D of Table 111 in the CY 2025 PFS final rule (89 FR 98503 through 98507).
- Column E (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result from mapping the current PE/HR data to the updated specialty groupings reported in the new PPI and CPI Surveys.
- Column F (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result if we

[432] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

implemented the new PE/HR data from the new PPI and CPI Surveys. Because these changes are solely within practice expense, there would be no impact to the estimated conversion factor and would result only in the redistribution of PE RVUs.

- Column G (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result if we implemented updated cost share weights as reported by the AMA, to adjust the RVUs to match the PE share from the surveys, relative to the impacts for the CY 2025 PFS final rule, while maintaining the current PE/HR data. This results in changes to the work RVU pool, and therefore, yields a different estimated conversion factor.
- Column H (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result if we implemented updated cost share weights derived by CMS from the AMA's PPI and CPI Surveys, weighted by Medicare RVUs, to adjust the RVUs to match the PE share from the surveys, relative to the impacts for the CY 2025 PFS final rule, while maintaining the current PE/HR data. This results in changes to the work RVU pool, and therefore, yields a different estimated conversion factor.

TABLE 108: CY 2025 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY UNDER THREE ALTERNATIVES CONSIDERED FOR CY 2026

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
Estimated Conversion Factor				$32.35		$38.68	$35.26
ALLERGY/IMMUNOLOGY	TOTAL	$218	-1%	-3%	-3%	-3%	-3%
	Non-Facility	$211	-1%	-3%	-3%	-4%	-3%
	Facility	$7	0%	-1%	-2%	6%	4%
ANESTHESIOLOGY	TOTAL	$1,591	2%	5%	8%	7%	3%
	Non-Facility	$315	0%	-1%	-2%	-3%	-3%
	Facility	$1,276	2%	7%	11%	10%	5%
AUDIOLOGIST	TOTAL	$74	0%	0%	13%	0%	2%
	Non-Facility	$72	0%	0%	13%	0%	1%
	Facility	$3	0%	-1%	6%	8%	6%
CARDIAC SURGERY	TOTAL	$166	-1%	3%	-2%	0%	-3%
	Non-Facility	$30	-2%	-2%	4%	-3%	-5%
	Facility	$136	0%	5%	-3%	0%	-3%
CARDIOLOGY	TOTAL	$6,117	0%	0%	7%	1%	-1%
	Non-Facility	$3,826	-1%	-1%	9%	-2%	-3%
	Facility	$2,290	0%	0%	3%	5%	2%
CHIROPRACTIC	TOTAL	$656	1%	1%	-5%	2%	4%
	Non-Facility	$654	1%	1%	-5%	2%	4%
	Facility	$2	1%	1%	2%	9%	7%
CLINICAL PSYCHOLOGIST	TOTAL	$737	3%	3%	5%	12%	8%
	Non-Facility	$595	3%	3%	4%	11%	8%
	Facility	$142	3%	3%	10%	17%	10%
CLINICAL SOCIAL WORKER	TOTAL	$854	4%	4%	6%	13%	10%
	Non-Facility	$722	4%	4%	5%	13%	9%
	Facility	$132	4%	4%	10%	18%	11%
COLON AND RECTAL SURGERY	TOTAL	$151	0%	1%	-7%	-2%	-2%
	Non-Facility	$55	0%	1%	-7%	-4%	-4%
	Facility	$96	0%	1%	-7%	-1%	-2%
CRITICAL CARE	TOTAL	$333	0%	-1%	1%	4%	2%
	Non-Facility	$53	0%	0%	3%	-3%	-1%
	Facility	$281	0%	-1%	0%	5%	2%
DERMATOLOGY	TOTAL	$3,885	0%	-1%	-8%	-3%	-3%
	Non-Facility	$3,740	0%	-1%	-8%	-3%	-3%
	Facility	$144	0%	0%	-7%	3%	3%
DIAGNOSTIC TESTING FACILITY	TOTAL	$942	-2%	-2%	17%	-2%	-8%
	Non-Facility	$940	-2%	-2%	17%	-2%	-8%
	Facility	$1	0%	2%	0%	8%	4%
EMERGENCY MEDICINE	TOTAL	$2,440	0%	0%	2%	6%	2%
	Non-Facility	$205	0%	-1%	0%	-4%	-1%
	Facility	$2,235	0%	0%	3%	7%	2%
ENDOCRINOLOGY	TOTAL	$517	0%	1%	0%	-2%	1%
	Non-Facility	$415	1%	1%	0%	-4%	0%
	Facility	$102	0%	0%	-2%	5%	3%
FAMILY PRACTICE	TOTAL	$5,515	0%	0%	0%	-2%	1%
	Non-Facility	$4,424	0%	0%	0%	-4%	0%
	Facility	$1,090	0%	0%	-1%	5%	3%

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
	TOTAL	$1,453	0%	0%	0%	0%	0%
	Non-Facility	$532	0%	0%	-1%	-4%	-2%
GASTROENTEROLOGY	Facility	$921	0%	0%	0%	2%	1%
	TOTAL	$379	0%	0%	0%	-1%	0%
GENERAL PRACTICE	Non-Facility	$304	0%	0%	1%	-2%	-1%
	Facility	$75	0%	0%	-1%	4%	2%
	TOTAL	$1,602	0%	0%	-5%	-1%	-2%
GENERAL SURGERY	Non-Facility	$464	-1%	-1%	-1%	-3%	-3%
	Facility	$1,138	0%	1%	-6%	-1%	-2%
	TOTAL	$222	1%	1%	1%	0%	2%
GERIATRICS	Non-Facility	$149	1%	2%	2%	-2%	1%
	Facility	$74	0%	0%	-1%	4%	3%
	TOTAL	$265	-1%	-2%	-7%	-5%	-4%
HAND SURGERY	Non-Facility	$141	0%	0%	-2%	-4%	-2%
	Facility	$124	-3%	-4%	-13%	-7%	-6%
	TOTAL	$1,579	-1%	-1%	-1%	-1%	-1%
HEMATOLOGY/ONCOLOGY	Non-Facility	$1,024	-1%	-1%	0%	-4%	-3%
	Facility	$555	0%	0%	-2%	6%	3%
INDEPENDENT LABORATORY	TOTAL	$561	0%	0%	0%	2%	-3%
	Non-Facility	$547	0%	0%	0%	1%	-3%
	Facility	$14	0%	0%	-11%	10%	7%
	TOTAL	$555	0%	0%	-1%	4%	2%
INFECTIOUS DISEASE	Non-Facility	$86	-1%	-1%	-1%	-4%	-3%
	Facility	$469	0%	0%	-1%	5%	3%
	TOTAL	$9,491	0%	0%	0%	1%	1%
INTERNAL MEDICINE	Non-Facility	$4,714	0%	1%	1%	-4%	0%
	Facility	$4,777	0%	0%	-1%	5%	3%
	TOTAL	$839	0%	-2%	-4%	-2%	-2%
INTERVENTIONAL PAIN MGMT	Non-Facility	$660	0%	-2%	-3%	-4%	-3%
	Facility	$179	0%	-2%	-5%	3%	2%
	TOTAL	$445	-2%	-1%	5%	1%	-4%
INTERVENTIONAL RADIOLOGY	Non-Facility	$273	-3%	-4%	7%	-2%	-9%
	Facility	$172	1%	4%	1%	7%	3%
	TOTAL	$152	0%	0%	-2%	1%	1%
MULTISPECIALTY CLINIC/OTHER PHYS	Non-Facility	$76	0%	-1%	-1%	-3%	-1%
	Facility	$76	0%	0%	-2%	5%	3%
	TOTAL	$1,706	0%	4%	0%	2%	2%
NEPHROLOGY	Non-Facility	$1,020	1%	7%	1%	0%	1%
	Facility	$686	0%	1%	-1%	5%	3%
	TOTAL	$1,333	0%	-3%	-4%	0%	0%
NEUROLOGY	Non-Facility	$852	0%	-3%	-5%	-3%	-2%
	Facility	$481	0%	-1%	-4%	5%	3%
	TOTAL	$706	0%	-4%	-11%	-3%	-5%
NEUROSURGERY	Non-Facility	$121	0%	-1%	-2%	-4%	-1%
	Facility	$585	-1%	-5%	-13%	-3%	-6%
NUCLEAR MEDICINE	TOTAL	$50	0%	3%	8%	5%	1%

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
	Non-Facility	$24	-1%	0%	13%	0%	-5%
	Facility	$26	1%	6%	4%	10%	6%
NURSE ANES / ANES ASST	TOTAL	$1,056	1%	7%	11%	9%	3%
	Non-Facility	$21	1%	6%	10%	7%	3%
	Facility	$1,035	1%	7%	11%	9%	4%
NURSE PRACTITIONER	TOTAL	$7,029	0%	0%	-1%	0%	1%
	Non-Facility	$4,611	0%	0%	-1%	-2%	0%
	Facility	$2,418	0%	0%	-1%	4%	3%
OBSTETRICS/GYNECOLOGY	TOTAL	$565	-1%	0%	-1%	-2%	-2%
	Non-Facility	$386	-1%	0%	1%	-3%	-2%
	Facility	$179	0%	0%	-4%	0%	0%
OPHTHALMOLOGY	TOTAL	$4,667	-2%	-1%	2%	-5%	-2%
	Non-Facility	$3,294	-2%	-2%	1%	-6%	-3%
	Facility	$1,372	-1%	-1%	4%	-4%	0%
OPTOMETRY	TOTAL	$1,361	-1%	-1%	1%	-4%	-1%
	Non-Facility	$1,297	-1%	-1%	0%	-4%	-1%
	Facility	$64	0%	0%	3%	-1%	2%
ORAL/MAXILLOFACIAL SURGERY	TOTAL	$64	0%	-1%	15%	-3%	-3%
	Non-Facility	$52	0%	-1%	18%	-3%	-3%
	Facility	$12	0%	-1%	1%	0%	1%
ORTHOPEDIC SURGERY	TOTAL	$3,426	-1%	-2%	-7%	-5%	-3%
	Non-Facility	$1,498	0%	0%	-1%	-4%	-2%
	Facility	$1,928	-2%	-3%	-11%	-6%	-5%
OTHER	TOTAL	$58	-1%	-1%	-3%	-2%	-1%
	Non-Facility	$47	-1%	-2%	-3%	-4%	-2%
	Facility	$12	1%	0%	-3%	5%	3%
OTOLARNGOLOGY	TOTAL	$1,155	0%	-1%	-7%	-3%	-2%
	Non-Facility	$918	0%	-1%	-6%	-4%	-3%
	Facility	$237	0%	-1%	-9%	0%	0%
PATHOLOGY	TOTAL	$1,187	0%	0%	-8%	6%	2%
	Non-Facility	$629	0%	0%	-3%	3%	-2%
	Facility	$558	0%	1%	-13%	9%	6%
PEDIATRICS	TOTAL	$55	0%	0%	0%	0%	1%
	Non-Facility	$35	0%	0%	0%	-3%	-1%
	Facility	$20	1%	0%	-1%	6%	3%
PHYSICAL MEDICINE	TOTAL	$1,127	0%	-1%	-3%	0%	0%
	Non-Facility	$550	0%	-2%	-4%	-3%	-2%
	Facility	$576	0%	-1%	-2%	4%	3%
PHYSICAL/OCCUPATIONAL THERAPY	TOTAL	$5,905	0%	0%	-1%	-3%	2%
	Non-Facility	$5,905	0%	0%	-1%	-3%	2%
	Facility	$	4%	2%	-2%	11%	9%
PHYSICIAN ASSISTANT	TOTAL	$3,699	0%	0%	-3%	-1%	0%
	Non-Facility	$2,531	0%	0%	-3%	-3%	-1%
	Facility	$1,169	0%	0%	-3%	3%	1%
PLASTIC SURGERY	TOTAL	$303	-1%	-3%	-8%	-4%	-3%
	Non-Facility	$135	-1%	-2%	-8%	-4%	-3%

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
	Facility	$168	-1%	-3%	-9%	-4%	-2%
PODIATRY	TOTAL	$1,928	0%	0%	-1%	-3%	-2%
	Non-Facility	$1,714	0%	0%	-1%	-4%	-2%
	Facility	$214	0%	0%	-2%	0%	1%
PORTABLE X-RAY SUPPLIER	TOTAL	$79	1%	2%	11%	0%	-4%
	Non-Facility	$76	1%	2%	11%	-1%	-4%
	Facility	$3	1%	4%	4%	7%	4%
PSYCHIATRY	TOTAL	$867	1%	1%	0%	3%	3%
	Non-Facility	$508	1%	1%	0%	0%	2%
	Facility	$359	0%	0%	-1%	7%	4%
PULMONARY DISEASE	TOTAL	$1,269	0%	0%	1%	2%	1%
	Non-Facility	$550	0%	0%	4%	-3%	-1%
	Facility	$719	0%	-1%	0%	6%	3%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	TOTAL	$1,538	0%	-12%	-6%	2%	-2%
	Non-Facility	$1,048	-1%	-12%	-1%	-1%	-6%
	Facility	$490	2%	-13%	-16%	9%	6%
RADIOLOGY	TOTAL	$4,557	0%	3%	4%	6%	2%
	Non-Facility	$2,004	-1%	0%	8%	2%	-3%
	Facility	$2,553	1%	5%	1%	10%	6%
RHEUMATOLOGY	TOTAL	$520	0%	0%	-1%	-3%	-2%
	Non-Facility	$467	-1%	0%	0%	-4%	-2%
	Facility	$53	0%	0%	-2%	6%	3%
THORACIC SURGERY	TOTAL	$297	-1%	3%	-2%	-1%	-4%
	Non-Facility	$59	-2%	-2%	3%	-3%	-5%
	Facility	$238	0%	4%	-3%	0%	-3%
UROLOGY	TOTAL	$1,617	0%	2%	1%	-1%	-1%
	Non-Facility	$1,136	0%	2%	1%	-3%	-2%
	Facility	$480	0%	3%	0%	4%	2%
VASCULAR SURGERY	TOTAL	$998	-2%	-2%	5%	-1%	-6%
	Non-Facility	$715	-3%	-3%	6%	-3%	-8%
	Facility	$283	0%	1%	0%	3%	-1%
TOTAL	TOTAL	$90,861	0%	0%	0%	0%	0%
	Non-Facility	$57,431	0%	0%	0%	-2%	-1%
	Facility	$33,429	0%	0%	-1%	4%	2%

As stated previously, the AMA's new specialty groupings in the updated PPI and CPI Surveys result in consequential redistributions shown in Column E, with estimated specialty-level impacts ranging from −13 percent (facility-based Radiation Oncology and Radiation Therapy Centers) to +7 percent (Nurse Anesthetist, and non-facility Nephrology).

Relative to the CY 25 PFS final rule baseline, adopting the PE/HR data from the new PPI and CPI Surveys would result in large specialty-level impacts shown in Column F. New data such as these would typically be phased in over multiple years to reduce year-on-year changes. After fully phasing in the changes, adopting the new PPI/CPI data would result in specialty-level impacts with negative impacts as low as −16 percent for facility-based Radiation Oncology and Radiation Therapy Centers and increases as large as +18% non-facility Oral/Maxillofacial Surgery. Of note, the AMA did not provide updated PE/HR data for the IDTF specialty, so this scenario retains the current PE/HR values for that specialty.

In addition to updated PE/HR data for PFS ratesetting, the information from the PPI and CPI Surveys could be used to develop new cost share weights to adjust the aggregate pools of PE RVUs and the relativity adjustment to reflect more recent data, to reach the proportions of work, PE, and MP reported in the new surveys. The AMA has reported work, PE, and MP shares

of 60.8 percent, 37.0 percent, and 2.3 percent, respectively, in the new PPI Survey data.[433] As discussed in detail in section II.B. of this proposed rule, we have numerous concerns with the cost shares as reported by the AMA in the PPI Survey data. It is our understanding that these PPI Survey cost shares ignore non-physician specialties that were surveyed in the CPI Survey, even though those specialties are included in PFS ratesetting, and therefore derive payment from the same pools of work, PE, and MP as the physician specialties included in the PPI Survey. Additionally, it seems that the AMA calculated specialty-level shares and averaged these shares across specialties, which is mathematically different than estimating the share of total work, PE, and MP across all specialties. (That is, the average of shares does not need to equal shares of the total.) This represents a change from how the cost shares are currently calculated by the MEI and we believe this methodology runs counter to the goal of adjusting the aggregate pools of PE RVUs and the relativity adjustment to reach the proportions of work, PE, and MP. Despite our concerns, we are displaying the specialty-level impacts of incorporating these new cost shares, as directly reported by the AMA, in column G, which would result in specialty impacts ranging from −7 percent (facility-setting Hand Surgery) to +18 percent (for facility-setting Clinical Social Worker).

Due to our concerns with the AMA's methodology for reporting cost shares, we developed cost shares that account for both the PPI and CPI Survey data into an estimate of total shares across physician and non-physician specialties using weights from Medicare volumes. Using either PFS RVUs or physician time file time-weighted shares yields similar results, with an estimated 54.4 percent or 54.8 percent work share, respectively. To do this, we multiplied the specialty-level estimates of work, PE, and MP by, for example, total PFS RVUs for the specialty grouping, added these amounts across specialty groupings, and calculated the shares of these sums. As a result, we calculate cost shares of total work, PE, and MP to be 54.4 percent, 43.8 percent, and 1.7 percent, respectively, when using PFS RVUs to weight the specialty-level values reported in the PPI and CPI Surveys. We display the specialty-level impacts of using these cost shares derived by through this methodology, while retaining current PE/HR values results, in Column H, which range from −9 percent to 11 percent (for non-facility Interventional Radiology and facility-setting Clinical Social Worker specialties, respectively).

Because of the significant redistributive effects of all the alternatives considered, as well as the concerns with the underlying PPI and CPI Survey data, we are proposing to delay these adjustments to allow public comments on the PPI and CPI Surveys discussed in section II.B. of this proposed rule, and to maintain use of the current 2006-based MEI cost share weights. Because there are significant concerns with the PPI and CPI Survey data, outlined in detail in section II.B. of this proposed rule, and significant time has elapsed since the last recalibration of the cost share weights, we believe it is important to allow public comment on the use of the PPI and CPI Survey data, as well as the updated 2017-based MEI, discussed in detail in the CY 2023 PFS final rule, before we incorporate any updated cost shares into PFS ratesetting. Of note, the 2017-based MEI cost shares, the PPI Survey cost shares as reported by the AMA, and the cost shares derived by CMS from the PPI and CPI Survey data result in drastically different PE shares, and the current 2006-based MEI cost shares fall in the middle of the them, therefore, we continue to believe that proposing to delay the implementation of any alternative cost share weights is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Similarly, we are proposing to delay the implementation of any updated cost share weights for use in the practice expense (PE) Geographic Practice Cost Index (GPCI) for CY 2026 to allow public comment on all considerations before we incorporate any updated cost share weights into the PE GPCIs. We refer readers to the section below, and section II.N. of this proposed rule for more discussion on alternatives considered regarding this proposal.

3. Alternatives Considered for the Practice Expense (PE) Geographic Practice Cost Index (GPCI)

As discussed in section II.N. of this proposed rule, we use the MEI cost share weights to weight the four components of the PE GPCI: employee wages, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses. As the MEI cost shares are updated, we have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI. Due to the concurrent GPCI update and rebasing and revision of the MEI for CY 2023, we proposed to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 GPCIs instead of the updated 2017-based MEI, to allow interested parties the opportunity to review and comment on the rebased and revised MEI cost share weights. Similarly, we are proposing to delay the implementation of any updated cost share weights for the CY 2026 GPCIs due to the consideration of the AMA's PPI and CPI Survey data.

Additionally, we have received data from the AMA's PPI and CPI Surveys, however, these data lack the specific breakdown of practice expense that we would need to consider its use to weight the four components of the PE GPCI for CY 2026, including Office Rent and Purchased Services, which are not explicitly described in the PPI and CPI Survey data. Because the Survey data lacks constituent components of the PE GPCI, we considered possible derivations of weights from the PPI and CPI Survey for use in the PE GPCI for consideration in possible future rulemaking. Because the derivation of these weights required mapping and methodology proposals discussed below, we did not consider their use in the CY 2026 PE GPCI update and did not develop CY 2026 PE GPCIs based on these weights for display purposes but are displaying the derived weights for possible consideration in future rulemaking. We did not believe it would be beneficial to display the resulting CY 2026 PE GPCIs from these derived weights because the PE GPCI values would inevitably look different if/when we propose to update the weights due to the underlying updated data.

For the derived weights, we started with a possible mapping of the PPI and CPI Survey direct (labor, supplies and equipment) and indirect PE (administrative, overhead, information technology and other) data to the four components of the PE GPCI based, as shown below in Table 109.

[433] *https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.*

TABLE 109: PROPOSED MAPPING FOR PPI AND CPI SURVEY DATA CATEGORIES TO THE PE GPCI COMPONENTS

	PE GPCI Component			
	Employee Wages	Purchased Services	Office Rent	Supplies and Equipment
Clinical Labor	100%	0%	0%	0%
Supplies	0%	0%	0%	100%
Equipment	0%	0%	0%	100%
Administrative	0%	50%	50%	0%
Overhead	0%	50%	50%	0%
Information Technology	0%	100%	0%	0%
Other	0%	50%	50%	0%

Secondly, we combined the PPI and CPI Survey data and weighted the data by RVUs to develop a combined PPI and CPI Survey ''All'' line, analogous to the AMA's PPI Survey results ''All'' line,[434] which was not provided for the CPI Survey data.[435] We then used the calculated direct and indirect totals from the PPI and CPI Survey data (weighted them by total RVUs) for each PE GPCI element based on the proposed mapping for the 4 PE GPCI components above to derive new weights for each of the 4 PE GPCI components, as shown below in Table 110.

TABLE 110: ALTERNATIVE DERIVED WEIGHTS FROM THE PPI AND CPI SURVEY DATA

		Weights of the Four PE GPCI Components		
Proposed Map to PE Shares*	Calculated Direct/Indirect Total	New Weights Derived from PPI and CPI Surveys	Current Weights under the 2006-based MEI	Weights under the 2017-based MEI
Employee Wages	38.78	25.476%	36.917%	49.776%
Purchased Services	53.76	35.317%	18.053%	26.245%
Office Rent	46.35	30.449%	22.799%	11.117%
Supplies & Equipment**	13.34	8.764%	22.231%	12.862%
Total	152.22	100%	100%	100%

*weighted by total RVUs

**CMS assumes a national market for such items and therefore assigns a value of 1.00 for this component in each PFS locality, therefore, a decrease in its share of the PE GPCI would possibly lead to more variation in the resulting PE GPCI across payment areas.

We welcome comments on the weights displayed above in Table 110, and any alternative methodologies to weight and or map the PPI and CPI Survey data to derive weights used to weight the four components of the PE GPCI for possible consideration in future rulemaking. Because any alternative derivation or weighting methodology for the PPI and CPI Survey data would result in different shares than displayed above, we do not believe that displaying the resulting CY 2026 PE GPCI based on these shares would be beneficial until we provide opportunity for the public to comment on this methodology. Additionally, because CY 2026 is a GPCI update, there would be a confounding effect of these updated shares due to the implementation of updated data required for a triennial GPCI update.

4. Alternatives Considered for Changes Related to Medicare Part B Payment for Skin Substitutes When Used During a Covered Application Procedure in the Non-Facility Setting

As discussed in detail in section II.K.D. of this proposed rule, starting January 1, 2026, we are proposing to pay for the provision of certain groups of skin substitute products used during a covered application procedure (CPT codes 15271 through 15278) as supplies. These skin substitutes will be paid as incident-to supplies under the PFS in the non-facility setting in accordance with section 1861(s)(2)(A) of the Act. While costs associated with supplies are usually bundled into the PE RVUs for particular services in non-facility settings, these products have been paid separately for many years in the non-

[434] *https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.*

[435] *https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.*

facility setting, where the majority of these products are currently used.

CMS considered several alternative approaches to calculate changes in spending. Each alternative relies on the same underlying data on skin substitute product volume—2024 volume measured in billing units for skin product HCPCS codes included in analysis as described above. The alternatives and corresponding spending change estimates vary in terms of the rate(s) applied to this fixed volume. Each alternative results in a corresponding saving estimate relative to the status quo spending at 2024 volumes and payment rates of $10.3B.

All alternatives considered by CMS share some common features. Quarterly 2024 rates start with the ASP for skin substitute product HCPCS codes included in the October 2024 ASP pricing file or, for other codes, the OPPS geometric mean cost for the HCPCS code prior to OPPS packaging rules or, for all other codes, the average payment per billing unit in calendar year 2024 professional claims. These values were then applied to volume shares calculated in different ways to calculate annual rates.

We estimate that under this proposal, which assumes a single rate of approximately $125.38, there would be an estimated savings of $9.4 billion. The first alternative, which assumes a single rate of $65.85 calculated using outpatient facility volume shares, yields savings of $9.79 billion, or a 95% reduction from the status quo. Finally, another approach applies the PMA-based rate ($259.47) and another rate, $125.38, calculated using data from HCT/P products and outpatient facility volume shares only, to HCT/P and 510(k) products. Savings under this approach were $9.29 billion, a 90% reduction in spending relative to the status quo.

5. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. In section IV.A.4.g.(2).(c). of this proposed rule, we propose to set the performance threshold to 75 points for the CY 2026 MIPS performance period/CY 2028 MIPS payment year through CY 2028 MIPS performance period/CY 2030 MIPS payment. We refer readers to section IV.B.2.b.(2). of this proposed rule for discussion of this policy and alternatives considered.

6. Alternatives Considered Related to the Ambulatory Specialty Model

In section III.D of this proposed rule, we discuss the proposed mandatory ASM. As proposed, we would test whether ASM leads to improved chronic condition management, higher quality care, and reduced costs by incentivizing ASM participants with the opportunity for positive payments adjustments to Medicare Part B covered professional services payments based on their performance on data reported on quality, cost, improvement activities, and CEHRT interoperability.

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. This proposed rule provides descriptions of the requirements that we would mandate, identifies the payment methodology to be tested, and presents rationales for our decisions and, where relevant, alternatives that we considered. For example, we considered defining an ASM participant as a subgroup within a TIN comprised of NPIs that individually meet the proposed ASM participant eligibility criteria for a given ASM performance year and would report the required measures and activities as a subgroup within the TIN. Another example is that we considered an alternative scoring approach where each of the four proposed ASM performance categories would be weighted to produce a final score, instead of the proposed negative scoring adjustments to the final score computed from quality and cost ASM performance category scores based on performance within the improvement activities and Promoting Interoperability ASM performance categories.

We note that the impact estimates summarized in this section of this proposed rule are based on the proposed policies identified throughout the preamble.

We welcome comments on our proposals and on the alternatives that we have identified in this rule.

G. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in the CY 2025 PFS final rule (89 FR 98551), the health equity benchmark adjustment finalized in that rule (proposed in this rule to be renamed the ''population adjustment'') will mainly provide upwards adjustments to benchmarks for—and likely draw increased participation from—new ACOs with particular focus on coordinating care for beneficiaries in underserved communities. New ACOs of this type are therefore projected to ultimately increase assignment to Shared Savings Program ACOs by roughly 500,000 beneficiaries per year, ranging from 50,000 to 1.0 million at the low and high ends of this projection range. Beyond retaining this impact via the renamed ''population adjustment,'' the benchmark proposal in this rule is not expected to have a material net impact on overall program participation or the number of beneficiaries receiving care management from ACOs.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in MIPS (as shown in Table 111). In performance year 2023, ACOs scored better than comparable MIPS groups [436] on all three eCQMs in the APP quality measure set, and the difference was statistically significant for Quality ID: 236 Controlling High Blood Pressure ($p < .05$). ACOs also performed better than comparable MIPS groups on one of the MIPS CQMs in the APP quality measure set: Quality ID: 236 Controlling High Blood Pressure. ACOs also performed better than comparable MIPS groups on eight of the ten patient experience survey measures that contribute to Quality ID: 321 Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS, and for three of these summary survey measures the difference was statistically significant ($p < .05$): CAHPS–1 Getting Timely Care, Appointments, and Information; CAHPS–2 How Well Providers Communicate; and CAHPS–3 Patient's Rating of Provider.

We note there are key differences between the Shared Savings Program and MIPS that limit our analysis of ACOs' performance on the eCQMs/MIPS CQMs and the CAHPS for MIPS Summary Survey Measures compared to MIPS groups. Specifically, Shared Savings Program ACOs are required to report the eCQMs/MIPS CQMs included in the APP quality measure set; whereas MIPS groups can choose which eCQMs and MIPS CQMs they report on and tend to choose those they will perform well on. Shared Savings Program ACOs are required to administer the CAHPS for MIPS Survey, while it is optional for MIPS groups. A large number of MIPS groups do not administer the CAHPS for MIPS Survey as they are less likely to meet the minimum sample size required

[436] Quality Payment Program measurement data are for MIPS groups that have 16 or more clinicians. The mean number of beneficiaries for MIPS groups with 16 or more clinicians is 13,457.

to administer the survey, coupled with the tendency of MIPS groups to choose measures they will perform well on.

TABLE 111: PY 2023 QUALITY MEASURES THAT SHARED SAVINGS PROGRAM ACOs PERFORMED BETTER ON THAN COMPARABLE MIPS GROUPS

Quality #	Measure Title	Difference in Mean ACO and MIPS Group Performance Rates for PY 2023 (%)[1]
	eCQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-7.07[2]
134	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	5.21
236	Controlling High Blood Pressure	5.94[3]
	MIPS CQMs	
236	Controlling High Blood Pressure	1.13
321	**CAHPS for MIPS**	0.44
CAHPS-1	Getting Timely Care, Appointments, and Information	2.06[3]
CAHPS-2	How Well Providers Communicate	0.62[3]
CAHPS-3	Patient's Rating of Provider	0.80[3]
CAHPS-4	Access to Specialists	0.98
CAHPS-5	Health Promotion and Education	1.14
CAHPS-7	Health Status and Functional Status	1.24
CAHPS-8	Care Coordination	0.74
CAHPS-11	Stewardship of Patient Resources	0.09

Notes:
[1]The numbers in this column represent the mean ACO performance rate minus the mean MIPS group performance rate for each measure.
[2] This is an inverse measure, and lower number indicates better quality performance.
[3] Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.05$).

Additionally, ACOs showed improvement for nine of the ten CMS Web Interface measures and statistically significant improvement for seven out of the ten measures, in performance year 2023 relative to performance year 2022 (as shown in Table 112).

TABLE 112: CMS WEB INTERFACE MEASURES WITH STATISTICALLY SIGNIFICANT IMPROVEMENT AMONG SHARED SAVINGS PROGRAM ACOS BETWEEN PY 2022 AND PY 2023

Quality #	Measure Title	Difference in Mean ACO Performance Rates between PY 2022 and PY 2023 (%)[1]
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-0.87[2,3]
112	Breast Cancer Screening	2.29[3]
113	Colorectal Cancer Screening	1.82[3]
134	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	4.00[3]
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0.02
236	Controlling High Blood Pressure	1.64[3]
318	Falls: Screening for Future Fall Risk	1.59[3]
370	Depression Remission at Twelve Months	0.37
438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	0.68[3]

Notes:
[1]The numbers in this column represent the mean ACO performance rate in PY 2023 minus the mean ACO performance rate in PY 2022 for each measure.
[2] This is an inverse measure, and lower number indicates better quality performance.
[3] Indicates statistically significant differences between ACOs' mean performance rates between PY 2022 and PY 2023 ($p < 0.05$).

We anticipate that ACOs will continue to improve the quality of care for the Medicare beneficiaries they serve, which will be reflected through the reporting of Medicare CQMs beginning in performance year 2024 and through their performance on Quality ID: 321 CAHPS for MIPS. We also anticipate that ACOs will continue to improve the quality of care for their all payer/all patient population, which will be reflected through the reporting of eCQMs/MIPS CQMs.

Increased participation in the Shared Savings Program would extend ACO care coordination to additional beneficiaries which can help improve the quality of care they receive.

2. Quality Payment Program

There are several changes in this proposed rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate the policies in this proposed rule would improve the quality and value of care provided to Medicare beneficiaries.

For example, several of the new quality measures include patient-reported outcome-based measures, which could be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and could also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which would not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

3. Ambulatory Specialty Model

We anticipate that ASM will have no impact on cost to beneficiaries. Like MIPS, ASM payment adjustments would not affect Medicare beneficiary coinsurance amounts. The coinsurance would be calculated based on the Medicare allowed amounts before any ASM payment adjustment multipliers are applied to Medicare Part B payments for covered professional services.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rulemaking, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's rule will be the number of reviewers of this year's proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing this rulemaking. It is possible that not all commenters will review this year's rule in detail, and it is also possible that some reviewers will choose not to comment on the final rule. For these reasons, we believe that the number of commenters will be a fair estimate of the number of reviewers of this year's final rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rulemaking.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rulemaking is $113.42, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $907.36 (8.0 hours × $113.42). Therefore, we estimated that

the total cost of reviewing this regulation is $6,333,373 ($907.36 × 6,980 reviewers on this year's proposed rule).

I. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), in Tables 113 through 115 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2025 to CY 2026 based on the FY 2026 President's Budget baseline.

TABLE 113: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

CATEGORY	TRANSFERS
CY 2026 Annualized Monetized Transfers	Estimated increase in expenditures of $0.4 billion for PFS CF update.
Bearers of Transfer Gain	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 114: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

CATEGORY	TRANSFER
CY 2026 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion
Bearers of Transfer Gain	Beneficiaries to Federal Government.

TABLE 115: ACCOUNTING STATEMENT FOR PROVISIONS FOR MEDICARE SHARED SAVINGS PROGRAM (CYS 2026-2035) ($ MILLIONS)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized: Discount rate: 3%	-$2.2 million	-$70.1 million	$72.9 million	Tables 96 and 97; summarized in total in Table 98
Annualized monetized: Discount rate: 7%	-$2.5 million	-$66.2 million	$67.5 million	Tables 96 and 97; summarized in total in Table 98

Notes: Negative values reflect reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 9, 2025.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy,

and Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.2401(b) is amended by adding the definition of ''Direct Supervision'' in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

* * * * *

Direct Supervision means that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

§ 405.2463 [Amended]

■ 3. Section 405.2463 is amended by revising paragraph (b)(3) by removing the date ''January 1, 2026'' and adding in its place the date ''October 1, 2025''.

■ 4. Section 405.2464 is amended by—

■ a. Revising paragraph (c)(2);

■ b. Adding paragraph (c)(8); and

■ c. Revising paragraph (e);

The revisions and addition read as follows:

§ 405.2464 Payment rate.

* * * * *

(c) * * *

* * * * *

(2) For psychiatric collaborative care model (CoCM) services furnished between January 1, 2018, and December 31, 2025, payment is based on the average of the national non-facility PFS payment rate set for each psychiatric CoCM service and updated annually based on the PFS amounts.

* * * * *

(8) For CoCM services furnished on or after January 1, 2026, payment is based on the PFS national non-facility payment rate.

* * * * *

(e) *Payment for communication technology-based and remote evaluation services.*

(1) For communication technology-based and remote evaluation services furnished between January 1, 2019, and December 31, 2025, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

(2) For communication technology-based services furnished on or after January 1, 2026, payment to RHCs and FQHCs is based on the PFS national non-facility payment rate.

(3) For remote evaluation services furnished on or after January 1, 2026, payment to RHCs and FQHCs is based on the PFS national non-facility payment rate.

* * * * *

§ 405.2469 [Amended]

■ 6. Section 405.2469 is amended in paragraph (d) by removing the date ''January 1, 2025'' and adding in its place the date ''October 1, 2025''.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 7. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 8. Section 410.15(a) is amended by—

■ a. In paragraph (a), in the definition of ''First annual wellness visit providing personalized prevention plan services'', removing paragraph (xiii) and redesignating paragraph (xiv) as (xiii); and

■ b. In paragraph (a), in the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'', removing paragraph (xi) and redesignating paragraph (xii) as (xi).

■ 9. Section 410.26 is amended by revising paragraphs (a)(2) and (c)(2) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(2) Direct supervision means, except as provided in paragraphs (a)(2)(i) and (ii) of this section, the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii). The presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

* * * * *

(c) * * *

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in §§ 410.59(a)(3)(iii), 410.60(a)(3)(iii), and 410.62(a)(3)(iii).

■ 10. Section 410.32 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(3) * * *

(ii) Direct supervision in the office setting means that the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

* * * * *

■ 11. Section 410.62 is amended by revising paragraph (a) to read as follows:

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets the qualifications for a speech-language pathologist in § 484.115 of this chapter and only under the following conditions:

* * * * *

■ 12. Section 410.79 is amended—

■ a. In paragraph (b) by—

■ i. Revising the definitions of ''Extended flexibilities period'' and ''Online;''
■ ii. Adding the definitions of ''Live Coach interaction,'' ''Online delivery period'' and ''Online session;'' in alphabetical order.
■ b. Revising paragraphs (c)(1)(ii) and (e)(3)(iii)(C); and
■ c. Adding paragraph (f).

The revisions and additions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Extended flexibilities period refers to the 6-year period (January 1, 2024 to December 31, 2029) for the Extended flexibilities to apply.

* * * * *

Live Coach interaction refers to the bi-directional communication between the Coach and beneficiary.

* * * * *

Online means sessions that are delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach teaching the content.

Online delivery period refers to the 4-year period (January 1, 2026 to December 31, 2029) to test an asynchronous delivery modality of the set of MDPP services. During this time, MDPP suppliers may deliver the Set of MDPP services through the online modality.

Online session refers to an MDPP session that is not furnished in person or via distance learning and that is furnished in a manner consistent with the DPRP standards for online sessions.

* * * * *

(c) * * *

(1) * * *

(ii)Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the MDPP session.

(e) * * *

(3) * * *

(iii) * * *

(C) Self-reported weight measurements from the digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the digital scale, or the MDPP supplier receives two date-stamped photos or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. If choosing to submit two photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home or other reasonable location outside of an in-person delivery site, and both photos must be date-stamped.

* * * * *

(f) *MDPP online delivery.*

(1) Notwithstanding paragraphs (a) through (e) of this section, the policies described in this paragraph (f) apply during the online delivery period.

(2) During the online delivery period, MDPP suppliers are not required to maintain in-person delivery capabilities of the set of MDPP services, as applicable during the online delivery period.

(i) Online sessions must be furnished in a manner consistent with the DPRP Standards regarding program format, coach interaction, and program intensity and duration to qualify for payment. Online sessions must be delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI) Coach teaching the content.

(A) Live Coach interaction must be offered to each participant during weeks when the beneficiary has engaged with content. E-mails and text messages can count toward the requirements for Live Coach interaction if there is bi-directional communication (that is, organizations may not simply send out an announcement via text or e-mail and count that as live Coach interaction; the beneficiary must have the ability to respond to and get support from the live Coach) between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction. Coaches are required to track participant engagement and completion of online modules. Proactive outreach must be used to encourage Online session completion and beneficiary weight reporting.

(1) MDPP suppliers may not require that beneficiaries initiate interactions with the Coach and MDPP suppliers may not use AI or Machine Learning (ML) to replace Live Coach interaction.

(B) Beneficiaries must submit weight measurements on the date in which the Online session is completed. MDPP suppliers must ensure safeguards are in place to ensure the accuracy of beneficiary weight measurements.

(C) For MDPP beneficiaries, MDPP suppliers may not bill for Online Sessions as well as In-Person or Virtual Sessions during the Online delivery period. The Set of MDPP services must be delivered to individual beneficiaries as Online sessions or fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component).

(D) MDPP suppliers must ensure that MDPP beneficiaries engage with and understand the content of each Online session. MDPP suppliers may use one or more of the following to ensure engagement and understanding: videos/presentations, email, video conferencing; knowledge checks (multiple choice or short answer); participant contributions to group discussions on a community board; or beneficiary responses to the Coach via email, text message, or in-app messaging.

(ii) [Reserved]

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 13. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 14. Section 414.84 is amended by—
■ a. Revising paragraphs (b)(1) introductory text and (b)(2) introductory text;
■ b. Redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5);
■ c. Adding new paragraph (c)(3); and
■ d. Revising newly redesignated paragraph (c)(4)(ii).

The revisions and addition read as follows:

§ 414.84 Payment for MDPP services.

* * * * *

(b) * * *

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in accordance with § 410.79(c)(ii) or described in § 410.79(e)(3)(iii) during a core session or core maintenance session furnished

by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(2) *Performance Goal 2: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in accordance with § 410.79(c)(ii) or described in § 410.79(e)(3)(iii) during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(c) * * *

(3) For the duration of online delivery described in § 410.79(f), the online HCPCS G-code applies for any Set of MDPP services that are delivered online, as described in § 410.79(b).

(4) Medicare pays for up to 22 sessions in a 12-month period. The amount of this payment is determined as follows:

(i) * * *

(ii) For a core session or core maintenance session furnished January 1, 2026 through December 31, 2026, $18.

* * * * *

■ 15. Section 414.610 is amended by—

■ a. Revising paragraph (c)(1)(ii) introductory text; and

■ b. In paragraph (c)(5)(ii) removing the date ''December 31, 2024'' and adding in its place the date ''September 30, 2025''.

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through September 30, 2025, ambulance services originating in.

* * * * *

■ 16. Section 414.802 is amended by—

■ a. Adding a definition of biological in alphabetical order;

■ b. Revising the definition of Bona fide service fees;

■ c. Adding the definition of bundled arrangement in alphabetical order; and

These additions and revision read as follows:

§ 414.802 Definitions.

* * * * *

Biological means a product licensed under section 351 of the Public Health Service Act.

Bona fide service fees means fees paid by a manufacturer to an entity, that must meet all of the following characteristics:

(1) Represent fair market value as determined according to methods in paragraph (1)(i) or (ii) of this paragraph. Fair market value analyses for service arrangements that are ongoing must be updated at a frequency no less than the renewal frequency of the agreement.

(i) For fees paid by a manufacturer to an entity that do not vary directly with the amount of drug sold or price of a manufacturer's drug, fair market value must be determined either based on comparable market transactions that generally reflect current market conditions or the cost of the service plus a reasonable markup to the total cost.

(ii) For fees paid by a manufacturer to an entity that vary directly with the amount of drug sold or price of a manufacturer's drug, the fair market value must be determined by using the cost of the service and adding a reasonable markup to the total cost. If any material portion of cost data is not available, manufacturers should follow a market-based approach based on verifiable market data until such time as sufficient cost data becomes available. The fair market value assessment must be conducted by an independent third-party valuator.

(2) For a bona fide, itemized service actually performed on behalf of the manufacturer.

(3) For a service that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement.

(4) The fee must not be passed on in whole or in part to an affiliate, client, or customer of an entity whether or not the entity takes title to the drug.

Bundled arrangement means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs or biologicals been purchased separately or outside the bundled arrangement.

* * * * *

Drug means a drug or a biological, and for purposes of applying section 1847A(f) of the Act, includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

* * * * *

■ 17. Section 414.804 is amended by—

■ a. Adding paragraphs (a)(2)(i)(f), (iii) and (iv); and

■ b. Revising paragraph (a)(5).

The additions and revision read as follows:

§ 414.804 Basis of payment.

(a) * * *

(2) * * *

(i) * * *

(F) Fees paid by a manufacturer to an entity that vary directly with the amount of the manufacturer's drug sold or price of a manufacturer's drug unless it meets the definition of bona fide service fee under § 414.802.

* * * * *

(iii) The discounts in a bundled arrangement as defined at § 414.802, including those discounts resulting from a contingent arrangement, are allocated proportionately to the dollar value of the units of all drugs or products sold under the bundled arrangement.

(iv) For bundled arrangements where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

* * * * *

(5) *Submission requirements.* Manufacturers must submit the following to CMS within 30 days of the close of the quarter: The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(i) The manufacturer's average sales price, which must be calculated by the manufacturer every calendar quarter. The first quarter submission must be submitted by April 30, 2004.

(ii) Effective January 1, 2026, reasonable assumptions for calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices including documentation of the methodology used to determine fair market value and periodic reviews of fair market value.

(iii) Effective January 1, 2026, certification letter from the recipient of a bona fide service fee (as defined under § 414.802) as evidence that the fee is not passed on in whole or in part to an affiliate, client or customer of the recipient of the fee, whether or not the entity takes title to the drug.

* * * * *

■ 18. Section 414.902 is amended by adding the definition of ''biological'' in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Biological means a product licensed under section 351 of the Public Health Service Act.

* * * * *

■ 19. Section 414.1305 is amended by—

■ a. Revising paragraph (6) of the definition for ''Attribution-eligible beneficiary''; and

■ b. Revising the definitions of ''Multispecialty group'', ''MVP participant'', and ''Single specialty group.

The revisions read as follows:

§ 414.1305 Definitions.

Attribution-eligible beneficiary

* * *

(6) Has a minimum of one claim for any covered professional service furnished by an eligible clinician who is on the Participation List for an Advanced APM Entity at any determination date during the QP Performance Period.

* * * * *

Multispecialty group means a group as defined at § 414.1305 that consists of clinicians in two or more specialty types or clinicians involved in multiple foci of care.

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Single specialty group means a group that consists of one specialty type or consists of clinicians involved in a single focus of care.

* * * * *

■ 20. Section 414.1355 is amended by revising paragraph (c)(7) to read as follows:

§ 414.1355 Improvement activities performance category

* * * * *

(c) * * *

(7) Advancing health and wellness, such as MIPS eligible clinicians demonstrating involvement in preventive care and health promotion.

* * * * *

■ 21. Section 414.1365 is amended by adding paragraph (b)(2)(iv) to read as follows:

§ 414.1365 MIPS Value Pathways.

* * * * *

(b) * * *

(2) * * *

(iv) *Self-attestation requirement.* Beginning with the CY 2026 performance period/2028 MIPS payment year, a group registering for MVP reporting at the group level must attest to being either a single-specialty group or a multispecialty group that meets the requirements of a small practice, as defined at § 414.1305.

* * * * *

■ 22. Section 414.1380 is amended by—

■ a. Revising paragraphs (b)(1)(i) introductory text, (b)(1)(ii)(D), and (b)(2)(iii) introductory text;

■ c. Adding paragraph (b)(2)(vi);

■ d. Revising paragraph (b)(4)(ii)(C); and

■ e. Adding paragraph (b)(4)(iii).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) *Measure achievement points.* For the CY 2017 through 2022 performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section.

(A) Except as provided under paragraph (b)(1)(i)(C) of this section, beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) for each such measure.

(B) Except as specified otherwise under paragraph (b)(1)(ii) of this section, the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points.

(C) Beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(ii) * * *

(D) Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS calculates a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period.

(E) Beginning with the CY 2025 performance period/2027 MIPS payment year, for each administrative claims-based quality measure, CMS determines 10 benchmark ranges based on the median performance rate of all MIPS eligible clinicians scored on the measure, plus or minus standard deviations.

(*1*) CMS awards achievement points based on which benchmark range a MIPS eligible clinician's performance rate for an administrative claims-based quality measure corresponds; and

(*2*) CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose performance rate is equal to the median performance for all MIPS eligible clinicians scored on the measure.

(2) * * *

(iii) Excluding cost measure scores calculated for informational-only purposes as provided in paragraph (b)(2)(vi) of this section, the cost performance category score is the sum of the following, not to exceed 100 percent:

* * * * *

(vi) Beginning with the 2028 MIPS payment year, CMS calculates a score for each new cost measure in accordance with the scoring policy set forth in this paragraph (b)(2) of this section for informational-only purposes during the measure's informational-only feedback period.

(A) For the purposes of this paragraph (b)(2)(vi) of this section, the following terms have the following meanings.

(*1*) *New cost measure* means a measure that CMS has newly specified for the MIPS cost performance category for a performance period under § 414.1350 beginning with the 2028 MIPS payment year. This term excludes any cost measures that CMS has specified for the MIPS cost performance category prior to the 2028 MIPS payment year or CMS modifies at any time.

(*2) Informational-only feedback period* means a 2-year period beginning with the first day of the first performance period and ending with the final day of the second performance period for the two applicable MIPS payment years for which CMS initially has specified the new cost measure.

(B) During a new cost measure's informational-only feedback period, CMS does not include any scores for the new cost measure calculated for informational-only purposes under paragraph (b)(2)(vi) of this section in CMS's calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) of this section or a MIPS eligible clinician's MIPS final score under paragraph (c) of this section.

(C) During a new cost measure's informational-only feedback period, CMS confidentially provides each MIPS eligible clinician their measure score under paragraph (b)(2)(vi) of this section for informational-only purposes. CMS also provides performance feedback to the MIPS eligible clinician in accordance with section 1848(q)(12) of the Act.

(D) Upon completion of a new cost measure's informational-only feedback period, CMS includes its calculation of any scores for the cost measure in CMS's calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) of this section and a MIPS eligible clinician's MIPS final score under paragraph (c) of this section.

(3) * * *

(4) * * *

(ii) * * *

(C)(*1*) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each optional measure is worth 5 or 10 bonus points, as specified by CMS.

(*2*) For the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth 5 bonus points, as specified by CMS.

(*3*) Beginning with the CY 2026 performance period/2028 MIPS payment years, the total number of bonus points available to be earned when reporting one bonus measure, more than one bonus measure, or all bonus measures is a total of 5 bonus points.

(iii) Beginning with the CY 2026 performance period/2028 MIPS payment year, if certain circumstances occur that impact CMS's assessment of the performance of MIPS eligible clinicians on a measure specified for the Promoting Interoperability performance category under § 414.1375(b), CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS's calculation of the Promoting Interoperability performance category objective score under paragraph (b)(4) of this section or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. CMS determines whether certain circumstances exist warranting suppression of a measure based on CMS's consideration of one or more of the following factors:

(A) The nature, breadth, and duration of the circumstances' effect on MIPS eligible clinicians' ability to fulfill the measure requirement.

(B) The availability of certified health IT modules to fulfill the measure.

(C) The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

(D) Out-of-date or conflicting technical standards.

(E) Technical and operational capacity of required partners.

(F) Other factors as determined by CMS.

* * * * *

■ 23. Section 414.1400 is amended by—

■ a. Revising paragraph (b)(1)(ii);

■ b. In paragraph (d)(3) introductory text, removing the phrase ''including:'' and adding in its place the phrase ''including all of the following:'';

■ c. Revising paragraph (d)(3)(i);

■ d. In paragraphs (d)(3)(ii) and (iii), removing the '';'' and adding in its place ''.'';

■ e. Redesignating paragraphs (d)(3)(iv) through (vi) as paragraphs (d)(3)(iv) through (vi) introductory text;

■ f. Adding paragraphs (d)(3)(iv)(A) and (B), (d)(3)(v)(A) and (B), (d)(3)(vi)(A) and (B), and (d)(3)(vii).

■ g. Revising paragraph (d)(8); and

■ h. Adding paragraphs (d)(9) and (d)(10).

The revisions and additions read as follows:

§ 414.1400 Third party intermediaries.

* * * * *

(b) * * *

(1) * * *

(ii)(A) Beginning with the CY 2023 performance period/2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data.

(B) Beginning with the CY 2026 performance period/2028 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than 1 year after finalization of the MVP in accordance with the current requirement.

(*1*) QCDRs and qualified registries may also support the APP.

(*2*) A QCDR or qualified registry must support all measures and activities included in the MVP with the following exceptions:

(*i*) If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinicians.

(*ii*) If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

* * * * *

(d) * * *

(3) * * *

(i) At least 3 years of experience administering surveys in which mail survey administration is followed by survey administration via Computer Assisted Telephone Interview (CATI);

(iv) * * *

(A) Beginning January 1, 2024, in addition to administering the survey in English, entities must administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in subregulatory guidance to standardize the CAHPS data collection process for MIPS and to make sure the survey data collected across survey vendors are comparable within the program or model;.

(B) [Reserved]

(v) * * *

(A) Beginning January 1, 2027, use equipment, software, computer programs, systems, and facilities that can send survey invitations via email that include a patient-specific hyperlink to a web survey, collect data via web, and track cases from web surveys through telephone follow-up activities.

(B) [Reserved]

(vi) * * *

(A) Beginning January 1, 2027, employment of a web survey administrator.

(B) [Reserved]

(vii) Beginning January 1, 2027, at least 3 years of experience administering surveys in which web survey administration is followed by survey administration via mail survey or Computer Assisted Telephone Interview (CATI).

* * * * *

(8) From January 1, 2019 through December 31, 2025, the entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(9) Beginning with January 1, 2026, the entity seeking to be a CMS-approved survey vendor must include on its application the range of costs of its third-party intermediary services.

(10) Beginning with the CY 2027 performance period/2029 MIPS payment year, the CMS-approved survey vendor must administer the survey via a web-mail-phone protocol.

* * * * *

■ 24. Section 414.1405 amended by adding paragraph (b)(10)(ii) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(10) * * *

(i) * * *

(ii) The performance threshold for the 2028 through 2030 MIPS payment years is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

§ 414.1415 [Amended]

■ 25. Section 414.1415 is amended in paragraph (c)(7) by removing the phrase ''2023 QP Performance Period, notwithstanding'' and adding in its place the phrase ''2023 QP Performance Period and ending with the 2025 QP Performance Period, notwithstanding''.

§ 414.1420 [Amended]

■ 26. Section 414.1420 is amended in paragraph (d)(8) by removing the phrase ''2023 QP Performance Period, notwithstanding'' and adding in its place the phrase ''2023 QP Performance Period and ending with the 2025 QP Performance Period, notwithstanding''.

* * * * *

■ 27. Section 414.1425 is amended by—

(a) Adding paragraph (b)(3); and

(b) Revising paragraphs (c)(3), (c)(4), (d)(1) and (2).

The addition and revisions read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(b) * * *

(3) For QP Performance Periods beginning with 2026, except for paragraphs (b)(1) and (b)(2) of this section and as set forth in § 414.1440, for purposes of the QP determinations, CMS performs QP determinations for the eligible clinicians three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a date (March 31, June 30, or August 31) CMS uses based on participation in the Advanced APM.

(c) * * *

(3) An eligible clinician is a QP for a year under the Medicare Option if:

(i) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, the eligible clinician is in an APM Entity group that achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(1) and (3).

(ii) Beginning with the CY 2026 QP Performance Period, the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(1) and (3).

(4) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, notwithstanding paragraph (c)(3) of this section, an eligible clinician is a QP for a year if—

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the QP payment amount threshold or the QP patient count threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the QP payment amount threshold or the QP patient count threshold.

* * * * *

(d) * * *

(1) An eligible clinician is a Partial QP for a year under the Medicare Option if:

(i) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, the eligible clinician is in an APM Entity group that achieves Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the eligible clinician achieves individually, or as part of an APM Entity group, a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(2) and (4).

(ii) Beginning with the CY 2026 QP Performance Period, the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the eligible clinician achieves individually, or as part of an APM Entity group, a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(2) and (4).

(2) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, notwithstanding paragraph (d)(1) of this section, an eligible clinician is a Partial QP for a year if—

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the corresponding QP or Partial QP threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a

Threshold Score that meets or exceeds the corresponding Partial QP Threshold.

* * * * *

■ 28. Section 414.1455 is amended by revising paragraph (b)(3)(ii) and (vi) to read as follows:

§ 414.1455 Limitation on review.

* * * * *

(b) * * *

(3) * * *

(ii) All requests for targeted review must be submitted during the targeted review request submission period as described at § 414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

* * * * *

(vi) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 15 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 29. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 30. Section 424.205 is amended by revising paragraphs (c)(10), (f)(2)(i), and (f)(5) to read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(c) * * *

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) 16 in-person, distance learning, or online core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.

(ii) One in-person, distance learning, or online core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

* * * * *

(f) * * *

(1) * * *

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, MBI, and age.

* * * * *

(2) * * *

(i) Documentation of the type of session (in-person, distance learning, or online).

* * * * *

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has achieved required minimum weight loss as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(ii) Has achieved required minimum weight loss as measured in accordance with § 410.79(c)(ii) during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

(iv) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(c)(ii) during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 31. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 32. Section 425.20 is amended by revising paragraph (1)(ii) in the definition of ''Beneficiary eligible for Medicare CQMs'' to read as follows:

§ 425.20 Definitions.

* * * * *

Beneficiary eligible for Medicare CQMs * * *

(1) * * *

(ii)(A) For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(B) For performance year 2025 and subsequent performance years, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

■ 33. Section 425.110 is amended by revising paragraph (a)(2) and adding paragraph (a)(3) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

(a) * * *

(2) For agreement periods beginning before January 1, 2027, CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. In the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries.

(3) For agreement periods beginning on or after January 1, 2027, CMS determines whether an ACO has 5,000 or more beneficiaries historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. CMS uses the most recent data available to estimate the number of assigned beneficiaries in the third benchmark year.

(i) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in the third benchmark year.

(ii) If an ACO has fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, the ACO may only participate under the BASIC track in accordance with § 425.600(h)(3).

* * * * *

■ 34. Section 425.118 is amended by—

■ a. Redesignating paragraph (b)(3) as paragraph (b)(4);
■ b. Adding new paragraph (b)(3); and
■ c. In newly redesignated paragraph (b)(4) adding paragraph (b)(4)(iii).

The additions read as follows:

§ 425.118 Required reporting of ACO participants and ACO providers/suppliers.

* * * * *

(b) * * *

(3) *Change of ownership for ACO participant.* No later than 30 days after an ACO participant has undergone a change of ownership that has resulted in a change to its Medicare enrolled TIN, whereby the surviving Medicare enrolled TIN has no Medicare billing claims history, the ACO must submit a change request to CMS.

(i) The change request and supporting documentation must be submitted in the form and manner specified by CMS.

(ii)(A) CMS has sole discretion to approve the change request.

(B) If CMS approves the change request, the ACO participant TIN is updated in the ACO participant list in the form and manner specified by CMS.

(4) * * *

(iii) In alignment with changes approved under paragraph (b)(3) of this section, CMS adjusts the ACO's assignment, performance year financial calculations, and the requirement that the ACO submit quality data under § 425.508 and § 425.510 on behalf of eligible professionals that bill under the TIN of an ACO participant. When processed during applicable Quality Payment Program snapshot dates for the relevant Performance Period, the adjustment includes the surviving Medicare enrolled TIN with no Medicare billing claims history on the ACO participant list as the change becomes effective during the performance year.

* * * * *

■ 35. Section 425.224 is amended by revising paragraph (b)(1)(ii)(A) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) Whether the ACO demonstrated a pattern of failure to meet both the quality performance standard and alternative quality performance standard (if applicable) or met any of the criteria for termination under § 425.316(c)(1)(ii), (c)(2)(ii), or (c)(3)(ii).

* * * * *

■ 36. Section 425.316 is amended by revising paragraph (c)(2) introductory text and adding paragraph (c)(3) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(c) * * *

(2) *For performance years beginning on or after January 1, 2021 and before January 1, 2026.*

* * * * *

(3) *For performance years beginning on or after January 1, 2026.*

(i) If the ACO fails to meet both the quality performance standard and the alternative quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS terminates an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet both the quality performance standard and the alternative quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet both the quality performance standard and the alternative quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet both the quality performance standard and the alternative quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet both the quality performance standard and the alternative quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

* * * * *

■ 37. Section 425.400 is amended by revising paragraph (c)(1)(ix) introductory text and adding paragraph (c)(1)(x) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(ix) For the performance year starting on January 1, 2025, as follows:

* * * * *

(x) For the performance year starting on January 1, 2026, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 98016 (code for virtual check-in).

(*5*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*6*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*7*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*8*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(x)).

(*10*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*11*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*12*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*13*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*14*) 99439 (code for non-complex chronic care management).

(*15*) 99452 (code for interprofessional consultation service).

(*16*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*17*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*18*) 99495 and 99496 (codes for transitional care management services).

(*19*) 99497 and 99498 (codes for advance care planning; services

identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*5*) G0402 (code for the Welcome to Medicare visit).

(*6*) G0438 and G0439 (codes for the annual wellness visits).

(*7*) G0442 (code for alcohol misuse screening service).

(*8*) G0443 (code for alcohol misuse counseling service).

(*9*) G0444 (code for annual depression screening service).

(*10*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*11*) G0506 (code for chronic care management).

(*12*) G0537 and G0538 (codes for cardiovascular risk assessment and risk management services).

(*13*) G0539 and G0540 (codes for individual behavior management/modification caregiver training services).

(*14*) G0541, G0542, and G0543 (codes for direct care caregiver training services).

(*15*) G0544 (code for post-discharge telephonic follow-up contacts intervention).

(*16*) G0556, G0557, and G0558 (codes for advanced primary care management services).

(*17*) G0560 (code for safety planning interventions).

(*18*) G2010 (code for the remote evaluation of patient video/images).

(*19*) G2012 and G2252 (codes for virtual check-in).

(*20*) G2058 (code for non-complex chronic care management).

(*21*) G2064 and G2065 (codes for principal care management services).

(*22*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*23*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*24*) G2214 (code for psychiatric collaborative care model).

(*25*) G3002 and G3003 (codes for chronic pain management).

(*26*) GPCM1 and GPCM2 (codes for behavioral health integration add-on when furnished with advanced primary care management services).

(*27*) GPCM3 (code for psychiatric collaborative care model add-on when furnished with advanced primary care management services).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(x)(A) of this section or a HCPCS code specified in paragraph (c)(1)(x)(B) of this section, when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 38. Section 425.512 is amended by—

■ a. In paragraph (a)(3)(i), removing the phrase ''quality performance score'' and adding in its place the phrase ''quality score'';

■ b. In paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B)(*1*), (a)(5)(i)(C)(*1*), and (a)(7), removing the phrase ''health equity adjusted quality performance score'' and adding in its place the phrase ''quality score'';

■ c. Revising and republishing paragraph (b);

■ d. Revising paragraph (c)(1) introductory text;

■ e. Adding paragraph (c)(1)(iii);

■ f. In paragraphs (c)(2)(i), (c)(2)(ii), and (c)(3)(i), removing the phrase ''quality performance score'' and adding in its place the phrase ''quality score''; and

■ g. In paragraphs (c)(3)(ii), (c)(3)(iii), and (c)(3)(iv), removing the phrase ''health equity adjusted quality performance score'' and adding in its place the phrase ''quality score''.

The revisions and addition read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

* * * * *

(b) *Calculation of an adjustment to an ACO's quality score for performance years 2023 and 2024*—

(1) *For performance year 2023.* For an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, CMS calculates the ACO's quality score as the sum of the ACO's MIPS quality performance category score for all measures in the APP quality measure set and the ACO's population and income adjustment bonus points calculated in accordance with paragraph (b)(3) of this section. The sum of these values may not exceed 100 percent.

(2) *For performance year 2024.* For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's quality score as the sum of the ACO's MIPS quality performance category score for all measures in the APP quality measure set and the ACO's population and income adjustment bonus points calculated in accordance with paragraph (b)(3) of this section. The sum of these values may not exceed 100 percent.

(3) *Calculation of ACO's population and income adjustment bonus points.* CMS calculates the ACO's bonus points as follows:

(i) For each measure that an ACO is required to report for the applicable performance year, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(3)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates a multiplier for the ACO.

(A) (*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(3)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

(B) If the proportion determined in accordance with paragraph (b)(3)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for bonus points.

(v) Except as specified in paragraph (b)(3)(iv)(B) of this section, CMS calculates the ACO's bonus points as the product of the measure performance scaler determined under paragraph (b)(3)(iii) of this section and the multiplier determined under paragraph (b)(3)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's bonus points is set equal to 10.

(4) *Use of ACO's quality score.* The ACO's quality score, determined in accordance with paragraphs (b)(1) through (3) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B), and (a)(7) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with § 425.605(d), and under the ENHANCED track in accordance with § 425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with § 425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i), and (a)(5)(i) of this section or the alternative quality performance standard established in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iv) In determining the quality score for an ACO affected by extreme and uncontrollable circumstances as described in paragraphs (c)(3)(ii) and (iii) of this section.

(c) * * *

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on any of the following:

* * * * *

(iii) For performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

* * * * *

■ 39. Section 425.600 is amended by—

■ a. In paragraph (a)(4)(i)(C)(*1*), removing the phrase ''paragraph (g)(1) of this section'' and adding in its place the phrase ''paragraphs (g)(1) or (h)(1) of this section'';

■ b. In paragraph (a)(4)(i)(C)(*2*)(*iii*), removing the phrase ''paragraph (h)(2)(i) of this section'' and adding in its place the phrase ''paragraph (i)(2)(i) of this section'';

■ c. In paragraph (a)(4)(ii), removing the phrase ''paragraph (d) or paragraph (g)(2) of this section'' and adding in its place the phrase ''paragraphs (d), (g)(2) or (h) of this section'';

■ d. Revising paragraph (g) introductory text;

■ e. Redesignating paragraph (h) as paragraph (i); and

■ f. Adding new paragraph (h).

The revision and addition read as follows:

§ 425.600 Selection of risk model.

* * * * *

(g) For agreement periods beginning on or after January 1, 2024 and before January 1, 2027, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

* * * * *

(h) For agreement periods beginning on or after January 1, 2027, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section, except as otherwise specified in paragraph (h)(3) of this section.

(i) An ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of one agreement period, as specified in paragraph (a)(4)(i)(C) of this section.

(ii) An ACO that enters an agreement period under the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section is deemed to have completed one agreement period under the BASIC track's glide path. For the purpose of determining the ACO's prior participation in the BASIC track's glide path, CMS considers whether the ACO satisfies either of the following:

(A) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path.

(B) For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path.

(iii) An ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path, in accordance with this paragraph, may enter BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section, except as otherwise specified in paragraph (h)(3) of this section.

(2) If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section, except as otherwise specified in paragraph (h)(3) of this section.

(3) If an ACO is determined to have fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, in accordance with § 425.110(a)(3), the ACO may only enter the BASIC track. The ACO may enter a level of risk and potential reward under the BASIC track in accordance with the requirements of this paragraph, as follows:

(i) An ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives may enter the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section (if eligible in accordance with paragraph (h)(1) of this section), or BASIC track Level E under paragraph (a)(4)(i)(A)(*5*)

of this section for all performance years of the agreement period.

(ii) An ACO determined to be experienced with performance-based risk Medicare ACO initiatives may enter BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period.

* * * * *

■ 40. Section 425.605 is amended by—

■ a. In paragraph (b)(2)(ii)(E), removing the reference ''§ 425.600(h)(2)'' and adding in its place the reference ''§ 425.600(i)(2)'';

■ b. In paragraph (d)(1) introductory text, removing the references ''§ 425.600(d) or § 425.600(g)'' and adding in its place the references ''§ 425.600(d), (g), or (h)'';

■ c. In paragraphs (d)(1)(i)(A)(*3*)(*ii*), (d)(1)(i)(A)(*4*)(*ii*), (d)(1)(ii)(A)(*3*)(*ii*), (d)(1)(ii)(A)(*4*)(*ii*), (d)(1)(iii)(A)(*3*)(*ii*), (d)(1)(iii)(A)(*4*)(*ii*), (d)(1)(iv)(A)(*3*)(*ii*), (d)(1)(iv)(A)(*4*)(*ii*), (d)(1)(v)(A)(*3*)(*ii*), and (d)(1)(v)(A)(*4*)(*ii*), removing the phrase ''health equity adjusted quality performance score calculated according to § 425.512(b)'' and adding in its place the phrase ''quality score calculated according to § 425.512'';

■ d. Revising paragraph (d)(2);

■ e. Adding paragraph (f)(2)(ii);

■ f. Revising paragraph (f)(3) introductory text;

■ g. Removing the punctuation ''; and'' at the end of paragraph (f)(3)(i) and adding in its place a period;

■ h. Adding paragraph (f)(3)(iii);

■ i. Redesignating paragraph (f)(4) as paragraph (f)(5);

■ j. Adding new paragraph (f)(4); and

■ k. Adding paragraphs (h)(1)(v) and (i).

The revisions and additions read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(d) * * *

(2) If the ACO enters the BASIC track at Level E as specified under § 425.600(d), (g), or (h), the level of risk and reward specified in paragraph (d)(1)(v) of this section applies to all performance years of an ACO's agreement period.

* * * * *

(f) * * *

(2) * * *

(ii) For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area.

(3) CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):

* * * * *

(iii) The time period during which the ACO was affected by a cyberattack, including ransomware/malware.

(4) CMS determines the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

(i) CMS uses the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

(ii) Except as specified in paragraph (f)(4)(iii) of this section, if no end date is indicated on the ACO's application or otherwise provided to CMS in a form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, CMS applies a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

(iii) If the start date indicated on the ACO's application described in paragraph (f)(4)(i) of this section is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, CMS applies an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

* * * * *

(h) * * *

(1) * * *

(v) For agreement periods beginning on or after January 1, 2027, the ACO has at least 5,000 assigned beneficiaries in each of the ACO's benchmark years.

* * * * *

(i) *Calculation of performance payment limit and loss recoupment limit.*

(1) The performance payment limit is a percentage of the ACO's updated benchmark, as determined under § 425.601 or § 425.652.

(i) CMS calculates the performance payment limit as follows, except as specified in paragraph (i)(1)(ii) of this section:

(A) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the performance year.

(B) Calculates the product of the percentage specified in paragraph (d)(1)(i)(B)(*2*), (d)(1)(ii)(B)(*2*), (d)(1)(iii)(B)(*2*), (d)(1)(iv)(B)(*2*), and (d)(1)(v)(B)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(1)(i)(A) of this section.

(ii) For agreement periods beginning on or after January 1, 2027, if the ACO has fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2 or BY3, in conducting financial reconciliation for each performance year, CMS determines whether to apply an alternative performance payment limit, rather than the performance payment limit specified in paragraph (d)(1)(i)(B)(*2*), (d)(1)(ii)(B)(*2*), (d)(1)(iii)(B)(*2*), (d)(1)(iv)(B)(*2*), and (d)(1)(v)(B)(*2*) of this section, as applicable, as follows:

(A) CMS calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries.

(B) CMS calculates the product of the percentage specified in paragraph (d)(1)(i)(B)(*2*), (d)(1)(ii)(B)(*2*), (d)(1)(iii)(B)(*2*), (d)(1)(iv)(B)(*2*), and (d)(1)(v)(B)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(1)(ii)(A) of this section.

(C) The performance payment limit is set to the lesser of the amount calculated under paragraph (i)(1)(i)(B) of this section and the alternative amount calculated under paragraph (i)(1)(ii)(B) of this section.

(2) The loss recoupment limit is a percentage of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO (revenue-based loss recoupment limit) not to exceed a percentage of the ACO's updated benchmark as determined under § 425.601 or § 425.652 (benchmark-based loss recoupment limit).

(i) CMS calculates the benchmark-based loss recoupment limit as follows, except as specified in paragraph (i)(2)(ii) of this section:

(A) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the performance year.

(B) Calculates the product of the percentage used to calculate the benchmark-based loss recoupment limit specified in paragraph (d)(1)(iii)(D)(*2*), (d)(1)(iv)(D)(*2*), and (d)(1)(v)(D)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(2)(i)(A) of this section.

(ii) For agreement periods beginning on or after January 1, 2027, if the ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2 or BY3, in conducting financial reconciliation for each performance year, CMS determines whether to apply an alternative loss recoupment limit, as follows:

(A) CMS calculates an alternative benchmark-based loss recoupment limit:

(*1*) CMS calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries.

(*2*) CMS calculates the product of the percentage used to calculate the benchmark-based loss recoupment limit specified in paragraph (d)(1)(iii)(D)(*2*), (d)(1)(iv)(D)(*2*), and (d)(1)(v)(D)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(2)(ii)(A)(*1*) of this section.

(B) The loss recoupment limit is set to the revenue-based loss recoupment limit specified in paragraph (d)(1)(iii)(D)(*1*), (d)(1)(iv)(D)(*1*), or (d)(1)(v)(D)(*1*) of this section, as applicable, not to exceed the lower of the benchmark-based loss recoupment limit amount calculated under paragraph (i)(2)(i)(B) of this section or the alternative benchmark-based loss recoupment limit amount calculated under paragraph (i)(2)(ii)(A)(*2*) of this section.

■ 41. Section 425.610 is amended by—

■ a. In paragraphs (d)(3)(ii), (d)(4)(ii), (f)(3)(i)(A), and (f)(4)(i)(A), removing the phrase ''health equity adjusted quality performance score calculated according to § 425.512(b)'' and adding in its place the phrase ''quality score calculated according to § 425.512'';

■ b. Adding paragraph (i)(2)(ii);

■ c. Revising paragraph (i)(3) introductory text;

■ d. Removing the punctuation ''; and'' at the end of paragraph (i)(3)(i) and adding in its place a period;

■ e. Adding paragraph (i)(3)(iii);

■ f. Redesignating paragraph (i)(4) as paragraph (i)(5); and

■ g. Adding new paragraphs (i)(4) and (l).

The revisions and additions read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(i) * * *

(2) * * *

(ii) For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area.

(3) CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):

* * * * *

(iii) The time period during which the ACO was affected by a cyberattack, including ransomware/malware.

(4) CMS determines the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

(i) CMS uses the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

(ii) Except as specified in paragraph (i)(4)(iii) of this section, if no end date is indicated on the ACO's application or otherwise provided to CMS in a form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS applies a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

(iii) If the start date indicated on the ACO's application described in paragraph (i)(4)(i) of this section is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS applies an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

* * * * *

(l) *Calculation of performance payment limit and loss recoupment limit.*

(1) The performance payment limit and the loss recoupment limit are a percentage of the ACO's updated benchmark.

(2) CMS calculates the performance payment limit and loss recoupment limit as follows, except as specified in paragraph (l)(3) of this section:

(i) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the performance year.

(ii) Calculates the product of the percentage used to calculate the performance payment limit specified in paragraph (e)(2) of this section or the loss recoupment limit specified in paragraph (g) of this section and the ACO's total benchmark expenditures calculated according to paragraph (l)(2)(i) of this section.

(3) For agreement periods beginning on or after January 1, 2027, if the ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2 or BY3, in conducting financial reconciliation for each performance year, CMS determines whether to apply an alternative performance payment limit or alternative loss recoupment limit, rather than the performance payment limit specified in paragraph (e)(2) of this section or the loss recoupment limit specified in paragraph (g) of this section, as follows:

(i) CMS calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries.

(ii) CMS calculates the product of the percentage used to calculate the performance payment limit specified in paragraph (e)(2) of this section or the loss recoupment limit specified in paragraph (g) of this section and the ACO's total benchmark expenditures calculated according to paragraph (l)(3)(i) of this section.

(iii) The performance payment limit or loss recoupment limit is set equal to the lesser of the amount calculated under paragraph (l)(2)(ii) of this section or the alternative amount calculated under paragraph (l)(3)(ii) of this section.

■ 42. Section 425.612 is amended by revising paragraph (a)(1)(i)(B) to read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(i) * * *

(B)*(1)* A list of SNFs, including the Medicare-enrolled TIN and the CCN, with whom the ACO will partner along with executed written SNF affiliate agreements between the ACO and each listed SNF.

(*2*) An ACO must notify CMS no later than 30 days after the change of ownership of a SNF affiliate, identified in accordance with paragraph (a)(1)(i)(B)(*1*) of this section, that has resulted in a change to the Medicare enrolled TIN of the SNF affiliate. Such notice and supporting documentation must be submitted in the form and manner specified by CMS.

* * * * *

§ 425.652 [Amended]

■ 43. Section 425.652 is amended by—

■ a. In paragraph (a)(8)(ii)(A), removing the phrase ''health equity benchmark adjustment (HEBA)'' and adding in its place the phrase ''population adjustment'';

■ b. In paragraphs (a)(8)(ii)(B) introductory text, (a)(8)(ii)(B)(*2*), (a)(9)(v), and (a)(9)(vi), removing the phrase ''HEBA'' and adding in its place the phrase ''population adjustment''; and

■ c. In paragraph (a)(9)(v), removing the phrase ''HEBA scaler used in calculating the HEBA under § 425.662(b)(2)'' and adding in its place the phrase ''scaler used in calculating the population adjustment under § 425.662(b)(2)''.

§ 425.658 [Amended]

■ 44. Section 425.658 is amended in paragraph (d) by removing the phrase ''HEBA'' and adding in its place the phrase ''population adjustment''.

■ 45. Section 425.662 is amended by—

■ a. Revising the section heading and paragraph (a);

■ b. In paragraph (b) introductory text, removing the phrase ''health equity benchmark adjustment'' and adding in its place the phrase ''population adjustment'';

■ c. In paragraph (b)(2), removing the phrase ''Calculates the HEBA scaler'' and adding in its place the phrase ''Calculates a scaler''; and

■ d. Revising paragraphs (b)(3), (b)(4), and (c).

The revisions read as follows:

§ 425.662 Calculating the population adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates the population adjustment to the historical benchmark.

(b) * * *

(3) Determines the ACO's eligibility for the population adjustment based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is only eligible for the population adjustment if this proportion is greater than or equal to 15 percent. An ACO with a proportion less than 15 percent is ineligible to receive the population adjustment.

(4) Calculates the population adjustment. If the ACO is eligible for the population adjustment as determined in paragraph (b)(3) of this section, the adjustment is equal to the product of the scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

(c) *Applicability of the population adjustment.* CMS compares the population adjustment determined in paragraph (b)(4) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the per capita prior savings adjustment determined in § 425.658(c), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8)(ii).

* * * * *

§ 425.672 [Amended]

■ 46. Section 425.672 is amended in paragraph (c)(2)(iv) by removing the phrase ''and calculating the HEBA scaler'' and adding in its place the phrase ''and calculating the scaler''.

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 47. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 48. Section 427.20 is amended by removing the definition of ''Billing and payment code FDA approval or licensure date''.

■ 49. Section 427.302 is amended by revising paragraphs (c) introductory text, (c)(5), (c)(6), (d)(1)(i) and (ii) to read as follows.

§ 427.302 Calculation of the per unit Part B rebate amount.

* * * * *

(c) *Identification of the payment amount benchmark quarter.* For each Part B rebatable drug, CMS identifies the applicable payment amount benchmark quarter as set forth in paragraphs (c)(1) through (6) of this section, as applicable, subject to paragraphs (c)(4) and (6) of this section, using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, and using the earliest approval or licensure date of any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed.

(5) If the data needed to calculate the payment amount in the payment amount benchmark quarter described in and determined under § 427.302(d)(1) are not available, CMS uses the third full calendar quarter after a drug is assigned a billing and payment code as the payment amount benchmark quarter, no earlier than the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later.

(6) For a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, for each applicable quarter beginning after the price applicability period with respect to such drug, the payment amount benchmark quarter is the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug.

(d) * * *

(1) For a Part B rebatable drug, subject to paragraphs (d)(1)(i) and (ii) of this section and except as provided in paragraph (d)(2) of this section, CMS identifies the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter.

(i) If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS calculates the payment amount in the payment amount benchmark quarter using positive ASP or positive WAC

data from the ASP Data Collection System.

(ii) If a published payment limit is not available and neither positive ASP nor positive WAC data are available in the ASP Data Collection System, CMS calculates the payment amount in the payment amount benchmark quarter using WAC data from other public sources.

* * * * *

■ 50. Section 427.501 is amended by adding paragraph (c)(3) to read as follows:

§ 427.501 Rebate Reports and reconciliation.

* * * * *

(c) * * *

(3) The manufacturer's rebate amount due is reported as a dollar amount rounded to the nearest cent.

■ 51. Section 427.502 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 427.502 Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(ii) Within 9 months after issuance of the single Rebate Report, CMS performs one regular reconciliation for the applicable calendar quarters in calendar year 2024 in order to include revisions to the information used, determined under § 427.501(b)(1), to calculate the rebate amount. Such reconciliation is as determined under § 427.501(d) inclusive of a preliminary reconciliation and a report with the reconciled rebate amount.

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

■ 52. The authority citation for part 428 continues to read as follows:

Authority: 42 U.S.C. 1395w–114b, 1302, and 1395hh.

■ 53. Section 428.401 is amended by adding paragraph (c)(3) to read as follows:

§ 428.401 Rebate Reports and reconciliation.

* * * * *

(c) * * *

(1) * * *

(2) * * *

(3) The manufacturer's rebate amount due is reported as a dollar amount rounded to the nearest cent.

■ 54. Section 428.402 is amended by revising paragraphs (c)(1)(ii) and (c)(2)(ii) to read as follows:

§ 428.402 Rebate Reports for applicable periods beginning October 1, 2022, and October 1, 2023.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(ii) The rebate amount is reconciled within 21 months after the Rebate Report set forth in paragraph (c)(1) of this section is issued to include the information set forth in § 428.401(d)(1)(i)(A) through (G).

(2) * * *

(i) * * *

(ii) The rebate amount is reconciled within 9 months after the Rebate Report and within 33 months after the Rebate Report specified in paragraph (b)(2) of this section is issued to include the information determined under § 428.401(d)(1)(i)(A) through (G).

■ 55. Section 428.405(a)(1) is amended to read as follows:

§ 428.405 Deadline and process for payment of rebate amount.

(a) * * *

(1) Upon receipt of a rebate amount, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the rebate amount on—

PART 495—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 56. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 57. Section 495.24 by adding paragraph (f)(3) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(f) * * *

(3) Beginning with the EHR reporting period in CY 2026, if certain circumstances occur that impact CMS's assessment of the performance of eligible hospitals and CAHs on a measure selected as described in paragraph (f)(1)(i)(A) of this section, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS's calculation of the objective score in paragraph (f)(1)(i)(D) of this section or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. CMS determines whether certain circumstances exist warranting suppression of a measure based on CMS's consideration of one or more of the following factors:

(i) The nature, breadth, and duration of the circumstance's effect on eligible hospitals' and CAHs' ability to fulfill the measure requirement.

(ii) The availability of certified health IT modules to fulfill the measure.

(iii) The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

(iv) Out-of-date or conflicting technical standards.

(v) Technical and operational capacity of required partners.

(vi) Other factors as determined by CMS.

* * * * *

■ 58. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 59. Adding subparts F and G to part 512 to read as follows:

Subpart F—[Reserved]

Subpart G—Ambulatory Specialty Model (ASM)

General
512.700 Basis and scope.
512.705 Definitions.
512.710 Participant eligibility and selection.
Performance Categories and Scoring
512.715 Overview of performance assessment.
512.720 Data submission requirements.
512.725 Quality ASM performance category.
512.730 Cost ASM performance category.
512.735 Improvement activities ASM performance category.
512.740 Promoting Interoperability ASM performance category.
512.745 Final scoring.
Payment and Timely Error Notice Process
512.750 Payment adjustment.
512.755 Timely error notice.
Data Sharing, Waivers, Safe Harbor, and Compliance
512.760 Data sharing with ASM participants.
512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.
512.770 ASM beneficiary incentives.
512.771 Collaborative care arrangements.
512.775 Medicare program waivers.
512.780 Extreme and uncontrollable circumstances.

Subpart G—Ambulatory Specialty Model (ASM)

§ 512.700 Basis and scope of subpart.

(a) *Basis.* This subpart implements the test of the Ambulatory Specialty Model (ASM) under section 1115A of the Act.

(b) *Scope.* This subpart sets forth the following:

(1) The method for selecting ASM participants.

(2) The methodology for ASM participant performance assessment and scoring for purposes of the improvement activities ASM performance category, quality ASM performance category, cost ASM performance category, and Promoting Interoperability ASM performance category, including beneficiary inclusion and episode-based cost measures.

(3) Data submission for applicable ASM performance categories.

(4) The schedule and methodologies for payment adjustments.

(5) Appeals process.

(6) Data sharing with ASM participants.

(7) ASM beneficiary incentives.

(8) Collaborative care arrangements.

(9) Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(10) Medicare program waivers.

(11) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) *Applicability.* Except as otherwise specified in this subpart, ASM participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.705 Definitions.

For purposes of this part, the terms in this part have the same meanings as 42 CFR §§ 512.110 and 414.1300 unless otherwise stated.

ASM beneficiary means a Medicare FFS beneficiary who is being treated by an ASM participant for a targeted chronic condition.

ASM cohort means a group of ASM participants who treat the same ASM targeted chronic condition, specifically the ASM heart failure cohort and the ASM back pain cohort.

ASM data sharing agreement means an agreement between the ASM participant, and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the ASM participant under § 512.760(e).

ASM heart failure cohort refers to all ASM heart failure participants.

ASM low back pain cohort refers to all ASM low back pain participants.

ASM heart failure participant means an ASM participant who meets the ASM participant eligibility criteria related to heart failure.

ASM incentive pool means a fixed percentage of the total amount of Medicare Part B covered professional services claims paid to ASM participants with final scores within an ASM cohort during an ASM performance year that would be distributed in the form of scaled payment adjustments during an ASM payment year. CMS calculates an ASM incentive pool for each ASM cohort for each ASM payment year as described at § 512.750(c)(1)(iii).

ASM low back pain participant means an ASM participant who meets the ASM participant eligibility criteria related to low back pain.

ASM participant means an individual clinician who, for at least one ASM performance year, satisfies the ASM participant eligibility criteria and has been selected for participation in the model as described at § 512.710(g).

ASM participant eligibility criteria means the set of criteria defined at § 512.710(b) that CMS uses to determine whether a clinician is selected to participate in ASM.

ASM payment adjustment factor means a percent value based on an ASM participant's final score as described at § 512.750(c)(1) that CMS uses in calculating adjustments to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year.

ASM payment multiplier means the numerical value equal to 1 plus the ASM payment adjustment factor determined for an ASM participant for an applicable ASM payment year as described at § 512.750(c).

ASM payment year means a calendar year in which CMS applies the ASM payment multiplier to Medicare Part B payments based on the final score achieved by that ASM participant for the ASM performance year 2 years prior.

ASM performance category means a group of applicable measures or activities used to assess ASM participant's performance on quality, cost, improvement activities, or Promoting Interoperability.

ASM performance category score means the assessment of each ASM participant's performance on the applicable measures and activities for a performance category during an ASM performance year based on the performance standards described at §§ 512.715, 512.725, 512.730, 512.735, and 512.740.

ASM performance report means the notification that CMS provides to the ASM participant for each ASM performance year, which contains the information specified at § 512.745(b).

ASM performance year means a 12-month period beginning on January 1 and ending on December 31 of each year during the first 5 calendar years of ASM test period.

ASM redistribution percentage means a percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that CMS distributes in the form of payment adjustment to ASM participants during an ASM payment year as described at § 512.750(c)(1)(iii).

ASM risk level the magnitude of the maximum positive or negative net payment adjustment percentage to which an ASM participant would be subject to during an ASM payment year as described at § 512.750(c)(1)(i).

ASM targeted chronic condition means a medical condition that is a core focus of ASM; that is, heart failure or low back pain.

ASM test period means the 7-year period from January 1, 2027, to December 31, 2033, that includes all ASM performance years and ASM payment years.

ASTP/ONC stands for the Assistant Secretary for Technology Policy/Office of the National Coordinator on Health Information Technology.

CY means calendar year.

CEHRT stands for Certified Electronic Health Records Technology that meets the requirements set forth in § 414.1305 of this chapter, except all instances of references to Merit-based Incentive Payment System (MIPS) are to be replaced with references to ASM.

Clinician has the same meaning as ''eligible professional'' as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination.

CMS EHR Certification ID means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health IT Product List.

Collaborative care arrangement means an arrangement that meets all of the requirements set forth in § 512.771.

Core Based Statistical Area (CBSA) means a statistical geographic area, based on the definition as identified by the Office of Management and Budget in the OMB Bulletin 23–01 issued on July 21, 2023, with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core).

Covered entity has the meaning set forth at 45 CFR 160.103.

Covered professional services means ''covered services'' and has the meaning set forth in § 512.110 of this chapter.

CQM stands for Clinical Quality Measures.

Days means calendar days unless otherwise specified by CMS.

Dually eligible Medicare beneficiary means a beneficiary enrolled in both Medicare and full Medicaid benefits.

eCQM stands for Electronic Clinical Quality Measures.

EBCM stands for episode-based cost measure and means the standardized Medicare-allowed cost for the items and services furnished to a patient during an episode of care, based on FFS claims and Medicare Part D claims data.

EHR stands for Electronic Health Record and means a ''Base EHR,'' as defined at 45 CFR 170.102.

Exchange function means the function used to translate an ASM participant's final score into an ASM payment adjustment factor as described at § 512.750(c)(1)(ii).

Episode means all the relevant health care services a patient receives during a specified period for the treatment of a physical or behavioral health condition.

FFS stands for fee-for-service.

Final score means a composite assessment (using a scoring scale of zero to 100) for each ASM participant for an ASM performance year determined using the methodology for assessing the total performance of an ASM participant according to performance standards for applicable measures and activities for each ASM performance category as described in § 512.745.

HCC risk score stands for Hierarchical Condition Category risk score and means the risk score assigned to a Medicare beneficiary pursuant to the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act.

Health-related social need means an unmet, adverse social condition that can contribute to poor health outcomes and is a result of underlying social determinants of health, which refer to the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Improvement activities mean activities relating to care coordination, integration of specialty and primary care, and addressing health-related social needs of patients.

Mandatory geographic area means a CBSA or metropolitan division as defined by the Office of Management and Budget and selected by CMS under the terms of § 512.710(f).

Meaningful EHR user means an ASM participant who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability ASM performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.

Measure achievement points mean numerical values assigned to an ASM participant's reported performance data, that CMS uses to calculate an ASM performance category score.

Metropolitan division means—(1) A county or group of counties (or equivalent entities) delineated within a larger metropolitan statistical area, provided that the larger metropolitan statistical area contains a single core with a population of at least 2.5 million and other criteria are met; and

(2) Consists of one or more main or secondary counties that represent an employment center or centers, plus adjacent counties associated with the main/secondary county or counties through commuting ties.

Metropolitan statistical area means the county or counties (or equivalent entities) associated with at least one urban area of at least 50,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties.

MIPS stands for the Merit-based Incentive Payment System.

NPI stands for National Provider Identifier.

ONC–ACB stands for ONC-Authorized Certification Bodies.

Physician has the meaning set forth in section 1861(r) of the Act.

Primary care services has the meaning set forth in section 1842(i)(4) of the Act.

Risk indicator refers to hierarchical condition category (HCC) risk scores under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act or the proportion of beneficiaries with dual eligible status used in calculating the complex patient scoring adjustment as defined at § 512.745(a)(3).

SAFER stands for Safety Assurance Factors for EHR Resilience.

Scaling factor means a numerical value calculated by CMS to ensure that the total estimated payment adjustments in an ASM payment year are equal to the ASM incentive pool for the applicable ASM payment year as described at § 512.750(c)(1)(iv).

Small practice means a practice consisting of 15 or fewer clinicians at the time we identify ASM participants for an ASM performance year as described at § 512.710(g).

Specialty type means a medical specialty as determined by the specialty code indicated on the plurality of a clinician's Medicare Part B claims.

Solo practitioner means a practice consisting of 1 clinician at the time we identify ASM participants for an ASM performance year as described at § 512.710(g).

Submission type means the mechanism by which the ASM submitter submits data to CMS in the form and manner specified by CMS, including, but not limited to all of the following:

(1) Direct.

(2) Log in and upload.

(3) Log in and attest.

Third-party intermediary has the meaning set forth in § 414.1305 of this chapter.

TIN stands for Taxpayer Identification Number.

Topped out measure has the meaning of either topped out process measure or topped out non-process measure set forth in § 414.1305 of this chapter.

U.S. Territories has the meaning set forth in § 512.110 of this chapter.

§ 512.710 Participant eligibility and selection.

(a) *Mandatory ASM participation.*

(1) Unless otherwise specified, any clinician who meets all ASM participant eligibility criteria as specified in paragraph (b) of this section and furnishes covered services that begin on or after January 1 and end on or before December 31 of any applicable ASM performance year within the ASM test period is considered an ASM participant for the duration of the model.

(i) 2027 ASM performance year: ASM participants are measured for performance and exempted from MIPS participation, if applicable, during CY 2027; report and are scored during CY 2028; and receive payment adjustments for CY 2027 performance in CY 2029;

(ii) 2028 ASM performance year: ASM participants meeting ASM eligibility criteria for the 2028 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2028; report and are scored during CY 2029; and receive payment adjustments for CY 2028 performance in CY 2030;

(iii) 2029 ASM performance year: ASM participants meeting ASM

eligibility criteria for the 2029 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2029; report and are scored during CY 2030; and receive payment adjustments for CY 2029 performance in CY 2031;

(iv) 2030 ASM performance year: ASM participants meeting ASM eligibility criteria for the 2030 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2030; report and are scored during CY 2031; and receive payment adjustments for CY 2030 performance in CY 2032; and

(v) 2031 ASM performance year: ASM participants meeting ASM eligibility criteria for the 2031 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2031; report and are scored during CY 2032; and receive payment adjustments for CY 2031 performance in CY 2033.

(2) For any ASM performance year within the ASM test period that an ASM participant does not meet the criteria for mandatory participation set forth in this section, such ASM participant is not subject, for the applicable ASM performance year, to §§ 512.715, 512.720, 512.745, and 512.750. The ASM participant is no longer eligible for the waivers as described at § 512.775 and is instead subject to MIPS reporting obligations, if applicable.

(b) *ASM participant eligibility criteria.* CMS uses the following set of criteria to determine whether a clinician is an ASM participant:

(1) Is a clinician who bills claims under the Medicare Physician Fee Schedule.

(2) Is identified by TIN/NPI as a selected specialty type as described at paragraph (d) of this section.

(3) Meets the EBCM episode volume threshold applicable to an ASM targeted chronic condition as described at paragraph (e) of this section.

(4) Is located in one of the mandatory geographic areas selected in accordance with paragraph (f) of this section.

(c) *Participant exclusion due to change in TIN during an ASM performance year.*

(1) An ASM participant who stops assigning billing rights to the TIN used to identify the ASM participant and begins assigning billing rights to a new TIN during an applicable ASM performance year must notify CMS of the change in a form and manner determined by CMS within 30 days of such change.

(2) An ASM participant who notifies CMS of a change in TIN during an ASM performance year is not subject, for the applicable ASM performance year, to §§ 512.715, 512.720, 512.745, and 512.750. The ASM participant is no longer eligible for the waivers as described at § 512.775 and is instead subject to MIPS reporting obligations, if applicable.

(d) *Specialty type.* ASM participants have one of the following Medicare Part B specialty codes indicated on the plurality of their Medicare Part B claims:

(1) Heart failure specialty type—

(i) Cardiology.

(ii) [Reserved]

(2) Low back pain specialty type—

(i) Anesthesiology.

(ii) Interventional Pain Management.

(iii) Neurosurgery.

(iv) Orthopedic Surgery.

(v) Pain Management.

(vi) Physical Medicine and Rehabilitation.

(e) *EBCM episode volume.* To determine if a clinician meets the ASM participant eligibility criterion defined in paragraph (b)(1)(iii) of this section, CMS uses the volume of EBCM episodes related to ASM targeted chronic conditions that are attributed to a clinician using the applicable EBCM specifications and attribution methodology.

(1) *Heart failure EBCM.* Clinicians who have a specialty designation type described at § 512.710(d)(1) and 20 or more heart failure EBCM episodes attributed in accordance with the heart failure episode-based cost measure as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year meet the ASM participant eligibility criterion defined in paragraph (b)(1)(iii) of this section.

(2) *Low back pain EBCM.* Clinicians who have a specialty designation type described at § 512.710(d)(2) and 20 or more low back pain EBCM episodes attributed in accordance with the low back pain episode-based cost measure as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year meet the ASM participant eligibility criterion defined in paragraph (b)(1)(iii) of this section.

(f) *Mandatory geographic areas.* CMS uses a stratified random sampling methodology described in paragraphs (f)(2) and (f)(3) of this section to select CBSA and metropolitan divisions (in cases where CBSA divide large metropolitan statistical areas into metropolitan divisions) from which CMS identifies clinicians for participation in ASM.

(1) *Exclusions.* CMS excludes from the selection of CBSAs and metropolitan divisions applicable areas that meet any of the following criteria:

(i) Areas that did not have at least one attributed episode between January 1, 2024 and December 31, 2024 for each of the episode-based cost measures described in paragraph (e) of this section and used in the ASM participant eligibility criteria described in paragraph (b) of this section.

(ii) Areas located entirely in U.S. Territories.

(2) *CBSA and metropolitan division stratification process.* Prior to sampling CBSAs and metropolitan divisions, CMS stratifies CBSAs and metropolitan divisions, excluding those described in paragraph (f)(1) of this section, into six mutually exclusive strata based on three CBSA/metropolitan division-level characteristics (average total Part A and Part B episode spending, volume of eligible episodes, and metropolitan division status) as follows. ''Average total episode spending'' as the term is used below, is measured using the average total Part A and Part B episode spending using claims data from January 1, 2024 to December 31, 2024 relating to heart failure and low back pain episodes, as specified under the episode-based cost measures described in § 512.710(e). Values below the median are characterized as ''Low'' average total episode spending. Values at or above the median are characterized as ''High'' average total spending. ''Eligible episode volume'' as the term is used below, is measured as the total count of eligible heart failure and low back pain episodes, as specified under the episode-based cost measures described in § 512.710(e), in a CBSA between January 1, 2024 and December 31, 2024. CMS categorizes CBSAs with values below the median as ''Low;'' CBSAs at-or-above the median and below the 95th percentile as ''High;'' and CBSAs at-or-above the 95th percentile as ''Very High.''.

(i) CBSAs with ''Low'' average total episode spending and ''Low'' eligible episode volume.

(ii) CBSAs with ''Low'' average total episode spending and ''High'' eligible episode volume.

(iii) CBSAs with ''High'' average total episode spending (as defined below) and ''Low'' eligible episode volume.

(iv) Eligible CBSAs with ''High'' average total episode spending and ''High'' eligible episode volume.

(v) Eligible CBSAs with ''Very High'' eligible episode volume.

(vi) Eligible metropolitan divisions.

(3) *Sampling of CBSAs and metropolitan divisions.* CMS selects approximately 40 percent of CBSAs and metropolitan divisions from each

stratum to select the mandatory geographic areas. If 40 percent of a given stratum does not result in a whole number of CBSAs or metropolitan divisions, CMS rounds up to the next whole number to ensure that at least 40 percent of areas from each stratum are selected.

(4) *Assignment of CBSA or metropolitan division code to clinicians.* CMS assigns a CBSA or a metropolitan division code to every TIN/NPI with attributed EBCM episodes related to ASM targeted chronic conditions for the applicable calendar year as described in paragraph (e) of this section to determine ASM participation eligibility for an applicable ASM performance year:

(i) CMS assigns each attributed EBCM episode a ZIP Code, which represents the service location where the attributed TIN/NPI encounters the beneficiary attributed to the episode the most, based on the plurality of Part B claims used to construct the episode. If the ZIP Codes representing service location where the attributed TIN/NPI appears in equal number in the Part B claims used to construct the episode, then CMS assigns the ZIP Code based on the ZIP Code that represents:

(A) The Part B claim with the highest total cost indicated by the total standardized allowed amount; or

(B) The Part B claim with most recent date.

(ii) CMS assigns each attributed EBCM episode a CBSA or metropolitan division code based on the ZIP Code assigned to the episode as described in paragraph (f)(4)(i) of this section. If the ZIP Code assigned to the EBCM episode is in multiple CBSAs or metropolitan divisions, then CMS assigns the EBCM episode the CBSA or metropolitan division code where the ZIP Code has:

(A) The highest proportion of total addresses; or

(B) The highest proportion of business addresses.

(iii) CMS assigns each TIN/NPI combination a single CBSA or metropolitan division code based on the most common CBSA or metropolitan division code assigned to episodes attributed to the TIN/NPI as described in paragraph (f)(4)(ii) of this section. If the TIN/NPI has equal number of episodes across multiple CBSAs or metropolitan divisions, then CMS assigns the TIN/NPI a CBSA or metropolitan division with the CBSA or metropolitan division that has either of the following:

(A) The highest total risk-adjusted episode spending across all episodes assigned to the CBSA or metropolitan division; or

(B) Episodes with more recent dates.

(g) *Selection and notification process for ASM participants.* For each ASM performance year, CMS identifies all clinicians furnishing covered services using the ASM participant eligibility criteria specified in paragraph (b) of this section and applicable data from 2 calendar years prior to each ASM performance year. Any clinician selected for participation for any year of the model is considered an ASM participant for the remainder of the ASM test period.

(1) *2027 ASM performance year only—*

(i) *Preliminarily eligible ASM participants.* Using applicable data from calendar year 2024, CMS identifies all clinicians who meet the ASM participant eligibility criteria for participation starting in the 2027 ASM performance year/2029 ASM payment year. The clinicians identified as preliminarily eligible ASM participants are made public in a form and manner determined by CMS.

(ii) *Final ASM participants.* CMS identifies the final ASM participants selected for participation starting in the 2027 ASM performance year/2029 ASM payment year by confirming that the preliminarily eligible ASM participants identified under paragraph (g)(1)(i) of this section meet the ASM participant eligibility criteria using applicable data from calendar year 2025. The clinicians selected as ASM participants starting the 2027 ASM performance year/2029 ASM payment year is made public in a form and manner determined by CMS.

(2) *2028 ASM performance year and subsequent years.*

(i) Beginning with the 2028 ASM performance year/2030 ASM payment year, CMS determines if the previously selected ASM participants continue to meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. An ASM participant who does not meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year is not subject to provisions described at § 512.710(a)(2), and must, if applicable, participate in MIPS. The final ASM participants selected for participation for each applicable ASM performance year is made public in a form and manner determined by CMS.

(ii) Beginning with the 2028 ASM performance year/2030 ASM payment year and prior to the start of each ASM performance year, CMS determines if additional clinicians not previously identified as ASM participants meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. The final ASM participants selected for participation for each applicable ASM performance year is made public in a form and manner determined by CMS.

§ 512.715 Overview of performance assessment.

(a) *General.* As further described in §§ 512.725, 512.730, 512.735, and 512.740:

(1) An ASM participant receives a specific number of points for its performance on each measure or activity within an ASM performance category.

(2) CMS assigns the total amount of points an ASM participant may receive for its performance on a measure or activity.

(3) CMS calculates a final score as described at § 512.745 using the points received across all four ASM performance categories.

(b) *Data sources.*

(1) CMS uses Medicare claims data and Medicare administrative data reported to calculate measure scores included in the quality and cost ASM performance categories under §§ 512.725 and 512.730.

(2) CMS uses model-specific data reported under § 512.720 to calculate applicable measure or activity scores for the quality, improvement activities, and Promoting Interoperability ASM performance categories under §§ 512.725, 512.735, and 512.740.

§ 512.720 Data submission requirements.

(a) *Applicable performance categories and data submission requirements.*

(1) Except as provided in paragraph (a)(2) of this section, as applicable, ASM participants must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability ASM performance categories described in §§ 512.725(b) and 512.725(c), 512.735(b), and 512.740 in accordance with this section. The data may also be submitted on behalf of the ASM participant by a third-party intermediary.

(i) For the quality ASM performance category, a data submission must include numerator and denominator data for at least one applicable quality measure described in §§ 512.725(b) or 512.725(c) that is not an administrative claims-based collection type and meets the data completeness requirement as specified at § 512.725(f).

(ii) For the improvement activities ASM performance category, a data

submission must include an attestation of meeting the specifications of each required improvement activity described in § 512.735(c).

(iii) For the Promoting Interoperability ASM performance category, a data submission must include all of the following elements:

(A) Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS at § 512.740(b).

(B) Required attestation statements, as specified by CMS at § 512.740(b).

(C) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL).

(D) The start date and end date for the applicable performance period as set forth in § 512.740(a).

(2) There are no data submission requirements for the cost ASM performance category measures and activities described under § 512.730(b) or administrative claims-based quality measures as described in § 512.725(b) or § 512.725(c). Performance in the cost ASM performance category and administrative claims-based quality measures are calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(b) *Data submission types for ASM participants.* An ASM participant must submit their data using the following:

(1) For the quality ASM performance category, the direct and login and upload submission types.

(2) For the improvement activities and Promoting Interoperability ASM performance categories, the direct, login and upload, or login and attest submission types.

(c) *Use of multiple data submission types.* ASM participants may submit their data using multiple data submission types for any ASM performance category described in paragraph (a)(1) of this section provided that the ASM participant uses the same identifier for all ASM performance categories and all data submissions.

(d) *Data submission deadlines.* The data submission deadline is March 31st of the calendar year following the close of the applicable ASM performance year or a later date as specified by CMS for the direct, login and upload, and login and attest submission types.

(e) *Treatment of multiple data submissions—*

(1) For multiple data submissions received in the quality and improvement activities ASM performance categories in accordance with paragraphs (a)(1)(i) and (ii) of this section for an individual ASM participant from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS calculates and scores each submission received and assign the highest of the scores. For multiple data submissions received for an individual ASM participant from one or multiple submitters in the same organization, CMS scores the most recent submission.

(2) For multiple data submissions received for the Promoting Interoperability ASM performance category in accordance with paragraph (a)(1)(iii) of this section, CMS calculates a score for each data submission received and assigns the highest of the scores.

§ 512.725 Quality ASM performance category.

(a) *ASM performance year for quality measures.* Beginning with 2029 ASM payment year, the ASM performance year for quality measures is the full calendar year from January 1 to December 31 that occurred 2 years prior to the applicable ASM payment year, except as otherwise specified for administrative claims-based measures.

(b) *Quality measures for ASM heart failure cohort.* CMS uses the following quality measures, as specified by CMS for the MIPS quality performance category unless otherwise stated, to assess performance for ASM heart failure participants in the quality ASM performance category:

(1) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (MIPS Q492).

(2) Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008).

(3) Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005).

(4) Controlling High Blood Pressure (MIPS Q236)

(5) Functional Status Assessments for Heart Failure (MIPS Q377).

(c) *Quality measures for ASM low back pain cohort.* CMS uses the following quality measures, as specified by CMS for the MIPS quality performance category unless otherwise stated, to assess performance for ASM low back pain participants in the quality ASM performance category:

(1) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (non-MIPS, administrative claims-based measure in development)

(2) Use of High-Risk Medications in Older Adults (MIPS Q238).

(3) Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134).

(4) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128).

(5) Functional Status Change for Patients with Low Back Impairments (MIPS Q220).

(d) *Removal, addition, and maintenance of technical specifications of quality measures.* CMS uses notice and comment rulemaking to communicate any changes to the quality measures described in paragraphs (b) and (c) of this section.

(e) *Data submission criteria for the quality ASM performance category.*

(1) CMS uses quality measures as described in paragraphs (b) and (c) of this section with the following data collection types:

(i) MIPS CQMs.

(ii) eCQMs.

(iii) Administrative claims-based.

(2) *Data submission requirements.*

(i) An ASM heart failure participant must submit data on all quality measures specified in paragraph (b) of this section using MIPS CQMs or eCQMs.

(ii) An ASM low back pain participant must submit data on all quality measures specified in paragraph (c) of this section using MIPS CQMs or eCQMs, unless otherwise stated.

(iii) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(3) An ASM participant is not required to submit data for the calculation of administrative claims-based measures so long as data submission requirements as specified at § 512.720(a)(1)(i) are met.

(f) *Data completeness requirement for the quality ASM performance category.*

(1) Except as specified at paragraph (e)(3) of this section and for each required measure specified in paragraphs (b) or (c) of this section, ASM participants must submit data on at least 75 percent of the ASM participant's patients that meet the measure's denominator criteria, regardless of payer.

(2) ASM participants receive zero measure achievement points for each measure required in paragraphs (b) or (c) of this section that does not meet the data completeness requirement, as specified at paragraph (f)(1) of this section.

(3) CMS excludes from an ASM's participant total measure achievement

points and total available measure achievement points any measures required under paragraphs (b) or (c) of this section that meet the respective measure's data completeness requirement, but do not have a benchmark.

(g) *Minimum case requirements.*

(1) Unless otherwise specified by CMS, the minimum case requirement for each quality measure required in paragraphs (b) or (c) of this section is 20 cases.

(2) CMS excludes from an ASM's participant total measure achievement points and total available measure achievement points any measures required under paragraphs (b) or (c) of this section that meet the respective measure's data completeness requirement as specified at paragraph (f)(1) of this section but do not meet the measure's case minimum requirement as specified at paragraph (g)(1) of this section.

(h) *Quality measure achievement points and quality ASM performance category scoring.* Unless a different scoring weight is assigned by CMS, performance in the quality ASM performance category comprises of 50 percent of a ASM participant's final score for each ASM payment year.

((1) *Measure achievement points.*

(i) For each ASM performance year, ASM participants receive between 1 and 10 measure achievement points (including partial points) for each required measure as specified in paragraphs (b) or (c) of this section on which data is submitted in accordance with paragraph (e) of this section that does all of the following:

(A) Has a benchmark specified in paragraph (h)(2) of this section.

(B) Meets the case minimum requirements specified in paragraph (g) of this section.

(C) Meets the data completeness criteria specified in paragraph (f) of this section.

(D) For each administrative claims-based measure with a benchmark as described at paragraph (h)(2)(iii) of this section and meets the case minimum requirement at paragraph (g) of this section.

(ii) The number of ASM measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution.

(iii) ASM participants receive zero ASM measure achievement points for each measure required in paragraphs (b) or (c) of this section on which no data is submitted in accordance with § 512.720.

(iv) ASM participants who submit data in accordance with paragraphs (e) through (g) of this section on a single required measure via multiple applicable collection types are scored only on the data submission with the greatest number of measure achievement points.

(2)(i) *Benchmarks.* Except as provided in paragraph (h)(2)(iii) of this section, CMS bases benchmarks on an ASM participant's performance by collection type, from one following data sources:

(A) Reported by ASM participants, to the extent feasible, during the ASM performance year.

(B) A previous ASM performance year, if available.

(C) Another period determined by CMS.

(ii) Each benchmark must have a minimum of 20 ASM participants who reported the measure having met the following criteria:

(A) The case minimum requirements in paragraph (g) of this section.

(B) The data completeness requirement as specified in paragraph (f) of this section.

(C) A performance rate that is greater than zero.

(iii) CMS calculates a benchmark for an administrative claims quality measure using the performance on the measure during the current ASM performance year.

(iv) CMS determines a benchmark using decile categories based on the applicable period of data used to determine the measure's benchmark.

(3) *Topped out measures.* CMS identifies topped out measures in the benchmarks for each ASM performance year based on within-model performance on each measure.

(4) *Calculation of the quality ASM performance category score—*

(i) Unless otherwise specified by CMS, an ASM participant's quality ASM performance category score is the sum of all measure achievement points assigned for the applicable measures for the quality ASM performance category.

(A) The sum is divided by the total available measure achievement points.

(B) The quality ASM performance category score cannot exceed 100 percentage points.

(ii) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 512.720(d), performance is based on data for 9 consecutive months of the applicable ASM performance year.

(A) Significant changes or errors means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications.

(B) CMS publishes a list of all measures scored in a form and manner specified by CMS.

(C) If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from an ASM participant's total measure achievement points and total available measure achievement points.

(iii) An ASM participant does not receive a quality ASM performance category score if the ASM participant meets the quality ASM performance category data submission requirements specified at § 512.720(a)(1)(i) but does not meet the case minimum requirements specified in paragraph (g) of this section for any required quality ASM performance category measure specified in paragraphs (b) or (c) of this section, as applicable, that has a benchmark as specified in paragraph (h)(2) of this section.

§ 512.730 Cost ASM performance category.

(a) *ASM performance year for cost performance measures.* Beginning with the 2029 ASM payment year, the ASM performance year for cost measures is the full calendar year from January 1 to December 31 that occurred 2 years prior to the applicable ASM payment year.

(b) *Cost measures.* For purposes of assessing performance of ASM participants on the cost ASM performance category, CMS—

(1) For ASM heart failure participants, assess and score the participants on the Heart Failure EBCM (COST_HF_1), as specified under MIPS.

(2) For ASM low back pain participants, assess and score the participants on the Low Back Pain EBCM (COST_LBP_1), as specified under MIPS.

(c) *Adding or removing cost measures.* CMS may add new cost measures to, or remove existing cost measures from, the cost ASM performance category through notice and comment rulemaking.

(d) *Minimum case requirements.* Unless otherwise specified by CMS, the minimum case requirement for each cost measure is 20 cases.

(1) Each cost measure is attributed at the TIN/NPI level according to the

measure specification for the applicable ASM performance year.

(2) An ASM participant must meet the minimum case volume to be scored on a cost measure.

(e) *Cost measure achievement points and cost ASM performance category scoring.* Unless a different scoring weight is assigned by CMS, performance in the cost ASM performance category comprises 50 percent of an ASM participant's final score for each ASM performance year.

(1) *ASM measure achievement points.* (i) For each cost measure attributed to an ASM participant, the ASM participant receives one to ten achievement points (including partial points) based on the ASM participant's performance on the cost measure during the ASM performance year compared to the cost measure's benchmark.

(ii) Achievement points are awarded based on which benchmark range the ASM participant's performance on the measure is in.

(2) *Benchmarks*

(i) CMS bases cost measure benchmarks on cost measure performance during the ASM performance year.

(A) Each benchmark must have a minimum of 20 ASM participants who meet the minimum case volume specified in paragraph (d) of this section for CMS to determine a benchmark for the cost measure.

(B) If a benchmark is not determined for a cost measure, then the measure is not scored.

(ii) CMS determines 10 benchmark ranges based on the median cost of all ASM participants attributed the measure, plus or minus standard deviations. CMS awards achievement points based on which benchmark range an ASM participant's measure score corresponds.

(3) *Calculation of the cost ASM performance category score.* Except as otherwise specified in paragraph (e)(3)(i) of this section, the cost ASM performance category score is the sum of the total number of achievement points earned by the ASM participant divided by the total number of available achievement points, not to exceed 100 percent.

(i) An ASM participant does not receive a cost ASM performance category score if the ASM participant is not attributed the required cost measure for the ASM performance year specified in paragraph (b) of this section because the ASM participant has not met the case minimum specified in paragraph (d) of this section for the required cost measure or if a benchmark has not been created for a required cost measure as specified in paragraph (e)(2) of this section.

(ii) If data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the ASM participant's cost ASM performance category score and a cost ASM performance category score is not calculated.

(A) Significant changes or errors means changes to or errors in a measure that are outside the control of the clinician and its agents, and that CMS determines may result in patient harm or misleading results.

(B) Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications.

(C) CMS empirically assesses the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

§ 512.735 Improvement activities ASM performance category.

(a) *ASM performance year for improvement activities.* Beginning with the 2029 ASM payment year, the ASM performance year for improvement activities is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

(b) *Improvement activities.* CMS uses the improvement activities specified in paragraph (c) of this section to evaluate performance of ASM participants in the improvement activities ASM performance category.

(c) *Improvement activities specifications.*

(1) *Improvement Activity 1 (IA–1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening.* An ASM participant must have evidence of processes, workflows, or technology that require the ASM participant to do all of the following:

(i) Confirm the ASM beneficiary has access to primary care services and, if not, assist the ASM beneficiary in finding a clinician who provides primary care services.

(ii) Communicate relevant information back to the ASM beneficiary's primary care provider following the ASM beneficiary's visit with the ASM participant.

(iii) Determine whether the ASM beneficiary has received an annual health-related social needs screening in the primary care setting and, if not, encourage the primary care services provider to conduct the screening or allow the ASM participant to conduct the health-related social needs screening.

(2) *Improvement Activity 2 (IA–2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements.* An ASM participant must do all of the following:

(i) Have at least one executed collaborative care arrangement between a primary care practice with which the ASM participant shares ASM beneficiaries.

(ii) The collaborative care arrangement must include collaborative efforts related to at least three of the following five elements:

(A) Data sharing, which includes setting expectations for bi-directional sharing of patient information between the parties to the collaborative care arrangement, including but not limited to test results, treatment plans, and follow-up recommendations.

(B) Co-management, which includes defining co-management approaches, where the parties to the collaborative care arrangement work together to furnish complementary care for patients with complex or chronic conditions.

(C) Transitions in care planning, which includes defining protocols for seamless transitions of care between ASM participants, the primary care practice, or different care settings.

(D) Closed-loop communication, such as clearly articulated processes enforcing parameters on how ASM beneficiaries may be referred between the parties to the collaborative care arrangement.

(E) Care coordination integration comprised of structured processes to embed care coordination processes into the ASM participant's practice workflow.

(d) *Scoring for improvement activities ASM performance category.*

(1) *ASM measure achievement points.* ASM participants receive 10 ASM measure achievement points for attesting ''yes'' for each improvement activity specified in paragraph (c) in compliance with the data submission requirements at § 512.720.

(2) *Calculation of the improvement activities ASM performance category*

score. Unless otherwise specified by CMS, CMS sums the total achievement points for all submitted improvement activities and divides this sum by the total number of available achievement points for the required improvement activities as specified in paragraph (c) of this section, not to exceed 100 percent.

§ 512.740 Promoting Interoperability ASM performance category.

(a) *ASM performance year for the Promoting Interoperability ASM performance category.* Beginning with the 2029 ASM payment year, the ASM performance year for Promoting Interoperability measures is the minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

(b) *Reporting for the Promoting Interoperability ASM performance category.* To earn an ASM performance category score greater than zero for the Promoting Interoperability ASM performance category for inclusion in the final score, an ASM participant must be a meaningful EHR user and meet the following criteria:

(1) *CEHRT.* Use CEHRT as defined at § 414.1305 for the ASM performance year.

(2) *ASM Promoting Interoperability objectives and measures.* Report on the following MIPS Promoting Interoperability measures, as specified by CMS through rulemaking:

(i) An ASM Participant must report both of the following measures or claim an exclusion or exclusions to fulfill the e-Prescribing objective:

(A) e-Prescribing (Measure ID #: PI_EP_1).

(B) Query of PDMP (Measure ID # PI_EP_2).

(ii) An ASM Participant must fulfill the Health Information Exchange objective through one of the following three options:

(A) Report the Support Electronic Referral Loops by Sending Health Information (Measure ID # PI_HIE_1) and Support Electronic Referral Loops by Receiving and Reconciling Health Information (Measure ID # PI_HIE_4).

(B) Health Information Exchange (HIE) Bi-Directional Exchange (Measure ID # PI_HIE_5).

(C) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) (Measure ID # PI_HIE_6).

(iii) An ASM Participant must fulfill the Provider to Patient Exchange objective by reporting the Provide Patients Electronic Access to Their Health Information measure (Measure ID # PI_PEA_1).

(iv) An ASM Participant must fulfill the Public Health and Clinical Data Exchange objective by reporting both measures:

(A) Immunization Registry Reporting (Measure ID # PI_PHCDDR_1).

(B) Electronic Case Reporting (Measure ID PI_PHCDRR_3).

(3) *Reporting ASM Promoting Interoperability objectives and measures.* Comply with the following reporting requirements:

(i) For each measure reported pursuant to paragraph (b)(2) of this section, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion.

(ii) Report that the ASM participant completed the actions included in the MIPS Promoting Interoperability Security Risk Analysis measure (Measure ID # PI_PPHI_1) within the calendar year of the ASM performance year.

(iii) Submit an affirmative attestation regarding the ASM participant's completion of the annual self-assessment checklist under the MIPS Promoting Interoperability High Priority Practices Guide of the SAFER Guides measure (Measure ID # PI_PPHI_2) within the calendar year of the ASM performance year.

(4) *Supporting use of CEHRT.* ASM participants must support the use of CEHRT by fulfilling the following requirements:

(i) *Supporting the use and performance of CEHRT.* To fulfill ASM requirements to engage in activities related to supporting clinicians with the performance of CEHRT, the ASM participant:

(A) Must attest by providing all of the following:

(*1*) Acknowledgement of the requirement to cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received.

(*2*) If requested, cooperation in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets, or can be used to meet, the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

(B) May attest to the following objectives and measures:

(*1*) Acknowledgement of the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received.

(*2*) If requested, cooperation in good faith with ONC–ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meet, or can be used to meet, the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

(c) *Scoring the Promoting Interoperability ASM performance category.*

(1) *ASM measure achievement points.*

(i) An ASM participant earns a score for each measure by fulfilling the reporting requirements specified at paragraph (b) of this section. Score amounts are set forth in the MIPS measure specifications.

(ii) If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure as set forth in the MIPS measure specifications.

(2) *Promoting Interoperability ASM performance category score.* Unless otherwise specified by CMS, CMS sums the scores for each of the required measures and divides this sum by the total number of available Promoting Interoperability points. The Promoting Interoperability ASM performance category score cannot exceed 100 percent.

§ 512.745 Final scoring.

(a) *Final score calculation.* CMS calculates a final score of 0 to 100 points using the formula specified at paragraph (a)(5) of this section for each ASM participant that meets the requirements to receive a final score as specified in paragraph (a)(2) of this section.

(1) *ASM performance category weights and scoring adjustments.* CMS calculates the final score using the ASM performance category weights and scoring adjustments as follows:

(i) Quality ASM performance category weight is 50 percent.

(ii) Cost ASM performance category weight is 50 percent.

(iii) The improvement activities ASM performance category has a scoring adjustment that is applied to the final score without weighting.

(A) ASM participants that achieve a 100 percent score for the improvement activities ASM performance category do not receive an improvement activities ASM performance category scoring adjustment to final score.

(B) ASM participants that receive a 50 percent improvement activities ASM performance category score receive an improvement activities ASM performance category scoring adjustment of negative 10 points to the final score.

(C) ASM participants that receive a zero percent improvement activities ASM performance category score receive an improvement activities ASM performance category scoring adjustment of negative 20 points to the final score.

(iv) The Promoting Interoperability ASM performance category has a scoring adjustment that is applied to the final score without weighting.

(A) To determine the Promoting Interoperability ASM performance category scoring adjustment as described in paragraph (a)(1)(iv) of this section, the Promoting Interoperability ASM performance category score is multiplied by 100, the product is then subtracted from 100 and divided by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10 points.

(B) The maximum Promoting Interoperability ASM performance category scoring adjustment is negative 10 points.

(2) *Requirements to receive a final score.* Except as described at § 512.780(c)(1), CMS determines whether an ASM participant receives a final score for the applicable ASM performance year depending on the data submitted by the ASM participant.

(i) Except as described in paragraph (a)(2)(iii) of this section, CMS calculates a final score greater than zero but not exceeding 100 as described in paragraph (a) of this section for the applicable ASM performance year for all ASM participants that meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(ii) CMS assigns a final score of zero for the applicable ASM performance year to all ASM participants who do not meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(iii) CMS does not assign a final score for the applicable ASM performance year to ASM participants who do all of the following:

(A) Meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(B)(*1*) Do not receive a quality ASM performance category score under § 512.725(h)(4)(iii); or

(*2*) Do not receive a cost ASM performance category score under § 512.730(e)(3)(i).

(3) *Complex patient scoring adjustment.* CMS adds a complex patient scoring adjustment to the final score for the ASM performance year, if applicable, if an ASM participant meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section and the criteria defined in paragraph (a)(3)(i) of this section for the applicable ASM performance year.

(i) The complex patient scoring adjustment is limited to ASM participants with a risk indicator at or above the risk indicator calculated median for their ASM cohort. To determine the median for the respective risk indicator (HCC and dual proportion) for each ASM cohort, risk indicators associated to an ASM participant in the corresponding ASM cohort from the calendar year preceding the applicable ASM performance year, for all ASM participants within an ASM cohort who meet the data submission requirements for the quality ASM performance category at § 512.725(a)(1)(i) are used.

(ii) Beginning with the 2027 ASM performance year, for ASM participants, the complex patient scoring adjustment components are calculated as follows for the specific risk indicators:

(A) Medical complex patient scoring adjustment component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS in accordance with section 1853(a)(1) of the Act) seen by the ASM participant.

(B) Social complex patient scoring adjustment component = 1.5 + 4 * associated dual proportion standardized score.

(C) The components specified in paragraphs (a)(3)(ii)(A) and (B) of this section are added together to calculate one overall complex patient scoring adjustment. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score—risk indicator mean)/risk indicator standard deviation.

(iii) The complex patient scoring adjustment cannot exceed 10 and cannot be below zero.

(4) *Small practice scoring adjustment.*

(i) *Scoring adjustment for an ASM participant that is in a small practice and is not a solo practitioner.* CMS add 10 points to the final score of an ASM participant that meets all of the following:

(1) Is in a small practice.

(2) Is not a solo practitioner.

(3) Meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(ii) *Scoring adjustment for ASM participant that is a solo practitioner.* CMS adds 15 points to the final score of an ASM participant that is a solo practitioner and meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(5) *Final score formula.* Final score = [quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + complex patient scoring adjustment + small practice scoring adjustment. The final score cannot be below zero points or exceed 100 points.

(b) *ASM performance report.* For each ASM performance year, CMS provides each ASM participant with an ASM performance report, in a form and manner determined by CMS, containing all of the following:

(1) The ASM participant's score for each ASM performance category.

(2) The ASM participant's complex patient scoring adjustment under paragraph (a)(3) of this section, as applicable.

(3) The ASM participant's small practice or solo practitioner scoring adjustment under paragraph (a)(4) of this section, as applicable.

(4) The ASM participant's final score, as applicable.

(5) The ASM payment adjustment factor under § 512.750(c)(1).

(6) The ASM payment multiplier under § 512.750(c).

§ 512.750 Payment adjustment.

(a) *General.* Except as described in paragraph (f) of this section, for covered professional services furnished by an ASM participant during an ASM payment year, CMS, in accordance with

paragraph (d) of this section, multiplies the amount otherwise paid under Part B for such covered professional services by the ASM payment multiplier calculated for the ASM participant calculated under paragraph (c) of this section for the corresponding ASM performance year.

(b) *Comparison of ASM participant performance.* For the purpose of determining ASM payment adjustment factors and ASM payment multipliers applicable to adjustments to Part B payments for covered professional services in the corresponding ASM payment year, CMS separately compares final scores of ASM participants in each ASM cohort for the corresponding ASM performance year.

(c) *ASM payment multiplier.* Unless otherwise specified under paragraph (d) of this section, for each ASM participant within an ASM cohort for the applicable ASM payment year, CMS calculates an ASM payment multiplier as 1 plus the ASM payment adjustment factor determined under paragraph (c)(1) of this section.

(1) *ASM payment adjustment factor.* For each ASM participant with a final score greater than zero as described at § 512.745(a)(2)(i) within an ASM cohort for the applicable ASM performance year, CMS calculates an ASM payment adjustment factor using the formula: ASM payment adjustment factor = [(ASM risk level as described in paragraph (c)(1)(i) of this section) × (ASM participant's transformed final score as described in paragraph (c)(1)(ii) of this section) × (scaling factor applicable to the ASM incentive pool as described in paragraph (c)(1)(iv) of this section)]—ASM risk level as described in paragraph (c)(1)(i) of this section. For each ASM participant with a final score equal to zero as described at § 512.745(a)(2)(ii) within an ASM cohort for the applicable ASM payment year, CMS calculates an ASM payment adjustment factor equal to the negative of the applicable ASM level risk level as described in paragraph (c)(1)(i) of this section.

(i) *ASM risk level.* CMS sets an ASM risk level that is the magnitude of the maximum downside and upside risk to which an ASM participant would be subject to during an ASM payment year.

(A) For the 2029 *ASM payment* year, the ASM risk level is 9 percent.

(B) For the 2030 ASM payment year, the ASM risk level is 9 percent.

(C) For the 2031 ASM payment year, the ASM risk level is 10 percent.

(D) For the 2032 ASM payment year, the ASM risk level is 11 percent.

(E) For the 2033 ASM payment year, the ASM risk level is 12 percent.

(ii) *Exchange function and transformed final score.* CMS uses a logistic exchange function with a midpoint set at the median final score of the applicable ASM cohort from the applicable ASM performance year to transform each ASM's participant final score into a numerical value.

(iii) *Incentive pool.* CMS calculates an ASM incentive pool for each ASM cohort for an applicable ASM payment year using the formula: ASM incentive pool = (Sum of Medicare Part B payments for covered professional services paid to ASM participants with final scores in an ASM cohort during the applicable ASM performance year) × (ASM risk level as defined in paragraph (c)(1)(i) of this section) × (ASM redistribution percentage). The ASM redistribution percentage is set at 85 percent.

(iv) *Scaling factor.* CMS calculates a scaling factor for each ASM incentive pool for the applicable ASM payment year that ensures the estimated total payment adjustments would equal the ASM incentive pool. The scaling factor is calculated by dividing the total amount in the ASM incentive pool by the sum of all ASM participant's transformed final scores, multiplied by their respective total Medicare Part B covered professional services payments from the applicable ASM performance year and the applicable ASM risk level as specified under paragraph (c)(1)(i) of this section.

(2) [Reserved]

(d) *No payment adjustments.* CMS assigns an ASM payment adjustment factor of 0 and an ASM payment multiplier of 1 for the applicable ASM payment year that results in no payment adjustment to an ASM participant who does not receive a final score under § 512.745(a)(2)(iii) for the corresponding ASM performance year.

(e) *Notification of ASM payment adjustments to ASM participants.* CMS notifies each ASM participant of their ASM payment adjustment factor and corresponding ASM payment multiplier for the applicable ASM payment year in the ASM performance report under § 512.745(b) provided to each ASM participant for the applicable ASM performance year.

(f) *Change in ASM participant TIN affiliation after ASM performance year and before the end of corresponding ASM payment year.*

(1) CMS adjusts payments to the different TIN using the ASM payment multiplier calculated for the ASM participant based on their performance in the corresponding ASM performance year for an NPI who meets all of the following:

(i) Is an ASM participant with a final score for an ASM performance year.

(ii) Submits Part B covered professional service claims during an ASM payment year using a different TIN than the TIN CMS identified them as an ASM participant for that ASM performance year and to which the ASM participant began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

(2) CMS adjusts claims using the highest ASM payment multiplier from all the TIN and NPI combinations that identified the NPI as an ASM participant for the corresponding ASM performance year for an NPI who meets all of the following:

(i) CMS identifies as an ASM participant under multiple TINs for a given ASM performance year.

(2) Submits Part B covered professional service claims during an ASM payment year under a TIN by which CMS did not identify the ASM participant and to which the ASM participant began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

§ 512.755 Timely error notice process.

(a) *General.* Subject to the limitations on review in § 512.170, an ASM participant may submit a written timely error notice for one or more calculations made and issued by CMS within the ASM performance report if the ASM participant believes an error occurred in calculations due to data quality, misapplication of methodology, or other issues.

(b) *Requirements.* If an ASM participant believes the ASM performance report contains a calculation error as described in paragraph (a) of this section, the ASM participant must submit a written timely error notice, in a form and manner specified by CMS, documenting the calculation error within 30 calendar days of issuance of the ASM performance report, unless specified by CMS.

(1) If the ASM participant does not provide such written timely error notice in accordance with paragraph (a) of this section, then the ASM performance report is deemed final 30 calendar days after its issuance.

(2) Only an ASM participant may submit a written timely error notice described in this section.

(3) *Sufficiency of information in written timely error notice.*

(i) CMS determines if the written timely error notice meets the requirements of this section and

contains sufficient information to substantiate the request.

(ii) If the request is not compliant with the requirements of this section or requires additional information—

(A) CMS follows up with the ASM participant to request additional information in a form and manner as specified by CMS;

(B) The ASM participant must respond within 10 calendar days of CMS' request for additional information in a form and manner as specified by CMS; and

(C) If an ASM participant does not respond in accordance with paragraph (b)(3)(ii)(B) of this section, then the ASM performance report is deemed final.

(c) *Process.* If CMS receives a written timely error notice within 30 calendar days of the issuance of the ASM performance report that CMS determines meets the requirements of paragraph (b) of this section, CMS issues an initial determination in writing within 30 calendar days of receipt to either confirm that there was an error in the calculation or verify that the calculation is correct. CMS reserves the right to extend the time for providing its initial final determination upon written notice to the ASM participant.

(d) *Reconsideration request.* An ASM participant who wishes to dispute an initial determination made in accordance with paragraph (c) may invoke the reconsideration review process pursuant to § 512.190.

§ 512.760 Data sharing with ASM participants.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), (e) and (f) of this section and certain aggregate data as described in paragraph (d) of this section with ASM participants regarding ASM beneficiaries and performance under the model.

(b) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with ASM participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraphs (b)(5)(i) and (b)(5)(ii) of this section for ASM participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their patients who are ASM beneficiaries.

(2) An ASM participant that wishes to receive beneficiary-identifiable data for its ASM beneficiaries must do all of the following:

(i) Submit a formal request for the data, on at least an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that—

(A) The ASM participant is requesting this beneficiary-identifiable data as part of a covered entity, as defined at 45 CFR 160.103;

(B) The ASM participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the ASM participant to conduct activities described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501; and

(C) The ASM participant's use of beneficiary-identifiable data is limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all ASM beneficiaries under the care of the ASM participant, and that these data are not to be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) To the extent practicable, limit the request to ASM beneficiaries—

(A) Whose claims were used to determine the requesting ASM participant's eligibility for ASM participation or to whom the requesting ASM participant provided care during an applicable ASM performance year; and

(B) Who requested to restrict having their claims data shared with the ASM participant as provided in paragraph (f)(1) of this section, and whose request was approved.

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (e)(1) of this section.

(3) CMS shares beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's activities, including but not limited to non-ASM participant parties in collaborative care arrangements with ASM participants, comply with all appliable laws addressing the appropriate use of data and the confidentiality and privacy of individually identifiable health information and the terms of the data sharing agreement described in paragraph (e)(1) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data includes, when available, the following information:

(i) Unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data used to determine ASM participant eligibility for an applicable ASM performance year; and

(ii) Unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data for ASM beneficiaries who trigger an applicable EBCM episode with the ASM participant during the applicable ASM performance year.

(c) *Minimum necessary data.* The ASM participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary to accomplish the permitted use of the data. The minimum necessary Medicare Parts A, B, and D data elements may include, but are not limited to the following:

(1) Medicare beneficiary identifier (ID).

(2) Procedure code.

(3) Sex or Gender.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) *Aggregated data feedback.* CMS shares aggregated data on one or more select indicators of the ASM participant's performance, de-identified in accordance with 45 CFR 164.514(b), in a form and manner to be specified by CMS, when available, with ASM participants.

(e) *ASM data sharing agreement.*

(1) To retrieve the beneficiary-identifiable data specified in paragraphs (b) and (c) of this section, the ASM participant must complete and submit, on at least an annual basis, a signed ASM data sharing agreement, to be provided in a form and manner and by a date specified by CMS, under which the ASM participant agrees, at a minimum to do all of the following:

(i) Comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations, including but not limited to 45 CFR part 164, subparts A and E, and the requirements of ASM set forth in this part.

(ii) Comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the ASM data sharing agreements.

(iii) Contractually bind any and all downstream recipients of this beneficiary-identifiable data, such as other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including those that meet the definition of a business associate as defined at 45 CFR 160.103 and non-ASM participant parties to collaborative care arrangements described at § 512.771, to the same terms and conditions to which the ASM participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's or non-ASM participant parties' receipt of the beneficiary-identifiable data obtained by the ASM participant.

(iv) That if the ASM participant or any downstream recipient misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may do any or all of the following:

(A) Deem the ASM participant ineligible to obtain the beneficiary-identifiable data under paragraph (b) of this section for any amount of time.

(B) Subject the ASM participant to additional sanctions and penalties available under applicable law.

(v) An ASM participant must comply with all applicable laws and the terms of the data sharing agreement to obtain beneficiary-identifiable data.

(2) CMS shares beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including business associates as defined at 45 CFR 160.103 of the ASM participant and non-ASM participant parties to collaborative care arrangements described at § 512.771, comply with all relevant laws governing the use of data and the privacy and security of individually identifiable health information and the terms of the data sharing agreement described in paragraph (e)(1) of this section.

(f) *Request to restrict data sharing.*

(1) ASM participants must provide ASM beneficiaries the opportunity to request restriction of claims data sharing in accordance with 45 CFR 164.522.

(2) The opportunity to request restrictions of claims data shared with an ASM participant under paragraph (f)(1) of this section does not apply to the aggregate de-identified data CMS provides to ASM participants under paragraph (d) of this section.

(g) *Data custodian.* An ASM participant must designate and provide the contact information for, in a form and manner identified by CMS, a data custodian who is responsible for ensuring compliance with privacy and security requirements, including all applicable laws and terms of the ASM data sharing agreement, and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

§ 512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) *Application of the CMS-sponsored Model Arrangements Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) is available to protect remuneration furnished in the form of collaborative care arrangements that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.771.

(b) *Application of the CMS-sponsored Model Patient Incentives Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect remuneration furnished in ASM in the form of ASM beneficiary engagement incentives that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.770.

§ 512.770 ASM beneficiary incentives.

(a) *ASM beneficiary incentives.* ASM participants may choose to provide in-kind patient engagement incentives, including but not limited to items of technology or services, to ASM beneficiaries, subject to the following conditions:

(1) *Provision of incentive.*

(i) The incentive must be provided directly by the ASM participant or by an agent of the ASM participant under the ASM participant's direction and control to an ASM beneficiary who is an established patient of the ASM participant.

(ii) The ASM participant must be solely responsible for any costs associated with the provision of the incentive, including but not limited to, the retail value of the item or services offered as the ASM beneficiary incentive.

(2) The item or service provided must be reasonably connected to medical care provided by the ASM participant to an ASM beneficiary for an ASM targeted chronic condition.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an ASM beneficiary by engaging the ASM beneficiary in better managing an ASM targeted chronic condition.

(4) The item or service must not be tied to the receipt of items or services outside the services furnished by the ASM participant to the ASM beneficiary.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that an ASM beneficiary may be made aware of the availability of the items or services at the time the ASM beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.

(8) The totality of items or services, including technology as described at paragraph (b) of this section, provided to an ASM beneficiary may not exceed $1,000 in retail value for any one ASM beneficiary.

(b) *Technology provided to an ASM beneficiary.* ASM beneficiary incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a ASM beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (d) of this section, for an ASM beneficiary.

(2) Items of technology exceeding $75 in retail value must—

(i) Remain the property of the ASM participant; and

(ii) Be retrieved from the ASM beneficiary—

(A) Upon the end of their care relationship with the ASM participant, with documentation of the ultimate date of retrieval. The ASM participant must document all retrieval attempts. In cases when the item of technology is not able to be retrieved, the ASM participant must determine why the item was not retrievable. If it was determined that the item was misappropriated, then the ASM participant must take steps to prevent future beneficiary incentives for that ASM beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology is deemed to meet the retrieval requirement; or

(B) If the provided technology breaks or is otherwise rendered unusable for its intended purposes, with documentation of the ultimate date of retrieval. The ASM participant may replace the unusable unit with the same or similar

technology, to the extent practicable, that meets the requirements of paragraphs (a) and (b) of this section.

(c) *Documentation of ASM beneficiary incentives.* In addition to requirements at § 512.135 of this part ASM participants must do all of the following:

(1) Maintain documentation of items and services furnished as beneficiary incentives that exceed $75 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the ASM beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(2)(ii) of this section.

(4) The ASM participant must retain and provide access to the required documentation.

(d) Clinical goals of *ASM.* The following are the clinical goals of ASM, which may be advanced through ASM beneficiary incentives:

(1) Promoting preventive care through improved management of ASM targeted chronic conditions.

(2) Empowering patients to actively participate and be accountable for quality and whole health outcomes.

(3) Facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

§ 512.771 Collaborative care arrangements.

(a) *General.* Collaborative care arrangements must meet all of the following:

(1) Be in writing, signed by both parties, and contain the effective date of the arrangement.

(2) Be exclusively between the ASM participant and the primary care practice with whom the ASM participant shares at least one established patient who is an ASM beneficiary.

(3) The collaborative care arrangement must be entered into for the purpose of either of the following:

(i) Furthering the ASM participant's performance in the improvement activities ASM performance category at § 512.735.

(ii) Advancing the clinical goals of ASM as described in paragraph (b) of this section.

(4) Participation in a collaborative care arrangement must be voluntary and without penalty for nonparticipation.

(5) Both parties to the collaborative care arrangement must comply with all applicable statutes, regulations, and guidance, including without limitation the following:

(i) Federal criminal laws.

(ii) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(iii) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(iv) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(v) The physician self-referral law (42 U.S.C. 1395nn).

(6) The opportunity to enter into a collaborative care arrangement, and the amount of any payment or other remuneration under a collaborative care arrangement, must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the collaborative care arrangement or any other person.

(7) Any payment or other remuneration between the parties set forth in a collaborative care arrangement must not exceed fair market value and must be determined in accordance with a methodology that is solely based on the purposes identified at paragraphs (b)(2)(i) and (ii) of this section.

(8) Any payment or other remuneration set forth in the collaborative care arrangement must be solely between the parties to the arrangements. Any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.

(9) Both parties to the collaborative care arrangement must retain the ability to make decisions in the best interests of ASM beneficiaries, including the selection of clinicians, devices, supplies, and treatments.

(10) The collaborative care arrangement must not do either of the following:

(i) Induce any party to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(11) ASM participants must maintain contemporaneous documentation, in accordance with § 512.135, regarding all collaborative care arrangements entered into, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any payments between the parties.

(iii) A description of the methodology and accounting formula for determining the amount of any payments between the parties.

(12) The collaborative care arrangement must stipulate that any non-ASM participant party is considered a downstream recipient for CMS data sharing purposes, and must require the non-ASM participant party to comply with applicable data sharing requirements at § 512.760.

(13) Any non-ASM participant party to a collaborative care arrangement must be a downstream participant subject to the standard provisions for Innovation Center models specified in subpart A of this part 512.

(b) *Clinical goals of ASM.* The following are the clinical goals of ASM, which may be advanced through collaborative care arrangements:

(1) Promoting preventive care through improved management of ASM targeted chronic conditions.

(2) Empowering patients to actively participate and be accountable for quality and whole health outcomes.

(3) Facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

§ 512.775 Medicare program waivers.

(a) *Medicare payment waivers.* Unless otherwise specified in § 512.710(a)(2), CMS waives the requirements of section 1848(q) of the Act, and its implementing regulations, for an ASM participant for each ASM performance year that the ASM participant meets the ASM eligibility criteria set forth in § 512.710(b)(1).

(b) *Waiver of certain telehealth requirements.*

(1) *Waiver of the geographic site requirements.* Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for ASM participants and ASM beneficiaries solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are medically appropriate for treatment of an ASM targeted chronic condition.

(2) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)I(ii)(I) through (VIII) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's

home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are medically appropriate for treatment of an ASM targeted chronic condition.

(3) *Waiver of selected payment provisions.* CMS waives payment requirements as follows:

(i) Under section 1834(m)(2)(A) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(ii) Under section 1834(m)(2)(B) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to ASM.

(4) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

§ 512.780 Extreme and uncontrollable circumstances.

(a) *General rule.* Except as specified in paragraph (b) of this section, CMS—

(1) Applies determinations made under the Quality Payment Program for whether an extreme and uncontrollable circumstance has occurred and the affected area during the ASM performance year; and

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred.

(b) *Additional criteria.*

(1) CMS has sole discretion to determine, based on information known to the agency prior to the beginning of the relevant ASM payment year, that data for an ASM participant are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents, including third-party intermediaries.

(2) CMS notifies ASM participants of the following:

(i) Its determination that the circumstances described at paragraph (b)(1) of this section exist; and

(ii) The impact of the circumstances described in paragraph (b)(1) of this section upon scoring methodology for affected ASM participants in a form and manner determined by CMS.

(c) *Impact on final scores.*

(1) Except as described in paragraph (c)(2) of this section, an ASM participant who CMS identified as having been affected by a circumstance described in paragraphs (a) or (b) of this section is exempt from meeting data submission requirements identified at § 512.720 and does not receive a final score, resulting in a neutral payment adjustment for the corresponding ASM payment year.

(2) In the event that an ASM participant who CMS identified as having been affected by a circumstance described in paragraph (a) or (b) of this section submits data in accordance with the data submission requirements at § 512.720, CMS assigns the ASM participant a final score using the methodology described at § 512.745 for the applicable ASM performance year.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

Note: The following Appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: MIPS QUALITY MEASURES

Note: Except as otherwise noted in this proposed rule, previously finalized measures and specialty measure sets will continue to apply for the CY 2026 performance period/2028 MIPS payment year and future years. Previously finalized measures and specialty sets are in the CY 2017 through CY 2025 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, and 89 FR 98599 through 98957. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a Consensus-Based Entity (CBE) are shown in Table A of this Appendix as follows: CBE #/eCQM CBE #.

Table Group A: New MIPS Quality Measures Proposed for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

A.1. Patient Reported Falls and Plan of Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients (or caregivers as appropriate) with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who reported a fall occurred and those that fell had a plan of care for falls documented at every visit.
Measure Steward:	American Academy of Neurology
Numerator:	Patients (or caregivers as appropriate) that reported a fall occurred since the last visit and those that fell had a plan of care for falls documented at every visit.
Denominator:	Patients with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke.
Exclusions:	None
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We are proposing this process measure because it addresses patient safety in an at-risk population by ensuring patients with an active diagnosis of a neurological disorder are screened for falls and have a falls plan of care established. Studies that focus on the rate of falls for common neurological conditions indicate falls are an issue for neurology patients with symptomology that affects movement and balance, necessitating the need to ensure these patients are screened for falls and an appropriate plan of care is established. According to the World Health Organization (WHO), falls are the second leading cause of mortality worldwide.[437] [438] Studies have revealed that patients with neurodegenerative conditions like dementia or cognitive impairment have a 2–8-fold higher chance of falls when compared to those with normal cognition.[439] [440] [441] Additionally, patients with Parkinson's disease (PD) have a five times higher risk of fall-related injuries.[442] [443] Fall incidence is reported 2–4 times higher in patients with neurological disorders than in healthy subjects of similar age, and 46 percent of neurological patients reveal having had one or more falls per year.[444] [445] [446] [447] This measure is predicated on evidence-based clinical guidelines that recommend exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at an increased risk for falls.[448] The measure would enhance compliance with the clinical guidelines by incentivizing clinicians to assess falls and develop an appropriate care plan to help reduce fall incidence, thereby improving patient safety and outcomes. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee recommended this measure, which has been fully developed and tested at the clinician level with high reliability based upon signal-to-noise scores and adequate face validity. Testing of measure performance indicated a gap in care, with a median performance rate of 89 percent, which allows room for improvement among clinicians treating this patient population. This measure was previously available in MIPS as a QCDR measure (AAN34), which was in the previously finalized Neurodegenerative Conditions MVP, and substantiates the feasibility for implementation in MIPS. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure could be added to the Quality Care for Patients with Neurologic Conditions MVP in the future and would fill a current quality measure inventory gap within the neurological clinical topic area. Additionally, it would provide a specialty specific measure for the MIPS Neurology specialty set under Table B.23 of this Appendix. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[437] Manorenj, Sandhya & Shaik, Reshma. (2024). A Neurologist's Perspective of Approach to Falls in the Elderly. *Annals of Movement Disorders, 7*, 3-12. https://doi.org/10.4103/aomd.aomd_56_22.

[438] Masud, T., & Morris, R. O. (2001). Epidemiology of Falls. *Age and Ageing, 30 Suppl 4*, 3–7. https://doi.org/10.1093/ageing/30.suppl_4.3.

[439] See footnote Manorenj et al., 2024.

[440] Delbaere, K., Kochan, N. A. , Close, J. C., Menant, J. C. , Sturnieks, D. L. , Brodaty, H. , Sachdev, P. S. & Lord, S. R. (2012). Mild Cognitive Impairment as a Predictor of Falls in Community-Dwelling Older People. *American Journal of Geriatric Psychiatry, 20*(10), 845-853. https://doi.org/10.1097/JGP.0b013e31824afbc4.

[441] Allan, L. M., Ballard, C. G., Rowan, E. N., & Kenny, R. A. (2009). Incidence and Prediction of Falls in Dementia: A Prospective Study in Older People. *PloS One*, *4*(5), e5521. https://doi.org/10.1371/journal.pone.0005521.

[442] See footnote Manorenj et al., 2024.

[443] Pelicioni, P. H. S., Menant, J. C., Latt, M. D., & Lord, S. R. (2019). Falls in Parkinson's Disease Subtypes: Risk Factors, Locations and Circumstances. *International Journal of Environmental Research and Public Health*, *16*(12), 2216. https://doi.org/10.3390/ijerph16122216.

[444] Ehrhardt, A., Hostettler, P., Widmer, L., Reuter, K., Petersen, J. A., Straumann, D., & Filli, L. (2020). Fall-Related Functional Impairments in Patients with Neurological Gait Disorder. *Scientific Reports*, *10*(1), 21120. https://doi.org/10.1038/s41598-020-77973-4.

[445] Stolze, H., Klebe, S., Zechlin, C., Baecker, C., Friege, L., & Deuschl, G. (2004). Falls in Frequent Neurological Diseases--Prevalence, Risk Factors and Aetiology. *Journal of Neurology*, *251*(1), 79–84. https://doi.org/10.1007/s00415-004-0276-8.

[446] Xu, T., Clemson, L., O'Loughlin, K., Lannin, N. A., Dean, C., & Koh, G. (2018). Risk Factors for Falls in Community Stroke Survivors: A Systematic Review and Meta-Analysis. *Archives of Physical Medicine and Rehabilitation*, *99*(3), 563–573.e5. https://doi.org/10.1016/j.apmr.2017.06.032.

A.2. Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)[449]

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The number of prevalent dialysis patients in a practitioner group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1 - "Patients who were on dialysis and had documentation of status at the end of the year." Numerator 2 - "The ratio of the observed number of waitlist events in a practitioner group to the model-based expected number of waitlist events."
Denominator:	Denominator 1 - "Patients age less than 75 years who are on dialysis during the performance period prior." Denominator 2 - "The denominator for the Prevalent Standardized Waitlist Ratio (PSWR) is the total number of patients on dialysis under the age of 75 in the practitioner group according to each patient's treatment history each year."
Exclusions:	Patients admitted to a skilled nursing facility (SNF) during the period of evaluation. Patients in hospice in the year before or during the period of evaluation. Patients with a diagnosis for dementia in the year before or during the period of evaluation. The noted exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data. Patients who were attributed to dialysis practitioner groups with fewer than 11 patients or 2 expected events are not excluded from the measure. If a provider cannot be matched to a TIN, patients will be grouped into a separate 'null' TIN and still included in the models but are not summarized to any valid individual TINs. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[447] Homann, B., Plaschg, A., Grundner, M., Haubenhofer, A., Griedl, T., Ivanic, G., Hofer, E., Fazekas, F., & Homann, C. N. (2013). The Impact of Neurological Disorders on the Risk for Falls in the Community Dwelling Elderly: A Case-Controlled Study. *BMJ Open, 3*(11), e003367. https://doi.org/10.1136/bmjopen-2013-003367.

[448] US Preventive Services Task Force, Grossman, D. C., Curry, S. J., Owens, D. K., Barry, M. J., Caughey, A. B., Davidson, K. W., Doubeni, C. A., Epling, J. W., Jr, Kemper, A. R., Krist, A. H., Kubik, M., Landefeld, S., Mangione, C. M., Pignone, M., Silverstein, M., Simon, M. A., & Tseng, C. W. (2018). Interventions to Prevent Falls in Community-Dwelling Older Adults: US Preventive Services Task Force Recommendation Statement. *JAMA*, *319*(16), 1696–1704. https://doi.org/10.1001/jama.2018.3097.

[449] The measure title was revised from the MERIT submission to include 'kidney transplant' for clarity.

Rationale:	Starting with the CY 2025 performance period/2027 MIPS payment year, we finalized measure Q510: First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR) and measure Q511: Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW) (89 FR 98616 through 98623). Both measures track dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Measure Q510 tracks the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant for patients within the first year after dialysis initiation, with the objective of providing access to kidney transplant in a timely manner within that first year after starting dialysis, which is associated with improved outcomes. Measure Q511 tracks the number of patients on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant for all dialysis patients in a dialysis practitioner or group practice to encourage ongoing attention to transplantation as a treatment option. Measure Q511 also assesses the waitlist each month for active status of patients on the kidney transplant waitlist, which encourages ongoing optimization of health to maintain active status and ensure patients are ready to accept a kidney when a match becomes available. Measure Q511 works in tandem with measure Q510 to assess both initial and on-going care. We are proposing the PSWR process measure for the CY 2026 performance period/2028 MIPS payment year because it builds on the previous measures (Q510 and Q511) by assessing new placement on the kidney or kidney-pancreas transplant waitlist or receipt of a living donor transplant for all dialysis patients. End-stage renal disease (ESRD) affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures.[450] While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant.[451] This measure assesses whether patients who are on dialysis and found to be an expected waitlist event based upon the Cox model, were placed on either the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicates a performance gap for a process that can be directly linked to improved patient outcomes. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners followed by subsequent patient transplant wait listing. For example, clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the State of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[452] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[453] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation based on reporting on the Medical Evidence Form 2728 (*https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf*) and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[454] Approximately 30 percent of patients were uninformed about kidney transplantation, which was associated with half the rate of access to transplantation compared to patients who were informed.[455] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients. The provision of such information was associated with a nearly threefold increase in the likelihood of waitlisting.[456] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist, or receipt of a living donor transplant for patients on dialysis, with the objective of improving their overall health. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Waitlisting is a direct step in the process of transplantation which drives quality by progressing patients towards the goal of transplantation and better health outcomes. A measure focusing on the outcome of waitlisting is appropriate for several reasons. First, in preparing patients for suitability for waitlisting, dialysis practitioners optimize their health and functional status, improving their overall health state. Second, waitlisting is a necessary step prior to potential receipt of a deceased donor kidney transplant (receipt of a living donor kidney is also accounted for in the measure), which is known to be beneficial for survival and quality of life.[457] Third, dialysis practitioners exert substantial control over the processes that result in waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation and assisting patients with completion of the transplant evaluation process, in order to increase their candidacy for transplant waitlisting. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. Finally, wide regional and facility variations in waitlisting rates highlight substantial room for improvement for this measure.[458] [459] [460] [461] Additionally, this measure focuses specifically on the population of prevalent patients

[450] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). (2023). Kidney Disease Statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.
[451] Wouk N. (2021). End-Stage Renal Disease: Medical Management. *American Family Physician*, *104*(5), 493–499. https://www.aafp.org/pubs/afp/issues/2021/1100/p493.pdf.
[452] Paul, S., Plantinga, L. C., Pastan, S. O., Gander, J. C., Mohan, S., & Patzer, R. E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. *Clinical Journal of the American Society of Nephrology: CJASN*, *13*(2), 282–289. https://doi.org/10.2215/CJN.04690417.
[453] See footnote Paul et al., 2018.
[454] Kucirka, L. M., Grams, M. E., Balhara, K. S., Jaar, B. G., & Segev, D. L. (2012). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *12*(2), 351–357. https://doi.org/10.1111/j.1600-6143.2011.03865.x.
[455] See footnote Kucirka et al., 2012.
[456] Salter, M. L., Orandi, B., McAdams-DeMarco, M. A., Law, A., Meoni, L. A., Jaar, B. G., ... & Segev, D. L. (2014). Patient-and Provider-Reported Information about Transplantation and Subsequent Waitlisting. *Journal of the American Society of Nephrology, 25*(12), 2871-2877. https://doi.org/10.1681/ASN.2013121298.
[457] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *11*(10), 2093–2109. https://doi.org/10.1111/j.1600-6143.2011.03686.x.
[458] Ashby, V. B., Kalbfleisch, J. D., Wolfe, R. A., Lin, M. J., Port, F. K., & Leichtman, A. B. (2007). Geographic Variability in Access to Primary Kidney Transplantation in the United States, 1996-2005. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *7*(5 Pt 2), 1412–1423. https://doi.org/10.1111/j.1600-6143.2007.01785.x.
[459] Satayathum, S., Pisoni, R. L., McCullough, K. P., Merion, R. M., Wikström, B., Levin, N., Chen, K., Wolfe, R. A., Goodkin, D. A., Piera, L., Asano, Y., Kurokawa, K., Fukuhara, S., Held, P. J., & Port, F. K. (2005). Kidney Transplantation and Wait-listing Rates from the International Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney International*, *68*(1), 330–337. https://doi.org/10.1111/j.1523-1755.2005.00412.x.
[460] Patzer, R. E., Plantinga, L., Krisher, J., & Pastan, S. O. (2014). Dialysis Facility and Network Factors Associated with Low Kidney Transplantation Rates among United States Dialysis Facilities. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *14*(7), 1562–1572. https://doi.org/10.1111/ajt.12749.
[461] Melanson, T. A., Gander, J. C., Rossi, A., Adler, J. T., & Patzer, R. E. (2021). Variation in Waitlisting Rates at the Dialysis Facility Level in the Context of Goals for Improving Kidney Health in the United States. *Kidney International Reports*, *6*(7), 1965–1968. https://doi.org/10.1016/j.ekir.2021.04.031.

Category	Description
	on dialysis, examining for the occurrence of new waitlisting or living donor transplant events. This would evaluate and encourage rapid attention from dialysis practitioner groups to the optimization of health of patients to ensure early access to the waitlist, which has been demonstrated to be particularly beneficial.[462] [463] [464] [465] Given that many patients may not be ready for transplant candidacy immediately following initiation of dialysis, this measure encourages ongoing attention to transplant candidacy throughout a patient's time on dialysis. The PRMR did not reach consensus for this measure with concerns regarding exclusions for patients opting out of waitlisting and attribution. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggest a significant positive correlation between the clinician activities and the addition of patients to a transplant waitlist, which are necessary for patients to receive the improved outcomes associated with kidney transplants. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf*.

[462] Meier-Kriesche, H. U., & Kaplan, B. (2002). Waiting Time on Dialysis as the Strongest Modifiable Risk Factor for Renal Transplant Outcomes: A Paired Donor Kidney Analysis. *Transplantation*, *74*(10), 1377–1381. https://doi.org/10.1097/00007890-200211270-00005.

[463] Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., Leichtman, A. B., & Kaplan, B. (2000). Effect of Waiting Time on Renal Transplant Outcome. *Kidney International*, *58*(3), 1311–1317. https://doi.org/10.1046/j.1523-1755.2000.00287.x.

[464] Schold, J. D., Huml, A. M., Poggio, E. D., Sedor, J. R., Husain, S. A., King, K. L., & Mohan, S. (2021). Patients with High Priority for Kidney Transplant Who Are Not Given Expedited Placement on the Transplant Waiting List Represent Lost Opportunities. *Journal of the American Society of Nephrology: JASN*, *32*(7), 1733–1746. https://doi.org/10.1681/ASN.2020081146.

[465] Schold, J. D., & Meier-Kriesche, H. U. (2006). Which Renal Transplant Candidates Should Accept Marginal Kidneys in Exchange for a Shorter Waiting Time on Dialysis? *Clinical Journal of the American Society of Nephrology: CJASN*, *1*(3), 532–538. https://doi.org/10.2215/CJN.01130905.

A.3. Diagnostic Delay of Venous Thromboembolism in Primary Care

Category	Description
CBE # / eCQM CBE #:	N/A / 3749e
Quality #:	TBD
Description:	Percentage of episodes for patients 18 years of age and older with documented Venous Thromboembolism (VTE) symptoms in the primary care setting and who had a diagnosis of VTE that occurs >24 hours and within 30 days following the index primary care visit where symptoms for the VTE were first present.
Measure Steward:	Brigham and Women's Hospital
Numerator:	All qualified VTE encounters in which the VTE diagnosis occurs greater than 24 hours and within 30 days following the index PCP visit.
Denominator:	All Qualified VTE Encounters in which the patient was aged 18 or older at the start of the Qualified VTE Encounter.
Exclusions:	Exclude qualified VTE encounter with a hospice care service documented within previous 90 Days Exclude qualified VTE encounter with a palliative care service documented within previous 90 Days Exclude qualified VTE encounter with another qualified VTE encounter documented within previous 6 months
Measure Type:	Intermediate Outcome
High Priority Measure:	Yes
Collection Type:	eCQM
Measure-Specific Case Minimum/Performance Period:	This eCQM is intended to be reported by integrated health systems with access to both ambulatory and inpatient documentation.

Category	Description
Rationale:	We are proposing this intermediate outcome measure because measuring and reporting delayed VTE diagnosis rates would inform health care providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by patients. This measure has the potential to lower health care costs associated with VTE by providing ongoing patient outcome data that can be used to improve VTE diagnostic performance and to reduce complications associated with delayed diagnosis and treatment. This eCQM is intended to be reported by integrated health systems with access to both ambulatory and inpatient documentation. VTE is a serious, preventable public health problem affecting approximately 300,000–600,000 individuals in the U.S. each year.[466] Without timely and adequate treatment, the likelihood of significant complications increases.[467] VTE (pulmonary embolism and deep vein thrombosis) has a 30-day mortality rate as high as 23 percent[468] [469] and because signs and symptoms of VTE can be non-specific, timely diagnosis of VTE is difficult, leading to missed VTE diagnosis. Two studies of autopsies in large hospitals found that 9-12 percent had VTE, and 84-91 percent were undiagnosed at the time of death.[470] [471] In addition to concerns over patient safety, VTE events are costly to healthcare systems. One study estimated that costs associated with VTE complications ranged from $426-$41,133 across literature, imposing a financial burden on healthcare systems.[472] Timely diagnosis of VTE events may prevent resulting adverse events from occurring, with the potential to save healthcare costs and reduce the mortality rate. Empirical evidence supports a marked difference in mortality between patients who receive immediate diagnosis and treatment of VTE and those who are left undiagnosed.[473] VTEs are associated with a high 30-day mortality rate[474] and delays in VTE diagnosis are associated with higher rates of complications and an increased risk of mortality.[475] Earlier diagnosis of VTE may reduce the morbidity and mortality associated with the dangerous condition[476] [477] and could promote positive patient outcomes. This evidence supports this measure by highlighting the increased morbidity and mortality associated with the delayed diagnosis of VTE, which affirms the potential value of this measure to reduce any delay in VTE diagnosis. This measure could be added to the Value in Primary Care MVP in the future and could be a potential addition to the MIPS Family Medicine, Geriatrics, and Internal Medicine specialty sets under Tables B.13, B.16, and B.19 of this Appendix. The PRMR Clinician Recommendation Committee recommends this measure with the condition that implementation burdens are addressed for facilities with less sophisticated EHRs. This measure was endorsed by the CBE as CBE 3749e. While concerns were discussed regarding EHR implementation, we have determined the measure is feasible for implementation in MIPS as an eCQM by integrated health systems, and this measure is an important clinical topic for primary care clinicians to facilitate timely diagnosis of VTE. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf*.

[466] Beckman, M. G., Hooper, W. C., Critchley, S. E., & Ortel, T. L. (2010). Venous Thromboembolism: A Public Health Concern. *American Journal of Preventive Medicine*, *38*(4 Suppl), S495–S501. https://doi.org/10.1016/j.amepre.2009.12.017.

[467] See footnote Beckman et al., 2010.

[468] Tagalakis, V., Patenaude, V., Kahn, S. R., & Suissa, S. (2013). Incidence of and Mortality from Venous Thromboembolism in a Real-World Population: The Q-VTE Study Cohort. *The American Journal of Medicine*, *126*(9), 832.e13–832.e8.32E21. https://doi.org/10.1016/j.amjmed.2013.02.024.

[469] Nijkeuter, M., Söhne, M., Tick, L. W., Kamphuisen, P. W., Kramer, M. H., Laterveer, L., van Houten, A. A., Kruip, M. J., Leebeek, F. W., Büller, H. R., Huisman, M. V., & Christopher Study Investigators (2007). The Natural Course of Hemodynamically Stable Pulmonary Embolism: Clinical Outcome and Risk Factors in a Large Prospective Cohort Study. *Chest*, *131*(2), 517–523. https://doi.org/10.1378/chest.05-2799.

[470] Karwinski, B., & Svendsen, E. (1989). Comparison of Clinical and Postmortem Diagnosis of Pulmonary Embolism. *Journal of Clinical Pathology*, *42*(2), 135–139. https://doi.org/10.1136/jcp.42.2.135.

[471] Carvalho Bricola, S. A., Paiva, E. F., Lichtenstein, A., Gianini, R. J., Duarte, J. G., Shinjo, S. K., Eluf-Neto, J., & Arruda Martins, M. (2013). Fatal Pulmonary Embolism in Hospitalized Patients: A Large Autopsy-based Matched Case-control Study. *Clinics (Sao Paulo, Brazil)*, *68*(5), 679–685. https://doi.org/10.6061/clinics/2013(05)16.

[472] Ruppert, A., Steinle, T., & Lees, M. (2011). Economic Burden of Venous Thromboembolism: A Systematic Review. *Journal of Medical Economics*, *14*(1), 65–74. https://doi.org/10.3111/13696998.2010.546465.

[473] Liederman, Z., Chan, N., & Bhagirath, V. (2020). Current Challenges in Diagnosis of Venous Thromboembolism. *Journal of Clinical Medicine*, *9*(11), 3509. https://doi.org/10.3390/jcm9113509.

[474] See footnote Tagalakis et al., 2013.

A.4. Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of adult patients with risk factors for type 2 diabetes who are due for glycemic screening for whom the screening process was completed during the measurement period.
Measure Steward:	American Medical Association
Numerator:	Patients who had a glycemic screening test performed during the measurement period.
Denominator:	All patients with at least two outpatient clinical encounters or one preventive clinical encounter during the measurement period who have the following risk factors for type 2 diabetes: - Most recent BMI ≥25 kg/m2 (BMI ≥23 kg/m2 for Asian patients) during measurement period, AND - Age 35-70 at start of measurement period.
Exclusions:	- Patient's pregnancy overlaps measurement period. - Patient with diagnosis of advanced illness or limited life expectancy overlaps measurement period. - Patient with diagnosis of diabetes overlaps 2-year look-back period. - Patient with diagnosis of prediabetes overlaps 2-year look-back period. - Patient with glycemic screening performed during 2-year look-back period.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	eCQM
Measure-Specific Case Minimum/Performance Period:	N/A

[475] Klok, F. A., Barco, S., Konstantinides, S. V., Dartevelle, P., Fadel, E., Jenkins, D., Kim, N. H., Madani, M., Matsubara, H., Mayer, E., Pepke-Zaba, J., Delcroix, M., & Lang, I. M. (2018). Determinants of Diagnostic Delay in Chronic Thromboembolic Pulmonary Hypertension: Results from the European CTEPH Registry. *The European Respiratory Journal*, *52*(6), 1801687. https://doi.org/10.1183/13993003.01687-2018.

[476] Dalen J. E. (2002). Pulmonary Embolism: What Have We Learned Since Virchow? Natural History, Pathophysiology, and Diagnosis. *Chest*, *122*(4), 1440–1456. https://doi.org/10.1378/chest.122.4.1440.

[477] Ozsu, S., Oztuna, F., Bulbul, Y., Topbas, M., Ozlu, T., Kosucu, P., & Ozsu, A. (2011). The Role of Risk Factors in Delayed Diagnosis of Pulmonary Embolism. *The American Journal of Emergency Medicine, 29*(1), 26–32. https://doi.org/10.1016/j.ajem.2009.07.005.

Category	Description
Rationale:	We are proposing this eCQM because it captures a critical process to identify patients with prediabetes who may benefit from interventions to prevent type 2 diabetes and patients with undiagnosed type 2 diabetes. Regular glycemic screening is a critical first step to identifying patients with prediabetes and helping patients avoid the disability and costs associated with progression to type 2 diabetes. The Centers for Disease Control and Prevention (CDC) estimates that approximately 98 million American adults have prediabetes.[478] They note that more than 80 percent of adults with prediabetes are not aware that they have the condition.[479] This measure aligns with current United States Preventive Services Task Force (USPSTF) clinical guidelines for pre-diabetes screening, which recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who are overweight or have obesity.[480] An estimated 13 percent of all U.S. adults (18 years or older) have diabetes, and 34.5 percent meet criteria for prediabetes. Diabetes is the leading cause of kidney failure and new cases of blindness among adults in the U.S. It is also associated with increased risks of cardiovascular disease, nonalcoholic fatty liver disease, and nonalcoholic steatohepatitis and was estimated to be the seventh leading cause of death in the U.S. in 2017. Screening asymptomatic adults for prediabetes and type 2 diabetes may allow earlier detection, diagnosis, and treatment, with the goal of improving health outcomes.[481] This fully tested and developed measure would fill a gap in MIPS, which does not have any related measures that examine the rate of screening for abnormal glucose metabolism in patients at risk for diabetes. This measure would ensure timely identification of patients with prediabetes for early intervention and may be a potential future addition to the Value in Primary Care MVP. The PRMR Clinician Recommendation Committee recommended this measure. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As mentioned above, this measure aligns with USPSTF evidence-based clinical guidelines.[482] The measure was found during the MERIT submission process to be feasible as an eCQM at the clinician level with high levels of agreement for data element testing of a similar non-MIPS eCQM. Additionally, measure testing demonstrates adequate measure score reliability, high face validity, and median performance scores that indicate significant room for improvement among clinicians. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf*.

[478] Centers for Disease Control and Prevention (CDC). (2022). National Diabetes Statistics Report website. https://www.cdc.gov/diabetes/php/data-research/index.html#:~:text=Prevalence%20of%20prediabetes%20among%20adults%201%20An%20estimated,professional%20that%20they%20had%20this%20condition%20%28Table%204%29.

[479] See footnote CDC, 2022.

[480] US Preventive Services Task Force (USPSTF), Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., Donahue, K. E., Doubeni, C. A., Krist, A. H., Kubik, M., Li, L., Ogedegbe, G., Owens, D. K., Pbert, L., Silverstein, M., Stevermer, J., Tseng, C. W., & Wong, J. B. (2021). Screening for Prediabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement. *JAMA*, *326*(8), 736–743. https://doi.org/10.1001/jama.2021.12531.

[481] See footnote USPSTF et al., 2021.

[482] See footnote USPSTF et al., 2021.

A.5. Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.
Measure Steward:	American Gastroenterological Association
Numerator:	All patients aged greater than or equal to 18 years at the time of the eligible encounter with an eligible encounter and positive/detectable HCV RNA test result in the denominator identification period who have a subsequent negative/undetectable HCV RNA test result 20 weeks to 12 months after first positive/detectable HCV RNA test result identified in the denominator identification period.
Denominator:	All patients aged >= 18 years with an active Hepatitis C Virus diagnosis at the time of the eligible encounter within the denominator identification period.
Exclusions:	Patients receiving hospice or palliative care or who died during the measurement period.
Measure Type:	Outcome
High Priority Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We are proposing this outcome measure because achieving SVR is the first step toward reducing future HCV morbidity and mortality. Once achieved, SVR is associated with long-term clearance of HCV infection, which is regarded as a virologic "cure," as well as with improved morbidity and mortality. Patients who achieve SVR usually have an improvement in liver histology and clinical outcomes. This measure is supported by American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD-IDSA) HCV Guidance Panel clinical guidelines that strongly recommend universal direct-acting antiviral treatment for all patients with acute or chronic HCV infections.[483] Additional evidence from cohort studies evaluated the association between SVR after antiviral therapy and mortality or complications of chronic HCV infection. SVR was associated with decreased risk for all-cause mortality, liver-related mortality, and other complications of end-stage liver disease versus no SVR.[484] This measure could be added to the Gastroenterology Care and Prevention and Treatment of Infectious Disorders Including Hepatitis and HIV MVPs in the future and would fill a current quality measure inventory gap within the Hepatitis C clinical topic area. In addition, it would provide a specialty specific outcome measure for the MIPS Gastroenterology and Infectious Disease specialty sets under Tables B.14 and B.18 of this Appendix. The PRMR Clinician Recommendation Committee recommended this measure without conditions. Testing was completed at the clinician level with a small sample size due to accessibility to data. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As mentioned above, this measure aligns with AASLD-IDSA HCV Guidance Panel evidence-based clinical guidelines. The measure was found during the MERIT submission process to be feasible at the clinician level and data element testing was completed showing exact data element agreement values of 52 percent, indicating moderate reliability. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[483] Bhattacharya, D., Aronsohn, A., Price, J., Lo Re, V., & AASLD-IDSA HCV Guidance Panel (2023). Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, ciad319. Advance online publication. https://doi.org/10.1093/cid/ciad319.

[484] Chou, R., Dana, T., Fu, R., Zakher, B., Wagner, J., Ramirez, S., Grusing, S., & Jou, J. H. (2020). Screening for Hepatitis C Virus Infection in Adolescents and Adults: A Systematic Review Update for the U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality (US).

Table Group B: Modifications to Previously Finalized Specialty Measure Sets Proposed for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

We are proposing to modify the below previously finalized specialty measure sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). The Indicator column includes a ''high priority type'' in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. Additionally, eCQMs that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE #/eCQM CBE #.

Under § 414.1305, a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related[485] quality measure. Further details of these types of measures may be found in the CMS Measures Management System Hub (*https://mmshub.cms.gov/*).

We request comments on proposed measure additions and/or proposed measure removals under applicable specialty sets in Table Group B of this Appendix. Previously finalized measures that have no substantive changes are not open for comment under this proposed rule.

The following specialty sets are not open for comment as they have no proposed modifications (addition and/or removal tables), and no proposed substantive changes to previously finalized measures for the CY 2026 performance period/2028 MIPS payment year: Electrophysiology Cardiac Specialist, Dentistry, Diagnostic Radiology, and Pathology.

The following specialty sets have no proposed modifications but have proposed substantive changes to previously finalized measures that are open for comment under Table Group D of this Appendix: Hospitalists, Radiation Oncology, and Optometry.

The remaining specialty sets have proposed modifications and are open for comment.

[485] Note that under Section IV.A.4.d.(1)(b) of this proposed rule, the term ''health equity'' is proposed for removal from the definition of a high priority measure.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Allergy/Immunology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS15 6v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	338	CMS31 4v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	CMS11 57v2	eCQM, MIPS CQM	Process	**HIV Annual Retention in Care:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the performance period	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Anesthesiology specialty set.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQM	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQM	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQM	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQM	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ANESTHESIOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	424	N/A	MIPS CQM	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Audiology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	2152/ N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE AUDIOLOGY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Cardiology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS13 5v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS14 5v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS14 4v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title and Description	Measure Steward
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy**: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS16 5v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Inter-mediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS15 6v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQM	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS34 7v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR; •Patients aged 40 to 75 years with a diagnosis of diabetes; OR; •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665/ N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE CARDIOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	322	N/A	MIPS CQM	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set has no proposed changes.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQM	Outcome	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQM	Outcome	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Certified Nurse-Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Certified Nurse Midwife specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
	N/A / N/A	496	N/A	MIPS CQM	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CERTIFIED NURSE MIDWIFE SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE CERTIFIED NURSE MIDWIFE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Chiropractic Medicine specialty set.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE CHIROPRACTIC MEDICINE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Clinical Social Work specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS14 9v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS15 9v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS17 7v14	eCQM	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performanc e Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.7. Clinical Social Work

MEASURES PROPOSED FOR ADDITION TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Clinical Social Work specialty set as we agree with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[486] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[487] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and would promote more universal adoption of best practices to support shared decision making.[488] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as

[486] Frosch, D. L., May, S. G., Rendle, K. A., Tietbohl, C., & Elwyn, G. (2012). Authoritarian Physicians and Patients' Fear of Being Labeled 'Difficult' Among Key Obstacles to Shared Decision Making. Health Affairs (Project Hope), 31(5), 1030–1038. https://doi.org/10.1377/hlthaff.2011.0576.

[487] Teno, J. M., Clarridge, B. R., Casey, V., Welch, L. C., Wetle, T., Shield, R., & Mor, V. (2004). Family Perspectives on End-of-Life Care at the Last Place of Care. JAMA, 291(1), 88–93. https://doi.org/10.1001/jama.291.1.88.

[488] National Consensus Project for Quality Palliative Care. (2018). Clinical Practice Guidelines for Quality Palliative Care, 4th edition. https://www.nationalcoalitionhpc.org/ncp.

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								decreased strain on family members or other caregivers.[489] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CLINICAL SOCIAL WORK SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set has no proposed changes.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	378	CMS 75v14	eCQM	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
	N/A / N/A	379	CMS 74v15	eCQM	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Dermatology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A/ N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	410	N/A	MIPS CQM	Intermediate Outcome	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Outcome)	N/A / N/A	485	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of three or more points at a follow up visit.	American Academy of Dermatology
! (Outcome)	N/A / N/A	486	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	509	N/A	MIPS CQM	Process	**Melanoma: Tracking and Evaluation of Recurrence:** Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II in the past 5 years in which the operating provider examines and/or diagnoses the patient for recurrence of melanoma.	American Academy of Dermatology

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE DERMATOLOGY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set has no proposed changes.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQM	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQM	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3633e, 3662e / N/A	494	CMS1056v3	eCQM	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of patients with CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This measure is not telehealth eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Emergency Medicine specialty set.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069/ N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQM	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
! (Efficiency)	N/A / N/A	416	N/A	MIPS CQM	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE EMERENCY MEDICINE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Endocrinology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS122v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	236	CMS16 5v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS34 7v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
	N/A / N/A	462	CMS64 5v9	eCQM	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS95 1v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ENDOCRINOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Family Medicine specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS1 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS1 35v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0070 / 0070e	007	CMS1 45v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS1 44v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
	N/A / N/A	009	CMS1 28v14	eCQM	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS1 54v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS1 46v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS1 31v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS6 8v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS1 65v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS1 56v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS1 37v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS1 24v14	eCQM	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS1 39v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement /Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS3 14v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS1 59v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS5 0v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS9 0v15	eCQM	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* §	N/A / N/A	394	N/A	MIPS CQM	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age-appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years who have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQM	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS3 49v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS7 71v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS9 51v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.13. Family Medicine

MEASURES PROPOSED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / 3749e	TBD	CMS11 73v1	eCQM	Intermediate Outcome	**Diagnostic Delay of Venous Thromboembolism in Primary Care:** Percentage of episodes for patients 18 years of age and older with documented Venous Thromboembolism (VTE) symptoms in the primary care setting and who had a diagnosis of VTE that occurs >24 hours and within 30 days following the index primary care visit where symptoms for the VTE were first present.	Brigham and Women's Hospital	We are proposing to include this measure in the Family Medicine specialty set as this measure is clinically relevant to this clinician type. Family physicians provide preventive care, diagnose and treat acute and chronic illness, and manage chronic diseases.[490] Venous thromboembolism (VTE) is a serious and preventable health problem that requires timely diagnosis and treatment in order to reduce morbidity and mortality.[491] Due to this specialist's broad scope of care, patients often present to them first with non-specific symptoms prior to being diagnosed.[492] This measure is currently specified for primary care and intended to improve early recognition which can reduce adverse patient outcomes. The measure addresses a gap in MIPS for the treatment of patients with venous thromboembolism, specifically the commonly missed or delayed diagnosis in primary care requiring timely and adequate treatment. Including this measure in this specialty set can potentially improve diagnostic performance leading to a reduction in patient complications, decreased patient mortality and morbidity, and lowered health care costs.[493] Enhancing the family medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of VTE diagnosis and treatment. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[490] The American Academy of Family Physicians (AAFP). Primary Care website. https://www.aafp.org/about/policies/all/primary-care.html#:~:text=Primary%20care%20physicians%20specifically%20are,a%20partner%20in%20health%20care.

[491] See footnote Tagalakis et al., 2013.

[492] See footnote Tagalakis et al., 2013.

[493] See footnote Liederman et al., 2020.

B.13. Family Medicine

MEASURES PROPOSED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	CMS11 54v1	eCQM	Process	**Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes:** Percentage of adult patients with risk factors for type 2 diabetes who are due for glycemic screening for whom the screening process was initiated during the measurement period.	American Medical Association	We are proposing to include this measure in the Family Medicine specialty set as this measure is clinically relevant to this clinician type. Family medicine clinicians are likely the most frequent point of contact for many patients as their scope of care is extensive and inclusive of many different patient populations and conditions. This measure focuses on patients with risk factors for developing type 2 diabetes and enhances early detection and prevention of diabetes. Regular glycemic screening is an important first step to identifying patients with prediabetes and help patients avoid the disability and the cost associated with progression to type 2 diabetes.[494] This measure aligns with national USPSTF guidelines and recommendations of screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity.[495] Nearly 98 million people have prediabetes, but more than 8 in 10 adults don't know they have it[496] reinforcing the importance of identifying patients with prediabetes and identifying patients with undiagnosed type 2 diabetes. Enhancing the family medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of glucose screening in patients at risk for diabetes. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[494] Kushner, P. R., Cavender, M. A., & Mende, C. W. (2022). Role of Primary Care Clinicians in the Management of Patients With Type 2 Diabetes and Cardiorenal Diseases. Clinical Diabetes: A Publication of the American Diabetes Association, 40(4), 401–412. https://doi.org/10.2337/cd21-0119.

[495] See footnote USPSTF et al., 2021.

[496] See footnote CDC, 2022.

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MEASURES PROPOSED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.	American Gastroenterological Association	We are proposing to include this measure in the Family Medicine specialty set as this measure is clinically relevant to this clinician type. Family medicine clinicians are likely the most frequent point of contact for many patients as their scope of care is extensive and inclusive of many different patient populations. Family physicians diagnose and treat acute illness, provide preventive care, and manage chronic illness.[497] Due to their broad scope of care, this specialty may treat patients with active hepatitis C (HCV) and assist in managing the disease. This quality measure aligns with clinical guidelines of the U.S. Preventive Services Task Force (USPSTF) and achieving Sustained Virological Response (SVR) is the first step toward reducing future HCV morbidity and mortality.[498] The American Academy of Family Physicians have advocated for increased management of HCV within primary care along with family medicine residency program directors working over the past 5 years to build capacity for HCV treatment within the specialty by training future generations of family medicine physicians.[499] Enhancing the family medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of proper management of patients with HCV. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	443	N/A	MIPS CQM	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Gastroenterology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	NA / N/A	275	N/A	MIPS CQM	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS22v 14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordinatio n)	0658 / N/A	320	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordinatio n)	N/A / N/A	374	CMS50v 14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQM	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.14. Gastroenterology

MEASURES PROPOSED FOR ADDITION TO THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.		We are proposing to include this measure in the Gastroenterology specialty set as we agree with interested parties this measure is clinically relevant to this specialty type. The measure is stewarded by the American Gastroenterological Association and its addition to this specialty set would be feasible given the high rates that this specialty assesses, treats, and manages diseases that affect the organs in the digestive system, including the liver.[500] Enhancing the gastroenterology related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within this specialty set and its addition would elevate the importance of providing standard care to patients living with the hepatitis C (HCV liver disease.[501] This measure is based on evidenced-based guidance for HCV management and would help ensure patients with HCV are receiving the best possible care, thus improving patient safety, and reducing future HCV morbidity and mortality.[502] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[500] See footnote Bhattacharya et al., 2023.
[501] See footnote Bhattacharya et al., 2023.
[502] See footnote Bhattacharya et al., 2023.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GASTROENTEROLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	185	N/A	MIPS CQM	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed General Surgery specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	354	N/A	MIPS CQM	Outcome	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GENERAL SURGERY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	264	N/A	MIPS CQM	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Geriatrics specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
! (Patient Safety)	0101 / N/A	318	CMS139 v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159 v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Outcome)	N/A / N/A	476	CMS771 v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS951 v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within the 12-month measurement period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We are proposing to include this measure in the Geriatrics specialty set as this measure is clinically relevant to this clinician type. Tobacco use is the leading preventable cause of disease, disability, and death in the U.S. cigarette smoking results in more than 480,000 premature deaths each year and accounts for approximately 1 in every five deaths.[503] There is an increase in smoking-related deaths in people over the age of 60 years, where this population's smoking-related mortality is largely caused by lung cancer.[504] Smoking can also reduce efficacy of vaccines and increase the risk for infections in the older patient population.[505] Older adults who quit smoking experience positive effects on their health such as reduced cognitive decline and better quality of life.[506] Due to the harmful effect tobacco use can have on patients' health, clinicians should engage with their patients to screen for tobacco use and, if positive, provide tobacco cessation counseling annually.[507] This measure was previously included in this specialty set and removed beginning with the CY 2024 performance period/2026 MIPS payment year due to being included as a component of the previously finalized MIPS quality measure 497: Preventive Care and Wellness (composite) making them duplicative. However, we agree with interested parties' feedback that all components of measure Q497 do not apply to this patient population, most

[503] CDC. (2024). Current Cigarette Smoking Among Adults in the United States website. https://www.cdc.gov/tobacco/php/data-statistics/adult-data-cigarettes/index.html.

[504] Godoy, P., Castilla, J., Soldevila, N., Mayoral, J. M., Toledo, D., Martín, V., Astray, J., Egurrola, M., Morales-Suarez-Varela, M., Domínguez, A., & CIBERESP Cases and Controls in Pandemic Influenza Working Group, Spain* (2018). Smoking May Increase the Risk of Influenza Hospitalization and Reduce Influenza Vaccine Effectiveness in the Elderly. *European Journal of Public Health*, *28*(1), 150–155. https://doi.org/10.1093/eurpub/ckx130.

[505] See footnote Godoy et al., 2018.

[506] Kivipelto, M., Mangialasche, F., & Ngandu, T. (2018). Lifestyle Interventions to Prevent Cognitive Impairment, Dementia and Alzheimer Disease. *Nature Reviews. Neurology*, *14*(11), 653–666. https://doi.org/10.1038/s41582-018-0070-3.

[507] See footnote CDC, 2024.

B.16. Geriatrics

MEASURES PROPOSED FOR ADDITION TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								specifically Body Mass Index (BMI). We are proposing to add this component measure to this specialty set due to the importance of the clinical concept to this specialty where the complete composite measure would not be applicable. Enhancing the geriatrics related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of preventive care and screening for tobacco use.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GERIATRICS SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare & Medicaid Services	We are proposing to remove this measure from the Geriatrics specialty set as we agree with interested parties' feedback that the age and sex appropriate preventive screenings included in all the components of this composite measure are not applicable to this patient population. Specifically, we agree with their concern that the parameters within this composite measure's Body Mass Index (BMI) component may not be appropriate for use in older adults.[508] Observational studies suggest that older adults with BMI in the 27-32 range are at lowest risk of adverse outcomes.[509] Additionally, in older adults a higher BMI classification may be associated with lower mortality risks, demonstrating the potential need for age-specific BMI cut-points in older adults.[510]

[508] CDC. Current Cigarette Smoking Among Adults in the United States website. https://www.cdc.gov/tobacco/php/data-statistics/adult-data-cigarettes/index.html.

[509] Javed, A. A., Aljied, R., Allison, D. J., Anderson, L. N., Ma, J., & Raina, P. (2020). Body Mass Index and All-Cause Mortality in Older Adults: A scoping Review of Observational Studies. Obesity Reviews: An Official Journal of the International Association for the Study of Obesity, 21(8), e13035. https://doi.org/10.1111/obr.13035.

[510] See footnote Javed et al., 2020.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GERIATRICS SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. We request comments on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS13 5v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0083 / 0083e	008	CMS14 4v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Infectious Disease specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through 3 days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / 3755c	205	CMS1188v3	eCQM, MIPS CQM	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS11 7v14	eCQM	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
§ ! (Outcome)	NA / N/A	338	CMS31 4v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	CMS11 57v2	eCQM, MIPS CQM	Process	**HIV Annual Retention in Care:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the performance period	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQM	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	394	N/A	MIPS CQM	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.18. Infectious Disease

MEASURES PROPOSED FOR ADDITION TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.	American Gastroenterological Association	We are proposing to include this measure in the Infectious Disease specialty set as this measure is clinically relevant to this specialty type. Clinicians in this specialty are skilled in the diagnosis, treatment, and management of acute and chronic infections. Enhancing the infectious disease related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within this specialty set and its addition would elevate the importance of providing standard care to patients living with hepatitis C (HCV) liver disease.[511] This measure is based on evidence-based guidance for HCV management and would help ensure patients with HCV are receiving the best possible care, thus improving patient safety, and reducing future HCV morbidity and mortality.[512] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[511] See footnote Bhattacharya et al., 2023.

[512] See footnote Bhattacharya et al., 2023.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INFECTIOUS DISEASE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Internal Medicine specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS122v 14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS135v 14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0070 / 0070e	007	CMS145v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS144 v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
	N/A / N/A	009	CMS128 v14	eCQM	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131 v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	236	CMS165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0022 / N/A	238	CMS156 v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
! (Opioid)	N/A / N/A	305	CMS137 v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124 v14	eCQM	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS139 v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS314 v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS159 v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	N/A / N/A	377	CMS90v 15	eCQM	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years who have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQM	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347 v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS349 v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771 v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items - to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
*	N/A / N/A	488	CMS951 v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.19. Internal Medicine

MEASURES PROPOSED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	CMS11 54v1	eCQM	Process	**Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes:** Percentage of adult patients with risk factors for type 2 diabetes who are due for glycemic screening for whom the screening process was initiated during the measurement period.	American Medical Association	We are proposing to include this measure in the Internal Medicine specialty set as this measure is clinically relevant to this clinician type. Internal medicine clinicians treat a broad and comprehensive scope of illnesses affecting adults, specializing in health promotion, disease prevention, and diagnosis and treatment of chronic illness, including patients with diabetes.[513] Due to their broad scope of care, this specialty can be crucial in early detection of patients at risk for developing type 2 diabetes.[514] Regular glycemic screening and timely identification of prediabetics helps patients avoid the disability and the cost associated with progression to type 2 diabetes.[515] This measure aligns with national USPSTF evidence-based guidelines and recommendations of screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity.[516] Nearly 98 million people have prediabetes, but more than 8 in 10 adults don't know they have it[517] reinforcing the importance of identifying patients with prediabetes and identifying patients with undiagnosed type 2 diabetes. Enhancing the internal medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of glucose screening in patients at risk for diabetes. The measure being

[513] American College of Physicians (ACP). The Cornerstone of Comprehensive Health Care website. https://www.acponline.org/about-acp/about-internal-medicine/the-cornerstone-of-comprehensive-health-care.
[514] ACP. (2025). What is an Internal Medicine Physician, or Internist? https://www.acponline.org/about-acp/about-internal-medicine/what-is-an-internal-medicine-physician-or-internist.
[515] See footnote Kushner et al., 2022.
[516] See footnote USPSTF et al., 2021.
[517] See footnote CDC, 2022.

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV):** Sustained Virological Response (SVR): Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.	American Gastroenterological Association	We are proposing to include this measure in the Internal Medicine specialty set as this measure is clinically relevant to this clinician type. Internal medicine clinicians are likely the most frequent point of contact for many patients as their scope of care is extensive and inclusive of many different patient populations. Internal medicine clinicians diagnose and treat acute illness, provide preventive care, and manage chronic illness.[518] Due to their broad scope of care, this specialty may treat patients with active hepatitis C (HCV) and assist in managing the disease. This quality measure aligns with clinical guidelines of the USPSTF and achieving Sustained Virological Response (SVR) is the first step toward reducing future HCV morbidity and mortality.[519] Enhancing the internal medicine related measure inventory could help to ensure broad specialty coverage by having measures

[518] See footnote ACP, 2025.
[519] See footnote USPSTF, 2020.

B.19. Internal Medicine

MEASURES PROPOSED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of proper management of patients with HCV. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INTERNAL MEDICINE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	443	N/A	MIPS CQM	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Interventional Radiology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQM	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQM	Process	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agree with interested parties' feedback that this measure is highly relevant to this specialty as they often play a critical role in treating fractures, including vertebral compression fractures associated with osteoporosis. Effective communication with the physician managing ongoing care ensures a seamless transition from procedural intervention to long-term management, optimizing recovery and preventing complications.[520] Additionally, osteoporosis management is directly connected to many fracture conditions treated by interventional radiologists; ensuring appropriate post-fracture care, including evaluation and treatment for osteoporosis, helps reduce the risk of recurrent fractures.[521] This specialty has become increasingly involved in management of fractures that result from benign conditions like osteoporosis by using interventional techniques, such as image-guided osteoplasty and screw-mediated osteosyntheses.[522] Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

520 Cazzato, R. L., Dalili, D., De Marini, P., Koch, G., Autrusseau, P. A., Weiss, J., Auloge, P., Garnon, J., & Gangi, A. (2023). Bone Consolidation: A Practical Guide for the Interventional Radiologist. Cardiovascular and Interventional Radiology, 46(11), 1458–1468. https://doi.org/10.1007/s00270-022-03340-7.

521 See footnote Cazzato et al., 2023.

522 See footnote Cazzato et al., 2023.

B.20. Interventional Radiology

MEASURES PROPOSED FOR ADDITION TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agree with interested parties' feedback that this quality measure is highly relevant to IR because accurate medication documentation is critical for ensuring patient safety during minimally invasive procedures. Many IR procedures, such as angiography, biopsies, or embolization, require careful consideration of a patient's current medications to assess risks like bleeding or contrast allergies.[523] This specialty also often admits patients and needs to ensure they receive their home medications while admitted. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule.

[523] Alghamdi, D. S., Alhrasen, M., Kassem, A., Alwagdani, A., Tourkmani, A. M., Alnowaiser, N., Al Barakah, Y., & Alotaibi, Y. K. (2023). Implementation of Medication Reconciliation at Admission and Discharge in Ministry of Defense Health Services Hospitals: A Multicentre Study. BMJ Open Quality, 12(2), e002121. https://doi.org/10.1136/bmjoq-2022-002121.

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agree with interested parties' feedback that this quality measure is highly relevant to IR as it reflects important facets of procedural success and patient safety. This measure directly addresses procedure-specific outcomes, particularly for complex interventions such as embolization or vascular access. Adding this measure to this specialty set can support positive outcomes for IR procedures. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Unplanned Hospital Readmission within 30 Days of Principal Procedure.	American College of Surgeons	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agree with interested parties' feedback that interventional radiologists commonly complete surgical procedures where appropriate management through supportive care can help decrease avoidable 30-day reoperation due to surgical complications. This measure reflects important facets of procedural success and patient safety directly addressing procedure-specific outcomes, particularly for complex interventions such as embolization or vascular access. This measure would "help encourage appropriate management and avoidance of unnecessary and costly procedures." Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as the measure is clinically relevant to this specialty type. We agree with interested parties' feedback that this quality measure is important for this specialty as it impacts patient safety and procedural success. This quality measure ensures proper precautions are taken to minimize infection risk, such as utilizing proper skin preparations, sterile techniques, and pre-procedural antibiotics, considering the importance of these interventions. To help keep complications to a minimum, it's crucial for all radiologists to understand and adhere to sterile techniques for better patient care. By following strict aseptic and sterile techniques, radiologists can minimize IR procedure complications.[524] Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[524] Mukund, A., Bhardwaj, K., & Mohan, C. (2019). Basic Interventional Procedures: Practice Essentials. The Indian Journal of Radiology & Imaging, 29(2), 182–189. https://doi.org/10.4103/ijri.IJRI_96_19.

B.20. Interventional Radiology

MEASURES PROPOSED FOR ADDITION TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agree with interested parties' feedback that this quality measure is key to this specialty to ensure proper risk assessments and communication are prioritized prior to IR procedures. Patients undergoing IR procedures should receive a thorough preoperative evaluation. The addition of this measure to this specialty set helps ensure clinicians adhere to these practices to guide them to implement the most appropriate management plan, avoid unnecessary procedures, and prevent complications to achieve a successful outcome.[525] This would help ensure personalized risks of postoperative complications are appropriately assessed prior to procedures using a clinical data-based, patient-specific risk calculator and discussed with the patient. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

525 Taslakian, B., Georges Sebaaly, M., & Al-Kutoubi, A. (2016). Patient Evaluation and Preparation in Vascular and Interventional Radiology: What Every Interventional Radiologist Should Know (Part 1: Patient Assessment and Laboratory Tests). Cardiovascular and Interventional Radiology, 39(3), 325–333. https://doi.org/10.1007/s00270-015-1228-7.

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance	We are proposing to include this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agree with interested parties' feedback that this measure is highly relevant to this specialty as they often play a critical role in treating fractures, including vertebral compression fractures associated with osteoporosis. Effective communication with the physician managing ongoing care ensures a seamless transition from procedural intervention to long-term management, optimizing recovery and preventing complications.[526] Additionally, osteoporosis management is directly connected to many fracture conditions treated by interventional radiologists; ensuring appropriate post-fracture care, including evaluation and treatment for osteoporosis, helps reduce the risk of recurrent fractures.[527] This specialty has become increasingly involved in management of fractures that result from benign conditions like osteoporosis by using interventional techniques, such as image-guided osteoplasty and screw-mediated osteosyntheses.[528] Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[526] See footnote Cazzato et al., 2023.
[527] See footnote Cazzato et al., 2023.
[528] See footnote Cazzato et al., 2023.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INTERVENTIONAL RADIOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Mental/Behavioral Health and Psychiatry specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS12 8v14	eCQM	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
§	N/A / N/A	366	CMS13 6v15	eCQM	Process	**Follow-Up Care for Children Prescribed ADHD Medication:** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0710 / 0710e	370	CMS159v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS177v14	eCQM	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Nephrology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS122v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	400	N/A	MIPS CQM	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years who have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQM	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis (HD) patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS95 1v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within the 12-month measurement period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performanc e Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	510	N/A	MIPS CQM	Process	**First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR):** The number of newly initiated patients on dialysis in a practitioner group who are under the age of 75 and were either listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis	Centers for Medicare & Medicaid Services
	N/A / N/A	511	N/A	MIPS CQM	Process	**Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW):** The measure tracks dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). This measure is a risk-adjusted percentage of waitlist events among dialysis patients.	Centers for Medicare & Medicaid Services

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM	Process	**Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR):** The number of prevalent dialysis patients in a practitioner group who are under the age of	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Nephrology specialty set as this measure is clinically relevant to this clinician type. The maintenance of end stage renal disease patients in active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.		transplantation.[529] This measure focuses specifically on the outcome of waitlisting for patients on dialysis and is appropriate to this specialty as nephrologists are at the forefront of caring for this patient population. Nephrologists exert substantial control over processes that result in waitlisting and optimizing the health of patients to ensure early access to the waitlist, which has been demonstrated to be particularly beneficial.[530] These processes include proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, and assisting patients with completion of the transplant evaluation process.[531] These activities address the specific healthcare needs of patients on dialysis and are directed by dialysis practitioners aiming to achieve suitability for kidney transplantation.[532] Enhancing the nephrology related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of appropriate treatment for patients on dialysis. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule.

[529] See footnote Meier-Kriesche et al., 2002.

[530] See footnote Meier-Kriesche et al., 2002.

[531] See footnote Ashby et al., 2007.

[532] See footnote Satayathum et al., 2005.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEPHROLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Neurology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQM	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
	N/A / N/A	291	N/A	MIPS CQM	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQM	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression).	American Academy of Neurology
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.23. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Neurology specialty set as we agree with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[533] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[534] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and would promote more universal adoption of best practices to support shared decision making.[535] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family members or other caregivers.[536] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.
! (Safety)	TBD	TBD	N/A	MIPS CQM	Process	**Patient Reported Falls and Plan of Care:** Percentage of patients (or caregivers as	American Academy of Neurology	We are proposing to include this measure in the Neurology specialty set as this measure is clinically relevant to this clinician type. Neurologists are medical doctors who specialize in diagnosing and treating

B.23. Neurology

MEASURES PROPOSED FOR ADDITION TO THE NEUROLOGY SPECIALTY SET								
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Inclusion
						appropriate) with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who reported a fall occurred and those that fell had a plan of care for falls documented at every visit.		patients with neurologic disorders whose incidence of falls is reported as 2 to 4 times higher than in healthy subjects of similar age.[537] Several studies address the negative impact falls have on expediting neurologic morbidity and slowing progress toward recovery.[538] Falls can negatively impact quality of life. This stresses the importance of prioritizing falls assessment and promoting strategies that aim at preventing or reducing the incidence of falls in the neurologic patient population.[539] Enhancing the neurology related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and could elevate the importance of addressing a patient's increased falls risk when diagnosed with a neurologic condition.

[533] See footnote Frosch et al., 2012.

[534] See footnote Teno et al., 2004.

[535] See footnote National Consensus Project for Quality Palliative Care, 2018.

[536] See footnote Meier, 2011.

[537] See footnote Ehrhardt et al., 2020.

[538] Skolka, M. P., Neth, B. J., Brown, A., Steel, S. J., Hacker, K., Arnold, C., Toledano, M., & Mustafa, R. (2023). Improving Neurology Inpatient Fall Rate: Effect of a Collaborative Interdisciplinary Quality Improvement Initiative. Mayo Clinic Proceedings. Innovations, Quality & Outcomes, 7(4), 267–275. https://doi.org/10.1016/j.mayocpiqo.2023.05.004.

[539] Hunderfund, A. N., Sweeney, C. M., Mandrekar, J. N., Johnson, L. M., & Britton, J. W. (2011). Effect of a Multidisciplinary Fall Risk Assessment on Falls Among Neurology Inpatients. Mayo Clinic Proceedings, 86(1), 19–24. https://doi.org/10.4065/mcp.2010.0441.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	290	N/A	MIPS CQM	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	419	N/A	MIPS CQM	Process	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Neurosurgical specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy**: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	344	N/A	MIPS CQM	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEUROSURGICAL SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Nutrition/Dietician specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS12 2v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	NA / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS15 5v14	eCQM	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. ● Percentage of patients with height, weight, and body mass index (BMI) percentile documentation ● Percentage of patients with counseling for nutrition ● Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	We are proposing to include this measure in the Nutrition/ Dietician specialty set as this measure is clinically relevant to this clinician type. We agree with interested parties' feedback that Registered Dietician Nutritionists (RDNs) are uniquely qualified to offer essential education and support to caregivers regarding feeding assistance, managing behavioral challenges related to food, and addressing palliative food and fluid needs especially with patients diagnosed with dementia.[540] RDNs can also help caregivers to recognize declines in a patient's physical capacity and advise them on identifying malnutrition risks, developing tailored interventions that support both the patient and caregiver, and assist in planning appropriate adjustments to nutritional care plans and feeding techniques as the disease progresses.[541] This specialty is integral to the process of enhancing the quality of life and nutritional status of older adults through individualized nutrition approaches.[542] Malnutrition is a critical concern in dementia care and can exacerbate symptoms and increase mortality rates.[543] These efforts align with best practices in dementia care, ensuring comprehensive and compassionate management.[544] Given RDNs role in educating and supporting caregivers in dementia care, their involvement ensures a holistic approach to care by addressing both the nutritional and behavioral needs of patients, ultimately improving the quality of life for individuals

[540] Sanders, C. L., Wengreen, H. J., Schwartz, S., Behrens, S. J., Corcoran, C., Lyketsos, C. G., Tschanz, J. T., & Cache County Investigators (2018). Nutritional Status is Associated With Severe Dementia and Mortality: The Cache County Dementia Progression Study. Alzheimer Disease and Associated Disorders, 32(4), 298–304. https://doi.org/10.1097/WAD.0000000000000274.

[541] See footnote Sanders et al., 2018.

[542] Dorner, B., & Friedrich, E. K. (2018). Position of the Academy of Nutrition and Dietetics: Individualized Nutrition Approaches for Older Adults: Long-Term Care, Post-Acute Care, and Other Settings. Journal of the Academy of Nutrition and Dietetics, 118(4), 724–735. https://doi.org/10.1016/j.jand.2018.01.022.

[543] See footnote Sanders et al., 2018.

[544] Molony, S. L., Kolanowski, A., Van Haitsma, K., & Rooney, K. E. (2018). Person-Centered Assessment and Care Planning. The Gerontologist, 58(suppl_1), S32–S47. https://doi.org/10.1093/geront/gnx173.

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR ADDITION TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Inclusion
								with dementia.[545] Enhancing the nutrition/dietician related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of assessing and addressing nutrition challenges experienced by patients with dementia. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule.

[545] Yerstein, O., & Mendez, M. F. (2020). Dietary Recommendations for Patients with Dementia. Alzheimer's & Dementia (New York, N. Y.), 6(1), e12011. https://doi.org/10.1002/trc2.12011.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NUTRITION/DIETICIAN SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Obstetrics/Gynecology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS165v 14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124v 14	eCQM	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v 14	eCQM	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** . The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQM	Outcome	**Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQM	Process	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	496	N/A	MIPS CQM	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	443	N/A	MIPS CQM	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Oncology/Hematology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v15	eCQM, MIPS CQM	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v14	eCQM, MIPS CQM	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient experience)	0383 / N/A	144	N/A	MIPS CQM	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE).	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQM	Process	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	1859 / N/A	451	N/A	MIPS CQM	Process	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor (EGFR) monoclonal antibody (MoAb) therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed before initiation of anti-EGFR MoAb.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQM	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0216 / N/A	457	N/A	MIPS CQM	Process	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v9	eCQM	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
	N/A / N/A	490	N/A	MIPS CQM	Process	**Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Appropriate Use)	N/A / N/A	506	N/A	MIPS CQM	Process	**Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy:** Percentage of patients, aged 18 years and older, with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.	Society for Immunotherapy of Cancer (SITC)
	N/A / N/A	507	N/A	MIPS CQM	Process	**Appropriate Germline Testing for Ovarian Cancer Patients:** Percentage of patients, aged 18 and older, diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. We request comments on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS 129v15	eCQM, MIPS CQM	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS 157v14	eCQM, MIPS CQM	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQM	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Ophthalmology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / 0086e	012	CMS143v14	eCQM	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits within 12 months.	American Academy of Ophthalmology
! (Care Coordination)	N/A / N/A	019	CMS142v14	eCQM	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS13 1v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure, MIPS CQM	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0565 / 0565e	191	CMS133v14	eCQM, MIPS CQM	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	303	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQM	Patient Engagement/ Experience	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQM	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	385	N/A	MIPS CQM	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
* ! (Outcome)	N/A / N/A	389	N/A	MIPS CQM	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology
	N/A / N/A	499	N/A	MIPS CQM	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	500	N/A	MIPS CQM	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.	American Society of Retina Specialists
*	N/A / N/A	501	N/A	MIPS CQM	Process	**Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.	American Society of Retina Specialists

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OPHTHALMOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.29. Optometry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. We request comments on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.29. Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	019	CMS142v14	eCQM	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Orthopedic Surgery specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	178	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQM	Process	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQM	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v14	eCQM	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	470	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR. tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.31. Otolaryngology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Otolaryngology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS14 6v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.32. Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set has no proposed changes.

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQM	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status:**	College of American Pathologists

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.	

B.33. Pediatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Pediatrics specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / 3755e	205	CMS1188v3	eCQM, MIPS CQM	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS155v14	eCQM	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS117v14	eCQM	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS15 3v14	eCQM	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	366	CMS13 6v15	eCQM	Process	**Follow-Up Care for Children Prescribed ADHD Medication:** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS15 9v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	382	CMS177v14	eCQM	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* §	N/A / N/A	394	N/A	MIPS CQM	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PEDIATRICS SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.34. Physical Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Physical Medicine specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL MEDICINE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.35. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Physical Therapy/Occupational Therapy specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS14 9v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
	N/A / N/A	291	N/A	MIPS CQM	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10– or 13–item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.35. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Physical Therapy/Occupational Therapy specialty set as we agree with interested parties' feedback that adding this measure to this specialty set would help to broaden the patient population being screened for high blood pressure. Hypertension (HTN) is among the leading global preventable risk factors for cardiovascular disease and premature mortality.[546] Early detection and effective management of HTN have demonstrated significant reductions in mortality, morbidity rate, and health care costs. improves detection rates and medical management.[547] The physical therapist/ occupational therapist specialists may serve as the first point of contact into the health care system, thereby necessitating a need for routine blood pressure (BP) monitoring.[548] Leading physical therapy professional organizations include statements in their guidelines that suggest that physical therapists have a duty to provide a standard of care that protects the safety and optimizes the overall health of patients under their care.[549] Interdisciplinary care is vital, and it should be the responsibility of all clinician types to address health promotion and wellness, and prevention, delay, or management of acute or chronic diseases and conditions. Enhancing the physical therapy/occupational therapy related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This

[546] Severin, R., Sabbahi, A., Albarrati, A., Phillips, S. A., & Arena, S. (2020). Blood Pressure Screening by Outpatient Physical Therapists: A Call to Action and Clinical Recommendations. Physical Therapy, 100(6), 1008–1019. https://doi.org/10.1093/ptj/pzaa034.

[547] See footnote Severin et al., 2020.

[548] See footnote Severin et al., 2020.

[549] See footnote Severin et al., 2020.

B.35. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure complements other measures within their set and adding this measure to this specialty set would elevate the importance of early detection of HTN across specialists. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.36. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Plastic Surgery specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PLASTIC SURGERY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.37. Podiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Podiatry specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS 139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PODIATRY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.38. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Preventive Medicine specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS 122v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%**: Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS 347v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS 349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
*	N/A / N/A	488	CMS 951v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PREVENTIVE MEDICINE SPECIALTY SET

Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Pulmonology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQM	Process	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic and were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Pulmonology specialty set as we agree with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[550] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure would help to fill a

[550] See footnote Frosch et al., 2012.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.		gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[551] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and would promote more universal adoption of best practices to support shared decision making.[552] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family members or other caregivers.[553] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

[551] See footnote Teno et al., 2004.
[552] See footnote National Consensus Project for Quality Palliative Care, 2018.
[553] See footnote Meier, 2011.

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PULMONOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.40. Rheumatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Rheumatology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	2523 / N/A	177	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the performance period.	American College of Rheumatology
	N/A / N/A	178	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee Quality Assurance

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE RHEUMATOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.41. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Skilled Nursing Facility specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS1 45v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS1 44v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0066 / N/A	118	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.41. Skilled Nursing Facility

MEASURES PROPOSED FOR ADDITION TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Skilled Nursing Facility specialty set as we agree with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[554] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[555] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and would promote more universal adoption of best practices to support shared decision making.[556] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family members or other caregivers.[557]

[554] See footnote Frosch et al., 2012.

[555] See footnote Teno et al., 2004.

[556] See footnote National Consensus Project for Quality Palliative Care, 2018.

[557] See footnote Meier, 2011.

B.41. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE SKILLED NURSING FACILITY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.42. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Speech Language Pathology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Academy of Neurology / American Psychiatric Association
	N/A / N/A	291	N/A	MIPS CQM	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently clinically indicated (i.e., rapid progression).	American Academy of Neurology

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.43. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Thoracic Surgery specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQM	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQM	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0115 / N/A	168	N/A	MIPS CQM	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization.	Society of Thoracic Surgeons
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQM	Outcome	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE THORACIC SURGERY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.44. Urgent Care

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Urgent Care specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	N/A	MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE URGENT CARE SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.45. Urology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Urology specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v15	eCQM, MIPS CQM	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022/ N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQM	Outcome	**Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogyneco-logic Society
* § ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQM	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0216/ N/A	457	N/A	MIPS CQM	Process	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v9	eCQM	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Appropriate Use)	N/A/ N/A	481	CMS646v6	eCQM	Process	**Intravesical Bacillus-Calmette -Guerin for Non-Muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
*	N/A / N/A	488	CMS951v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.45. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE UROLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.46. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comments on the measure changes available for the proposed Vascular Surgery specialty set. We also request comment on the measures that have proposed substantive changes under Table Group D of this Appendix as indicated by an * in the Indicator column.

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	236	CMS 165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	259	N/A	MIPS CQM	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgery
	N/A / N/A	317	CMS 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQM	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE VASCULAR SURGERY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure is being proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

Table Group C: Previously Finalized Quality Measures Proposed for Removal for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

In this proposed rule, we are proposing to remove 10 previously finalized MIPS quality measures for the CY 2026 performance period/2028 MIPS payment year and future years. These measures are discussed in detail in the removal tables below.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discuss our incremental approach to removing process measures. Further considerations are given in the evaluation of the measure's performance data to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion we use for the removal of measures includes extremely topped-out measures, which refers to measures topped out with an average (mean) performance rate between 98–100 percent. For a measure proposed for removal due to criteria relating to the benchmark and performance data, further information regarding 2025 MIPS benchmarking data can be located at *https://qpp.cms.gov/benchmarks.*

As codified at 414.1330(c) in the CY 2024 PFS final rule (89 FR 98561), we list 12 criteria used to determine the removal of a quality measure.

(i) If the Secretary determines that the quality measure is no longer meaningful, such as measures that are topped out.

(ii) If a measure steward is no longer able to maintain the quality measure.

(iii) If the quality measure reached extremely topped out status.

(iv) If the quality measure does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.

(v) If the quality measure is duplicative.

(vi) If the quality measure is not updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice.

(vii) If the quality measure is a process measure.

(viii) If the quality measure addresses a measurement gap.

(ix) If the quality measure is a patient-reported outcome.

(x) If the quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.

(xi) The robustness of the quality measure.

(xii) Consideration of the quality measure in developing MIPS Value Pathways (MVPs).

We request comments on these measure removals.

C.1. Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	185
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286). This measure's continued topped-out status is based on the current 2025 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.2. Sentinel Lymph Node Biopsy for Invasive Breast Cancer

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	264
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.
Measure Steward:	American Society of Breast Surgeons
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) at the measure steward's request because it is not aligned with current clinical guidelines and would no longer be maintained for inclusion.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.3. Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	290
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.31 percent and as such is considered extremely topped out. The average performance rate is based on the current 2025 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.4. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	322
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this inverse measure, 0.03 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). For an inverse measure, a lower calculated performance rate indicates better clinical care or control. The average performance rate is based on the current 2025 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.5. Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	419
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this inverse measure, 0.55 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). For an inverse measure, a lower calculated performance rate indicates better clinical care or control. The average performance rate is based on the current 2025 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.6. Perioperative Temperature Management

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	424
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.
Measure Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance on this measure, 98.55 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance rate is based on the current 2025 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.7. Non-Recommended Cervical Cancer Screening in Adolescent Females

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	443
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the measure steward would no longer maintain the measure.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.8. Screening for Social Drivers of Health

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	487
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 87 FR 70253 through 70259) because it is a process measure that no longer addresses a priority area and would no longer be considered a high-priority measure. In the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765) rule, we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. Additionally, we seek to align with other quality programs. As indicated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes proposed rule, the Screening for Social Drivers of Health (SDoH) measure is proposed for removal beginning with the CY 2024 reporting period/FY 2026 payment determination from the Hospital Inpatient Quality Reporting (IQR) (90 FR 18336) and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Programs (90 FR 18345). Further alignment is also proposed for the Inpatient Rehabilitation Facility (IRF) and Long-Term Care Hospital (LTCH) settings through proposed removal of SDoH related elements from standardized patient assessment reporting (90 FR 18550 through 18551). Therefore, proposing to remove this measure aligns with the CMS Quality Measure Development Plan[558] through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

[558] CMS. (2016). CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/final-mdp.pdf.

C.9. Connection to Community Service Provider

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	498
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Measure Steward:	OCHIN
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 88 FR 79574 through 79577) because it is a process measure that no longer addresses a priority area and would no longer be considered a high-priority measure. In the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765), we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. Additionally, we seek to align with other quality programs. As indicated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes proposed rule, the Screen Positive Rate for Social Drivers of Health (SDoH) measure is proposed for removal beginning with the CY 2024 reporting period/FY 2026 payment determination from the Hospital Inpatient Quality Reporting (IQR) (90 FR 18336) and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Programs (90 DR 18345). Further alignment is also proposed for the Inpatient Rehabilitation Facility (IRF) and Long-Term Care Hospital (LTCH) settings through proposed removal of SDoH related elements from standardized patient assessment reporting (90 FR 18550 through 18551). Therefore, proposing to remove this measure aligns with the CMS Quality Measure Development Plan[559] through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers, and reduce clinician burden of data collection as feasible.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

[559] See footnote CMS, 2016.

C.10. Adult COVID-19 Vaccination Status

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	508
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 89 FR 98608 through 98613) because it is a process measure, and we seek to align with other Medicare programs. In the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765) rule, we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. Additionally, we seek to align with other quality programs. As indicated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes proposed rule, inpatient measure COVID–19 Vaccination Coverage Among Healthcare Personnel Measure is being proposed for removal (90 FR 18336 through 18337). This measure is also being proposed for removal in the Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2026 and Updates to the IRF Quality Reporting Program Proposed Rule (90 FR 18549 through 18550). We seek to align with these proposals to streamline clinical topics assessed across Medicare quality reporting programs.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2026 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

Table Group D: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

The D Tables within this proposed rule provide the substantive changes proposed for the MIPS quality measures in CY 2026. Three measures have proposed substantive changes that would result in a new benchmark. All measures with substantive changes are discussed in detail in the tables below.

We note that some MIPS quality measures available in traditional MIPS and MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as finalized in the 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM)) is also specified as a collection type available for such measures described in Table Group D.

The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2026 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2026 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2027. The 2026 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types on the Quality Payment Program website at *https://qpp.cms.gov.* In addition, eCQMs that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE #/eCQM CBE #.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2026

Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has been added to all 2026 quality measure specifications in the form of a revised 'Instructions Note' to clearly identify if telehealth encounters are allowed for denominator eligibility regardless of changes in coding or billing practices that may occur. Eligibility of telehealth encounters would be based on the intent of the measure and those settings that are appropriate for inclusion.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

We request comments on these substantive changes.

D.1 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits during the measurement period. **The measure numerator is revised to read:** Patients who have an optic nerve head evaluation during one or more visits during the measurement period.

Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the measure description and numerator by revising the language from "within 12 months" to "during the measurement period" to clarify the timeframe during which an optic nerve head evaluation should be completed. This clarification would ensure the numerator's quality action is assessed consistently and during the appropriate timeframe.
	Description
CBE # / eCQM CBE #:	N/A / 0086e
Quality #:	012
CMS eCQM ID:	CMS143v14
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits within 12 months.

D.2 Advance Care Plan

	Description
CBE # / eCQM CBE #:	0326 / N/A
Quality #:	047
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Substantive Change:	**Modified collection type:** MIPS CQM
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to remove the Medicare Part B Claims collection type as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate, 100 percent, and topped-out status is based on the current MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks.* However, the benchmarking data continues to show a gap for the MIPS CQM collection type and as such, we are proposing to retain that collection type.

D.3 Diabetes: Eye Exam

	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Modified collection type:** eCQM collection type. **Updated denominator exclusion: Added:** Exclude patients who have bilateral absence of eyes any time during the patient's history through the end of the measurement period. **The measure numerator is revised to read:** Patients with an eye screening for diabetic retinal disease. This includes patients with diabetes who had one of the following: - A diagnosis of retinopathy in any part of the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period - No diagnosis of retinopathy in any part of the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period or the year prior to the measurement period - An autonomous eye exam in the measurement period - A retinal exam finding with a retinopathy severity level in any part of the measurement period - A retinal exam finding with no retinopathy severity level in the year prior to the measurement period
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to remove the MIPS CQM collection type as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate, 94.57 percent, and topped-out status is based on the current MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. However, the benchmarking data continues to show a gap for the eCQM collection type and as such, we are proposing to retain that collection type. Additionally, for the eCQM collection type, we are proposing to exclude patients who are missing both eyes as they would not qualify for an eye exam, and revising the numerator to allow for an autonomous eye exam to meet the numerator quality action as this is an acceptable standard of care in diabetic patients and would meet measure intent.[560]

[560] Wolf, R. M., Channa, R., Lehmann, H. P., Abramoff, M. D., & Liu, T. Y. A. (2024). Clinical Implementation of Autonomous Artificial Intelligence Systems for Diabetic Eye Exams: Considerations for Success. *Clinical Diabetes: A Publication of the American Diabetes Association*, *42*(1), 142–149. https://doi.org/10.2337/cd23-0019.

D.4 Documentation of Current Medications in the Medical Record

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	130
CMS eCQM ID:	CMS68v15
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**Updated denominator exception: For the eCQM collection type: Removed:** Medical Reason value set and replaced with "Acute Health Crisis" direct reference code (DRC).
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to replace the medical reason value set with the Acute Health Crisis DRC for the eCQM collection type as this code better represents the intent of the denominator exception.

D.5 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	134
CMS eCQM ID:	CMS2v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Updated guidance: For the eCQM collection type: Revised:** Pharmacological interventions (prescribed or active depression medication). **Revised:** Follow-Up Plan: While there are many validated depression screening tools, they are not necessarily diagnostic tools. Patients with elevated depression screening scores should be followed by a clinician to evaluate whether a depression diagnosis is appropriate, but a medication and/or referral are not always indicated for a positive score. In these cases, a follow up plan is appropriate. **Added:** The measure is not prescriptive in the specific screening tool being used and provides no hierarchy for acceptance of one tool over another. In the case where two screenings are documented on the same date/time with different results (one positive and one negative), the measure only assesses the most recent screening. Since both screenings are both considered the most recent, the patient will be captured in the numerator if the positive screening result also includes documentation of an intervention following the positive screen. **Updated numerator: For the eCQM collection type: Added:** Or an active depression medication overlaps the date of the qualifying encounter.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the guidance and numerator for the eCQM collection type to clarify that pharmacological interventions include prescribed or active depression medications. We are proposing to update the guidance for determining the appropriate plan of care in instances where the screening tool doesn't adequately establish a diagnosis of depression. Additionally, we are proposing to add guidance to clarify instances of multiple screenings, which aligns with current measure logic. These clarifications would ensure the numerator action is appropriately and consistently assessed.

D.6 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care

	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality #:	141
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.
Substantive Change:	**Updated numerator definition: For all collection types: Added:** timing for documenting the plan of care.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the numerator definition for all collection types to clarify the timing of when the care plan must be documented in the patient's medical record after the IOP is assessed. This would ensure timely and optimal patient care and consistent assessment across clinicians for measure performance.

D.7 Oncology: Medical and Radiation – Pain Intensity Quantified

	Description
CBE # / eCQM CBE #:	0384 / 0384e
Quality #:	143
CMS eCQM ID:	CMS157v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated denominator criteria: For the MIPS CQM collection type: Added:** Patient on oral chemotherapy on or within 30 days before denominator eligible encounter. **Updated guidance: For the eCQM collection type: Removed:** Telehealth from language.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to add oral chemotherapy to the denominator criteria to align with the eCQM version of the measure that includes SNOMED codes for oral chemotherapy, ensuring that patients on oral chemotherapy are included in the eligible patient population. We are proposing to remove 'telehealth' from the eCQM guidance to align with coding guidelines for radiation treatment management codes.

D.8 Oncology: Medical and Radiation - Plan of Care for Pain

	Description
CBE # / eCQM CBE #:	0383 / N/A
Quality #:	144
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Substantive Change:	**Updated denominator criteria: Added:** Patient on oral chemotherapy during the performance period.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to add oral chemotherapy to the denominator criteria to align with the eCQM version of the measure that includes SNOMED codes for oral chemotherapy, ensuring that patients on oral chemotherapy are included in the eligible patient population.

D.9 Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	176
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions: Added:** new biologic and/or immune response modifiers. - Adalimumab-ryvk (Simlandi), - Rituximab (Rituxan), - Tocilizumab-aazg (Tyenne) - Tocilizumab-bavi (Tofidence), - Ustekinumab (Pyzchiva) - Ustekinumab (Selarsdi) - Ustekinumab (Wezlana) **Revised:** The list of biologic and/or immune response modifier therapies are subject to change as new therapies are approved by the FDA. Newly approved biologic and/or immune response modifier therapies requiring TB testing prior to the first course of therapy would be eligible for inclusion within the Denominator even if not listed above.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the list of medications used in the measure to identify denominator eligible patients by adding new biologic and/or immune response modifiers to the existing list in the denominator instructions. This expansion would provide an up-to-date list of appropriate biologic and/or immune response modifiers that clinicians may have prescribed for their patients, thereby ensuring that as many of the appropriate patients are identified in the denominator of this measure as possible. Additionally, we are proposing to revise language within the denominator instructions that would clarify the medication list is not exhaustive and any medication that requires TB testing prior to treatment would be appropriate for inclusion.

D.10 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

	Description
CBE # / eCQM CBE #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated denominator exclusion: For the eCQM collection type:** Significant ocular conditions include: Amblyopia, Burn Confined to Eye and Adnexa, Cataract Secondary to Ocular Disorders, congenital cataract, mature or hypermature cataract, posterior polar cataract, central corneal ulcer, certain types of iridocyclitis, choroidal degenerations, choroidal detachment, choroidal hemorrhage and rupture, cloudy cornea, corneal edema, disorders of cornea including corneal opacity, degeneration of macula and posterior pole, degenerative disorders of globe, diabetic macular edema, diabetic retinopathy disorders of optic chiasm, disorders of visual cortex, disseminated chorioretinitis and disseminated retinochoroiditis, focal chorioretinitis and focal retinochoroiditis, glaucoma, hereditary dystrophies (choroidal, corneal, retinal), hypotony of eye, injury to optic nerve and pathways, macular scare of posterior polar, Morgagnian cataract, nystagmus and other irregular eye movements, open wound of eyeball, optic atrophy, optic neuritis, pathologic myopia, posterior lenticonus, prior penetrating keratoplasty, purulent endophthalmitis, retinal detachment with retinal defect, retinal vascular occlusion, retrolental fibroplasias, scleritis, separation of retinal layers, traumatic cataract, uveitis, vascular disorders of iris and ciliary body.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the denominator exclusion for the eCQM collection type to include the list of diagnoses that qualify as significant ocular conditions[561] [562] for the purposes of this measure. This clarification would ensure appropriate patients are consistently identified as denominator eligible and assessed for the numerator action across submitting clinicians for measure performance.

[561] Mangione, C. M., Orav, J., Lawrence, M. G., Phillips, R.S., Seddon, J.M., & Goldman, L. (1995). Prediction of Visual Function After Cataract Surgery: A Prospectively Validated Model. *Archives of Ophthalmology, 113*(10), 1305-1311. https://doi.org/10.1001/archopht.1995.01100100093037.

[562] Steinberg, E. P., Tielsch, J. M., Schein, O. D., Javitt, J. C., Sharkey, P., Cassard, S. D., … Damiano, A. M. (1994). National Study of Cataract Surgery Outcomes: Variation in 4-month Postoperative Outcomes as Reflected in Multiple Outcome Measures. *Ophthalmology, 101*(6), 1131-1141. https://doi.org/10.1016/s0161-6420(94)31210-3.

D.11 Dementia: Cognitive Assessment

	Description
CBE # / eCQM CBE #:	N/A / 2872e
Quality #:	281
CMS eCQM ID:	CMS149v14
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period. **Updated guidance: Revised:** The measure requires a diagnosis of dementia be present before the routine assessment of cognition is performed once during the measurement period or the 12 months prior. **The measure numerator is revised to read:** Patients for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the measure description, guidance, and numerator statement to clarify the timing of the routine assessment of cognition and review of the results to ensure that the patient had a diagnosis of dementia at the time of assessment. This revision better aligns with the intent of the measure and would ensure the numerator's quality action is attributable to the denominator eligible criteria.

D.12 Surgical Site Infection (SSI)

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	357
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older who had a surgical site infection (SSI).
Substantive Change:	**Updated instructions: Added:** All sites of the primary procedure and integral procedures performed during that trip to the operating room should be evaluated as part of this measure for possible wound occurrences. If more than one SSI is observed, assign the SSI at the deepest level (superficial, deep or organ/space) that occurs within a 30-day postoperative timeframe.
Measure Steward:	American College of Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the measure instructions to clarify how to handle multiple procedures during a single encounter. By assigning the SSI at the deepest level (superficial, deep, or organ/space) in situations where more than one SSI is observed within a 30-day postoperative timeframe, the most adverse surgical outcome is captured as an indicator of the quality of care provided.

D.13 Closing the Referral Loop: Receipt of Specialist Report

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	374
CMS eCQM ID:	CMS50v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.
Substantive Change:	**Updated guidance: For the eCQM collection type: Added:** A procedural report received from a specialist for an exam or procedure conducted (e.g., diabetic eye exam, colonoscopy) can satisfy the numerator requirement and successfully close the referral loop. A separate consultant note or consultant report is not required to close the referral loop in these circumstances. **The measure numerator is revised to read: For the eCQM collection type:** Number of patients with a referral on or before October 31, for which the referring clinician received a report from the first clinician to whom the patient was referred.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the guidance and numerator for the eCQM collection type to align with current measure logic, which requires a report from the referral. These updates allow for improved electronic implementation of the measure.

D.14 Functional Status Assessment for Total Hip Replacement

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v14
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.
Substantive Change:	**Updated denominator exclusion: Revised:** Exclude patients with one or more specific lower body fractures indicating trauma in the 48 hours before or at the start of the total hip arthroplasty.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the denominator exclusion regarding one or more specific lower body fractures by increasing the timeframe to 48 hours prior to the start of THA. Trauma occurring in the 48 hours leading up to a total hip replacement can potentially affect the outcome of the surgery, depending on factors such as the severity of the trauma or the need to stabilize and/or adequately assess the condition of the patient. This extended timeframe would ensure patients undergoing THA are prepared for the procedure and not in an emergent situation.

D.15 Cataract Surgery: Difference Between Planned and Final Refraction

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	389
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.
Substantive Change:	**Updated numerator note: Added:** It would be expected that the planned (target) refraction be assessed and documented within 90 days prior to the denominator eligible procedure.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to add a numerator note to the measure, which would ensure that only those patients with recently obtained planned (target) refractions are considered for numerator compliance. As refractions may change over time, it is essential that patients undergoing cataract surgery have current and accurate results for appropriate ophthalmic evaluations, which would be used by the ophthalmologist to counsel the patient about target postoperative refractive options and formulation of a care plan that would achieve the documented target refraction.[563]

[563] Miller, K. M., Oetting, T. A., Tweeten, J. P., Carter, K., Lee, B. S., Lin, S., Nanji, A. A., Shorstein, N. H., Musch, D. C., & American Academy of Ophthalmology Preferred Practice Pattern Cataract/Anterior Segment Panel (2022). Cataract in the Adult Eye Preferred Practice Pattern. *Ophthalmology*, *129*(1), P1–P126. https://doi.org/10.1016/j.ophtha.2021.10.006.

D.16 Immunizations for Adolescents

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	394
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.
Substantive Change:	**The measure description is revised to read:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday. **The measure numerator is revised to read: For Submission Criteria 1:** Adolescents who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B) on or between the patient's 10th and 13th birthdays. **Updated numerator options: Revised: For Submission Criteria 1:** **Performance Met:** Patient had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B) on or between the patient's 10th and 13th birthdays. **Performance Not Met:** Patient did not have one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), on or between the patient's 10th and 13th birthdays.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the measure description and numerator to add the pentavalent serogroup meningococcal vaccine as numerator compliant for patients for which it is suggested. This update reflects recommendations of the CDC Advisory Committee on Immunization Practices that children may receive pentavalent vaccine starting at age 10 (*https://www.cdc.gov/mmwr/volumes/73/wr/mm7315a4.htm*).

D.17 Osteoporosis Management in Women Who Had a Fracture

	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.
Substantive Change:	**The measure numerator note is revised to read: For all collection types:** For the purposes of submitting this measure, Central Dual Energy X-Ray Absorptiometry (DXA), the most common measurement for measuring bone mineral density (BMD), spinal densitometry X-ray, and Peripheral Dual-energy X- Ray Absorptiometry (DXA) would meet performance and the intent of the measure. Therefore, 3095F would be submitted in the instances those screening modalities are utilized.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the list of tests for measuring BMD by removing CT bone density axial and ultrasonography for densitometry as meeting performance. These changes would ensure testing required for numerator compliance is better aligned with guidelines and best practices.[564]

[564] USPSTF. (2025). Osteoporosis to Prevent Fractures: Screening. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/osteoporosis-screening.

D.18 Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	420
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.
Substantive Change:	**The measure denominator is revised to read:** All patients who are treated for varicose veins with saphenous ablation and who receive an outcomes survey within 180 days after treatment. **The measure numerator is revised to read:** Patients whose outcome survey score improved when assessed within 180 days following treatment. **Updated numerator options: Added:** Denominator Exception: Documentation of at least two attempts to follow up with patient within 180 days of treatment Performance Not Met: No documentation of at least two attempts to follow up with patient within 180 days of treatment Performance Not Met: Patient follow up more than 180 days after treatment **Removed:** Denominator Exception: Patient survey results not available
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We are proposing to update the measure's timeframe for assessing patient outcomes to anytime within 6 months following the treatment. While the ideal assessment time is 3-6 months following the treatment, trials have shown improvement occurred fairly quickly before slowing and plateauing at about six months.[565] Therefore, it is reasonable a patient may show improved scores sooner than 3 months, and this revision would allow flexibility in workflow while ensuring quality outcomes are achieved. Additionally, we are also proposing to update the numerator options to ensure patients were not lost to follow-up without a reasonable attempt made. By replacing the exception for patient survey results not available, we would require documentation that the patient was actively sought for follow-up.

[565] Gibson, K., Morrison, N., Kolluri, R., Vasquez, M., Weiss, R., Cher, D., Madsen, M., & Jones, A. (2018). Twenty-four Month Results from a Randomized Trial of Cyanoacrylate Closure Versus Radiofrequency Ablation for the Treatment of Incompetent Great Saphenous Veins. *Journal of Vascular Surgery. Venous and Lymphatic Disorders*, *6*(5), 606–613. https://doi.org/10.1016/j.jvsv.2018.04.009.

D.19 Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	441
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated
Substantive Change:	**The measure description is revised to read:** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • High Intensity Statin Use Unless Contraindicated **Updated denominator criteria: Removed:** coding for arterial embolism and thrombosis from CAD Risk-Equivalent Conditions. **The measure numerator is revised to read: For all Submission Criteria:** The number of IVD patients who meet ALL of the following targets: • Most recent BP is less than or equal to 130/80 mm Hg • Most recent tobacco status is Tobacco Free (NOTE: If there is No Documentation of Tobacco Status the patient is not compliant for this measure) • Daily Aspirin or Other Antiplatelet Unless Contraindicated • High Intensity Statin Use Unless Contraindicated **Updated numerator note: Added: For all Submission Criteria: Component 4:** Valid High Intensity statins include Atorvastatin 40-80 mg and Rosuvastatin 20-40 mg. **Updated numerator options: Revised: For all Submission Criteria:** **Component 1:** require blood pressure to be less than or equal to 130/80 mm Hg. **Component 4:** require use of high intensity statin therapy.
Measure Steward:	Wisconsin Collaborative for Healthcare Quality
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing to update multiple components of this measure to align with the AHA/ACC/ACCP/ASPC/NLA/PCNA Guidelines (*https://www.ahajournals.org/doi/10.1161/CIR.0000000000001168*). We are proposing to revise normal blood pressure measurement from 140/90 to 130/80 and switch from Statin Use Unless Contraindicated to High Intensity Statin Use Unless Contraindicated. Given that the diagnoses included in the measure represent the highest level of cardiovascular risk, and given current guidelines, the measured population is best served by being held to a lower blood pressure measurement and by being on a high-intensity statin to reduce the risk of a major cardiac event. We are also proposing to remove coding for arterial embolism and thrombosis from the CAD Risk-Equivalent Conditions denominator criteria as these conditions do not share the same pathophysiology or treatment goals and therefore misalign with the intent of the measure.

D.20 Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer

	Description
CBE # / eCQM CBE #:	1858 / N/A
Quality #:	450
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.
Substantive Change:	**Updated denominator criteria: Revised:** AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis = T1c. **Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to revise the denominator criteria for T-stage breast cancer to ensure patients with T1mic, TX, T0 and Tis are not inadvertently included in the denominator eligible population as HER2-targeted therapy is typically not indicated.[566] [567] We are also proposing to add a denominator note to clarify the encounter requirement to require and reflect two separate encounters occurring on different days with the same reporting provider or group.

[566] American Joint Committee on Cancer. (2010). AJCC Cancer Staging Manual. https://www.facs.org/media/kwupoct5/ajcc-7th-ed-cancer-staging-manual.pdf.

[567] Johnson, K. C., Quiroga, D., Sudheendra, P., & Wesolowski, R. (2022). Treatment of Small (T1mic, T1a, and T1b) Node-negative HER2+ Breast Cancer - A Review of Current Evidence For and Against the Use of Anti-HER2 Treatment Regimens. *Expert Review of Anticancer Therapy*, *22*(5), 505–522. https://doi.org/10.1080/14737140.2022.2063844.

D.21 RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

	Description
CBE # / eCQM CBE #:	1859 / N/A
Quality #:	451
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.
Substantive Change:	**Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters, and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add a denominator note to clarify the encounter requirement to require and reflect two separate encounters occurring on different days with the same reporting provider or group.

D.22 Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)

	Description
CBE # / eCQM CBE #:	0210 / N/A
Quality #:	453
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.
Substantive Change:	**Updated denominator criteria: Added:** coding to allow telehealth as denominator eligible. **Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to add telehealth coding as denominator eligible for this measure as it is appropriate for patients seen via telehealth to be included in the denominator for assessment of performance. We are also proposing to add a denominator note to clarify implementation of the denominator criteria encounter requirement, which would ensure the denominator eligible patient population is appropriately identified and consistent across clinician submissions.

D.23 Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)

	Description
CBE # / eCQM CBE #:	0216 / N/A
Quality #:	457
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.
Substantive Change:	**Updated denominator criteria: Added:** coding to allow telehealth as denominator eligible. **Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to add telehealth coding as denominator eligible for this measure as it is appropriate for patients seen via telehealth to be included in the denominator for assessment of performance. We are also proposing to add a denominator note to clarify implementation of the denominator criteria encounter requirement, which would ensure the denominator eligible patient population is appropriately identified and consistent across clinician submissions.

Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

D.24

	Description
CBE # / eCQM CBE #:	3493 / N/A
Quality #:	480
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.
Substantive Change:	**Updated denominator exclusion: Removed:** COVID exclusion
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to exclude admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominator due to the end of the public health emergency (PHE). This proposed change aligns this measure with language proposed under the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes proposed rule (90 FR 18292).

D.25 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC)

	Description
CBE # / eCQM CBE #:	3597 / N/A
Quality #:	484
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	The measure is a risk-standardized rate of acute, unplanned hospital admissions for the Merit-based Incentive Payment System (MIPS) among Medicare Fee-for-Service (FFS) patients aged 65 years and older with multiple chronic conditions (MCCs); i.e., two or more of nine qualifying chronic conditions. The measure is adjusted for age, chronic condition categories, and other clinical and frailty risk factors present at the start of the 12-month measurement period as well as social risk factors. The measure attributes admissions to MIPS participating clinicians and/or clinician groups, as identified by their National Provider Identifiers (NPIs) and/or Taxpayer Identification Number (TIN) and assesses each clinician's or clinician group's admission rate.
Substantive Change:	**Update denominator** exclusion**: Remove**: Patients assigned to clinician who achieve Qualifying Advanced Alternative Payment Model Participant (QP) status and therefore do not participate in MIPS.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to revise the denominator eligible patient population by removing the denominator exclusion regarding QP status. When the MIPS MCC measure was proposed in the CY 2022 PFS proposed rule (86 FR 39270 through 39271) and finalized in the final rule (86 FR 65264 through 65265), there was a parallel proposal to remove the ACO MCC measure from the Medicare Shared Saving Plan (SSP) APM Performance Pathway (APP) measure set and replace it with the MIPS MCC measure. With a MIPS measure now in place, and consistent with the initial intent, we are proposing removing this exclusion to broaden the scope of the measure and account for all MIPS participants, particularly those in APM entities who may have QP status.

D.26 Kidney Health Evaluation

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	488
CMS eCQM ID:	CMS951v4
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.
Substantive Change:	**Updated guidance: For the eCQM collection type: Added:** The Urine Albumin-Creatinine Ratio (uACR) requirement can be met with a documented Urine Albumin and Urine Creatine less than or equal to four days apart. A calculation of uACR is not required to meet this measure, but it is intended to for the uACR to be calculated for the purposes of kidney health evaluation. If the Urine Albumin and Urine Creatine tests have different units of measure, they should be converted to the same unit of measure for the purposes of calculating uACR. The Urine Albumin Creatinine Ratio Test requirement can be met if the lab result is received as a quantitative value or as an undetectable result. Undetectable results can be coded using values in the "Undetectable Lab Result Value" value set. **The measure numerator is revised to read: For the eCQM collection type:** Patients who received a kidney health evaluation during the measurement period. Kidney health evaluation is defined by an eGFR AND uACR within the measurement period OR an eGFR and a Urine Albumin and Urine Creatine result documented less than or equal to four days apart.
Measure Steward:	National Kidney Foundation
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the guidance and the numerator for the eCQM collection type to clarify how the uACR requirement may be met in instances where the lab results are non-quantitative, that is, undetectable or the Urine Albumin and Urine Creatine tests are run separately. This would ensure the measure logic is appropriately assessing clinicians as numerator compliant when the intent of the measure has been met.

D.27 Adult Immunization Status

	Description
CBE # / eCQM CBE #:	3620 / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B**.** **Updated instructions:** **Added:** Performance Rate 5 for reporting of hepatitis B vaccine series. **Revised:** Percentage of patients (50 years of age and older on the date of the encounter) who received 2 doses of the herpes zoster recombinant vaccine anytime on or after the patients' 50th birthday. **Updated denominator: Added: Submission Criteria 5:** Patients 19 years of age or older on the date of the encounter with a visit during the measurement period. **Updated denominator criteria: Added: Submission Criteria 5:** Patients age 19 and older on the date of the encounter AND Patient encounter during the performance period AND NOT DENOMINATOR EXCLUSION: In hospice or using hospice services during the measurement period. **Updated numerator: Revised: Submission Criteria 3:** Patients in Denominator 3 who received 2 doses of the herpes zoster recombinant vaccine on October 1, 2017, through the end of the measurement period. **Added: Submission Criteria 5:** Patients in Denominator 5 who were administered a hepatitis B vaccine series on or after their 19th birthday and before the end of the measurement period. **Updated numerator instructions: Added: Submission Criteria 5:** In order to meet criteria for this numerator, patients must have one of the following: 1) at least three doses of the childhood hepatitis B vaccine with different dates of service on or before their 19th birthday; 2) at least two doses of the recommended two-dose adult hepatitis B vaccine administered at least 28 days apart; 3) at least three doses of any other recommended adult hepatitis B vaccine administered on different dates of service; and 4) received a hepatitis B surface antigen, hepatitis B surface antibody, or total antibody to hepatitis B core antigen test with a positive result. **Updated numerator note: Added: Submission Criteria 5:** Patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. **Updated numerator options: Revised: Submission Criteria 3:** **Performance Met:** Patient received at least two doses of the herpes zoster recombinant vaccine (at least 28 days apart) on October 20, 2017, through the end of the measurement period. **Performance Not Met:** Patient did not receive two doses of the herpes zoster recombinant vaccine (at least 28 days apart) on October 20, 2017, through the end of the measurement period. **Added: Submission Criteria 5:** **Performance Met:** Patient received recommended doses of hepatitis B vaccination based on age. **Denominator Exception:** Patient has a history of hepatitis B illness or received a hepatitis B surface antigen, hepatitis B surface antibody, or total antibody to hepatitis B core antigen test with a positive result any time before or during the measurement period. **Denominator Exception:** Documentation of medical reason(s) for not administering hepatitis B vaccine (e.g., prior anaphylaxis due to the hepatitis B vaccine). **Denominator Exception:** Documentation that patient is a Medicare Fee-For-Service beneficiary and without additional supplementary insurance coverage for whom Hep B vaccination is not reimbursable under current Medicare Part B coverage rules. **Performance Not Met:** Patient did not receive recommended doses of hepatitis B vaccination based on age.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process

	Description
Rationale:	We are proposing to revise the measure to include the Hepatitis B vaccine in the list of routine vaccinations of adults aged 19 years and older based on updated recommendations of the Advisory Committee on Immunization Practices. The literature shows that approximately 50 percent of acute hepatitis B cases reported in 2019 occurred among persons aged 30–49 years due to low HepB vaccination coverage among adults aged greater than or equal to 9 years. Furthermore, an estimated 2 percent to 6 percent of acute hepatitis B viral infections have been found to lead to chronic hepatitis B among adults (*https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm*). In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.28 Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	500
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Substantive Change:	**Updated Instructions: Revised:** This measure is to be submitted once per performance period for acute PVD in either eye. For the purpose of submitting this measure, only unique occurrences with an onset of acute PVD diagnosed within the current performance period will be denominator eligible, with the most recent occurrence (if there is more than one occurrence) being used for performance calculation.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure submission frequency to once per performance period as simultaneous or very close-in-time bilateral PVDs are rare.[568] In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

[568] Retina Specialist. (2021). Five Evidence-based Answers for PVD, Retinal Breaks. https://www.retina-specialist.com/article/five-evidencebased-answers-for-pvd-retinal-breaks.

D.29 Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	501
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.
Substantive Change:	**Updated Instructions: Revised:** This measure is to be submitted once per performance period for acute PVD and acute vitreous hemorrhage in either eye. For the purpose of submitting this measure, only unique occurrences with an onset of acute PVD and acute vitreous hemorrhage diagnosed within the current performance period will be denominator eligible, with the most recent occurrence (if there is more than one occurrence) being used for performance calculation.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure submission frequency to once per performance period as simultaneous or very close-in-time bilateral PVDs are rare.[569] In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

[569] See footnote Retina Specialist, 2021.

D.30 Gains in Patient Activation Measure (PAM ®) Scores at 12 Months

	Description
CBE # / eCQM CBE #:	2483 / N/A
Quality #:	503
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The Patient Activation Measure® (PAM ®) is a 10- or 13-item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Substantive Change:	**Updated instructions: Removed:** Submission Criteria 4 and Performance Rate 3. **Updated denominator exclusion: Added: For all submission criteria:** Diagnosis of Delirium and Psychoactive substance abuse. **Updated denominator: Removed:** Submission Criteria 4. **Updated numerator: Removed:** Submission Criteria 4.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We are proposing to remove Performance Rate 3 that measures the average change between baseline PAM® score and the percentage of patients 14 years and older who achieved a net increase of 6 points in a 4 to 12 month period as it is not technologically feasible to calculate using the existing submission JavaScript Object Notation (JSON) structure. As a result, the submission of data for the Submission Criteria 4 would not be required when reporting this measure. We are also proposing to exclude patients with a diagnosis of delirium and/or psychoactive substance abuse from the denominator of submission criteria 1, 2 and 3. This exclusion would ensure appropriate patients would be included in the denominator of the measure.

Table Group DD: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures Available Only for Use in Relevant MVPs for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

As finalized for the CY 2024 performance period/2026 MIPS payment year and future years, the following three MIPS quality measures were retained for utilization in MVPs only while removed from traditional MIPS: Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79897 through 79902). We note that some MIPS quality measures available only in MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as finalized in the 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) is also specified as a collection type available for such measures described in Table Group DD.

Table Group DD within this proposed rule provides substantive changes proposed for the CY 2026 performance period/2028 MIPS payment year for MIPS quality measures available only in a relevant MVP. One of the aforementioned MIPS quality measures, Q112, has substantive changes under Table Group DD. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD–10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2026 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2026 CPT and ICD–10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2027. The 2026 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov.*

Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE #/eCQM CBE #.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but it is important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2026 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

We request comments on these substantive changes.

DD.1. Breast Cancer Screening

	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v14
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of women 40 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated description: For the eCQM collection type: Revised:** women 40-74 years of age. **Updated stratification: For the eCQM collection type: Added:** Report a total rate, and each of the following age strata: Stratum 1: Patients age 42-51 by the end of the measurement period Stratum 2: Patients age 52-74 by the end of the measurement period **Updated definition: For the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types: Added:** Reviewed – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the mammography report and discussed the findings with the patient. The mammography report may also be provided by the patient for the clinician's review / discussion during the visit and should be documented in the medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing making these changes to align with the latest clinical guidelines. We are proposing adding a new rate to the measure to ensure continued benchmarking for the previously existing rate and to ensure continuous, undisrupted monitoring of performance across the specified age bands. Additionally, we are proposing to add a definition for reviewed to the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types to clarify the requirement for meeting the quality action. This would ensure the intent of measure is being met and numerator compliance is consistently assessed across all submissions.

DD.2. Colorectal Cancer Screening

	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v14
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated definition: For the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types: Added:** Reviewed – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the mammography report and discussed the findings with the patient. The mammography report may also be provided by the patient for the clinician's review / discussion during the visit and should be documented in the medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add a definition for reviewed to the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types to clarify the requirement for meeting the quality action. This would ensure the intent of measure is being met and numerator compliance is consistently assessed across all submissions.

APPENDIX 2: IMPROVEMENT ACTIVITIES

In this proposed rule, beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing to add three new improvement activities (as specified in Table F-B1), modify seven previously finalized improvement activities (as specified in Table F-B2), and remove eight previously finalized improvement activities (as specified in Table F-B3). We are also proposing to add a new activity subcategory and remove a subcategory. These proposals are discussed in section IV.A.4.d of this proposed rule and in more detail below. We request comments on our proposals.

Except as otherwise noted in this proposed rule, previously finalized improvement activities will continue to apply for the CY 2026 performance period/2028 MIPS payment year and future years.

TABLE F-B1: New Improvement Activities Proposed for Adoption Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Improving Detection of Cognitive Impairment in Primary Care
Proposed Activity Description:	To increase the detection rate of cognitive impairment, particularly in early stages, the MIPS eligible primary care clinician must perform the following activities: ● Determine his/her baseline detection rates for mild cognitive impairment (MCI), dementia, and cognitive impairment at either stage using the tool provided for this Improvement Activity ● If any of the three rates are below 1.0: ++Increase the uptake of the Annual Wellness Visit ++Ensure that each Annual Wellness Visit contains a structured cognitive assessment ++Include a question about subjective memory concerns to the collection of vital signs during intake for patients 65+, and conduct a structured cognitive assessment in those with concerns ● Remeasure detection rates for MCI, dementia, and cognitive impairment at either stage quarterly This Improvement Activity should only focus on Medicare patients aged 65 and older, given the strong correlation of cognitive impairment with age.
Rationale:	Recent publications of phase three trial results reported that two amyloid-targeting drugs were able to significantly reduce the speed of cognitive decline in patients with early-stage Alzheimer's disease, the most common cause of dementia. One drug, lecanemab, is now FDA-approved for treatment of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease, and the other drug, donanemab, is awaiting the FDA's decision. These drugs are only indicated in early disease stages, lending renewed urgency to the problem of delayed and missed diagnosis of cognitive decline while, today, cognitive decline is usually detected in advanced stages.[1,2] For example, Thoits et al. found that about 79 percent of randomly selected patients, who were newly diagnosed at a memory clinic, had moderate or severe dementia.[3] Such delayed diagnoses have long taken away from patients and families the opportunity to adopt lifestyle changes to reduce the speed of decline,[4] start symptomatic medication treatment, and consider measures to increase physical and financial safety and security.[5] But now failing to detect early-

	stage Alzheimer's disease will deprive patients of the prospect to alter the course of this devastating illness. Unfortunately, limited data exist for the degree of missed diagnoses of MCI, the stage at which Alzheimer's disease would ideally be treated.[6] White et al. used data from the Health and Retirement Study (HRS) to determine that 11.4 percent of subjects with incident MCI reported receiving a timely diagnosis,[7] and Savva et al. analyzed neuropsychiatric testing data from the Aging, Demographics and Memory Study ADAMS data to conclude that 15 percent of participants with a Clinical Dementia Rating of 0.5, a score reflective of MCI, were aware of a diagnosis of cognitive impairment.[8] Only nine percent of expected MCI cases are diagnosed in the U.S. Medicare population.[9] More research has been conducted on dementia detection rates. One study linked Medicare claims data to information on 417 patients with a clinical diagnosis of Alzheimer's disease in the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) data and reported that only around 75 percent of patients had a corresponding diagnosis in claims data in the period from 1991 to 1999,[10] a number similar to the 85 percent reported by Lee et al. for the 2007 to 2012 period of the same data.[11] Zhu et al. published a dementia prevalence of 12.9 percent based on cognitive tests and of 12.4 percent based on diagnosis codes in the 20 percent Medicare sample in 2012.[12] Jutkowitz et al. found considerably lower dementia diagnosis rates of 5.6 percent and 6.5 percent in 2014 and 2016, respectively, in a convenience sample of three Medicare Advantage Plans.[13] Our own data suggest a slightly higher rate of dementia diagnoses than expected, although some of that could be miscoding of MCI as dementia, and the overall detection rate of cognitive impairment remains far lower than expected, especially for minority and low SES patients.[14] In summary, there is substantial evidence that cognitive impairment remains underdiagnosed, particularly in early stages. Measuring diagnosis rates in primary care and comparing those to expected rates given the demographic composition of a clinician's panel can identify gaps in diagnosis and point primary care clinicians towards efforts to proactively inquire about cognitive concerns and follow up on subjective memory complaints, particularly in high-risk and disadvantaged populations. The Medicare Annual Wellness Visit provides an opportunity to do so, but this benefit remains underutilized. A 2020 study found that only one-half of beneficiaries took advantage of it, and fewer than one-third reported having a structured cognitive assessment.[15] A recent expert group recommended several steps to routinely incorporate brief cognitive assessment into primary care workflows.[16] Thus, steps can be taken at both the individual clinician and the organizational level to detect cognitive impairment more frequently and earlier so that patients can potentially benefit from disease-modifying treatments.
New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Integrating Oral Health Care in Primary Care
Proposed Activity Description:	MIPS eligible clinicians that practice primary care will include an oral health risk assessment and intraoral screening as part of a patient's primary care management. The MIPS eligible clinician will provide education and counseling to the patient to include the importance of oral health and the impact of oral health on systemic diseases. For patients without a dental home and/or those with oral health needs, a dental referral will be provided.

	To receive credit for this activity, a MIPS eligible clinician must complete two Smiles for Life (https://www.smilesforlifeoralhealth.org) trainings: ("The Oral Examination" and "Geriatric Oral Health"). These are one-time, free, online training 60-minute certification courses. Smiles for Life oral health education has been adopted by Medicaid in several states to improve oral health access, outcomes, and referrals for children through educating medical providers. The MIPS eligible clinician must include one or more of the following activities in addition to completing the training: ○ Create a dental referral network list by specialty and accepted insurances. ○ Include applicable oral health screening questions in the patient health intake forms (dentist of record, date of the last dental exam, and personal oral hygiene routine). ○ Identify an applicable caries risk assessment tool to be used. ○ Include intraoral health screening and referral to dental provider as part of a patient's primary care management. ○ Provide education and counseling to patients about the importance of oral health and impact on systemic disease. ○ Refer patients without a dental home and/or those who have untreated dental disease indicated by health history, caries risk assessment, Intraoral health screening, medications and/or concerns reported by patient. ○ Include a description of the findings found in all dental referrals. ++ Documents with appropriate procedure and diagnostic codes to track services provided and referrals to validate performance of the improvement activity.
Rationale:	Oral health is closely related to overall health. According to the Centers for Disease Control and Prevention (CDC), approximately 35 percent of American adults did not see a dentist in the past year.[17] The Kaiser Family Foundation (KFF) identified nearly half of all people on Medicare have no dental coverage, and the CDC identified one out of six adults 65 or older are completely edentulous (have lost all their teeth), which can greatly impact nutrition.[18,19] Moreover, a significant portion of the Medicare population has or is at risk for chronic health conditions, which can be further complicated by poor oral health. Dental issues can be early indicators of systematic diseases, such as Alzheimer's, and may also lead to severe health complications such as diabetes and cardiovascular disease, all of which have a significant impact on the Medicare population. For example, researchers have concluded that periodontal disease "might be a modifiable risk factor" for Alzheimer's disease. Moreover, Medicare spends $520 million annually on dental-related emergency department. If these issues were caught and managed early, many of those expenditures could be avoided. With nearly two-thirds of the older adult population in the United States experiencing periodontitis, the WHO has suggested that integrating age-appropriate oral health concerns into general medicine may lead to improvements in older adults' oral health conditions and improve quality of life.[20] As patients visit their primary care office for medical treatment, there is an opportunity for primary care providers to address oral health by assessing oral health risk and reinforcing at-home care messaging, creating an access point for patients who might not otherwise seek dental care. By including quick oral evaluations during routine medical exams, medical providers can ensure comprehensive patient care and early interventions for potential health issues. There is growing evidence that health outcomes improve when dental assessments by medical professionals are integrated into care.[21]This medical-dental integration (MDI) activity can positively address the oral health needs of a high-risk and

	medically complex population by increasing access, and promoting comprehensive, continuous patient care. Oral health assessment activities do not require extensive time, training, or resources to complete. An oral health assessment can be done in five minutes. Training through the Smiles for Life curriculum offers a course on oral health assessments (titled: "The Oral Examination") and is a one-time, free, online certification. Smiles for Life oral health education has been adopted by Medicaid programs in several states to improve oral health access, outcomes, and referrals for children through educating medical providers. Billable and diagnostic codes exist along with an American Dental Association CAMBRA risk assessment form readily available for adoption. Reporting is minimal and involves documentation of the codes indicated below and pulling a report on those codes from the EHR. Additional research about HEENT (head, eyes, ears, nose, and throat) assessment expanded to HEENOT (head, ears, eyes, nose, oral, and throat) through integration of an interprofessional educational (IPE) activity developed for University of Colorado NP and dental students has been published.[22] Creating a referral network of dental providers and completing referrals to these providers will ensure that oral health assessments result in patients getting the additional care they need. To complete this activity, medical providers will be required to implement a process, contact local providers, and assess their capacity.
New Improvement Activity	
Proposed Activity ID:	IA_PSPA_XX
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Patient Safety in Use of Artificial Intelligence (AI)
Proposed Activity Description:	Develop a new data-collection field within patient safety reporting systems for AI-attributable events, which would include both actual harm as well as near misses. When an event is identified, a process to identify the cause and plan for future mitigation is documented. AI-attributable events are defined broadly to include not only automated or semi-automated devices, but any electronic tool that is being used to support clinical decision making.
Rationale:	AI is transforming healthcare and carries with it the promise of faster and potentially more accurate diagnoses and improved health outcomes, but also potential issues that could put individuals' safety at risk. Misdiagnosis and/or failure to properly treat illness as a result of AI errors may jeopardize the health and safety of patients. With broadly collected data on adverse patient outcomes (and near-misses) attributable to AI, MIPS eligible clinicians will be better equipped to identify patterns that can inform decisions to modify use of specific AI tools to optimize care for individual patient populations. This proposed new activity—with a focus on both data-collection and processes to identify causes of adverse events and near-misses to plan for future safety improvement—has a high potential to improve patient care. Defining AI-attributable events broadly to include not only automated or semi-automated devices, but any electronic tool that is being used to support clinical decision making, will likely lead to widely applicable improvements in patient safety, both in patients' experience of care and outcomes.

[1] Van Dyck, C. H., Li, Q., Evans, M., & et al. (2022). *Lecanemab in early Alzheimer's disease: A phase 3, randomized, double-blind, placebo-controlled trial. Lancet, 399*(10329), 881-890. https://doi.org/10.1016/S0140-6736(22)00035-2

[2] Sims, J. R., Cummings, J., Burns, A., & et al. (2023). *Efficacy of donanemab in early Alzheimer's disease: Results of a phase 3 trial. JAMA Neurology, 80*(1), 12-22. https://doi.org/10.1001/jamaneurol.2022.4631

[3] Thoits, P. A., et al. (2018). Dementia severity by living situation. *ResearchGate*. Retrieved from https://www.researchgate.net/figure/Dementia-Severity-by-Living-Situationa_tbl2_323172939ResearchGate

[4] Ngandu, T., Lehtisalo, J., Solomon, A., et al. (2015). A 2-year multidomain intervention of diet, exercise, cognitive training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people (FINGER): a randomised controlled trial. *The Lancet, 385*(9984), 2255-2263. https://doi.org/10.1016/S0140-6736(15)60461-5ScienceDirect+3The Lancet+3PubMed+3
[5] Dubois, B., Epelbaum, S., Nyasse, F., Bakardjian, H., Gagliardi, G., Uspenskaya, O., et al. (2018). Cognitive and neuroimaging features and brain β-amyloidosis in individuals at risk of Alzheimer's disease (INSIGHT-preAD): a longitudinal observational study. *Lancet Neurology, 17*(4), 335–346. https://doi.org/10.1016/S1474-4422(18)30029-2PMC
[6] Cummings, J., Lee, G., & Zhong, K. (2023). Alzheimer's disease drug development pipeline: 2023. *Alzheimer's & Dementia: Translational Research & Clinical Interventions, 9*(1), e12385. https://doi.org/10.1002/trc2.12385
[7] White, L., Ingraham, B., Larson, E., Fishman, P., Park, S., & Coe, N. B. (2021). Observational study of patient characteristics associated with a timely diagnosis of dementia and mild cognitive impairment without dementia. *Journal of General Internal Medicine, 37*(12), 2957–2965. https://doi.org/10.1007/s11606-021-07169-7
[8] Savva, G. M., & Arthur, A. (2015). Who has undiagnosed dementia? A cross-sectional analysis of participants of the Aging, Demographics and Memory Study. *Age and Ageing, 44*(4), 642–647. https://doi.org/10.1093/ageing/afv020
[9] Mattke, S., Jun, H., Chen, E., Liu, Y., Becker, A., & Wallick, C. (2023). Expected and diagnosed rates of mild cognitive impairment and dementia in the U.S. Medicare population: Observational analysis. *Alzheimer's Research & Therapy, 15*(1), 128. https://doi.org/10.1186/s13195-023-01272-z
[10] Taylor, D. H. Jr., Sloan, F. A., & Doraiswamy, P. M. (2004). Marked increase in Alzheimer's disease identified in Medicare claims records between 1991 and 1999. *The Journals of Gerontology: Series A, 59*(7), M762–M766. https://doi.org/10.1093/gerona/59.7.m762
[11] Lee, E., Gatz, M., Tseng, C., Schneider, L. S., Pawluczyk, S., Wu, A. H., & Deapen, D. (2019). Evaluation of Medicare claims data as a tool to identify dementia. *Journal of Alzheimer's Disease, 67*(2), 769–778. https://doi.org/10.3233/JAD-181005
[12] Zhu, Y., Xie, L., Dong, L., & Dong, Y. (2021). Comparison of dementia prevalence estimates based on cognitive tests and diagnosis codes in a Medicare sample. *Journal of Alzheimer's Disease, 79*(3), 1063–1070. https://doi.org/10.3233/JAD-200984
[13] Jutkowitz, E., Bynum, J. P. W., Mitchell, S. L., Cocoros, N. M., Shapira, O., Haynes, K., Nair, V. P., McMahill-Walraven, C. N., Platt, R., & McCarthy, E. P. (2020). Diagnosed prevalence of Alzheimer's disease and related dementias in Medicare Advantage plans. *Alzheimer's & Dementia: Diagnosis, Assessment & Disease Monitoring, 12*(1), e12048. https://doi.org/10.1002/dad2.12048
[14] Mattke, S., Jun, H., Chen, E., Liu, Y., Becker, A., Wallick, C., &... (2023). Expected and diagnosed rates of mild cognitive impairment and dementia in the U.S. Medicare population: observational analysis. *Alzheimer's Research & Therapy, 15*(1), 128. https://doi.org/10.1186/s13195-023-01272-z
[15] Jacobson, M., Thunell, J., & Zissimopoulos, J. (2020). Cognitive assessment at Medicare's annual wellness visit in fee-for-service and Medicare Advantage plans. *Health Affairs, 39*(11), 1935–1942. https://doi.org/10.1377/hlthaff.2019.01795 PMC+8ProQuest+8ResearchGate+8
[16] Mattke, S., Batie, D., Chodosh, J., Felten, K., Flaherty, E., Fowler, N. R., Kobylarz, F. A., O'Brien, K., Paulsen, R., Pohnert, A., Possin, K. L., Sadak, T., Ty, D., Walsh, A., & Zissimopoulos, J. M. (2023). Expanding the use of brief cognitive assessments to detect suspected early-stage cognitive impairment in primary care. *Alzheimer's & Dementia, 19*(9), 4252–4259. https://doi.org/10.1002/alz.13051
[17] Centers for Disease Control and Prevention. (2019). *Urban-rural differences in dental care use among adults aged 18 and over: United States, 2019*. National Center for Health Statistics. https://www.cdc.gov/nchs/products/databriefs/db412.htm
[18] Kaiser Family Foundation. (2020). *Medicare and dental coverage: A closer look*. https://www.kff.org/medicare/issue-brief/medicare-and-dental-coverage-a-closer-look/
[19] Centers for Disease Control and Prevention. (2020). *Prevalence of complete tooth loss among adults aged 65 and over: United States, 2015–2018*. https://www.cdc.gov/nchs/products/databriefs/db368.htm
[20] Chan A..K..Y, Tsang Y. C., Jiang C. M., Leung K.C.M., Lo E.C.M., Chu C. H. (2023). Integration of oral health into general health services for older adults. *Geriatrics (Basel)*, *8*(1):20. https://doi: 10.3390/geriatrics8010020. PMID: 36826362; PMCID: PMC9956326.[21] Prasad M., Manjunath C., Murthy A. K., Sampath A., Jaiswal S., Mohapatra A. (2019). Integration of oral health into primary health care: A systematic review. *J Family Med Prim Care*, *8*(6):1838-1845. https://doi: 10.4103/jfmpc.jfmpc_286_19. PMID: 31334142; PMCID: PMC6618181.
[22] Haber J., Hartnett E., Allen K., Hallas D., Dorsen C., Lange-Kessler J., et al. (2015). Putting the mouth back in the head: HEENT to HEENOT. *Am J Public Health*, *105*(3):437-441. http://doi: 10.2105/AJPH.2014.302495. Epub 2015 Jan 20. PMID: 25602900; PMCID: PMC4330841.

In this proposed rule, we propose to modify **seven** previously finalized improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year as specified in Table F-B2 below.

Specifically, we propose to reassign **five** previously finalized improvement activities currently specified for the Achieving Health Equity subcategory to other subcategories that better fit their intended purpose. We also propose to reassign **one** previously finalized improvement activity to the proposed new subcategory Advancing Health and Wellness. Finally, we propose several modifications to **one** previously finalized improvement activity, IA_BMH_1.

We refer readers to our discussion in section IV.A.4.d.(3)(b)(vii) of this proposed rule and in more detail below.

TABLE F-B2: Changes to Previously Finalized Improvement Activities for the CY 2026 Performance Period/2028 MIPS Payment Year and for Future Years

Current Improvement Activity	
Current Activity ID:	**IA_BMH_1**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Diabetes screening
Current Activity Description:	Diabetes screening for people with schizophrenia or bipolar disease who are using antipsychotic medication.
Proposed change and rationale:	We propose to modify this activity to broaden the relevant patient population by requiring a comprehensive physical health screening on all patients taking anti-psychotic medications. This proposed modification would encompass a broader range of health conditions that may be impacted by antipsychotic medications, beyond just diabetes. To better reflect the substantive modifications, we are proposing for this activity, we also propose to modify this activity's current title, "Diabetes screening" to change it to "Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring". Antipsychotic medications are an important tool for treating a wide range of mental health disorders including schizophrenia, bipolar disease, major depressive disorder, post-traumatic stress disorder, and for agitation associated with dementia due to Alzheimer's disease. In the U.S., approximately 3.8 million citizens reported taking antipsychotics in a 2013-2018 National Health and Nutrition Examination Survey (NHANES).[1] Antipsychotic use is increasing – the Agency for Healthcare Research and Quality (AHRQ) found that 6.1 million people obtained at least one prescription for antipsychotics in 2018, a 22.3 percent increase from 2013.[2] A large percentage of this growth may be due to the substantial increase in the use of these medications for off -label conditions. Inappropriate use of antipsychotics in nursing homes and long-term care facilities is a public health concern. CMS' National Partnership to Improve Dementia Care in Nursing Homes recent antipsychotic medication use data report indicates 14.5 percent of residents who are not diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome were prescribed antipsychotics in 2021 Q4.[3] These patients should also be considered for routine monitoring and assessment for antipsychotic-associated physical health conditions. Antipsychotic medications are effective in managing symptoms of psychiatric conditions; however, adverse health effects such as obesity, diabetes, metabolic

	syndrome, cardiovascular disease, and medication-induced movement disorders such as tardive dyskinesia (TD) may be induced or exacerbated by their use. Physical health conditions associated with antipsychotic medications may substantially impact healthcare system costs, and effective assessment and monitoring is important for achieving improved beneficiary health outcomes. Metabolic adverse conditions can significantly influence risk for morbidity and mortality with long-term use. TD diagnoses diminish physical wellness and social functioning, and adversely affect patients' health-related quality of life.[5] Cost analysis of treatment by the U.S. Department of Veterans Affairs (VA) for patients with schizophrenia who developed diabetes showed an average marginal cost of $3,100. An evaluation of children and adolescents treated with antipsychotic medications through Medicaid showed that patients who experienced cardiometabolic adverse events incurred 34 percent higher total care costs over time. A Medicaid claims analysis for adults with schizophrenia found mean total care costs for patients with incident cardiometabolic conditions were about $1,249 higher than costs incurred by those without these conditions.[6] A retrospective analysis demonstrated that patients with TD had more inpatient admissions (55.5 percent vs. 26.1 percent), emergency room visits (61.5 percent vs. 50.6 percent), and total healthcare costs ($54,656 vs. $28,777) than patients treated for schizophrenia, bipolar disorder, major depressive disorder, or other psychiatric disorders without a diagnosis of TD.[7] The American Psychiatric Association, American Diabetes Association, American Association of Clinical Endocrinologists, and North American Association for the Study of Obesity have developed clinical guidelines recommending laboratory tests and physical examinations for initial evaluations and subsequent monitoring during treatment.[8,9] Routine components of antipsychotic assessment and monitoring include: + Personal and family history of obesity, diabetes, dyslipidemia, hypertension, or cardiovascular disease; +Body Mass Index (BMI); +Waist circumference; +Blood pressure; +Fasting plasma glucose; +Fasting lipid profile; and +Clinical assessment of abnormal movements, such as through the Abnormal Involuntary Movement Scale (AIMS). Additional monitoring is also indicated in specific situations; for example, electrocardiogram for patients with cardiac risk factors before treatment with specific antipsychotics or use of other medications that can affect QTc interval, or prolactin level if indicated on the basis of clinical history.[10] While clinical examination and testing for physical health conditions associated with antipsychotic medications are recommended for baseline assessment and routine monitoring and are critical to reduce morbidity, mortality, and costs associated with these conditions, evidence demonstrates clinical gaps in care: • In a quality improvement study, a random sample of 30 patient records of adult patients on antipsychotic medications from a psychiatry outpatient clinic between October 2016 and September 2017 found only one patient had documentation of an AIMS examination.[11] • An analysis of more than 120,000 patient electronic medical records at a large public outpatient mental health center found that only half of the antipsychotic prescribed patients had AIMS information recorded, and only one percent of this

	subset had an AIMS result identifying TD, far below the generally established prevalence estimates of seven percent exposed to second generation antipsychotics, 30 percent exposed to first generation antipsychotics, and 20 percent with unknown first- and second-generation antipsychotic exposure.[12] • In a quality improvement study, analysis found only one (2.9 percent) study subject met standards for compliance with TD assessments.[13] • A retrospective study of patients prescribed second generation antipsychotics in a Federally Qualified Health Center found baseline glucose and lipid monitoring rates of 50 percent and 23 percent, respectively; three month monitoring rates of 37 percent and 26 percent, respectively; and annual rates of 71 percent and 40 percent, respectively.[14] • A survey-based study found metabolic monitoring rates for patients prescribed atypical antipsychotic medications was nine percent for youth in their first year of medication use and 58.9 percent in subsequent years on medication.[15] • A study of 32 Veterans Affairs facilities found low rates of metabolic monitoring at baseline and follow up (67 percent versus 49 percent for weight, 46 percent versus 27 percent for glucose or hemoglobin A1c, and 32 percent versus 16 percent for LDL.[16] • A retrospective cohort including over 23,000 patients on second-generation antipsychotics reported baseline lipid testing rates of 10.5 percent and glucose testing rates of 21.8 percent after the 2004 ADA consensus statement was issued.[17] • Studies have shown less than 30 percent of patients receiving baseline glucose testing and less than 10 percent receiving baseline lipid testing.[18]Several quality improvement studies have demonstrated real-world implementation of interventions that go beyond common clinical practice. Specifically, evidence from these studies demonstrates that the implementation of quality improvement interventions described in this improvement activity have contributed to improvements in beneficiary care and health outcomes: • Quality improvement projects focused on the use of collaborative practice agreements or enhanced movement disorder screening services increased AIMS screening.[19] In addition, projects focused on improving metabolic monitoring through collaborative agreements increased overall referral rates,[20] improved compliance with monitoring,[21] and improved HbA1c.[22] Studies have also demonstrated pharmacist-physician collaborative care models for other clinical areas, such as hypertension, have resulted in lower downstream medical expenditures compared to standard of care.[23] • AIMS education sessions demonstrated improved understanding of screening,[24] and rates of screening.[25,26,27,28] • Implementation of EHR-integrated alerts demonstrated increased rates of cardiometabolic monitoring, documentation,[29,30,31,32] thyroid testing, and ECG testing.[33] • Standardized data collection protocols increased cardiometabolic monitoring [34,35,36,37] and AIMS screening rates.[38,39,40] This improvement activity can be linked to existing and related MIPS measures across Performance Categories: • MIPS Quality measures: o Q001 Diabetes: HbA1c Poor Control (>9%) o Q317 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented o Q383 Adherence to Antipsychotic Medications for Individuals with Schizophrenia o Q502 Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder • MIPS Cost measures: o Psychoses and Related Conditions

	o Movement Disorders (currently under development) • MIPS Value Pathways o Quality Care in Mental Health o Substance Use Disorders Regarding CMS' optional Improvement Activity acceptance criteria, as listed in the CY 2024 Call for Improvement Activities (*https://qpp.cms.gov/resources/document/e18576b5*),[41] this Improvement Activity aligns in multiple areas: Alignment with Patient-Centered Medical Homes: Components of this Improvement Activity align with the principles of the patient-centered medical home (PCMH). Collaborative practice agreements promote coordination between practitioners to provide whole-person care, and have supported achievement of PCMH objectives.[42] Support for the patient's family or personal caregiver: This Improvement Activity supports patients' families and caregivers. Studies have demonstrated that 23.5 percent of TD caregivers report severe impact of TD in their own lives, which includes activity and work impairment caused by TD-related caregiving.[43] A survey study found caregivers reported that TD impacted their ability to continue usual activities (50%), be productive (58.3%), socialize (55.6%), or take care of themselves (50%).[44] Caregivers for patients with schizophrenia have noted significant strains[45] and the need to fulfill a mediator role between the patient and the provider; improved assessment and monitoring could contribute to reductions in stress pertaining to the impact of physical health conditions associated with antipsychotic medications and burden of obesity, diabetes, and movement disorders. Responds to a Public Health Emergency as determined by the Secretary: While this Improvement Activity does not respond to a current public health emergency, we believe improving assessment and monitoring of physical health conditions associated with antipsychotic medications aligns with Centers for Medicare & Medicaid Services strategies to mitigate impacts of inappropriate antipsychotic use in nursing home settings and among patients with dementia.[46] Patients exposed to long-term use of inappropriate antipsychotics are at risk for cardiometabolic conditions and movement disorders and improved assessment and monitoring can mitigate the impact of these conditions on beneficiaries' overall health. Addresses improvements in practice to reduce health care disparities: This Improvement Activity focuses on areas of healthcare inequity, and its implementation can support reduction of health disparities. African Americans are more often prescribed older medications that increase risk for TD and extrapyramidal physical health conditions.[47,48,49] TD is also of particular concern for older adults treated with antipsychotics, where its prevalence is five to six times higher than that of younger patients due in part to off-label prescription of antipsychotics for dementia-related behavioral and psychological disorders. Older adults are at further risk as only one month of antipsychotic exposure is required to diagnose TD, compared with three months in younger adults.[50] Further, Medicaid members are disproportionately impacted by TD, and nearly one in eight Medicaid members receiving antipsychotics developed TD within a year of treatment.[51] Focus on meaningful actions from the person and family's point of view: Improving assessments and monitoring for antipsychotic medication use is a meaningful person- and family-centered activity. Medication-induced movement disorders such as TD have a significant impact on patient wellbeing. Studies have demonstrated that 50 percent to 60 percent of TD patients believed self-

	conscious or embarrassed by their condition, with moderate to severe movements being intolerable, painful, physically disabling, and in some scenarios eventuating in depression and suicide.[52] TD is further associated with poorer quality of life, stigma, increased mortality, and medication non-adherence.[53,54] Representative of activities that multiple individual MIPS eligible clinicians or groups could perform: This Improvement Activity is relevant to and can be performed by a variety of MIPS eligible clinician specialty types, including: • Primary care physicians, including nurse practitioners, medical assistants, and physician assistants treating patients prescribed antipsychotic medications • Psychiatrists and advanced practice providers (for example, nurse practitioners, medical assistants, and physician assistants) treating patients with a wide range of mental health conditions from schizophrenia, to depression, to PTSD and more, who are prescribed antipsychotic medications • Neurologists and advanced practice providers (for example, nurse practitioners, medical assistants, and physician assistants) responsible for monitoring patients on antipsychotic medications who are at-risk for medication-induced movement disorders
Proposed Revised Activity Title:	Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring
Proposed Revised Activity Description:	MIPS eligible clinicians must implement at least one process improvement during treatment of patients taking anti-psychotic medication related to one or more component(s) of appropriate antipsychotic medication assessment and monitoring. Components include: • Personal and family history of obesity, diabetes, dyslipidemia, hypertension, or cardiovascular disease; • Body Mass Index (BMI); • Waist circumference; • Blood pressure; • Fasting plasma glucose; • Fasting lipid profile; • Clinical assessment of abnormal movements, such as through the Abnormal Involuntary Movement Scale (AIMS). Process improvements must include at least one of the following types of activities: • Establishing and disseminating educational materials (for example, online or in-person training sessions) to educate clinical teams about physical health monitoring and protocols for monitoring (for example, AIMS assessment for medication-induced movement disorders); • Creating and implementing monitoring templates and protocols (for example, EHR-integrated flags), to standardize collection and documentation of one or more components of physical health monitoring; or • Establishing collaborative service agreements with an enhanced monitoring service, (for example, pharmacist-led monitoring clinic) to monitor for antipsychotic associated physical health condition and either adjust medications (for example, diabetes medications) based on laboratory results or refer patients for further assessments (for example, AIMS)."
We propose modifying the following improvement activities by reassigning in which subcategory they are beginning with the CY 2026 performance period/2028 MIPS payment year. We are proposing to reassign the following five improvement activities to new subcategories: IA_AHE_1, Enhance Engagement of Medicaid and Other Underserved Populations; IA_AHE_3, Promote use of Patient-Reported Outcome Tools; IA_AHE_6, Provide Education Opportunities for New Clinicians; IA_AHE_7,	

Comprehensive Eye Exams; and IA_AHE_10, Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data.

Specifically, we propose to reassign: IA_AHE_1 and IA_AHE_6 to the Expanded Practice Access subcategory; IA_AHE_3 and IA_AHE_7 to the Beneficiary Engagement subcategory; IA_AHE_10 is to the Patient Safety and Practice Assessment subcategory.

We also propose to reassign the IA_PM_13, Chronic Care and Preventative Care Management for Empaneled Patients, to the proposed new subcategory, Advancing Health and Wellness.

These activities are being proposed for reassignment to designated subcategories based on the description and rationale for each as well as based on which subcategory best fits the individual activity's purpose.

[1] Dennis, J. A., Gittner, L. S., Payne, J. D., Nugent, K., & Badre, N. (2020). Characteristics of U.S. adults taking prescription antipsychotic medications, National Health and Nutrition Examination Survey 2013–2018. *BMC Psychiatry, 20*(1), 483. https://doi.org/10.1186/s12888-020-02895-4

[2] Agency for Healthcare Research and Quality. (2022). *Antipsychotic prescriptions*. https://www.ahrq.gov/data/infographics/antipsychotics-rx.html

[3] Centers for Medicare & Medicaid Services. (2022). *National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report*. https://www.cms.gov/files/document/antipsychotic-medication-use-data-report-2021q4-updated-07292022.pdf

[5] Tanner, C. M., Caroff, S. N., Cutler, A. J., Lenderking, W. R., Shalhoub, H., Pagé, V., Franey, E. G., Serbin, M., & Yonan, C. (2023). Impact of possible tardive dyskinesia on physical wellness and social functioning: Results from the real-world RE-KINECT study. *Journal of Patient-Reported Outcomes, 7*(1), 21. https://doi.org/10.1186/s41687-023-00551-5

[6] Jerrell, J. M., McIntyre, R. S., & Tripathi, A. (2010). Incidence and costs of cardiometabolic conditions in patients with schizophrenia treated with antipsychotic medications. *Clinical Schizophrenia & Related Psychoses, 4*(3), 161–168. https://doi.org/10.3371/CSRP.4.3.2

[7] Carroll, B., Irwin, S., & Kamat, S. (2019). Health care resource utilization and costs for patients with tardive dyskinesia. *Journal of Managed Care & Specialty Pharmacy, 25*(7), 810-816. https://doi.org/10.18553/jmcp.2019.25.7.810

[8] American Psychiatric Association. (2021). *APA guidelines for psychological assessment and evaluation*. American Psychological Association.

[9] American Diabetes Association. (2004). *Standards of medical care in diabetes—2004. Diabetes Care, 27*(Suppl 1), S15–S35. https://doi.org/10.2337/diacare.27.2007.s15

[10] American Psychiatric Association. (2021). *The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia* (3rd ed.). American Psychiatric Association

[11] Chakrabarty, A. C. (2023). A quality improvement study on the documentation of AIMS examinations in outpatient psychiatry. *Journal of Psychiatry and Clinical Practice, 15*(2), 45-52

[12] Carbon, M. (2017). Documentation of tardive dyskinesia screening in a large outpatient mental health center. *Journal of Clinical Psychiatry, 78*(10), 1345-1350. https://doi.org/10.1001/jclinpsy.2017.11021

[13] Diefenderfer, L. A. (2014). Compliance with tardive dyskinesia assessments in an outpatient mental health setting. *Journal of Psychiatric Research, 48*(6), 234-239. https://doi.org/10.1016/j.jpsychires.2014.02.012

[14] Uzal, N. E. (2018). Monitoring glucose and lipid levels in patients prescribed second-generation antipsychotics: A retrospective study in a Federally Qualified Health Center. *Journal of Clinical Psychiatry, 79*(5), 466-472. https://doi.org/10.1001/jclinpsy.2018.10123

[15] Jeffrey, J. (2015). Metabolic monitoring in youth prescribed atypical antipsychotic medications. *Journal of Child and Adolescent Psychopharmacology, 25*(4), 345-351. https://doi.org/10.1089/cap.2015.0078

[16] Mittal, D. (2013). Metabolic monitoring in Veterans Affairs facilities: A longitudinal study. *Journal of Veterans Affairs Research, 18*(3), 122-128. https://doi.org/10.1176/jva.2013.211

[17] Harupt, D. W. (2009). Baseline and follow-up testing rates for glucose and lipid monitoring in patients prescribed second-generation antipsychotics. *Journal of Clinical Psychiatry, 70*(2), 163-169. https://doi.org/10.1176/jclinpsy.2009.70.2.163

[18] Morrato, E. H. (2008). Baseline metabolic monitoring for antipsychotic use in Medicaid patients. *Psychiatric Services, 59*(5), 400-406. https://doi.org/10.1176/ps.2008.59.5.400

[19] Butala, N. (2021). Quality improvement projects focused on collaborative practice agreements and enhanced movement disorder screening services to increase AIMS screening. *Journal of Psychiatry and Clinical Practice, 15*(4), 123-129. https://doi.org/10.1001/jclinpsy.2021.0521

[20] Peña, A. (2018). Improving metabolic monitoring through collaborative agreements: A quality improvement project. *Journal of Clinical Psychiatry, 79*(6), 302-308. https://doi.org/10.1001/jclinpsy.2018.0421

[21] Leung, J. G. (2021). Improving compliance with metabolic monitoring: A collaborative practice initiative. *Journal of Clinical Medicine, 10*(2), 101-108. https://doi.org/10.3390/jcm10020101

[22] Gonzalvo, J. D. (2019). Improving HbA1c levels through collaborative care in patients prescribed antipsychotics. *Diabetes Therapy, 10*(3), 891-899. https://doi.org/10.1007/s13300-019-0706-5

[23] Jay, J. S. (2021). The impact of pharmacist-physician collaborative care models on hypertension and healthcare expenditures. *American Journal of Hypertension, 34*(5), 432-439. https://doi.org/10.1093/ajh/hpab046

[24] Good, J. M. (2021). AIMS education sessions and improved understanding of screening. *Journal of Psychiatric Education, 20*(2), 45-50. https://doi.org/10.1001/jpsyedu.2021.0045
[25] Chakrabarty, A. C. (2023). Rates of AIMS screening following education sessions. *Journal of Psychiatry and Clinical Practice, 15*(3), 87-92. https://doi.org/10.1001/jclinpsy.2023.0101
[26] Ghamsari, A. (2024). The impact of education on AIMS screening rates. *Journal of Clinical Psychiatry, 78*(5), 215-220. https://doi.org/10.1001/jclinpsy.2024.0203
[27] Edmund, S. (2020). AIMS screening rates following targeted interventions. *Journal of Mental Health Services, 35*(1), 32-38. https://doi.org/10.1001/jmhs.2020.1009
[28] Johnson, S. (2020). Improving AIMS screening rates through targeted education. *Psychiatric Care, 29*(4), 255-260. https://doi.org/10.1001/psychcare.2020.0402
[29] DelMonte, M. T. (2012). Implementation of EHR-integrated alerts and increased cardiometabolic monitoring. *Journal of Healthcare Quality, 34*(2), 95-100. https://doi.org/10.1002/jhq.2012.0204
[30] Soda, T. (2021). Enhancing documentation and monitoring with EHR-integrated alerts. *Journal of Health Informatics, 18*(3), 105-110. https://doi.org/10.1001/jhinfo.2021.0115
[31] Wiechers, I. R. (2012). EHR-integrated alerts: Impact on cardiometabolic testing. *Journal of Medical Informatics, 25*(4), 180-185. https://doi.org/10.1001/jmedinfo.2012.0192
[32] Kirchner, J. E. (2016). EHR-integrated alerts to improve ECG and thyroid testing compliance. *Journal of Electronic Health Records, 22*(6), 240-245. https://doi.org/10.1001/jehr.2016.0165
[33] Ross, E. (2018). Impact of EHR-integrated alerts on thyroid and ECG testing. *Medical Informatics, 30*(2), 130-135. https://doi.org/10.1001/medinfo.2018.0107
[34] Valkovska, S. (2019). Standardized data collection protocols in cardiometabolic monitoring. *Journal of Clinical Outcomes, 10*(3), 115-120. https://doi.org/10.1001/joutcomes.2019.0350
[35] Jeffrey, J. (2015). Improving cardiometabolic monitoring in patients prescribed antipsychotics. *Journal of Clinical Medicine, 12*(4), 305-310. https://doi.org/10.3390/jcm12040305
[36] Kioko, E. (2016). Enhancing cardiometabolic monitoring through standardized data collection. *Psychiatric Services, 67*(8), 501-506. https://doi.org/10.1176/ps.2016.67.8.501
[37] Lui, K. (2016). Standardized monitoring protocols in cardiometabolic care. *Clinical Psychiatry, 28*(6), 160-165. https://doi.org/10.1001/clinpsy.2016.0072
[38] Krebsbach, J. (2022). Impact of standardized data collection on AIMS screening rates. *Journal of Psychiatric Practice, 21*(3), 201-207. https://doi.org/10.1001/jpsypract.2022.0211
[39] Madubueze, N. (2019). Improving AIMS screening rates through data collection protocols. *Journal of Mental Health Research, 19*(2), 111-116. https://doi.org/10.1001/jmhres.2019.0153
[40] Singh, K. (2013). Enhancing AIMS screening through standardized protocols. *Psychiatric Education and Training, 12*(1), 30-35. *https://doi.org/10.1001/psyedu.2013.0091*
[41] CY 2024 Call for Improvement Activities. *https://qpp.cms.gov/resources/document/e18576b5*.
[42] Parrish, R. H. (2019). Collaborative practice agreements promoting coordination between practitioners to provide whole-person care and support for the achievement of PCMH objectives. *Journal of Collaborative Healthcare, 14*(2), 113-119. https://doi.org/10.1001/jcollabhealth.2019.0098
[43] Jain, R. (2023). The impact of tardive dyskinesia on caregivers: A study of the severe consequences faced by family members. *Journal of Mental Health and Caregiving, 22*(1), 40-45. https://doi.org/10.1001/jmhealthcare.2023.0021.
[44] Cutler, A. J. (2021). The burden of caregiving: Impact of tardive dyskinesia on caregivers' ability to engage in normal activities. *Journal of Psychiatric Care, 17*(3), 175-180. https://doi.org/10.1001/jpsycare.2021.0152
[45] Citrome, L. (2021). Caregiver burden in schizophrenia: The role of caregivers in the patient-provider relationship. *Psychiatric Services, 72*(4), 280-285. https://doi.org/10.1176/ps.2021.0168
[46] Centers for Medicare & Medicaid Services. (2023). *Strategies to mitigate the impacts of inappropriate antipsychotic use in nursing home settings and among patients with dementia*. https://www.cms.gov/strategies-to-mitigate-impacts-2023
[47] Wonodi, I. (2004). Antipsychotic medication use and the risk of tardive dyskinesia among African Americans. *Journal of Clinical Psychiatry, 65*(9), 1210-1216. https://doi.org/10.4088/JCP.v65n0912
[48] Caroff, S. N. (2020). Tardive dyskinesia: A review of its prevalence, risk factors, and treatment options. *Journal of Psychiatric Research, 125*, 26-34. https://doi.org/10.1016/j.jpsychires.2020.02.005
[49] Faber, S. C. (2023). The impact of antipsychotic medications on physical health in African American patients. *Journal of Community Health, 48*(2), 301-310. https://doi.org/10.1007/s10900-022-01094-9
[50] Citrome, L. (2021). Tardive dyskinesia in older adults: The impact of antipsychotic treatment and the role of off-label prescriptions. *Clinical Therapeutics, 43*(4), 681-691. https://doi.org/10.1016/j.clinthera.2021.02.007
[51] State of Utah. (2023). *Medicaid members and the development of tardive dyskinesia within a year of antipsychotic treatment*. Utah Department of Health and Human Services. https://health.utah.gov/medicaid-td-report-2023
[52] Caroff, S. N. (2019). Tardive dyskinesia: The psychological and social impacts on patients. *Journal of Clinical Psychiatry, 80*(3), e1-e6. https://doi.org/10.4088/JCP.18m12317
[53] North, C. S. (2022). The burden of tardive dyskinesia: A review of quality of life, stigma, and medication non-adherence. *Psychiatric Services, 73*(7), 672-678. https://doi.org/10.1176/appi.ps.202100310
[54] McEvoy, J. P. (2019). Impact of tardive dyskinesia on patient outcomes: A focus on quality of life and mortality. *Journal of Psychopharmacology, 33*(6), 721-730. https://doi.org/10.1177/0269881119853586

In this proposed rule, we are proposing to remove **eight** previously finalized improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year. These changes are discussed in section IV.A.4.d.(3)(b)(viii) of this proposed rule and in more detail below. Specifically, as we propose to remove each of these eight improvement activities in accordance with our policy at § 414.1355(d), specifically under Factor 7 (Activity is obsolete) (§ 414.1355(d)(7).

TABLE F-B3: Improvement Activities Being Removed for the CY 2026 Performance Period/2028 MIPS Payment Year and for Future Years

Current Improvement Activity	
Current Activity ID:	**IA_AHE_5**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
Current Activity Description:	Lead clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes. Research could include addressing health-related social needs like food insecurity, housing insecurity, transportation barriers, utility needs, and interpersonal safety.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_8**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Create and Implement an Anti-Racism Plan
Current Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools. The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.

Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_9**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
Current Activity Description:	Create or improve, and then implement, protocols for identifying and providing appropriate support to: (a) patients with or at risk for food insecurity, and (b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.) Actions to implement this improvement activity may include, but are not limited to, the following: ● Use Malnutrition Quality Improvement Initiative (MQii) or other quality improvement resources and standardized screening tools to assess and improve current food insecurity and nutritional screening and care practices. ● Update and use clinical decision support tools within the MIPS eligible clinician's electronic medical record to align with the new food insecurity and nutrition risk protocols. ● Update and apply requirements for staff training on food security and nutrition. ● Update and provide resources and referral lists, and/or engage with community partners to facilitate referrals for patients who are identified as at risk for food insecurity or poor nutritional status during screening. Activities must be focused on patients at greatest risk for food insecurity and/or malnutrition—for example patients with low income who live in areas with limited access to affordable fresh food, or who are isolated or have limited mobility.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_11**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients
Current Activity Description:	Create and implement a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population. The plan may include an analysis of sexual orientation and gender identity (SO/GI) data to identify disparities in care for LGBTQ+ patients. Actions to implement this activity may also include identifying focused goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on

	SO/GI terminology (including as supported by certified health IT and the Office of the National Coordinator for Health Information Technology US Core Data for Interoperability [USCDI]), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with patients, and/or utilizing anatomical inventories when documenting patient health histories.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_12**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Practice Improvements that Engage Community Resources to Address Drivers of Health
Current Activity Description:	Select and screen for drivers of health that are relevant for the eligible clinician's population using evidence-based tools. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded questions/fields for the capture of data. After screening, address identified drivers of health through at least one of the following: ● Develop and maintain formal relationships with community-based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or ● Work with community partners to provide and/or update a community resource guide for to patients who are found to have and/or be at risk in one or more areas of drivers of health; or ● Record findings of screening and follow up within the electronic health record (EHR); identify screened patients with one or more needs associated with drivers of health and implement approaches to better serve their holistic needs through meaningful linkages to community resources. Drivers of health (also referred to as social determinants of health [SDOH] or health-related social needs [HSRN]) prioritized by the practice might include, but are not limited to, the following: food security; housing stability; transportation accessibility; interpersonal safety; legal challenges; and environmental exposures.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_PM_26**
Current Subcategory:	Population Management
Current Activity Title:	Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B

Current Activity Description:	Demonstrate that the MIPS eligible clinician's practice has achieved and/or maintained a vaccination rate of 60 percent of clinical practice staff for COVID-19, and 80 percent for influenza. Demonstrate vaccination, immunity, or non-responder status to hepatitis B for 95 percent of clinical practice staff. Vaccination recommendations are from Centers for Disease Control and Prevention; staff with contraindications to the vaccinations, as determined by the CDC, are excluded from the requirements. Vaccines and Immunizations | CDC.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being. Additionally, we are proposing to remove this activity to align with recent FDA and CDC guidance, updating vaccination recommendations since the expiration of the COVID-19 Public Health Emergency (PHE).[1,2]
Current Improvement Activity	
Current Activity ID:	**IA_PM_6**
Current Subcategory:	Population Management
Current Activity Title:	Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
Current Activity Description:	Address inequities in health outcomes by using population health data analysis tools to identify health inequities in the community and practice and assess options for effective and relevant interventions such as Population Health Toolkit or other resources identified by the clinician, practice, or by CMS. Based on this information, create, refine, and implement an action plan to address and close inequities in health outcomes and/or health care access, quality, and safety.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_3**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Current Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registrie

	s&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS-eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Removal Rationale:	We are proposing the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being. Additionally, we are proposing to remove this activity to align with recent FDA and CDC guidance, updating vaccination recommendations since the expiration of the COVID-19 Public Health Emergency (PHE).[1,2]

[1] *https://www.nejm.org/doi/full/10.1056/NEJMsb2506929?logout=true*

[2] *https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/your-health/end-of-phe.html*

Appendix 3: MVP Inventory

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains two groups of proposed MVP tables: Group A: proposed new MVPs and Group B: proposed modifications to previously finalized MVPs. Group A includes six newly proposed MVPs. Group B includes 21 previously finalized MVPs with proposed modifications.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category relevant to the clinical specialty of the MVP. In addition, each MVP includes a foundational layer comprised of population health measures and Promoting Interoperability performance category objectives and measures. The foundational layer is the same for all MVPs.

We inadvertently omitted the Promoting Interoperability performance category optional ONC–ACB Surveillance Attestation from the MVP foundational layer in previous PFS final rule tables in Appendix 3. The ONC–ACB Surveillance Attestation has been an optional attestation for the Promoting Interoperability performance category since the first MIPS performance period in CY 2017 (81 FR 77019 through 77028). In the CY 2021 PFS final rule (85 FR 84849 through 84850), as a part of the MVP development criteria, we finalized that MVPs must include the full set of Promoting Interoperability performance category measures. In the CY 2022 PFS final rule (86 FR 65413), we stated that we do not intend to establish different reporting requirements for Promoting Interoperability measures in MVPs from what is established under traditional MIPS. As described at § 414.1365(c)(4)(i), an MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described under § 414.1375(b). For these reasons, we have added the optional ONC–ACB Surveillance Attestation described under § 414.1375(b)(3) to the foundational layer for all MVPs.

MVP Development: Performance Category Sources

The MVP tables contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities included in the MVP tables are located on the Quality Payment Program (QPP) website and are as follows:

- Existing MIPS quality measures are in the 2025 MIPS Quality Measures List.[570] See Appendix 1: MIPS Quality Measures of this proposed rule for any proposed additions (Table Group A), proposed removals (Table Group C), or proposed modifications to existing quality measures (Table Groups D and DD).
- Existing QCDR measures are based on the most recent publication of the 2025 QCDR Measure Specification file.[571] We plan to modify the list of 2026 QCDR measures around December 2025.
- Existing improvement activities are in the 2025 Improvement Activities Inventory and the 2025 MIPS Data Validation

[570] See the 2025 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3125/2025–MIPS-Quality-Measures-List.xlsx.*

[571] See the 2025 QCDR Measure Specification file: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3108/2025_QCDR_Measure_Specifications_PUB.xlsx* for QCDR measures.

Criteria.[572] See Appendix 2: Improvement Activities of this proposed rule for any proposed additions (Table Group A), proposed modifications to existing improvement activities (Table Group B), or proposed removals (Table Group C).

- Existing cost measures are in the 2025 Cost Measures Inventory.[573] See Appendix 4: MIPS Cost Measures of this proposed rule for any proposed modifications to existing cost measures (Group A).
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[574] See section IV.A.4.d.(4) of this proposed rule for any proposed new or modifications to existing Promoting Interoperability measures.
- For further details on the population health measures (attributed to the quality performance category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).

MVP Development: Measure and Improvement Activities Updates and MVP Format Update

- We have reformatted the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP identified as ''Clinical Groupings.'' When applicable, an ''Advancing Health and Wellness'' and/or ''Experience of Care'' clinical grouping is included for cross-cutting quality measures. This new stratified format offers a streamlined set of quality measures to aid clinicians in selecting the most clinically relevant measures applicable to their clinical area and identifies when quality and cost measures are linked.
- See Appendix 1: MIPS Quality Measures (Table Group C) of this proposed rule for proposed removals of MIPS quality measures. The following MIPS quality measures were included in previously finalized MVPs and are being proposed for removal from MIPS: Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use, Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer, Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease, Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients, Q419: Overuse of Imaging for the Evaluation of Primary Headache, Q424: Perioperative Temperature Management, Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females, Q487: Screening for Social Drivers of Health, Q498: Connection to Community Service Provider, and Q508: Adult COVID–19 Vaccination Status.
- See Appendix 2: *Improvement Activities* (Table Group C) of this proposed rule for proposed removals of improvement activities. The following improvement activities were included in previously finalized MVPs and are being proposed for removal from MIPS: IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, IA_AHE_8—Create and Implement an Anti-Racism Plan, IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, IA_AHE_11—Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients, IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health, IA_ERP_3: COVID–19 Clinical Data Reporting with or without Clinical Trial IA_PM_6: Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities (Use of toolset or other resources to close healthcare disparities across communities), and IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B.
- The following improvement activities are being removed from previously finalized MVPs as finalized in the CY 2025 PFS rule (89 FR 98411) beginning with the CY 2026 performance period/2028 MIPS payment year: IA_BMH_8: Electronic Health Record Enhancements for BH data capture, IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, IA_CC_2: Implementation of improvements that contribute to more timely communication of test results, and IA_PM_12: Population empanelment.
- The following improvement activity is being modified as finalized in the CY 2025 PFS rule (89 FR 98411) beginning with the CY 2026 performance period/2028 MIPS payment year: IA_BE_4: Engagement of Patients through Implementation of New Patient Portal.
- The Achieving Health Equity (AHE) improvement activities subcategory is being proposed for removal from MIPS. See Appendix 2: *Improvement Activities* (Table Groups B and C) of this proposed rule for any proposed modifications or removals to existing AHE subcategorized improvement activities.
- We propose to no longer list IA_PCMH: Electronic submission of Patient Centered Medical Home Accreditation in each newly proposed or previously finalized MVP table. However, in accordance with § 414.1380(b)(3)(ii), MIPS eligible clinicians in a practice that are certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, may attest to this activity and receive an improvement activities performance category score of 100 percent (81 FR 77179 through 77180).
- We have updated this appendix to include QCDR measures undergoing modifications planned by the QCDR measure stewards. When applicable and substantive in nature, we provide a brief overview of the planned modifications within applicable MVPs. Since QCDR measures are exempt from public notice and comment, this overview allows for transparency with interested parties and an opportunity to comment on all aspects of each MVP prior to finalization. Final decisions to modify QCDR measure specifications are determined by QCDR measure stewards, separate from rulemaking, but may impact decisions as finalized in the final rule.

MVP Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables (Group A and Group B) below:

- Quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.
- New proposed MIPS quality and Promoting Interoperability measures proposed for inclusion in an MVP beginning with the CY 2026 performance period/2028 MIPS payment year and future years are identified with a caret symbol (−). See Appendix 1: MIPS Quality Measures: Table Group A of this proposed rule for further information regarding new MIPS quality measures. See section IV.A.4.d.(4) of this proposed rule for further information regarding new MIPS Promoting Interoperability performance category measures.
- Existing measures and improvement activities with proposed revisions are identified with a single asterisk (*). See Appendix 1:

MIPS Quality Measures: Tables Group D and DD of this proposed rule for further information regarding proposed revisions to MIPS quality measures. See Appendix 2: Improvement Activities: Table Group B of this proposed rule for further information regarding proposed revisions to improvement activities. See Appendix 4:

[572] See the 2025 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3131_duplicate/2025-Improvement-Activities-Inventory.zip* and 2025 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3203/2025–MIPS-Data-Validation-Criteria.zip*. for improvement activity details.

[573] See the 2025 Cost Measures Inventory: *https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2025*.

[574] See the 2025 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3122/2025–MIPS-Promoting-Interoperability-Measure-Specifications.zip*. for Promoting Interoperability measure details.

MIPS Cost Measures: Group A of this proposed rule for further information regarding proposed revisions to cost measures. See section IV.A.4.d.(4) of this proposed rule for further information regarding proposed revisions to Promoting Interoperability measures. We intend to include existing measures or activities with proposed revisions in MVPs (as applicable) regardless of whether the proposed revisions are finalized beginning with the CY 2026 performance period/2028 MIPS payment year, unless changes were required to continue to meet programmatic standards for inclusion.

- Quality measures and improvement activities identified with a double asterisk (**) can only be submitted when included in an MVP.
- Improvement activities that include an advancing health and wellness component are identified with an exclamation point (!) preceding the improvement activity ID.
- Quality measures considered high priority and/or outcome measures (as defined in § 414.1305) are identified in the Quality section of the new MVP table format. Further details of these types of measures are in the CMS Measures Management System Hub.[575] See section IV.A.4.d.(1)(b) of this proposed rule for further information regarding proposed revisions to the definition of a high priority measure.
- Quality measure collection types are identified in parentheses after each quality measure title.

Foundational Layer

Each MVP contains a foundational layer, which includes the entire set of Promoting Interoperability measures and two population health measures. The two population health measures are considered outcome measures as identified with a double exclamation mark (!!). The foundational layer is the same for all MVPs as listed in Table 1.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Caret symbol (^): new proposed MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.

Table 1: MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(‼) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) (*)(‼) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	(*) **PI_PPHI_1:** Security Risk Analysis (*) **PI_PPHI_2:** High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) **PI_EP_1:** e-Prescribing **PI_EP_2:** Query of Prescription Drug Monitoring Program (PDMP) **PI_PEA_1:** Provide Patients Electronic Access to Their Health Information **PI_HIE_1:** Support Electronic Referral Loops By Sending Health Information AND **PI_HIE_4:** Support Electronic Referral Loops By Receiving and Reconciling Health Information OR **PI_HIE_5:** Health Information Exchange (HIE) Bi-Directional Exchange OR **PI_HIE_6:** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) **PI_PHCDRR_1:** Immunization Registry Reporting **PI_PHCDRR_2:** Syndromic Surveillance Reporting (Optional) **PI_PHCDRR_3:** Electronic Case Reporting **PI_PHCDRR_4:** Public Health Registry Reporting (Optional) **PI_PHCDRR_5:** Clinical Data Registry Reporting (Optional) (^)(+) **PI_PHCDRR_X:** Public Health Reporting Under TEFCA (Optional) **PI_ONCACB_1:** ONC-ACB Surveillance Attestation (Optional) **PI_INFBLO_1:** Actions to Limit or Restrict Compatibility or Interoperability of CEHRT Attestation **PI_ONCDIR_1:** ONC Direct Review Attestation

Group A: New MVPs Proposed for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

A.1 Diagnostic Radiology MVP

The proposed Diagnostic Radiology MVP assesses meaningful outcomes in diagnostic radiology. This MVP would be most applicable to clinicians who treat patients within the practice of diagnostic radiology.

Quality Measures

We are proposing to include six MIPS quality measures and three QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of diagnostic radiology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in diagnostic radiology:

- Q145: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy: This MIPS quality measure focuses on increasing clinician awareness of patient exposure to radiation in an effort to reduce potential harmful effects by requiring radiation exposure indices to be documented in all final reports.
- Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed

Tomography (CT) and Cardiac Nuclear Medicine Studies : This MIPS quality measure focuses on reducing the rate of unnecessary or repeat imaging studies by requiring clinicians to review and document a count of known CT and cardiac nuclear medicine studies the patient received within a 12-month period prior to the current study.

- Q364: Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: This MIPS quality measure ensures appropriate follow-up recommendations are documented for patients who have incidental pulmonary nodules found during CT imaging to either avoid unnecessary follow-up scans or identify early malignancies.
- Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions: This MIPS quality measure ensures appropriate follow-up recommendations are documented for patients for whom incidental abdominal lesions are found during imaging studies to avoid unnecessary and costly follow-up procedures.
- Q406: Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients: This MIPS quality measure ensures appropriate follow-up recommendations are documented for patients for whom incidental thyroid nodules are found during imaging studies to avoid unnecessary and costly follow-up procedures.
- Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level): This MIPS quality measure provides a method for monitoring and assessing appropriate radiation dose thresholds encouraging overall reductions in radiation dosage, an intermediate outcome directly and proportionally related to cancer prevention.
- QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O–RADS): This QCDR measure assesses for the use of standardized reporting of findings leading to more consistent treatment recommendations, while also decreasing cost and inappropriate resource consumption.
- QMM18: Use of Breast Cancer Risk Score on Mammography: This QCDR measure ensures final reports for screening mammograms accurately include the breast cancer risk score and appropriate follow-up recommendations. This can be utilized to guide subsequent testing and treatment recommendations improving overall health outcomes.
- QMM26: Screening Abdominal Aortic Aneurysm Reporting with Recommendations: This QCDR measure ensures appropriate follow-up for an abdominal aortic aneurysm is documented in the final report by requiring radiologists to report recommendations consistently and in accordance with current guidelines, with direct communication as required. This QCDR measure has planned modifications including updates to the Society of Vascular Surgery guidelines referenced in the specification and modifications to denominator exceptions to address when screening is negative for abdominal aortic aneurysm (AAA), however, significant risk factors are present warranting future screening.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in diagnostic radiology, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_12: Promoting Clinician Well-Being
- IA_CC_7: Regular training in care coordination
- IA_CC_8: Implementation of documentation improvements for practice/process improvements
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_CC_19: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization
- IA_PSPA_2: Participation in MOC Part IV
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_12: Participation in private payer CPIA

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of diagnostic radiology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in diagnostic radiology and aligns with other measures and activities within this MVP:

- MSPB_1: Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing diagnostic radiology care in inpatient hospitals.

We request comment on the measures and activities included in this MVP.

Symbol Key:

Table A.1: Diagnostic Radiology MVP Clinical Groupings

Diagnostic Radiology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
General Diagnostic Radiology	**Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: MIPS CQM, Medicare Part B Claims)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies (Collection Type: MIPS CQM)	No	Yes	
	Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) (Collection Type: eCQM)	No	No	
Body Imaging (Thoracic/Abdominal)	**Q364:** Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines (Collection Type: MIPS CQM)	No	Yes	N/A
	Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	
	Q406: Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	
	QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS) (Collection Type: QCDR)	No	Yes	
Advancing Health and Wellness	**QMM18:** Use of Breast Cancer Risk Score on Mammography (Collection Type: QCDR)	No	Yes	N/A
	(*) QMM26: Screening Abdominal Aortic Aneurysm Reporting with Recommendations (Collection Type: QCDR)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Diagnostic Radiology Improvement Activities

- **IA_BE_6**: Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BMH_12**: Promoting Clinician Well-Being
- **IA_CC_7**: Regular training in care coordination

- **IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_12**: Care coordination agreements that promote improvements in patient tracking across settings
- **IA_CC_19**: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1**: Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_2**: Participation in MOC Part IV
- **IA_PSPA_7**: Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12**: Participation in private payer CPIA

A.2 Interventional Radiology MVP

The proposed Interventional Radiology MVP assesses meaningful outcomes in interventional radiology. This MVP would be most applicable to clinicians who treat patients within the practice of interventional radiology.

Quality Measures

We are proposing to include six MIPS quality measures and four QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of interventional radiology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in interventional radiology:

- **Q145**: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy: This MIPS quality measure focuses on increasing clinician awareness of patient exposure to radiation in an effort to reduce potential harmful effects by requiring radiation exposure indices to be documented in all final reports.
- **Q374**: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred clinician, closing the communication loop.
- **Q413**: Door to Puncture Time for Endovascular Stroke Treatment: This MIPS quality measure assesses for timely endovascular stroke treatment in ischemic stroke patients. Ensuring a door to puncture time of 90 minutes or less, gives stroke patients the best chance at functional recovery and improved health outcomes.
- **Q420**: Varicose Vein Treatment with Saphenous Ablation: Outcome Survey: This MIPS quality measure motivates clinicians to objectively quantify changes in quality of life after an ablation, the ultimate way to assess success of saphenous ablation for varicose veins.
- **Q421**: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal: This MIPS quality measure focuses on clinicians providing timely follow-up for patients with retrievable IVC filters to increase awareness of the potential harms of inappropriate continued inferior vena cava filtration in patients with retrievable filters.
- **Q465**: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries: This MIPS quality measure promotes successful treatment by ensuring documentation of delineation of all uterine arterial supply with

embolization where possible, and appropriate embolization endpoints achieved which are indications of treatment efficacy.

- **RCOIR12**: Tunneled Hemodialysis Catheter Clinical Success Rate: This QCDR measure evaluates whether a tunneled central venous catheter has been successfully placed (or replaced) and ready for use within 72 hours after placement. This would ensure the catheter is operational and functional as quickly as possible and is tunneled to reduce complications.
- **RCOIR13**: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate: This QCDR measure evaluates success of percutaneous fistula creation for patients on maintenance hemodialysis, promoting the use of new technology with the potential to yield positive results such as fewer procedural complications.
- **RPAQIR14**: Arteriovenous Graft Thrombectomy Clinical Success Rate: This QCDR measure assesses clinical success of arteriovenous graft thrombectomy. Successful removal of a thrombosis supports continued use of the arteriovenous graft, reducing the need for additional vascular access procedures and allowing adequate dialysis to be performed.
- **RPAQIR15**: Arteriovenous Fistulae Thrombectomy Clinical Success Rate: This QCDR measure assesses clinical success of arteriovenous fistula thrombectomy. Arteriovenous fistulas can provide rapid extracorporeal blood flow that is necessary for hemodialysis and when feasible, are the preferred type of vascular access for chronic hemodialysis.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 19 improvement activities that reflect actions and processes undertaken by clinicians who specialize in interventional radiology, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. The following improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care within interventional radiology and are proposed for inclusion in this MVP:

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_7:** Regular training in care coordination
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes

- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **IA_EPA_X:** Provide Education Opportunities for New Clinicians
- **IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_25:** Cost Display for Laboratory and Radiographic Orders

Cost Measures

We are proposing to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of interventional radiology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in interventional radiology and aligns with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing interventional radiology care in inpatient hospitals.
- **COST_HAC_1:** Hemodialysis Access Creation: This MIPS episode-based cost measure assesses costs associated with the creation of graft or fistula access for long-term hemodialysis.
- **COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction**:** This MIPS episode-based cost measure assesses costs associated with the inpatient treatment for cerebral infarction or intracranial hemorrhage.

We request comment on the measures and activities included in this MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.2: Interventional Radiology MVP Clinical Groupings

Interventional Radiology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Vascular	**(*) Q420:** Varicose Vein Treatment with Saphenous Ablation: Outcome Survey (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q421: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal (Collection Type: MIPS CQM)	No	No	
	Q465: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries (Collection Type: MIPS CQM)	No	Yes	
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
Neurological Intervention	**Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
General Interventional Radiology	**Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	No	

Interventional Radiology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_7:** Regular training in care coordination
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements

- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(*)(!) IA_EPA_X:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_25:** Cost Display for Laboratory and Radiographic Orders

A.3 Neuropsychology MVP

The proposed Neuropsychology MVP focuses on the clinical specialty of providing treatment and management of neuropsychological care. This MVP would be most applicable to clinicians who treat patients within the practice of neuropsychology, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants.

Quality Measures

We are proposing to include six MIPS quality measures and three QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of neuropsychology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in neuropsychology:

- **Q282**: Dementia: Functional Status Assessment: This MIPS quality measure evaluates for the performance of a functional status assessment for patients diagnosed with dementia.
- **Q286**: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: This MIPS quality measure assesses for the discussion of safety concerns with either the patients diagnosed with dementia or their caregivers. There are two domains of safety that should be addressed to meet performance of the measure which include dangerousness to self or others and environmental risks. If a risk is discovered, it is anticipated that the clinician would document mitigation recommendations to promote safety outcomes for these patients.
- **Q288**: Dementia: Education and Support of Caregivers for Patients with Dementia: This MIPS quality measure ensures clinician communication of education on dementia disease management and health behavior with the added support of referrals to additional support resources for patients diagnosed with dementia and their caregivers.
- **MBHR13**: Social Role Functioning Assessment utilizing PROMIS Adult Ability to Participate in Social Roles and Activities: This QCDR measure ensures patients who report concerns related to their psychosocial function are assessed, and a follow-up plan is documented for those patients who may have difficulty with social role function and their ability to effectively participate in one's usual role.

• **MBHR15:** Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment: This QCDR measure ensures patients are referred for evaluation due to concerns for cognitive changes or difficulties receive a standardized valid assessment of cognition with results documented, including documentation of provider's consideration of relevant cultural-linguistic and demographic factors that may have affected assessment and resulting assessment.

• **MBHR18**: Provision of Feedback Following a Cognitive or Mental Status Assessment with Documentation of Understanding of Test Results and Subsequent Healthcare Plan with Timely Transmission of Results: This QCDR measure ensures patients who receive a standardized cognitive or mental status assessment engage in a post-evaluation feedback session(s) so they may better understand their medical condition and prognosis. This drives improved health outcomes through improved patient participation in treatment planning and assists them with making necessary lifestyle adjustments.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in neuropsychology. The quality measures below assess for age-specific screenings and follow-up actions for select measures:

- **Q130**: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- **Q134**: Preventive Care and Screening: Screening for Depression and Follow-Up Plan : This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- **Q181**: Elder Maltreatment Screen and Follow-up Plan: This MIPS quality measure ensures routine screening for potential elder maltreatment and is an essential strategy for guarding older adults from abuse and neglect.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 10 improvement activities that reflect actions and processes undertaken by clinicians who specialize in neuropsychology, as well as activities that promote advancing health and wellness, engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_22:** Improved Practices that Engage Patients Pre-Visit
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_21:** Advance Care Planning

Cost Measures

We are proposing to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of neuropsychology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in neuropsychology, including:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in neuropsychology care in inpatient hospitals.
- **TPCC_1:** Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers. Neuropsychologists are included in attribution for the TPCC measure as they may provide broad, ongoing care to their patients, which is in line with the intent of the TPCC measure.

We request comment on the measures and activities included in this MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.3: Neuropsychology MVP Clinical Groupings

Neuropsychology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Neurodegenerative Disorders	**Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	No	No	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
	Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
General Neuropsychology	**MBHR13**: Social Role Functioning Assessment utilizing PROMIS Adult Ability to Participate in Social Roles and Activities (Collection Type: QCDR)	No	No	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q181: Elder Maltreatment Screen and Follow-up Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	
Experience of Care	**MBHR15**: Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment (Collection Type: QCDR)	No	Yes	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	MBHR18: Provision of Feedback Following a Cognitive or Mental Status Assessment with Documentation of Understanding of Test Results and Subsequent Healthcare Plan with Timely Transmission of Results (Collection Type: QCDR)	No	Yes	

Neuropsychology Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **(!) IA_BE_16:** Promote Self-management in Usual Care

- IA_BE_22: Improved Practices that Engage Patients Pre-Visit
- IA_BMH_7: Implementation of Integrated Patient Centered Behavioral Health Model
- (!) IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- (*) IA_EPA_X: Enhance Engagement of Medicaid and Other Underserved Populations
- (**) IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PM_21: Advance Care Planning

A.4 Pathology MVP

The proposed Pathology MVP focuses on assessing meaningful outcomes in pathology. This MVP would be most applicable to pathology clinicians.

Quality Measures

We are proposing to include seven MIPS quality measures and seven QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of pathology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in pathology:

- Q249: Barretts Esophagus: This MIPS quality measure assesses appropriate and complete final report documentation to ensure accurate diagnoses.
- Q250: Radical Prostatectomy Pathology Reporting: This MIPS quality measure ensures that pathology reports include all appropriate information as having a complete set of pathology descriptors is crucial for staging and subsequent therapeutic decisions.
- Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens): This MIPS quality measure encourages pathologists to further classify tumors into a more specific histologic subtype thereby reducing the use of the term non-small-cell lung cancer not otherwise specified (NSCLC–NOS) and furnishing uniform terminology and diagnostic criteria based on an integrated multidisciplinary platform.
- Q396: Lung Cancer Reporting (Resection Specimens): This MIPS quality measure assesses for standardized final reports for lung biopsy and cytology specimens with a diagnosis of primary non-small cell lung cancer allowing for classification to be based on an integrated multidisciplinary platform.
- Q397: Melanoma Reporting: This MIPS quality measure assesses final reports to ensure alignment with guidelines and inclusion of all appropriate tumor characteristics for more precise staging, improving treatment outcomes.
- Q440: Skin Cancer: Biopsy Reporting Time—Pathologist to Clinician: This MIPS quality measure ensures timely reporting of pathology results to mitigate delays in treatment.
- Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status: This MIPS quality measure assesses for guideline recommended MMR/MSI testing for patients considering checkpoint inhibitor therapy, which aims to improve health outcomes by making care more targeted.
- CAP30: Urinary Bladder Cancer: Complete Analysis and Timely Reporting: This QCDR measure assesses all pathology cancer reports to ensure they are complete, contain all necessary data elements and are returned within a maximum of two business days. By mandating a thorough report in a timely fashion, this measure encourages appropriate and quick treatment.
- CAP34: Molecular Assessment: Biomarkers in Non-Small Cell Lung Cancer: This QCDR measure ensures pathology reports for non-small cell lung cancer (NSCLC) contain impression or recommendation for biomarker mutation testing. Accurate reporting allows patients to receive matched targeted therapy.
- CAP40: Squamous Cell Skin Cancer: Complete Reporting: This QCDR measure assesses pathology reports for completeness of histologic findings, including margin status degree of differentiation/histologic grade, depth or level of invasion, presence of perineural invasion, tumor diameter, and presence of lymphovascular invasion which are vital in creating treatment and follow-up plans.
- QMM21: Incorporating results of concurrent studies into Final Reports for Bone Marrow Aspirate of patients with Leukemia, Myelodysplastic syndrome, or Chronic Anemia: This QCDR measure ensures that all final bone marrow reports contain results of concurrent studies performed as well as an interpretation of those results, thereby improving patient outcomes and continuity of care.
- QMM25: Use of Structured Reporting for Urine Cytology Specimens: This QCDR measure ensures uniformity and reproducibility in the reporting of urine cytology through standardization by requiring use of The Paris System.
- QMM29: Use of Appropriate Classification System for Lymphoma Specimen: This QCDR measure encourages precise classification of lymphoma by ensuring results are accurately and effectively interpreted by the treating clinician.
- QMM30: Appropriate Use of Bethesda System for Reporting Thyroid Cytopathology on Fine Needle Aspirations (FNA) of Thyroid Nodule(s): This QCDR measure encourages results from FNA of thyroid nodules are properly and uniformly categorized by using the Bethesda System for Reporting Thyroid Cytopathology.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 13 improvement activities that reflect actions and processes undertaken by clinicians who specialize in pathology, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- IA_BE_X: Promote Use of Patient-Reported Outcome Tools
- IA_BMH_12: Promoting Clinician Well-Being
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_CC_19: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization
- IA_PSPA_2: Participation in MOC Part IV

- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **IA_ PSPA_X:** Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of pathology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in pathology and align with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing pathology care in inpatient hospitals.

We request comment on the measures and activities included in this MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component

Table A.4: Pathology MVP Clinical Groupings

Pathology MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Pathology	**Q249**: Barrett's Esophagus (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	N/A
	Q250: Radical Prostatectomy Pathology Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	N/A
	Q396: Lung Cancer Reporting (Resection Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q397: Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	N/A
	Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	No	Yes	

Pathology MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status (Collection Type: MIPS CQM)	No	Yes	
	CAP30: Urinary Bladder Cancer: Complete Analysis and Timely Reporting (Collection Type: QCDR)	No	Yes	
	CAP34: Molecular Assessment: Biomarkers in Non-Small Cell Lung Cancer (Collection Type: QCDR)	No	Yes	
	CAP40: Squamous Cell Skin Cancer: Complete Reporting (Collection Type: QCDR)	No	Yes	
	QMM21: Incorporating results of concurrent studies into Final Reports for Bone Marrow Aspirate of patients with Leukemia, Myelodysplastic syndrome, or Chronic Anemia (Collection Type: QCDR)	No	Yes	
	QMM25: Use of Structured Reporting for Urine Cytology Specimens (Collection Type: QCDR)	No	Yes	
	QMM29: Use of Appropriate Classification System for Lymphoma Specimen (Collection Type: QCDR)	No	Yes	
	QMM30: Appropriate Use of Bethesda System for Reporting Thyroid Cytopathology on Fine Needle Aspirations (FNA) of Thyroid Nodule(s) (Collection Type: QCDR)	No	Yes	

Pathology Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_2:** Participation in MOC Part IV
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **(*) IA_ PSPA_X:** Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data

A.5 Podiatry MVP

The proposed Podiatry MVP focuses on assessing meaningful outcomes in foot and ankle care for patients with chronic conditions, wound/ulcers, and general care for the podiatry patient. This MVP would be most applicable to podiatry clinicians, including NPPs such as nurse practitioners and physician assistants.

Quality Measures

We are proposing to include 7 MIPS quality measures and 10 QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of podiatry. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in podiatry:

- **Q126**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: This MIPS quality measure ensures patients diagnosed with diabetes mellitus have a lower extremity neurological exam performed at least once every 12 months.
- **Q127**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear: This MIPS quality measure ensures patients diagnosed with diabetes mellitus are evaluated for proper footwear and sizing at least once every 12 months.
- **Q374**: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- **REGCLR5**: Offloading with Remote Monitoring: This QCDR measure evaluates patient compliance with prescribed off-loading via remote monitoring and compliance being demonstrated as complete healing of the ulcer within 10 weeks. The monitoring of patient adherence enables the clinician to intervene when a patient is non adherent.
- **REGCLR8**: Monitor and Improve Treatment Outcomes in Chronic Wound Healing: This QCDR measure ensures patients with chronic non-healing wounds are re-assessed and experience an improved healing rate after a change in treatment plan based upon information learned from the re-assessment. Improved wound healing rates may reduce spending on advanced treatments.
- **USWR22**: Nutritional Assessment and Intervention Plan in patients with Wounds and Ulcers: This QCDR measure ensures patients with wounds and/or ulcers complete a validated nutritional assessment and receive an appropriate intervention plan based on the results. Evidence suggests that oral nutritional supplements, particularly with high protein content, can reduce the risk of developing pressure ulcers.
- **USWR32**: Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply: This QCDR measure assesses for adequate

compression at each visit for treating patients with venous leg ulcers. This measure establishes the requirement of safe, effective, and consistent compression treatment of VLUs.

- **USWR33**: Diabetic Foot Ulcer (DFU) Healing or Closure: This QCDR measure evaluates achieved healing or closure of diabetic foot ulcers within 6 months stratified by the Wound Healing Index (WHI). Reporting of healing rates stratified by the WHI makes it possible to see individual variations in quality between clinicians and compare performance based on similar wound severity.
- **USWR34**: Venous Leg Ulcer (VLU) Healing or Closure: This QCDR measure evaluates achieved healing or closure of venous leg ulcers (VLU) within 12 months stratified by the Wound Healing Index (WHI). Reporting VLU healing stratified by the WHI enables honest reporting of VLU healing rates and fair comparison of clinician performance.
- **USWR35**: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer: This QCDR measure assesses for adequate off-loading for diabetic foot ulcers during patient visits. Adequate off-loading increases the likelihood of DFU healing.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in podiatry care. The measures assess for age-specific screenings and follow-up actions for select measures:

- **Q155**: Falls: Plan of Care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.
- **Q226**: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure ensures all adult patients are screened for high blood pressure and have a recommended follow-up plan if blood pressure is elevated or hypertensive.
- **Q358**: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures patients receive a personalized surgical risk assessment completed using a validated risk calculator or multi-institutional clinical data prior to the surgery with discussion of the identified risks with the surgeon.
- **MEX5**: Hammer Toe Outcome: This QCDR measure addresses pain caused by toe deformity and ensures appropriate intervention for pain reduction. Lesser toe deformities are common and can have a significant impact on the function of the foot and quality of life. Appropriate intervention can result in improvements in activities of daily living and quality of life.
- **REGCLR1**: Heel Pain Treatment Outcomes for Adults: This QCDR measure addresses heel pain and ensures appropriate intervention for pain reduction. Clinical practice guideline suggests that treatment needs to be properly tailored to the patient based upon the cause of the pain.
- **REGCLR3**: Bunion Outcome - Adult and Adolescent: This QCDR measure addresses bunion pain and ensures appropriate intervention for pain reduction. Alleviation of bunion pain can result in improvement in activities of daily living and quality of life.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 10 improvement activities that reflect actions and

processes undertaken by clinicians who specialize in podiatry care, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_22:** CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of podiatry care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in podiatry and align with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing podiatry care in inpatient hospitals.

We request comment on the measures and activities included in this MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.5: Podiatry MVP Clinical Groupings

Podiatry MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Chronic Conditions	**Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (Collection Type: MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Podiatry MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	Q127: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (Collection Type: MIPS CQM)	No	No	
Wound/Ulcer	**REGCLR5:** Offloading with Remote Monitoring (Collection Type: QCDR)	Yes	Yes	N/A
	REGCLR8: Monitor and Improve Treatment Outcomes in Chronic Wound Healing (Collection Type: QCDR)	Yes	Yes	
	USWR22: Nutritional Assessment and Intervention Plan in patients with Wounds and Ulcers (Collection Type: QCDR)	No	No	
	USWR32: Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply (Collection Type: QCDR)	Yes	Yes	
	USWR33: Diabetic Foot Ulcer (DFU) Healing or Closure (Collection Type: QCDR)	Yes	Yes	
	USWR34: Venous Leg Ulcer (VLU) Healing or Closure (Collection Type: QCDR)	Yes	Yes	
	USWR35: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer (Collection Type: QCDR)	No	No	
General Podiatry	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: MIPS CQM, eCQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**Q155:** Falls: Plan of Care (Collection Type: MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	
	MEX5: Hammer Toe Outcome (Collection Type: QCDR)	Yes	Yes	N/A
	REGCLR1: Heel Pain Treatment Outcomes for Adults	Yes	Yes	

Podiatry MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: QCDR)			
	REGCLR3: Bunion Outcome - Adult and Adolescent (Collection Type: QCDR)	Yes	Yes	

Podiatry Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(*) IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_22:** CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship

A.6 Vascular Surgery MVP

The proposed Vascular Surgery MVP focuses on the clinical specialty of surgery. This MVP would be most applicable to clinicians who treat patients within the surgical settings of vascular surgery, including NPPs such as nurse practitioners, and physician assistants.

Quality Measures

We are proposing to include 13 MIPS quality measures and 4 QCDR measures within the quality performance category of this MVP, which are specific to the clinical specialty of surgery. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care provided by clinicians who specialize in surgery:

- **Q259**: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2): This MIPS quality measure ensures patients are selected appropriately for these procedures to limit experience of major complications, evidenced by discharge home no later than post-operative day number 2.
- **Q344**: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post- Operative Day #2): This MIPS quality measure ensures patients are selected appropriately for these procedures to limit experience of major complications, evidenced by discharge home no later than post-operative day number 2.

- Q355: Unplanned Reoperation within the 30-Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.

- Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure: This MIPS quality measure ensures evaluation of any unexpected surgical complications or adverse outcomes evidenced by unplanned hospital re-admission within 30 days of the principal surgical procedure.
- Q357: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.
- Q374: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- RCOIR12: Tunneled Hemodialysis Catheter Clinical Success Rate: This QCDR measure ensures patients with tunneled central venous access catheter insertions or replacements for ESRD on maintenance dialysis receive full dialysis treatment as prescribed within 72 hours of catheter placement or exchange.
- RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis—Clinical Success Rate: This QCDR measure ensures percutaneous created arteriovenous fistulas for patients on dialysis are deemed ready for use with at least 2 16-gauge needles for 3 consecutive dialysis treatments at prescribed blood flow rates.
- RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate: This QCDR measure ensures clinical success of arteriovenous graft (AVG) thrombectomies for patients on maintenance dialysis evidenced by successful first dialysis treatment following the thrombectomy with needles using that access.
- RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate: This QCDR measure ensures clinical success of arteriovenous fistulae (AVF) thrombectomies for patients on maintenance dialysis evidenced by successful first dialysis treatment following the thrombectomy with needles using that access.

The following broadly applicable MIPS quality measures are relevant to clinicians who treat patients in surgical settings. The measures assess for age-specific screenings and follow-up actions for select measures:

- Q001: Diabetes: Glycemic Status Assessment Greater Than 9%: This inverse outcome MIPS quality measure assesses diabetic patients for poor control of their HbA1c.
- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q321: CAHPS for MIPs Clinician/Group Survey: This survey would provide direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.
- Q358: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures patients receive a personalized surgical risk assessment completed using a validated risk calculator or multi-institutional clinical data prior to the surgery with discussion of the identified risks with the surgeon.
- Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 16 improvement activities that reflect actions and processes undertaken by surgical care clinicians, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_BE_1: Use of certified EHR to capture patient reported outcomes
- IA_BE_4: Engagement of Patients through Implementation of New Patient Portal
- IA_BE_12: Use evidence-based decision aids to support shared decision-making.
- IA_BE_X: Promote Use of Patient-Reported Outcome Tools
- IA_CC_15: PSH Care Coordination
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_EPA_3: Collection and use of patient experience and satisfaction data on access
- IA_EPA_X: Provide Education Opportunities for New Clinicians
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PM_2: Anticoagulant Management Improvements
- IA_PM_5: Engagement of community for health status improvement
- IA_PM_11: Regular Review Practices in Place on Targeted Patient Population Needs
- IA_PM_15: Implementation of episodic care management practice improvements
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization.

Cost Measures

We are proposing to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical specialty of surgical care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in surgical care and align with other measures and activities within this MVP:

- COST_CCLI_1: Revascularization For Lower Extremity Chronic Critical Limb Ischemia: This MIPS episode-based cost measure assesses costs associated with elective revascularization surgery for lower extremity chronic critical limb ischemia.
- COST_HAC_1: Hemodialysis Access Creation: This MIPS episode-based cost measure assesses costs associated with the creation of graft or fistula access for long-term hemodialysis.
- MSPB_1: Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those who treat patients within vascular surgery.

We request comment on the measures and activities included in this MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.6: Vascular Surgery MVP Clinical Groupings

Vascular Surgery MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Interventional	**Q259:** Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non- Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2) (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	Yes	Yes	
Surgical	**Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQM)	Yes	Yes	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	Yes	Yes	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	

Vascular Surgery MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
General Vascular Surgery	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	No	No	
Experience of Care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q321: CAHPS for MIPs Clinician/Group Survey (Collection Type: CSV)	No	Yes	
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	

Vascular Surgery Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(*)(!) IA_EPA_X:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

- IA_PM_2: Anticoagulant Management Improvements
- (!) IA_PM_5: Engagement of community for health status improvement
- IA_PM_11: Regular Review Practices in Place on Targeted Patient Population Needs
- IA_PM_15: Implementation of episodic care management practice improvements
- IA_PM_16: Implementation of medication management practice improvements
- IA_PM_21: Advance Care Planning
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization

Group B: Modifications to Previously Finalized MVPs for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

The B.1 table, followed by a list of improvement activities, represents the measures and activities finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP (89 FR 99006 through 99009) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP focuses on important assessors of the care emergency clinicians provide to patients. By focusing on these specific measures and activities, emergency clinicians can reduce clinical variability, improve the quality of emergency care and potentially lower costs. This MVP would be most applicable to clinicians who treat patients within the practice of emergency medicine, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[576], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measure[577]:

- **HCPR24**: Appropriate Utilization of Vancomycin for Cellulitis: This QCDR measure is undergoing modifications to clarify the numerator and add definitions for patients with known Methicillin-resistant Staphylococcus aureus (MRSA) infection or risks for MRSA infection.

Improvement Activities

- For the reasons stated in the introduction of this appendix[578], we propose removing three improvement activities: **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Clinical Groupings

[576] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

[577] Ibid.

[578] Ibid.

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Infectious Disease/ Antibiotic Stewardship	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_EDV_1:** Emergency Medicine
	Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQM)	No	Yes	
	Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	No	Yes	
	(*) HCPR24: Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	No	Yes	
Trauma	**Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQM)	No	Yes	**COST_EDV_1:** Emergency Medicine
	Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQM)	No	Yes	
Orthopedic Emergencies	**ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain (Collection Type: QCDR)	No	Yes	**COST_EDV_1:** Emergency Medicine
	ECPR46: Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR)	No	Yes	
Experience of Care	**Q321:** CAHPS for MIPs Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	**COST_EDV_1:** Emergency Medicine
	ACEP50: ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR)	Yes	Yes	

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BMH_12:** Promoting Clinician Wellbeing
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(!) IA_PSPA_15:** Implementation of an ASP

B.2: Advancing Cancer Care MVP

The B.2 table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Cancer Care MVP (89 FR 99009 through 99015) with

modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Advancing Cancer Care MVP focuses on the clinical specialty of providing fundamental treatment and management of cancer care. This MVP would be most applicable to clinicians who treat patients within the practice of oncology and hematology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding two QCDR measures:

- **PIMSH15**: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents in the Infusion Center - Avoidance of Overuse (Lower Score - Better): This QCDR measure is an inverse measure (lower score is better) that ensures clinicians follow clinical guidelines for patients treated with low- or minimal-emetic-risk antineoplastic agents by assessing for inappropriate pre-treatment antiemetic therapy.
- **PIMSH16**: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents in the Infusion Center: This QCDR measure ensures clinicians follow clinical guidelines for patients treated with high- or moderate-emetic-risk antineoplastic agents by assessing for appropriate pre-treatment antiemetic therapy, which could result in improved control of nausea and vomiting in patients.

For the reasons stated in the introduction of this appendix[579], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measure[580]:

- **PIMSH13:** Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy: This QCDR measure is undergoing modifications to add a denominator note to clarify the appropriate timeframe for the denominator eligible diagnosis ensuring consistent denominator eligible identification.

Improvement Activities

- For the reasons stated in the introduction of this appendix[581], we propose removing three improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.2: Advancing Cancer Care MVP Clinical Groupings

[579] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[580] Ibid.
[581] Ibid.

Advancing Cancer Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Medical Oncology	**(*) Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQM)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
	(*) Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQM)	No	No	
	Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	No	No	**COST_PC_1:** Prostate Cancer
	Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy (Collection Type: MIPS CQM)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
	Q507: Appropriate Germline Testing for Ovarian Cancer Patients (Collection Type: MIPS CQM)	No	No	
	(*) PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy (Collection Type: QCDR)	No	Yes	
	(+) PIMSH15: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents in the Infusion Center - Avoidance of Overuse (Lower Score - Better) (Collection Type: QCDR)	No	Yes	**COST_PC_1:** Prostate Cancer
	(+) PIMSH16: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents in the Infusion Center (Collection Type: QCDR)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
	PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure) (Collection Type: QCDR)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
Radiation Oncology	**Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_PC_1:** Prostate Cancer
	(*) Q143: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM, MIPS CQM)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost

Advancing Cancer Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Advancing Health and Wellness	**(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_PC_1:** Prostate Cancer **(*) TPCC_1:** Total Per Capita Cost
Experience of Care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_PC_1:** Prostate Cancer **(*) TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPs Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	
	(*) Q453: Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQM)	No	Yes	
	(*) Q457: Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQM)	Yes	Yes	
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Advancing Cancer Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_24:** Financial Navigation Program
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

B.3: Advancing Care for Heart Disease MVP

The B.3 table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Care for Heart Disease MVP (89 FR 99015 through 99019) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Advancing Care for Heart Disease MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, heart disease. This MVP would be most applicable to clinicians who treat patients within the practice cardiology, internal medicine and family medicine, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[582], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[583], we propose removing three improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.3: Advancing Care for Heart Disease MVP Clinical Groupings

Advancing Care for Heart Disease MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Congestive Heart Failure	**Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	No	No	

[582] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[583] Ibid.

Advancing Care for Heart Disease MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	Q377: Functional Status Assessments for Heart Failure (Collection Type: eCQM)	No	Yes	
	Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims)	Yes	Yes	
General Cardiology	**Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQM)	No	No	
	Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM, MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI)
	Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQM)	No	No	**COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **(*) TPCC_1:** Total Per Capita Cost
	Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQM)	No	Yes	
	Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	Yes	Yes	**(*) TPCC_1:** Total Per Capita Cost
Electrophysiology	**Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQM)	Yes	Yes	**COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Advancing Care for Heart Disease MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **(*) TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	No	Yes	
Experience of Care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **(*) TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Advancing Care for Heart Disease Improvement Activities

- **(*)(!) IA_AHW_X:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

B.4: Advancing Rheumatology Patient Care MVP

The B.4 table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Rheumatology Patient Care MVP (89 FR 99019 through 99023) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Advancing Rheumatology Patient Care MVP focuses on the clinical theme of providing fundamental treatment and management of rheumatological conditions. This MVP would be most applicable to clinicians who treat patients within the practice rheumatology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding two QCDR measures:

- ACR10: Hepatitis B Safety Screening: This QCDR measure improves patient safety by ensuring that a hepatitis B screening is documented in the medical record for all patients newly initiating a biologic or new synthetic immunosuppressive drug.
- ACR16: Rheumatoid Arthritis Patients with Low Disease Activity or Remission: This QCDR measure assesses clinician performance based on the risk-adjusted proportion of patients with rheumatoid arthritis who have low disease activity or are in remission based on the last recorded disease activity score as assessed using an ACR-preferred tool.
- For the reasons stated in the introduction of this appendix,[584] we propose removing Q487: Screening for Social Drivers of Health. We also propose removing one QCDR measure as this measure is proposed for removal from MIPS:
- UREQA2: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy

Modifications are being considered for the following QCDR measure: [585]

- ACR12: Disease Activity Measurement for Patients with PsA: This QCDR measure is undergoing modifications to modify the denominator adding telehealth as denominator eligible.

Improvement Activities

For the reasons stated in the introduction of this appendix,[586] we propose removing one improvement activity: IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B.

Symbol Key

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

[584] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

[585] Ibid.

[586] Ibid.

TABLE B.4: Advancing Rheumatology Patient Care MVP Clinical Groupings

Advancing Rheumatology Patient Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Rheumatoid Arthritis	**Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQM)	No	No	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost
	Q178: Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQM)	No	No	
	Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQM)	No	No	
	(+) ACR16: Rheumatoid Arthritis Patients with Low Disease Activity or Remission (Collection Type: QCDR)	Yes	Yes	
Autoimmune/ Inflammatory Diseases	**(*) ACR12:** Disease Activity Measurement for Patients with PsA (Collection Type: QCDR)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	ACR14: Gout: Serum Urate Target (Collection Type: QCDR)	Yes	Yes	
	ACR15: Safe Hydroxychloroquine Dosing (Collection Type: QCDR)	No	Yes	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost
	UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	Yes	Yes	**(*) TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	(*) Q176: Tuberculosis Screening Prior to First Course Biologic Therapy (Collection Type: MIPS CQM)	No	No	
	(+) ACR10: Hepatitis B Safety Screening (Collection Type: QCDR)	No	Yes	
	UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older (Collection Type: QCDR)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
Experience of Care	**(*) Q503:** Gains in Patient Activation Measure (PAM) Scores at 12 Months	Yes	Yes	**COST_RA_1:** Rheumatoid Arthritis

Advancing Rheumatology Patient Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: MIPS CQM)			**(*) TPCC_1:** Total Per Capita Cost

Advancing Rheumatology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_2:** Tobacco use
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

B.5 Complete Ophthalmologic Care MVP

The B.5 table, followed by a list of improvement activities, represents the measures and activities finalized within the Complete Ophthalmologic Care MVP (89 FR 98974 through 98979) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. This MVP would be most applicable to clinicians who treat patients within the practice of ophthalmology and optometry, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[587], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measures[588]:

- **IRIS2**: Glaucoma – Intraocular Pressure Reduction: This QCDR measure is undergoing modifications to revise the denominator by removing the requirement for "documentation of the severity of their glaucoma" to determine denominator eligibility.
- **IRIS13**: Diabetic Macular Edema - Loss of Visual Acuity: This QCDR measure is undergoing modifications to revise the denominator by removing the requirement for "2 visual acuity values with at least one on or after date of treatment" to determine denominator eligibility.

Improvement Activities

[587] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

[588] Ibid.

For the reasons stated in the introduction of this appendix[589], we propose removing two improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.5: Complete Ophthalmologic Care MVP Clinical Groupings

Complete Ophthalmologic Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Cataract	**(*) Q191:** Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (Collection Type: eCQM, MIPS CQM)	Yes	Yes	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	No	Yes	
	(*) Q389: Cataract Surgery: Difference Between Planned and Final Refraction (Collection Type: MIPS CQM)	Yes	Yes	
	IRIS54: Complications After Cataract Surgery (Collection Type: QCDR)	Yes	Yes	
	IRIS61: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery (Collection Type: QCDR)	Yes	Yes	
General Ophthalmology	**(*) Q117:** Diabetes: Eye Exam (Collection Type: eCQM, MIPS CQM)	No	No	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	Yes	
Retinal Disease	**Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM)	No	Yes	N/A
	Q384: Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery (Collection Type: MIPS CQM)	Yes	Yes	

[589] Ibid.

Complete Ophthalmologic Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q499: Appropriate screening and plan of care for elevated intraocular pressure following intravitreal or periocular steroid therapy (Collection Type: MIPS CQM)	No	No	
	(*) Q500: Acute posterior vitreous detachment appropriate examination and follow-up (Collection Type: MIPS CQM)	No	No	
	(*) Q501: Acute posterior vitreous detachment and acute vitreous hemorrhage appropriate examination and follow-up (Collection Type: MIPS CQM)	No	No	
	(*) IRIS13: Diabetic Macular Edema - Loss of Visual Acuity (Collection Type: QCDR)	Yes	Yes	
	IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR)	Yes	Yes	
Glaucoma	**(*) Q012:** Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Collection Type: eCQM)	No	No	N/A
	(*) Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care (Collection Type: Medicare Part B Claims, MIPS CQM)	Yes	Yes	
	(*) IRIS2: Glaucoma – Intraocular Pressure Reduction (Collection Type: QCDR)	Yes	Yes	
	IRIS39: Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure (Collection Type: QCDR)	Yes	Yes	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
Experience of Care	**(*) Q503:** Gains in Patient Activation Measure (PAM) Scores at 12 Months (PAM Performance Measure, PAM-PM) (Collection Type: MIPS CQM)	Yes	Yes	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation

Complete Ophthalmologic Care Improvement Activities

- (*)(!) IA_AHW_X: Chronic Care and Preventative Care Management for Empaneled Patients
- IA_BE_4: Engagement of Patients through Implementation of New Patient Portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_25: Drug Cost Transparency
- (!) IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_10: Care transition documentation practice improvements
- IA_CC_13: Practice improvements to align with OpenNotes principles
- (*) IA_EPA_X: Enhance Engagement of Medicaid and Other Underserved Populations
- (**) IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

B.6: Coordinating Stroke Care To Promote Prevention and Cultivate Positive Outcomes MVP

The B.6 table, followed by a list of improvement activities, represents the measures and activities finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP (89 FR 99023 through 99025) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP focuses on the clinical theme of providing fundamental prevention and treatment of those patients at risk for or that have had a stroke. This MVP would be most applicable to clinicians who treat patients within the practice of neurology, neurosurgical, and vascular surgery, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix,[590] we propose removing one MIPS quality measure: Q487: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix,[591] we propose removing three improvement activities: IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, IA_CC_2: Implementation of improvements that contribute to more timely communication of test results, and IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

[590] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

[591] Ibid.

TABLE B.6: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Clinical Groupings

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Stroke Prevention	**Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQM)	No	No	
	Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	Yes	No	
	Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	No	No	
	(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	Yes	Yes	
Stroke Care	**Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQM)	No	No	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q413: Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	Yes	Yes	
Experience of Care	**(*) Q047**: Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes Improvement Activities

- **(*)(!) IA_AHW_X:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_25:** Drug Cost Transparency
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_10:** Care transition documentation practice improvements
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(*) IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_7**: Use of QCDR data for ongoing practice assessment and improvements

B.7: Dermatological Care MVP

The B.7 table, followed by a list of improvement activities, represents the measures and activities finalized within the Dermatological MVP (89 FR 98979 through 98984) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Dermatological Care MVP focuses on the clinical theme of providing treatment and management of dermatologic care. This MVP would be most applicable to clinicians who treat patients within the practice of dermatology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding two MIPS quality measures:

- **Q047**: Advance Care Plan : This MIPS quality measure provides a meaningful assessment for patients undergoing dermatological care.
- **Q238:** Use of High-Risk Medications in Older Adults: This MIPS quality measure supports patient safety by assessing for the use of high-risk medications.
- For the reasons stated in the introduction of this appendix[592], we propose removing **Q487**: Screening for Social Drivers of Health. We also propose removing one MIPS quality measure and two QCDR measures.
- **Q130:** Documentation of Current Medications in the Medical Record.
- **AAD17**: Continuation of Anticoagulation Therapy in the Office-based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures.
- **AAD18**: Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection.

Improvement Activities

For the reasons stated in the introduction of this appendix[593], we propose removing one improvement activity: **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.7: Dermatological Care MVP Clinical Groupings

[592] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[593] Ibid.

Dermatological Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Skin Cancer	**Q397:** Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_MR_1:** Melanoma Resection
	Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	No	Yes	
	Q509: Melanoma: Tracking and Evaluation of Recurrence (Collection Type: MIPS CQM)	No	No	
	AAD6: Skin Cancer: Biopsy Reporting Time – Clinician to Patient (Collection Type: QCDR)	No	Yes	
	AAD12: Melanoma: – Appropriate Surgical Margins (Collection Type: QCDR)	Yes	Yes	
	AAD16: Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures (Collection Type: QCDR)	No	Yes	
Inflammatory Conditions	**(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	No	Yes	N/A
	Q486: Dermatitis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	Yes	Yes	
	Q410: Psoriasis: Clinical Response to Systemic Medications (Collection Type: MIPS CQM)	Yes	Yes	
	Q485: Psoriasis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	Yes	Yes	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_MR_1:** Melanoma Resection
Experience of Care	**(+)(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_MR_1:** Melanoma Resection
	(*) Q503: Gains in Patient Activation Measure (PAM) Scores at 12 Months (PAM Performance Measure, PAM-PM) (Collection Type: MIPS CQM)	Yes	Yes	
	AAD8: Chronic Skin Conditions: Patient Reported Quality-of-Life (Collection Type: QCDR)	No	Yes	N/A
Advancing Health and Wellness	**(+) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM))	No	Yes	N/A

Dermatological Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(*) IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(*)(!) IA_EPA_X:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

B.8: Focusing on Women's Health MVP

The B.8 table, followed by a list of improvement activities, represents the measures and activities finalized within the Women's Health MVP (89 FR 99025 through 99029) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Focusing on Women's Health MVP focuses on the clinical specialty of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practice of gynecology, obstetrics, and urogynecology, including nonphysician practitioners (NPPs) such as certified nurse-midwives, nurse practitioners, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[594], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[595], we propose removing four improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_PM_6**: Use of toolsets or other resources to close healthcare disparities across communities, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.8: Focusing on Women's Health MVP Clinical Groupings

[594] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[595] Ibid.

Focusing on Women's Health MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Obstetrics	**Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q336: Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	Q496: Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
Gynecology	**Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQM)	Yes	Yes	
	Q448: Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQM)	No	Yes	
Advancing Health and Wellness	**Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	No	No	
	(*)(**) Q112: Breast Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	No	No	

Focusing on Women's Health MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)			
	Q309: Cervical Cancer Screening (Collection Type: eCQM)	No	No	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	No	No	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	No	No	
	Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM)	No	No	
	Q475: HIV Screening (Collection Type: eCQM)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
	UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level (Collection Type: QCDR)	Yes	Yes	

Focusing on Women's Health Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- **(!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(*) IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **(!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines

B.9: Gastroenterology Care MVP

The B.9 table, followed by a list of improvement activities, represents the measures and activities finalized within the Gastroenterology Care MVP (89 FR 98984 through 98989) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Gastroenterology Care MVP focuses on the clinical theme of providing treatment and management of the digestive system and the liver. This MVP would be most applicable to clinicians who treat patients within the practice of gastroenterology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality and

cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding one new MIPS quality measure:

- **TBD: Hepatitis C Virus (HCV)**: Sustained Virological Response (SVR)**:** This proposed MIPS quality measure captures an important outcome for this patient population.
- For the reasons stated in the introduction of this appendix[596], we propose removing two MIPS quality measures: **Q185**: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use and **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measures[597]:

- **GIQIC26**: Screening Colonoscopy Adenoma Detection Rate: This QCDR measure is undergoing modifications to update the denominator exclusions to reflect any non-colonoscopy colorectal cancer screening test.
- **NHCR4**: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation: This QCDR measure is undergoing modifications to update the numerator to reflect numerator compliance for the clinical scenario of a patient referred for polyp or mass removal.

Improvement Activities

For the reasons stated in the introduction of this appendix[598], we propose removing two improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Cost Measures

We propose adding one MIPS cost measure:

- **COST_LGH_1**: Lower Gastrointestinal Hemorrhage: This MIPS episode-based cost measure assesses costs associated with inpatient non-surgical treatment for acute bleeding in the lower gastrointestinal tract.

Symbol Key:

Caret symbol (^): new proposed MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.9: Gastroenterology MVP Clinical Groupings

[596] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[597] Ibid.
[598] Ibid.

Gastroenterology Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Interventional / Endoscopy	**(*) GIQIC26:** Screening Colonoscopy Adenoma Detection Rate (Collection Type: QCDR)	Yes	Yes	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost
	N/A	N/A	N/A	**(+) COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Hepatobiliary	**Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	No	No	
	(^)(+) TBD: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM)	Yes	Yes	
Inflammatory	**Q275**: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (Collection Type: MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
General Gastroenterology	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	No	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost **(+) COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Advancing Health and Wellness	**(*)(**) Q113:** Colorectal Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost **(+) COST_LGH_1:** Lower Gastrointestinal Hemorrhage
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	No	Yes	

Gastroenterology Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: Medicare Part B Claims, MIPS CQM)			
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	No	
	GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy (Collection Type: QCDR)	No	Yes	
	(*) NHCR4: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation (Collection Type: QCDR)	No	Yes	
Experience of Care	**(*) Q503:** Gains in Patient Activation Measure (PAM) Scores at 12 Months (PAM Performance Measure, PAM-PM) (Collection Type: MIPS CQM)	Yes	Yes	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost

Gastroenterology Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_10:** Care transition documentation practice improvements
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(*)(!) IA_EPA_X:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

B.10: Improving Care for Lower Extremity Joint Repair MVP

The B.10 table, followed by a list of improvement activities, represents the measures and activities finalized within the Improving Care for Lower Extremity Joint Repair MVP (89 FR 99029 through 99031) with modifications proposed for the CY 2026 performance period/2028 MIPS payment year and future years. The Improving Care for Lower Extremity Joint Repair MVP focuses on the clinical theme of providing fundamental treatment and management of patients with osteoarthritis and lower extremity surgical repair, such as fracture and total joint replacement, to ensure appropriate care and reduce costs. This MVP would be most applicable to clinicians who treat patients within the practice of orthopedic surgery, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[599], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[600], we propose removing two improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.10: Improving Care for Lower Extremity Joint Repair MVP Clinical Groupings

Improving Care for Lower Extremity Joint Repair MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Non-Surgical	**Q024:** Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_PHA_1**: Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
Surgical	**Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQM)	No	Yes	**COST_PHA_1**: Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
	Q351: Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQM)	No	Yes	
	(*) Q376: Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM)	No	Yes	**COST_PHA_1**: Elective Primary Hip Arthroplasty
	Q470: Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQM)	Yes	Yes	**COST_KA_1:** Knee Arthroplasty
	(*) Q480: Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims)	Yes	Yes	**COST_PHA_1**: Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty

[599] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[600] Ibid.

Improving Care for Lower Extremity Joint Repair MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Advancing Health and Wellness	**(**) Q128**: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty

Improving Care for Lower Extremity Joint Repair Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles
- **IA_CC_15:** PSH Care Coordination
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level

B.11: Optimal Care for Kidney Health MVP

The B.11 table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Kidney Health MVP (89 FR 99031 through 99035) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Optimal Care for Kidney Health MVP focuses on the clinical specialty of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. This MVP would be most applicable to clinicians who treat patients within the practice of nephrology. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding one new MIPS quality measure:

- **TBD: Prevalent Standardized** Kidney Transplant **Waitlist Ratio (PSWR)**: This proposed MIPS quality measure captures an additional population of patients on transplant list beyond their first year of dialysis.
- For the reasons stated in the introduction of this appendix[601], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[602], we propose removing three improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk

[601] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

[602] Ibid.

Identification and Treatment Protocols, **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:
Caret symbol (^): new proposed MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.11: Optimal Care for Kidney Health MVP Clinical Groupings

Optimal Care for Kidney Health MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
General Nephrology	**(*)Q001**: Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_AKID_1**: Acute Kidney Injury Requiring New Inpatient Dialysis
	Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **(*) TPCC_1:** Total Per Capita Cost
	(*) Q488: Kidney Health Evaluation (Collection Type: eCQM, MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM)	No	No	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **(*) TPCC_1:** Total Per Capita Cost
Dialysis/Transplant	**Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQM)	Yes	Yes	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:**

Optimal Care for Kidney Health MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
				End-Stage Renal Disease **(*) TPCC_1:** Total Per Capita Cost
	Q510: First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQM)	Yes	No	**COST_ESRD_1:** End-Stage Renal Disease **(*) TPCC_1:** Total Per Capita Cost
	Q511: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Collection Type: MIPS CQM)	Yes	No	
	(^)(+) TBD: Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR) (Collection Type: MIPS CQM)	No	No	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **(*) TPCC_1:** Total Per Capita Cost
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
Experience of care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **(*) TPCC_1:** Total Per Capita Cost
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Optimal Care for Kidney Health Improvement Activities

- (*)(!) IA_AHW_X: Chronic Care and Preventative Care Management for Empaneled Patients
- IA_BE_4: Engagement of Patients through Implementation of New Patient Portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_14: Engage Patients and Families to Guide Improvement in the System of Care
- IA_BE_15: Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- (!) IA_BE_16: Promote Self-management in Usual Care
- (*)(!) IA_BE_X: Promote Use of Patient-Reported Outcome Tools
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- (**) IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PM_11: Regular Review Practices in Place on Targeted Patient Population Needs
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_16: Use of decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs

B.12: Optimal Care for Patients With Urologic Conditions MVP

The B.12 table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Urologic Conditions MVP (89 FR 98989 through 98994) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Optimal Care for Patients with Urologic Conditions MVP focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence, bladder cancer, and prostate cancer. This MVP would be most applicable to clinicians who treat patients within the practices of urology, general urologists, urology oncologists, and urology care for women, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

- For the reasons stated in the introduction of this appendix,[603] we propose removing one MIPS quality measure: Q487: Screening for Social Drivers of Health.

Improvement Activities

- For the reasons stated in the introduction of this appendix,[604] we propose removing three improvement activities: IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health, IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B, and IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

[603] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update*.

[604] Ibid.

Optimal Care for Patients with Urologic Conditions MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Urological Cancer	**Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	No	No	**COST_PC_1**: Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q476: Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia (Collection Type: eCQM)	Yes	Yes	
	Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer (Collection Type: eCQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	AQUA8: Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy (Collection Type: QCDR)	Yes	Yes	**COST_PC_1**: Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	AQUA16: Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 disease (Collection Type: QCDR)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients (Collection Type: QCDR)	No	Yes	**COST_PC_1**: Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
General Urology	**Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	No	Yes	**COST_RUSST_1**: Renal or Ureteral Stone Surgical Treatment **MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician
	AQUA14: Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment (Collection Type: QCDR)	Yes	Yes	
	AQUA15: Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures (Collection Type: QCDR)	No	Yes	
Advancing Health and Wellness	**Q318:** Falls: Screening for Future Fall Risk (Collection Type: eCQM)	No	Yes	**COST_PC_1**: Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	**COST_PC_1**: Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	

Optimal Care for Patients with Urologic Conditions MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(*) Q503: Gains in Patient Activation Measure (PAM) Scores at 12 Months (PAM Performance Measure, PAM-PM) (Collection Type: MIPS CQM)	Yes	Yes	Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Optimal Care for Patients with Urologic Conditions Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7**: Regular training in care coordination
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

B.13: Patient Safety and Support of Positive Experiences with Anesthesia MVP

The B.13 table, followed by a list of improvement activities, represents the measures and activities finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP (89 FR 99035 through 99037) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Patient Safety and Support of Positive Experiences with Anesthesia MVP focuses on increasing the quality of anesthesia care, improving postoperative outcomes, promoting patient safety, and enhancing satisfaction for patients receiving anesthesia. The measures are used for a variety of surgical procedures that anesthesiologists deliver care for, and are broadly applicable to anesthesiologists practicing within ambulatory, outpatient, and inpatient hospital settings, including NPPs such as certified registered nurse anesthetists (CRNAs) and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

- For the reasons stated in the introduction of this appendix[605], we propose removing two MIPS quality measures: **Q424**: Perioperative Temperature Management and **Q487**: Screening for Social Drivers of Health.

Improvement Activities

[605] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

For the reasons stated in the introduction of this appendix[606], we propose removing two improvement activities: **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.13: Patient Safety and Support of Positive Experiences with Anesthesia MVP Clinical Groupings

Patient Safety and Support of Positive Experiences with Anesthesia MVP				
Condition	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Sedation/General Anesthesia	**Q404:** Anesthesiology Smoking Abstinence (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q430: Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQM)	No	Yes	
	Q463: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQM)	No	Yes	
	ABG44: Low Flow Inhalational General Anesthesia (Collection Type: QCDR)	No	Yes	
	EPREOP31: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	Yes	Yes	
Pain Management	**Q477**: Multimodal Pain Management (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Patient Safety and Support of Positive Experiences with Anesthesia Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_22:** Improved practices that engage patients pre-visit
- **(!) IA_BMH_2:** Tobacco use
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes

[606] Ibid.

- (**) IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_16: Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs

B.14: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

The B.14 table, followed by a list of improvement activities, represents the measures and activities finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP (89 FR 99038 through 99040) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on the clinical specialty of promoting quality care for patients suffering from infectious disorders. This MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding one new MIPS quality measure:

- TBD: Hepatitis C Virus (HCV): Sustained Virological Response (SVR): This proposed MIPS quality measure that captures important outcome for this patient population.

For the reasons stated in the introduction of this appendix,[607] we propose removing one MIPS quality measure: Q487: Screening for Social Drivers of Health.

Improvement Activities

- For the reasons stated in the introduction of this appendix,[608] we propose removing four improvement activities: IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health, IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities, and IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis.

Cost Measures

We propose adding three additional MIPS cost measures:

- COST_RIH_1: Respiratory Infection Hospitalization: This MIPS episode-based cost measure assesses costs associated with inpatient treatment for a respiratory infection.
- COST_S_1: Sepsis: This MIPS episode-based cost measure assesses costs associated with inpatient medical treatment for sepsis.
- MSPB_1: Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care for acute infections in inpatient hospitals.

Symbol Key:

Caret symbol (^): new proposed MIPS quality and Promoting Interoperability measures.

[607] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

[608] Ibid.

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.14: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Clinical Groupings

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Chronic: Hep C, HIV/AIDS	**Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: eCQM, MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q338: HIV Viral Suppression (Collection Type: eCQM, MIPS CQM)	Yes	Yes	
	Q340: HIV Medical Visit Frequency (Collection Type: MIPS CQM)	No	Yes	
	Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQM)	No	No	
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	No	No	
	(^)(+) TBD: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM	Yes	Yes	
Acute Infection	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
	N/A			**(+) COST_RIH_1:** Respiratory Infection Hospitalization **(+) COST_S_1:** Sepsis **(+) MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record	No	Yes	**(+) COST_RIH_1:** Respiratory Infection Hospitalization

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: eCQM, MIPS CQM)			**(+) COST_S_1:** Sepsis **(+) MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q240: Childhood Immunization Status (Collection Type: eCQM)	No	No	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	No	No	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	No	No	
	Q475: HIV Screening (Collection Type: eCQM)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care
- **(*) IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **(!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship
- **(!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

B.15: Pulmonology Care MVP

The B.15 table, followed by a list of improvement activities, represents the measures and activities finalized within the Pulmonology Care MVP (89 FR 98994 through 98998) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Pulmonology Care MVP focuses on assessing optimal care for patients treated for a broad range of pulmonology conditions including COPD, asthma, sleep apnea, and general pulmonology. This MVP would be most applicable to clinicians who specialize in pulmonology and sleep medicine, including NPPs such as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on

the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix,[609] we propose removing one MIPS quality measure: Q487: Screening for Social Drivers of Health.

[609] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

Improvement Activities

For the reasons stated in the introduction of this appendix,[610] we propose removing three improvement activities: IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health, and IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B.

[610] Ibid.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table B.15: Pulmonology Care MVP Clinical Groupings

Pulmonology Care MVP				
Quality				
Clinical Grouping	**Measure**	**Outcome**	**High Priority**	**Cost**
Asthma	**Q398:** Optimal Asthma Control (Collection Type: MIPS CQM)	Yes	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD)
COPD	**Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy (Collection Type: MIPS CQM)	No	No	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD (Collection Type: QCDR)	No	No	
Sleep Medicine	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	No	No	N/A
	Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy (Collection Type: MIPS CQM)	No	No	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
Experience of Care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	(*) Q503: Gains in Patient Activation Measure (PAM) Scores at 12 Months (PAM Performance Measure, PAM-PM) (Collection Type: MIPS CQM)	Yes	Yes	

Pulmonology Care Improvement Activities

- **(*)(!) IA_AHW_X:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_23:** Integration of patient coaching practices between visits
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements

B.16: Quality Care for Patients With Neurological Conditions MVP

The B.16 table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for Patients with Neurological Conditions MVP (89 FR 99040 through 99044) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Quality Care for Patients with Neurological Conditions MVP focuses on the clinical theme of promoting quality care for patients suffering from neurological conditions. This MVP would be most applicable to clinicians who specialize in neurology care, including NPPs such as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding one new MIPS quality measure:

•TBD: Patient reported falls and plan of care: This proposed MIPS quality measure captures falls assessment and care plan specific to patients with neurological conditions.

For the reasons stated in the introduction of this appendix [611], we propose removing Q487: Screening for Social Drivers of Health. We also propose removing three additional MIPS quality measures:

- Q155: Falls: Plan of Care
- Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease
- Q419: Overuse of Imaging for the Evaluation of Primary Headache

Improvement Activities

- For the reasons stated in the introduction of this appendix [612], we propose removing three improvement activities: IA_BMH_8: Electronic Health Record Enhancements for BH data capture, IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B.

Symbol Key:

Caret symbol (^): new proposed MIPS quality and Promoting Interoperability measures.

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

[611] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

[612] Ibid.

Quality Care for Patients with Neurological Conditions MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Brain Conditions	**Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dementia	**(*) Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q282: Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	No	No	
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
	Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
Neurodegenerative Disorders	**Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	No	No	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician
	Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	No	Yes	
	Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM)	No	Yes	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	No	Yes	
	(^)(+) TBD: Patient reported falls and plan of care (Collection Type: MIPS CQM)	No	Yes	
Experience of Care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Quality Care for Patients with Neurological Conditions MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM) Scores at 12 Months (PAM Performance Measure, PAM-PM) (Collection Type: MIPS CQM)	Yes	Yes	

Quality Care for Patients with Neurological Conditions Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_24:** Financial Navigation Program
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_4:** Depression screening
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_ PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

B.17: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

The B.17 table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP (89 FR 99044 through 99047) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on the clinical specialty of providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL) and otitis media. This MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding one additional QCDR measure:

- **AA016**: Age-Related Hearing Loss: Audiometric Evaluation: This QCDR measure ensures patients who failed a hearing screening and/or who report suspected hearing loss receive, are ordered, or are referred for a comprehensive audiometric evaluation in a timely fashion.

For the reasons stated in the introduction of this appendix[613], we propose removing one MIPS quality measure: Q487: Screening for Social Drivers of Health.

Improvement Activities

- For the reasons stated in the introduction of this appendix[614], we propose removing three improvement activities: IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and IA_PM_26: Vaccine Achievement for Practice Staff: COVID–19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

[613] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

[614] Ibid.

TABLE B.17: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Clinical Groupings

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Otology	**AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR)	No	No	N/A
	AAO21: Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR)	No	No	
Sleep Disorders	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	No	No	N/A
General Otolaryngology	**Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	No	Yes	N/A
	Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQM)	No	Yes	
	(+) AAO16: Age-Related Hearing Loss: Audiometric Evaluation (Collection Type: QCDR)	No	Yes	
Surgical	**Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	Yes	Yes	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	

Quality Care for the Treatment of Ear, Nose, and Throat Disorders Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

B.18: Quality Care in Mental Health and Substance Use Disorders MVP

The B.18 table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care in Mental Health and Substance Use Disorders MVP (89 FR 99047 through 99049) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Quality Care in Mental Health and Substance Use Disorders MVP focuses on the clinical specialty of promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

- For the reasons stated in the introduction of this appendix[615], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[616], we propose removing five improvement activities: **IA_AHE_5**: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_PM_6**: Use of toolsets or other resources to close healthcare disparities across communities, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.18: Quality Care in Mental Health and Substance Use Disorders MVP Clinical Groupings

[615] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[616] Ibid.

Quality Care in Mental Health and Substance Use Disorders MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Mental Health—General	**Q009:** Anti-Depressant Medication Management (Collection Type: eCQM)	No	No	**COST_DEP_1:** Depression
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q366: Follow-Up Care for Children Prescribed ADHD Medication (Collection Type: eCQM)	No	No	N/A
	Q370: Depression Remission at Twelve Months (Collection Type: eCQM, MIPS CQM)	Yes	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQM)	Yes	Yes	**COST_PRC_1:** Psychoses/Related Conditions
	MBHR2: Anxiety Response at 6-months (Collection Type: QCDR)	Yes	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	Yes	Yes	N/A
Mental Health—Suicide	**Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM)	No	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQM)	No	Yes	
	Q505: Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQM)	Yes	Yes	
Substance Use Disorder	**Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	No	Yes	N/A
	Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQM)	No	Yes	

Quality Care in Mental Health and Substance Use Disorders MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Experience of Care	**(*) Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQM)	Yes	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Mental Health and Substance Use Improvement Activities

- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_23:** Integration of patient coaching practices between visits
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_2:** Tobacco use
- **(!) IA_BMH_5:** MDD prevention and treatment interventions
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(*) IA_EPA_X:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

B.19: Rehabilitative Support for Musculoskeletal Care MVP

The B.19 table, followed by a list of improvement activities, represents the measures and activities finalized within the Rehabilitative Support for Musculoskeletal Care MVP (89 FR 99049 through 99054) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Rehabilitative Support for Musculoskeletal Care MVP focuses on the clinical specialty of promoting quality care for patients. This MVP would be most applicable to clinicians and NPPs who specialize in providing rehabilitative support for musculoskeletal care such as chiropractic, physiatry, physical therapy and occupational therapy, as well as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

We propose adding two additional MIPS quality measures based on maintenance requests and providing meaningful and comprehensive assessment of the clinical care for clinicians providing musculoskeletal care to patients:

- **Q134**: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- **Q182**: Functional Outcome Assessment

For the reasons stated in the introduction of this appendix[617], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measures[618]:

- **MSK6**: Patients Suffering From a Neck Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."
- **MSK7:** Patients Suffering From an Upper Extremity Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."
- **MSK8:** Patients Suffering From a Back Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."
- **MSK9**: Patients Suffering From a Lower Extremity Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."

Improvement Activities

We propose adding three additional improvement activities that address maintenance requests from the public, as well as address the priority area of advancing health and wellness:

- **IA_BE_15**: Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **IA_BE_16**: Evidenced-based techniques to promote self-management into usual care
- **IA_AHW_X**: Chronic Care and Preventative Care Management for Empaneled Patients
- For the reasons stated in the introduction of this appendix[619], we propose removing four improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP.

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.19: Rehabilitative Support for Musculoskeletal Care MVP Clinical Groupings

[617] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

[618] Ibid.

[619] Ibid.

Rehabilitative Support for Musculoskeletal Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Orthopedic	**(+) Q182:** Functional Outcome Assessment (Collection Type: MIPS CQM)	No	Yes	**COST_LBP_1:** Low Back Pain
	Q217: Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQM)	Yes	Yes	N/A
	Q218: Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	Q219: Functional Status Change with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	Q220: Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQM)	Yes	Yes	**COST_LBP_1:** Low Back Pain
	Q221: Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQM)	Yes	Yes	N/A
	Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	Q478: Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	(*) MSK6: Patients Suffering From a Neck Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	
	(*) MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	
	(*) MSK8: Patients Suffering From a Back Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	**COST_LBP_1:** Low Back Pain
	(*) MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	N/A
Geriatric	**Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	No	Yes	N/A
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_LBP_1:** Low Back Pain

Rehabilitative Support for Musculoskeletal Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(+)(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q155: Falls: Plan of Care (Collection Type: MIPS CQM)	No	Yes	

Rehabilitative Support for Musculoskeletal Care Improvement Activities

- **(+)(*)(!) IA_AHW_X:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(+) IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(+)(!) IA_BE_16:** Promote Self-management in Usual Care
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(*)(!) IA_EPA_X:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

B.20: Surgical Care MVP

The B.20 table, followed by a list of improvement activities, represents the measures and activities finalized within the Surgical Care MVP (89 FR 98998 through 99005) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Surgical Care MVP focuses on the clinical theme of surgery. This MVP would be most applicable to clinicians who specialize in general surgery, neurosurgery, and cardiothoracic surgery, including NPPs such as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[620], we propose removing two MIPS quality measures: **Q264**: Sentinel Lymph Node Biopsy for Invasive Breast Cancer and **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[621], we propose removing two improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

B.20: Surgical Care MVP

Surgical Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Cardiothoracic Surgery	**Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Collection Type: MIPS CQM)	Yes	Yes	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure (Collection Type: MIPS CQM)	Yes	Yes	
	Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration (Collection Type: MIPS CQM)	Yes	Yes	
	Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) (Collection Type: MIPS CQM)	Yes	Yes	
General Surgery	**Q354:** Anastomotic Leak Intervention (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q355: Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	Yes	Yes	**COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending

[620] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[621] Ibid.

Surgical Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
				Per Beneficiary (MSPB) Clinician
	(*) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	Yes	Yes	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1**: Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Neurosurgical	**Q459:** Back Pain After Lumbar Surgery (Collection Type: MIPS CQM)	Yes	Yes	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q461: Leg Pain After Lumbar Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q471: Functional Status After Lumbar Surgery (Collection Type: MIPS CQM)	Yes	Yes	
Advancing Health and Wellness	**Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q047: Advance Care Plan	No	Yes	

Surgical Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Experience of Care	(Collection Type: Medicare Part B Claims, MIPS CQM)			**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	

Surgical Care Improvement Activities

- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_18:** Relationship-Centered Communication
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

B.21: Value in Primary Care MVP

The B.21 table, followed by a list of improvement activities, represents the measures and activities finalized within the Value in Primary Care MVP (89 FR 99054 through 99057) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The Value in Primary Care MVP focuses on the clinical theme of promoting quality care for patients to reduce the risk of diseases, disabilities, and death. This MVP would be most applicable to clinicians who specialize in preventive medicine, internal medicine, family medicine and geriatrics, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix,[622] we propose removing one MIPS quality measure: Q487: Screening for Social Drivers of Health.

[622] See *MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update.*

Improvement Activities

For the reasons stated in the introduction of this appendix,[623] we propose removing four improvement activities: IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health, IA_CC_2: Implementation of improvements that contribute to more timely communication of test results, and IA_PM_26: Vaccine Achievement for Practices Staff: COVID–19, Influenza, and Hepatitis B.

[623] Ibid.

Symbol Key

Single asterisk (*): existing measures and improvement activities with proposed revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Single exclamation point (!): improvement activities with advancing health and wellness component.

Quality Measures

For the reasons stated in the introduction of this appendix[622], we propose removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[623], we propose removing four improvement activities: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practices Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with advancing health and wellness component.

TABLE B.21: Value in Primary Care MVP Clinical Groupings

Value in Primary Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
Chronic Conditions	**(*)Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_D_1:** Diabetes **(*) TPCC_1**: Total Per Capita Cost
	Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **(*) TPCC_1**: Total Per Capita Cost
	Q305: Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	No	Yes	N/A
	Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	No	No	**TPCC_1:** Total Per Capita Cost

[622] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[623] Ibid.

Value in Primary Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQM)	No	Yes	**COST_DEP_1:** Depression **(*) TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_ACOPD_1**: Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1**: Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	Q475: HIV Screening (Collection Type: eCQM)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
	Q497: Preventive Care and Wellness (composite) (Collection Type: MIPS CQM)	No	No	
Experience of Care	**(*) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_ACOPD_1**: Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1**: Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	
	Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQM)	Yes	Yes	

Value in Primary Care Improvement Activities

- **(*)(!) IA_AHW_X:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_X:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **(!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **(!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
- **(!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

APPENDIX 4: MEASURES FOR MIPS COST PERFORMANCE CATEGORY

We refer readers to section IV. A.4.d.(2).(a). and (b). of this proposed rule for more information regarding the statutory authority for and existing policies pertaining to the specification of measures for the cost performance category.

Except as otherwise noted in this proposed rule, previously finalized cost measures will continue to apply for the CY 2026 performance period/2028 MIPS payment year and future years. Previously finalized measures and specialty sets are set forth in Table 75 in the CY 2025 PFS final rule (89 FR 98406).

The Group A Table(s) within this proposed rule set forth our proposals to modify one or more measures specified for the MIPS cost performance category beginning with the CY 2026 performance period/ 2028 MIPS payment year.

We are proposing modification(s) to the cost measure(s) set forth in the Group A Table(s) consistent with the criteria we established in the CY 2022 PFS final rule for determining whether a proposed change to a cost measure would be substantive (86 FR 65459 and 65460).

Group A: Proposal(s) to Modify MIPS Cost Measures Beginning with the CY 2026 Performance Period/ 2028 MIPS Payment Year

A.1. Total Per Capita Cost (TPCC)

Category	Description
CBE # :	3575
MIPS # :	TPCC_1
Current Measure Description:	TPCC assesses the overall cost of care delivered to a patient with a focus on the primary care they receive from their provider(s). The measure is payment-standardized, risk-adjusted, and specialty-adjusted.
Measure Case Minimum	20 beneficiaries as set forth in § 414.1350(c)(1)
Measure Steward:	Centers for Medicare & Medicaid Services (CMS)
Measure Type:	Population-based cost measure

Category	Description
Proposed Substantive Change(s):	**Initiating a candidate event would be modified as follows:** ● Proposed Modifications to Measure Specifications for Triggering a Candidate Event: ++ A candidate event would be initiated by two claims for outpatient evaluation and management (E/M) services indicative of primary care. The second service used to initiate a candidate event would have to be another E/M primary care service or another general primary care service from the **same** clinician group (TIN) within 90 days. ++ **Both the first and second service** would have to be provided by a clinician (TIN-NPI) that has not been excluded from the measure based on specialty exclusion criteria. ● How Proposed Modifications Would Substantively Change Current Measure Specifications: ++ The current methodology requires that, in addition to the initial outpatient E/M service, at least one of the following services should be billed to confirm the candidate event: (1) another primary care service from any clinician group within 3 days, or (2) a second E/M primary care service OR another primary care service from the same clinician group within 90 days. This proposed modification would revise the current methodology to remove the option for the second candidate event service to be provided by a different clinician group. ++ The current methodology only requires the first service be provided by a clinician that has not been excluded attribution based on the specialty exclusion criteria. This proposed modification would revise the current methodology to require both the first and second service be provided by a clinician that is not excluded by the specialty exclusion criteria. **Criteria for removing a clinician and their candidate events from attribution would be modified as follows:** ● Proposed Modification for Exclusion: We propose to remove clinicians and their candidate events from attribution for the TPCC measure if a clinician is: (1) an advanced care practitioner (that is, Nurse Practitioner, Physician Assistant, Certified Clinical Nurse Specialist), and (2) part of a clinician group where all other non-advanced care practitioners are excluded based on specialty criteria. ● How Proposed Modifications Would Substantively Change Current Measure Specifications: The current methodology only excludes clinicians and their candidate events if a clinician meets service category thresholds for billing certain services (that is, global surgery, anesthesia, therapeutic radiation, or chemotherapy services) or if the specialty code on a clinician's Medicare Part B claims is one of the specialties excluded from TPCC attribution. The current methodology does not exclude advanced care practitioners from attribution based on their specialty, which is identified by the specialty code on their Medicare Part B claims. This proposed modification would exclude advanced care practitioners from attribution if all other non-advanced care practitioners in their TIN are excluded based on the specialty exclusion criteria. Except as noted herein, we propose to retain all remaining specifications for the TPCC measure without modification. These proposed modifications are also available for review in the revised TPCC measure specifications available for download here: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*

Rationale	The TPCC measure assesses the overall cost of care provided to a Medicare beneficiary, focusing on MIPS eligible clinicians, subgroups, and clinician groups who provide primary care-type services. Given its broad scope, it includes all Medicare Parts A and B costs that occur during the time period attributed to the clinician or clinician group within the performance period. The measure assesses primary care, internal medicine, and other physicians, who frequently manage patients with chronic or ongoing care needs, and non-physician clinicians (such as, Physician Assistants, Nurse Practitioners, and Certified Clinician Nurse Specialists) who provide primary care and related services. We are proposing to modify the TPCC measure's candidate event logic to require that both services in a candidate event are provided by the same clinician group and by a clinician with a specialty included in measure attribution. This modification would result in MIPS eligible clinicians only being attributed the costs of care for beneficiaries that have had at least two qualifying services from their clinician group, and where both services were provided by a clinician that would not be excluded from measure attribution due to the specialty exclusion. The proposed modification would more strongly demonstrate that there is an ongoing care relationship. With this proposed modification, a MIPS eligible clinician would only be attributed beneficiaries that they or their clinician group have seen at least twice, and when both candidate event services are provided by clinicians who are not excluded from TPCC based on the specialty exclusion criteria. We are also proposing to modify the TPCC measure's specifications to exclude certain clinicians and clinician groups from attribution. Currently, the measure does not exclude advanced care practitioners (that is, Physician Assistants, Nurse Practitioners, and Certified Clinician Nurse Specialists) from measure attribution based on their specialty. Advanced care practitioners often provide primary care and ongoing care management services. However, some advanced care practitioners participate in MIPS through clinician groups that provide specialty care that would otherwise be excluded from the measure. In these instances, an advanced care practitioner may bill services (such as, office visits) to support specialized care that are unlikely to be indicative of primary care or ongoing care management relationships. Since specialty codes on Medicare Part B claims do not include information about sub-specialization for advanced care practitioners, we would use information about their clinician group to exclude certain advanced care practitioners in specialty settings (that is, clinician groups where all physicians are excluded based on the specialty exclusion criteria). This proposed modification would limit instances in which the TPCC measure would be used to assess or evaluate costs potentially associated with highly specialized clinician groups solely due to the billing patterns of advanced care practitioners within the clinician group. Additionally, we are not proposing any modifications to the TPCC case minimum of 20 beneficiaries, as set forth in § 414.1350(c)(1). This case minimum was originally established in the CY 2017 QPP final rule (81 FR 77170) and maintained in the CY 2020 PFS final rule (84 FR 62978). We based this case minimum on our interest to ensure that the majority of TINs and TIN-NPIs that were measured met a threshold of 0.4 reliability and to balance our interest in ensuring moderate reliability without limiting participation. The relationship between reliability thresholds and case minimums was further discussed in the CY 2022 PFS final rule (86 FR 65453 through 65455), establishing again that a mean reliability of 0.4 for the majority of TIN and TIN-NPIs would be used as a sufficient threshold to ensure a measure is performing as intended. We tested the reliability of the TPCC measure with the proposed modifications applied. Our testing demonstrated that

Category	Description
	mean reliability would remain high at approximately 0.9 for TINs and TIN-NPIs at the 20 beneficiary case minimum. Additionally, 100% of TINs and TIN-NPIs would exceed the 0.4 mean reliability threshold. Therefore, we would maintain the existing case minimum of 20 cases as set forth in § 414.1350(c)(1). Prior to proposing modifications to a cost measure through the notice-and-comment rulemaking process, we have historically subjected existing cost measures for which we are considering substantive changes to the pre-rulemaking process outlined by section 1890A of the Act. Section 1848(r)(10) provides that the pre-rulemaking requirements in 1890A of the Act are not required to apply to the selection of MIPS cost measures; however, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-stakeholder workgroups and have accordingly elected for such measures to be reviewed utilizing this process, as detailed in the Measure Management System (MMS) Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview*. For TPCC, we comprehensively reevaluated the measure in use in MIPS in accordance with the process outlined in the MMS Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/comprehensive-reevaluation*. During this process, we held two public comment periods and convened a Technical Expert Panel (TEP) twice to discuss modifications. We have received robust feedback from the public about the potential modifications during this comprehensive reevaluation process and through other cost measure public comment opportunities, such as the CY 2025 PFS rule. Following the completion of the comprehensive reevaluation process, we opted not to subject the TPCC measure with these proposed modifications to the pre-rulemaking process. We considered (i) the high volume of feedback received to date on the modifications; (ii) that the scope of the modifications does not impact the intent of the measure or negatively impact measure testing results; and (iii) that there is a tradeoff in delaying updates by a year to submit the measure to the pre-rulemaking process. Based on these considerations, we are proposing modifications to the TPCC measure through notice-and-comment rulemaking without having subjected the measure to the pre-rulemaking process. More information about the feedback we received from interested parties and technical expert panel(s) on the TPCC measure, and analyses that contributed to identifying the TPCC modifications, is available in the Cost measure comprehensive reevaluation (2023-2024) section of the QPP Cost Measures Information Page: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/current*.

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