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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 19 and 109

Notification of Inflation Adjustments for Civil Money Penalties

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notification of monetary penalties 2022.

SUMMARY: This document announces changes to the Office of the Comptroller of the Currency's (OCC) maximum civil money penalties as adjusted for inflation. The inflation adjustments are required to implement the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: The adjusted maximum amount of civil money penalties in this document are applicable to penalties assessed on or after January 12, 2022 for conduct occurring on or after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Lee Walzer, Counsel, Chief Counsel's Office, (202) 649–5490, Office of the Comptroller of the Currency.

SUPPLEMENTARY INFORMATION: This document announces changes to the maximum amount of each civil money penalty (CMP) within the OCC's jurisdiction to administer to account for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Adjustment Act),[1] as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Adjustment Act).[2] Under the 1990 Adjustment Act, as amended, federal agencies must make annual adjustments to the maximum amount of each CMP they administer. The Office of Management and Budget (OMB) is required to issue guidance to federal agencies no later than December 15 of each year providing an inflation adjustment multiplier (*i.e.,* the inflation adjustment factor agencies must use) applicable to CMPs assessed in the following year. The agencies are required to publish their CMPs, adjusted pursuant to the multiplier provided by the OMB, by January 15 of the applicable year.

To the extent an agency codified a CMP amount in its regulations, the agency would need to update that amount by regulation. However, if an agency codified a formula for making the CMP adjustments, then subsequent adjustments can be made solely by notice.[3] In 2018, the OCC published a final regulation that removed the CMP amounts from its regulations while updating the CMP amounts for inflation through the notice process.[4]

On December 15, 2021, the OMB issued guidance to affected agencies on implementing the required annual adjustment, which included the relevant inflation multiplier.[5] The OCC has applied that multiplier to the maximum CMPs allowable in 2021 for national banks and Federal savings associations as listed in the 2021 CMP notice[6] to calculate the maximum amount of CMPs that may be assessed by the OCC in 2022.[7] There were no new statutory CMPs administered by the OCC during 2021.

The following charts provide the inflation-adjusted CMPs for use beginning on January 12, 2022, pursuant to 12 CFR 19.240(b) and 109.103(c)(2) for conduct occurring on or after November 2, 2015:

PENALTIES APPLICABLE TO NATIONAL BANKS

U.S. code citation	Description and tier (if applicable)	Maximum penalty amount (in dollars)[1]
12 U.S.C. 93(b)	Violation of Various Provisions of the National Bank Act:	
	Tier 1	11,011
	Tier 2	55,052
	Tier 3	[2] 2,202,123
12 U.S.C. 164	Violation of Reporting Requirements:	
	Tier 1	4,404
	Tier 2	44,043
	Tier 3	[2] 2,202,123
12 U.S.C. 481	Refusal of Affiliate to Cooperate in Examination	11,011
12 U.S.C. 504	Violation of Various Provisions of the Federal Reserve Act:	
	Tier 1	11,011
	Tier 2	55,052
	Tier 3	[2] 2,202,123

[1] Public Law 101–410, Oct. 5, 1990, 104 Stat. 890, codified at 28 U.S.C. 2461 note.

[2] Public Law 114–74, Title VII, section 701(b), Nov. 2, 2015, 129 Stat. 599, codified at 28 U.S.C. 2461 note.

[3] *See* OMB Memorandum M–18–03, Implementation of the 2018 Annual Adjustment Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, at 4, which permits agencies that have codified the formula to adjust CMPs for inflation to update the penalties through a notice rather than a regulation.

[4] 83 FR 1517 (Jan. 12, 2018) (final rule); 83 FR 1657 (Jan. 12, 2018) (2018 CMP Notice).

[5] The inflation adjustment multiplier for 2022 is 1.06222. *See* OMB Memorandum M–22–07, Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Dec. 15, 2021).

[6] *See* 85 FR 86795 (Dec. 31, 2020).

[7] Penalties assessed for violations occurring prior to November 2, 2015, will be subject to the maximum amounts set forth in the OCC's regulations in effect prior to the enactment of the 2015 Adjustment Act.

PENALTIES APPLICABLE TO NATIONAL BANKS—Continued

U.S. code citation	Description and tier (if applicable)	Maximum penalty amount (in dollars) [1]
12 U.S.C. 1817(j)(16)	Violation of Change in Bank Control Act:	
	Tier 1	11,011
	Tier 2	55,052
	Tier 3	[2] 2,202,123
12 U.S.C. 1818(i)(2) [3]	Violation of Law, Unsafe or Unsound Practice, or Breach of Fiduciary Duty:	
	Tier 1	11,011
	Tier 2	55,052
	Tier 3	[2] 2,202,123
12 U.S.C. 1820(k)(6)(A)(ii).	Violation of Post-Employment Restrictions:	
	Per violation	362,217
12 U.S.C. 1832(c)	Violation of Withdrawals by Negotiable or Transferable Instrument for Transfers to Third Parties:	
	Per violation	3,198
12 U.S.C. 1884	Violation of the Bank Protection Act	320
12 U.S.C. 1972(2)(F)	Violation of Anti-Tying Provisions regarding Correspondent Accounts, Unsafe or Unsound Practices, or Breach of Fiduciary Duty:	
	Tier 1	11,011
	Tier 2	55,052
	Tier 3	[2] 2,202,123
12 U.S.C. 3110(a)	Violation of Various Provisions of the International Banking Act (Federal Branches and Agencies)	50,326
12 U.S.C. 3110(c)	Violation of Reporting Requirements of the International Banking Act (Federal Branches and Agencies):	
	Tier 1	4,027
	Tier 2	40,259
	Tier 3	[2] 2,013,008
12 U.S.C. 3909(d)(1)	Violation of International Lending Supervision Act	2,739
15 U.S.C. 78u–2(b)	Violation of Various Provisions of the Securities Act, the Securities Exchange Act, the Investment Company Act, or the Investment Advisers Act:	
	Tier 1 (natural person)—Per violation	10,360
	Tier 1 (other person)—Per violation	103,591
	Tier 2 (natural person)—Per violation	103,591
	Tier 2 (other person)—Per violation	517,955
	Tier 3 (natural person)—Per violation	207,183
	Tier 3 (other person)—Per violation	1,035,909
15 U.S.C. 1639e(k)	Violation of Appraisal Independence Requirements:	
	First violation	12,647
	Subsequent violations	25,293
42 U.S.C. 4012a(f)(5)	Flood Insurance:	
	Per violation	2,392

[1] The maximum penalty amount is per day, unless otherwise indicated.
[2] The maximum penalty amount for a national bank is the lesser of this amount or 1 percent of total assets.
[3] These amounts also apply to CMPs in statutes that cross-reference 12 U.S.C. 1818, such as 12 U.S.C. 2804, 3108, 3349, 4309, and 4717 and 15 U.S.C. 1607, 1693o, 1681s, 1691c, and 1692l.

PENALTIES APPLICABLE TO FEDERAL SAVINGS ASSOCIATIONS

U.S. code citation	CMP description	Maximum penalty amount (in dollars) [8]
12 U.S.C. 1464(v)	Reports of Condition:	
	1st Tier	4,404
	2nd Tier	44,043
	3rd Tier	[2] 2,202,123
12 U.S.C. 1467(d)	Refusal of Affiliate to Cooperate in Examination	11,011
12 U.S.C. 1467a(r)	Late/Inaccurate Reports:	
	1st Tier	4,404
	2nd Tier	44,043
	3rd Tier	[2] 2,202,123
12 U.S.C. 1817(j)(16)	Violation of Change in Bank Control Act:	
	1st Tier	11,011
	2nd Tier	55,052
	3rd Tier	[2] 2,202,123
12 U.S.C. 1818(i)(2) [3]	Violation of Law, Unsafe or Unsound Practice, or Breach of Fiduciary Duty:	
	1st Tier	11,011
	2nd Tier	55,052
	3rd Tier	[2] 2,202,123

PENALTIES APPLICABLE TO FEDERAL SAVINGS ASSOCIATIONS—Continued

U.S. code citation	CMP description	Maximum penalty amount (in dollars) [8]
12 U.S.C. 1820(k)(6)(A)(ii).	Violation of Post-Employment Restrictions:	
	Per violation	362,217
12 U.S.C. 1832(c)	Violation of Withdrawals by Negotiable or Transferable Instruments for Transfers to Third Parties:	
	Per violation	2,907
12 U.S.C. 1884	Violation of the Bank Protection Act	320
12 U.S.C. 1972(2)(F)	Violation of Provisions regarding Correspondent Accounts, Unsafe or Unsound Practices, or Breach of Fiduciary Duty:	
	Tier 1	11,011
	Tier 2	55,052
	Tier 3	[2] 2,202,123
15 U.S.C. 78u–2(b)	Violations of Various Provisions of the Securities Act, the Securities Exchange Act, the Investment Company Act, or the Investment Advisers Act:	
	1st Tier (natural person)—Per violation	10,360
	1st Tier (other person)—Per violation	103,591
	2nd Tier (natural person)—Per violation	103,591
	2nd Tier (other person)—Per violation	517,955
	3rd Tier (natural person)—Per violation	207,183
	3rd Tier (other person)—Per violation	1,035,909
15 U.S.C. 1639e(k)	Violation of Appraisal Independence Requirements:	
	First violation	12,647
	Subsequent violations	25,293
42 U.S.C. 4012a(f)(5)	Flood Insurance:	
	Per violation	2,392

[8] The maximum penalty amount is per day, unless otherwise indicated.
[2] The maximum penalty amount for a federal savings association is the lesser of this amount or 1 percent of total assets.
[3] These amounts also apply to statutes that cross-reference 12 U.S.C. 1818, such as 12 U.S.C. 2804, 3108, 3349, 4309, and 4717 and 15 U.S.C. 1607, 1681s, 1691c, and 1692l.

Benjamin W. McDonough,
Senior Deputy Comptroller and Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–00109 Filed 1–11–22; 8:45 am]
BILLING CODE 4810–33–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Parts 1209, 1217, and 1250

RIN 2590–AA43

Rules of Practice and Procedure; Civil Money Penalty Inflation Adjustment

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA) is adopting this final rule amending its Rules of Practice and Procedure and other agency regulations to adjust each civil money penalty within its jurisdiction to account for inflation, pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: *Effective* January 12, 2022, and applicable beginning January 15, 2022.

FOR FURTHER INFORMATION CONTACT: Frank R. Wright, Assistant General Counsel, at (202) 649–3087, *Frank.Wright@fhfa.gov* (not a toll-free number); Federal Housing Finance Agency, 400 7th Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

I. Background

FHFA is an independent agency of the Federal government, and the financial safety and soundness regulator of the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises), as well as the Federal Home Loan Banks (collectively, the Banks) and the Office of Finance under authority granted by the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act).[1] FHFA oversees the Enterprises and Banks (collectively, the regulated entities) and the Office of Finance to ensure that they operate in a safe and sound manner and maintain liquidity in the housing finance market in accordance with applicable laws, rules and regulations. To that end, FHFA is vested with broad supervisory discretion and specific civil administrative enforcement powers, similar to such authority granted by Congress to the Federal bank regulatory agencies.[2] Section 1376 of the Safety and Soundness Act (12 U.S.C. 4636) empowers FHFA to impose civil money penalties under specific conditions. FHFA's Rules of Practice and Procedure (12 CFR part 1209) (the Enforcement regulations) govern cease and desist proceedings, civil money penalty assessment proceedings, and other administrative adjudications.[3] FHFA's Flood Insurance regulation (12 CFR part 1250) governs flood insurance responsibilities as they pertain to the Enterprises.[4] FHFA's Implementation of the Program Fraud Civil Remedies Act of 1986 regulation (12 CFR part 1217) sets forth procedures for imposing civil penalties and assessments under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 *et seq.*) on any person that makes a false claim for property, services or money from FHFA, or makes a false material statement to FHFA in connection with a claim, where the

[1] *See* Safety and Soundness Act, 12 U.S.C. 4513 and 4631–4641.

[2] *Id.*

[3] *See* 12 CFR part 1209.

[4] *See* 12 CFR part 1250.

amount involved does not exceed $150,000.[5]

The Adjustment Improvements Act

The Federal Civil Penalties Inflation Adjustment Act of 1990 (Inflation Adjustment Act), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Adjustment Improvements Act), requires FHFA, as well as other federal agencies with the authority to issue civil money penalties (CMPs), to adjust by regulation the maximum amount of each CMP authorized by law that the agency has jurisdiction to administer.[6] The Adjustment Improvements Act required agencies to make an initial ''catch-up'' adjustment of their CMPs upon the statute's enactment,[7] and further requires agencies to make additional adjustments on an annual basis following the initial adjustment.[8]

The Adjustment Improvements Act sets forth the formula that agencies must apply when making annual adjustments, based on the percent change between the October Consumer Price Index for All Urban Consumers (the CPI–U) preceding the date of the last adjustment and the October CPI–U for the year before that.

II. Description of the Rule

This final rule adjusts the maximum penalty amount within each of the three tiers specified in 12 U.S.C. 4636 by amending the table contained in 12 CFR 1209.80 of the Enforcement regulations to reflect the new adjusted maximum penalty amount that FHFA may impose upon a regulated entity or any entity-affiliated party within each tier. The increases in maximum penalty amounts contained in this final rule may not necessarily affect the amount of any CMP that FHFA may seek for a particular violation, which may not be the maximum that the law allows; FHFA would calculate each CMP on a case-by-case basis in light of a variety of factors.[9] This rule also adjusts the maximum penalty amounts for violations under the FHFA Flood Insurance regulation by amending the text of 12 CFR 1250.3 to reflect the new adjusted maximum penalty amount that FHFA may impose for violations under that regulation. This rule also adjusts the maximum amounts for civil money penalties under the Program Fraud Civil Remedies Act by amending the text of 12 CFR 1217.3 to reflect the new adjusted maximum penalty amount that FHFA may impose for violations under that regulation.

The Adjustment Improvements Act directs federal agencies to calculate each annual CMP adjustment as the percent change between the CPI–U for the previous October and the CPI–U for October of the calendar year before.[10] The maximum CMP amounts for FHFA penalties were last adjusted in 2021.[11] Since FHFA is making this round of adjustments in calendar year 2022, and the maximum CMP amounts were last set in calendar year 2021, the inflation adjustment amount for each maximum CMP amount was calculated by comparing the CPI–U for October 2020 with the CPI–U for October 2021, resulting in an inflation factor of 1.06222. For each maximum CMP calculation, the product of this inflation adjustment and the previous maximum penalty amount was then rounded to the nearest whole dollar as required by the Adjustment Improvements Act, and was then summed with the previous maximum penalty amount to determine the new adjusted maximum penalty amount.[12] The tables below set out these items accordingly.

U.S. Code citation	Description	Previous maximum penalty amount	Rounded inflation increase	New adjusted maximum penalty amount
Enforcement Regulations				
12 U.S.C. 4636(b)(1)	First Tier	12,023	748	12,771
12 U.S.C. 4636(b)(2)	Second Tier	60,115	3,740	63,855
12 U.S.C. 4636(b)(4)	Third Tier (Entity-affiliated party or Regulated entity)	2,404,608	149,615	2,554,223
Program Fraud Civil Remedies Regulation				
31 U.S.C. 3802(a)(1)	Maximum penalty per false claim	11,803	734	12,537
31 U.S.C. 3802(a)(2)	Maximum penalty per false statement	11,803	734	12,537
Flood Insurance Regulation				
42 U.S.C. 4012a(f)(5)	Maximum penalty per violation	585	36	621
42 U.S.C. 4012a(f)(5)	Maximum total penalties assessed against an Enterprise in a calendar year.	168,631	10,492	179,123

III. Differences Between the Federal Home Loan Banks and the Enterprises

When promulgating any regulation that may have future effect relating to the Banks, the Director is required by section 1313(f) of the Safety and Soundness Act to consider the differences between the Banks and the Enterprises with respect to the Banks' cooperative ownership structure, mission of providing liquidity to members, affordable housing and community development mission, capital structure, and joint and several liability (12 U.S.C. 4513(f)).[13] The Director considered the differences between the Banks and the Enterprises, as they relate to the above factors, and determined that this final rule is appropriate. The inflation adjustments effected by the final rule are mandated by law, and the special features of the Banks identified in section 1313(f) of the Safety and Soundness Act can be accommodated, if appropriate, along with any other relevant factors, when determining any actual penalties.

[5] *See generally,* 31 U.S.C. 3801 *et seq.*

[6] *See* 28 U.S.C. 2461 note.

[7] FHFA promulgated its catch-up adjustment of its CMPs with an interim final rule published July 1, 2016. 81 FR 43028.

[8] FHFA promulgated its most recent annual adjustment of its CMP with a final rule published January 29, 2021. 86 FR 7493.

[9] *See, e.g.,* 12 CFR 1209.7(c); FHFA Enforcement Policy, AB 2013–03 (May 31, 2013).

[10] 28 U.S.C. 2461 note.

[11] *See* 86 FR 7493 (January 29, 2021).

[12] 28 U.S.C. 2461 note.

[13] So in original; no paragraphs (d) and (e) were enacted. *See* 12 U.S.C.A. 4513 n 1.

IV. Regulatory Impact

Administrative Procedure Act

FHFA finds good cause that notice and an opportunity to comment on this final rule are unnecessary under section 553(b) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b). The Adjustment Improvements Act states that the annual civil money penalty adjustments shall be made notwithstanding the rulemaking provisions of 5 U.S.C. 553.[14] Furthermore, this rulemaking conforms with and is consistent with the statutory directive set forth in the Adjustment Improvements Act. As a result, there are no issues of policy discretion about which to seek public comment. Accordingly, FHFA is adopting these amendments as a final rule.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA),[15] an agency must prepare a regulatory flexibility analysis for all proposed and final rules that describes the impact of the rule on small entities, unless the head of an agency certifies that the rule will not have ''a significant economic impact on a substantial number of small entities.'' However, the RFA applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to the APA.[16] As discussed above, FHFA has determined for good cause that the APA does not require a general notice of proposed rulemaking for this rule. Thus, the RFA does not apply to this final rule.

Congressional Review Act

The rule is not a ''major rule'' as defined by the Congressional Review Act, codified at 5 U.S.C. 801 *et seq.* The rule will not result in: (1) An annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies.[17]

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) requires that regulations involving the collection of information receive clearance from the Office of Management and Budget (OMB). This rule contains no such collection of information requiring OMB approval under the Paperwork Reduction Act. Consequently, no information has been submitted to OMB for review.

Lists of Subjects

12 CFR Part 1209

Administrative practice and procedure, Penalties.

12 CFR Part 1217

Civil remedies, Program fraud.

12 CFR Part 1250

Flood insurance, Government-sponsored enterprises, Penalties, Reporting and record keeping requirements.

Accordingly, for the reasons stated in the preamble and under the authority of 12 U.S.C. 4513b and 12 U.S.C. 4526, the Federal Housing Finance Agency hereby amends subchapters A and C of chapter XII of Title 12 of the Code of Federal Regulations as follows:

Subchapter A—Organization and Operations

PART 1209—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 1209 continues to read as follows:

Authority: 5 U.S.C. 554, 556, 557, and 701 *et seq.;* 12 U.S.C. 1430c(d); 12 U.S.C. 4501, 4502, 4503, 4511, 4513, 4513b, 4517, 4526, 4566(c)(1) and (c)(7), 4581–4588, 4631–4641; and 28 U.S.C. 2461 note.

■ 2. Revise § 1209.80 to read as follows:

§ 1209.80 Inflation adjustments.

The maximum amount of each civil money penalty within FHFA's jurisdiction, as set by the Safety and Soundness Act and thereafter adjusted in accordance with the Inflation Adjustment Act, is as follows:

TABLE 1 TO § 1209.80

U.S. Code citation	Description	New adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First Tier	$12,771
12 U.S.C. 4636(b)(2)	Second Tier	63,855
12 U.S.C. 4636(b)(4)	Third Tier (Regulated Entity or Entity-Affiliated party)	2,554,223

■ 3. Revise § 1209.81 to read as follows:

§ 1209.81 Applicability.

The inflation adjustments set out in § 1209.80 shall apply to civil money penalties assessed in accordance with the provisions of the Safety and Soundness Act, 12 U.S.C. 4636, and subparts B and C of this part, for violations occurring on or after January 15, 2022.

PART 1217—PROGRAM FRAUD CIVIL REMEDIES ACT

■ 4. The authority citation for part 1217 continues to read as follows:

Authority: 12 U.S.C. 4501; 12 U.S.C. 4526; 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812.

■ 5. Amend § 1217.3 by revising paragraphs (a)(1) introductory text and (b)(1) introductory text to read as follows:

§ 1217.3 Basis for civil penalties and assessments.

(a) * * *

(1) A civil penalty of not more than $12,537 may be imposed upon a person who makes a claim to FHFA for property, services, or money where the person knows or has reason to know that the claim:

* * * * *

(b) * * *

(1) A civil penalty of up to $12,537 may be imposed upon a person who makes a written statement to FHFA with respect to a claim, contract, bid or proposal for a contract, or benefit from FHFA that:

* * * * *

Subchapter C—Enterprises

PART 1250—FLOOD INSURANCE

■ 6. The authority citation for part 1250 continues to read as follows:

[14] 28 U.S.C. 2461 note, section 4(b)(2).

[15] 5 U.S.C. 603.

[16] 5 U.S.C. 603(a), 604(a).

[17] 5 U.S.C. 804(2).

Authority: 12 U.S.C. 4521(a)(4) and 4526; 28 U.S.C. 2461 note; 42 U.S.C. 4001 note; 42 U.S.C. 4012a(f)(3), (4), (5), (8), (9), and (10).

■ 7. Amend § 1250.3 by revising paragraph (c) to read as follows:

§ 1250.3 Civil money penalties.

* * * * *

(c) *Amount.* The maximum civil money penalty amount is $621 for each violation that occurs before January 15, 2022, with total penalties not to exceed $179,123. For violations that occur on or after January 15, 2022, the civil money penalty under this section may not exceed $621 for each violation, with total penalties assessed under this section against an Enterprise during any calendar year not to exceed $179,123.

* * * * *

Sandra L. Thompson,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2022–00361 Filed 1–11–22; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2021–0484; Special Conditions No. 25–794–SC]

Special Conditions: Learjet, Inc.; Electronic System Security Protection From Unauthorized External Access

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for a supplemental type certificate on certain transport category airplanes. These airplanes, as modified by Learjet, Inc. (Learjet), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is the installation of a system that allows connection to airplane electronics and networks, and access from aircraft external sources (*e.g.,* operator networks, wireless devices, internet connectivity, service provider satellite communications, electronic flight bags, etc.) to the previously isolated airplane electronic assets (networks, systems, and databases). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Learjet on January 12, 2022. Send comments on or before February 28, 2022.

ADDRESSES: Send comments identified by Docket No. FAA–2021–0484 using any of the following methods:

- *Federal eRegulations Portal:* Go to *https://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14, Code of Federal Regulations (14 CFR) 11.35, the FAA will post all comments received without change to *https://www.regulations.gov/,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to the person indicated in the Contact section below. Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for this rulemaking.

Docket: Background documents or comments received may be read at *https://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Varun Khanna, Aircraft Information Systems Section, AIR–622, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3159; email *varun.khanna@faa.gov.*

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to § 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On May 15, 2020, Learjet applied for a supplemental type certificate to install an Aircraft Health Management System (AHMS) in the airplanes listed on the approved model list (AML) for STC No. ST01970WI. These airplanes are super-midsize-category business jets with maximum passenger capacity of 16. These airplanes have a maximum takeoff weight of 38,850 pounds.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Learjet must show that airplanes for which they make application to modify by STC no. ST01970WI, as changed, continue to meet the applicable provisions of the regulations

listed in each airplane's respective type certificate or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the listed airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the models for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other models included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other models under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the airplanes listed in the AML must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions as defined in § 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The airplanes listed on the AML in STC no. ST01970WI will incorporate the following novel or unusual design features:

The installation of an AHMS that allows connection to airplane electronics and networks, and access from aircraft external sources (*e.g.,* operator networks, wireless devices, internet connectivity, service provider satellite communications, electronic flight bags, etc.) to the previously isolated airplane electronic assets (networks, systems, and databases).

Discussion

The architecture and network configuration of the airplanes listed on the AML of STC no. ST01970WI are novel or unusual for commercial transport airplanes because they may allow increased connectivity to and access from external network sources, airline operations, and maintenance networks to the airplanes' control domain and airline information-services domain. The airplanes' control domain and airline information-services domain perform functions required for the safe operation and maintenance of the airplanes. Previously, these domains had very limited connectivity with external network sources. This data network and design integration creates a potential for unauthorized persons to access the aircraft-control domain and airline information-services domain, and presents security vulnerabilities related to the introduction of computer viruses and worms, user errors, and intentional sabotage of airplane electronic assets (networks, systems, and databases) critical to the safety and maintenance of the airplanes.

The existing FAA regulations did not anticipate these networked airplane-system architectures. Furthermore, these regulations and the current guidance material do not address potential security vulnerabilities, which could be exploited by unauthorized access to airplane networks, data buses, and servers. Therefore, these special conditions ensure that the security (*i.e.,* confidentiality, integrity, and availability) of airplane systems is not compromised by unauthorized wired or wireless electronic connections. This includes ensuring that the security of the airplanes' systems is not compromised during maintenance of airplane electronic systems. These special conditions also require the applicant to provide appropriate instructions to the operator to maintain all electronic-system safeguards that have been implemented as part of the original network design, so that this feature does not allow or reintroduce security threats.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to airplanes listed in the AML of STC no. ST01970WI. Should Learjet apply at a later date for another STC, to include another airplane model with the same novel or unusual design feature, these special conditions would also apply to that model as well. These special conditions are not applicable to those airplane models for which special conditions for protection from unauthorized external access have already been issued to the type certificate for those specific models.

These special conditions are only applicable to design changes applied for after its effective date.

Conclusion

This action affects only a certain novel or unusual design feature for airplane models listed on the AML of STC no. ST01970WI, as modified by Learjet. It is not a rule of general applicability and affects only the applicant.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for airplane models listed on the approved model list of supplemental type certificate no. ST01970WI, as modified by Learjet.

1. The applicant must ensure airplane electronic-system security protection from access by unauthorized sources external to the airplane, including those possibly caused by maintenance activity.

2. The applicant must ensure that electronic-system security threats are identified and assessed, and that effective electronic-system security-protection strategies are implemented to protect the airplane from all adverse impacts on safety, functionality, and continued airworthiness.

3. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post-type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Kansas City, Missouri, on January 6, 2022.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–00390 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1182; Project Identifier AD–2021–01393–E; Amendment 39–21902; AD 2022–02–05]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Pratt & Whitney (P&W) PW1500G and PW1900G model turbofan engines. This AD was prompted by an analysis of an event involving an International Aero Engines AG (IAE) V2533–A5 model turbofan engine, which experienced an uncontained failure of a high-pressure turbine (HPT) 1st-stage disk that resulted in high-energy debris penetrating the engine cowling. This AD requires removing certain HPT 1st-stage and HPT 2nd-stage disks from service and replacing with parts eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 27, 2022.

The FAA must receive comments on this AD by February 28, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Pratt & Whitney, 400 Main Street, East Hartford, CT 06118; phone: (800) 565–0140; email: *help24@prattwhitney.com;* website: *https://fleetcare.prattwhitney.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1182; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Mark Taylor, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7229; fax: (781) 238–7199; email: *Mark.Taylor@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On March 18, 2020, an Airbus Model A321–231 airplane, powered by IAE V2533–A5 model turbofan engines, experienced an uncontained HPT 1st-stage disk failure that resulted in high-energy debris penetrating the engine cowling. Based on a preliminary analysis of this event, on March 21, 2020, the FAA issued Emergency AD 2020–07–51 (followed by publication in the **Federal Register** on April 13, 2020, as a Final Rule, Request for Comments (85 FR 20402)), which requires the removal from service of certain HPT 1st-stage disks installed on IAE V2522–A5, V2524–A5, V2525–D5, V2527–A5, V2527E–A5, V2527M–A5, V2528–D5, V2530–A5, and V2533–A5 model turbofan engines.

Since the FAA issued AD 2020–07–51, P&W determined that the failure of the IAE V2533–A5 model turbofan engine was due to an undetected subsurface material defect in an HPT disk that may affect the life of the part. In June 2021, P&W expanded its root cause analysis to include a review of records for all other IAE and P&W engines that contain parts of similar material.

P&W's analysis identified a different population of HPT 1st-stage and HPT 2nd-stage disks installed on P&W PW1519G, PW1521G, PW1521G–3, PW1521GA, PW1524G, PW1524G–3, PW1525G, and PW1525G–3 (PW1500G) model turbofan engines, and P&W PW1919G, PW1921G, PW1922G, PW1923G, and PW1923G–A (PW1900G) model turbofan engines that are subject to the same unsafe condition identified in AD 2020–07–51 and require removal from service. This condition, if not addressed, could result in uncontained HPT disk failure, release of high-energy debris, damage to the engine, damage to the airplane, and loss of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information

The FAA reviewed Pratt & Whitney Special Instruction (SI) No. 225F–21, dated December 1, 2021. This SI describes procedures for removing and replacing the affected HPT 1st-stage and HPT 2nd-stage disks, identified by part number (P/N) and serial number (S/N), installed on PW1500G model turbofan engines.

The FAA reviewed Pratt & Whitney SI No. 226F–21, dated December 1, 2021. This SI describes procedures for removing and replacing the affected HPT 1st-stage and HPT 2nd-stage disks, identified by P/N and S/N, installed on PW1900G model turbofan engines.

AD Requirements

This AD requires the removal from service of certain HPT 1st-stage and HPT 2nd-stage disks installed on PW1500G and PW1900G model turbofan engines.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule. On March 18, 2020, an Airbus Model A321–231 airplane, powered by IAE V2533–A5 model turbofan engines, experienced an uncontained HPT 1st-stage disk failure that resulted in high-energy debris penetrating the engine cowling. Based on a preliminary

analysis of this event, on March 21, 2020, the FAA issued Emergency AD 2020–07–51 (followed by publication in the **Federal Register** on April 13, 2020, as a Final Rule, Request for Comments (85 FR 20402)), which requires the removal from service of certain HPT 1st-stage disks installed on IAE V2522–A5, V2524–A5, V2525–D5, V2527–A5, V2527E–A5, V2527M–A5, V2528–D5, V2530–A5, and V2533–A5 model turbofan engines. Since the FAA issued AD 2020–07–51, the manufacturer conducted a root cause analysis and identified a different population of HPT 1st-stage and HPT 2nd-stage disks installed on P&W PW1500G and PW1900G model turbofan engines that are subject to the same unsafe condition identified in AD 2020–07–51. The FAA considers removal of the affected HPT 1st-stage and HPT 2nd-stage disks to be an urgent safety issue. These HPT disks have the highest risk of failure and removal is required within 30 days after the effective date of this AD to prevent additional HPT disk failures and maintain an acceptable level of safety. This unsafe condition, if not addressed, could result in uncontained HPT disk failure, release of high-energy debris, damage to the engine, damage to the airplane, and loss of the airplane. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1182 and Project Identifier AD–2021–01393–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Mark Taylor, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 8 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace HPT 1st-stage or HPT 2nd-stage disk.	316 work-hours × $85 per hour = $26,860	$121,516	$148,376	$1,187,008

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2022–02–05 Pratt & Whitney: Amendment 39–21902; Docket No. FAA–2021–1182; Project Identifier AD–2021–01393–E.

(a) Effective Date

This airworthiness directive (AD) is effective January 27, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pratt & Whitney (P&W) PW1519G, PW1521G, PW1521G–3, PW1521GA, PW1524G, PW1524G–3, PW1525G, PW1525G–3, PW1919G, PW1921G, PW1922G, PW1923G, and PW1923G–A model turbofan engines with an installed:

(1) High-pressure turbine (HPT) 1st-stage disk, part number (P/N) 30G5701, with serial number (S/N) LKLBCY9473, LKLBDG4865, LKLBDG4877, LKLBDG5064, LKLBDG4951, LKLBEH5482, LKLBCY9462, LKLBDG5142, LKLBFL9238, or LKLBF88737; or

(2) HPT 2nd-stage disk, P/N 30G5002, with S/N LKLBCT8724, LKLBDA4633, LKLBDA4689, LKLBD40801, LKLBEL3603, LKLBD40863, LKLBCT8771, LKLBDA4691, LKLBEL3600, LKLBD40830, or LKLBD40845.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by an analysis performed by P&W of an event involving an uncontained failure of an HPT 1st-stage disk that resulted in high-energy debris penetrating the engine cowling. The FAA is issuing this AD to prevent failure of HPT 1st-stage and HPT 2nd-stage disks. The unsafe condition, if not addressed, could result in uncontained HPT disk failure, release of high-energy debris, damage to the engine, damage to the airplane, and loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) For affected engines with an installed HPT 1st-stage disk, P/N 30G5701, having an S/N listed in paragraph (c)(1) of this AD, within 30 days after the effective date of the AD, remove the HPT 1st-stage disk from service and replace with a part eligible for installation.

(2) For affected engines with an installed HPT 2nd-stage disk, P/N 30G5002, having an S/N listed in paragraph (c)(2) of this AD, within 30 days after the effective date of the AD, remove the HPT 2nd-stage disk from service and replace with a part eligible for installation.

(h) Definition

For the purpose of this AD, a ''part eligible for installation'' is an HPT 1st-stage disk or HPT 2nd-stage disk that is not identified in paragraph (c)(1) or (2) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact Mark Taylor, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7229; fax: (781) 238–7199; email: *Mark.Taylor@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued on January 6, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–00414 Filed 1–7–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1175; Project Identifier MCAI–2021–01409–G; Amendment 39–21897; AD 2022–01–09]

RIN 2120–AA64

Airworthiness Directives; Stemme AG Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Stemme AG Model Stemme S 10–VT and Stemme S 12 gliders. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as unintended slipping of the freewheel clutch with overheating (burnishing) of the friction pads inside of the clutch. This AD requires removing the affected freewheel clutch from service. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 27, 2022.

The FAA must receive comments on this AD by February 28, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Stemme AG, Flugplatzstrasse F2, Nr. 6–7, D–15344 Strausberg, Germany; phone: +49 (0) 3341 3612–0; fax: +49 (0) 3341 3612–30; email: *airworthiness@stemme.de;* website: *https://www.stemme.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1175; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0278–E, dated December 15, 2021

(referred to after this as ''the MCAI''), to address an unsafe condition on Stemme AG Model Stemme S10–VT and Stemme S12 gliders. The MCAI states:

Occurrences have been reported of unintended slipping of the freewheel clutch (P/N 12AK) during operation and, subsequently, overheating (burnishing) of the friction pads inside of the clutch.

This condition, if not corrected, could lead to total loss of thrust, possibly resulting in loss of control of the powered sailplane.

Even after a successful implementation of the recommendations for safe operation of the clutch, published in Stemme AG Service Information P064–8900057/01, it has been determined that loss of thrust could occur without signs in advance.

To address this potential unsafe condition, Stemme AG issued the SB [service bulletin], as defined in this AD, to provide applicable instructions.

For the reasons described above, this [EASA] Emergency AD prohibits operation of certain powered sailplanes [glider], and prohibits installation of affected parts.

This [EASA] AD is considered to be an interim action and further AD action may follow.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1175.

Related Service Information

The FAA reviewed Stemme Service Bulletin Doc. No. P062–980058, Revision 1, dated December 14, 2021. This service information specifies procedures for identifying the serial number of a part number (P/N) 12AK freewheel clutch.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD after determining the unsafe condition is likely to exist or develop in other products of the same type design.

AD Requirements

This AD applies to gliders with a P/N 12AK freewheel clutch with a serial number starting with ''12-'' and requires removing the freewheel clutch from service. This AD also prohibits installing a P/N 12AK freewheel clutch with a serial number starting with ''12-'' on any glider.

Differences Between This AD and the MCAI

The MCAI applies to all Stemme AG Model Stemme S10–VT and Stemme S12 gliders and requires an inspection to determine whether an affected P/N 12AK freewheel clutch is installed. This AD only applies to Stemme AG Model Stemme S 10–VT and Stemme S 12 gliders with an affected P/N 12AK freewheel clutch installed.

In addition, EASA considers its MCAI as interim action. The FAA does not identify this AD as interim action since there is no indication that a modification of the affected freewheel clutch is forthcoming and since this AD requires removing the affected clutch from service.

FAA's Justification and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because unintended slipping of the freewheel clutch and the consequent overheating (burnishing) of the friction pads inside of the clutch could result in a loss of thrust and loss of glider control. Because this could happen without advance warning, the corrective action must be accomplished before further flight. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1175 and Project Identifier MCAI–2021–01409–G'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Jim Rutherford, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 66 gliders of U.S. registry and estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per glider	Cost on U.S. operators
Remove freewheel clutch from service	4 work-hours × $85 per hour = $340	$500	$840	$55,440

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2022–01–09 Stemme AG: Amendment 39–21897; Docket No. FAA–2021–1175; Project Identifier MCAI–2021–01409–G.

(a) Effective Date

This airworthiness directive (AD) is effective January 27, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Stemme AG Model Stemme S 10–VT and Stemme S 12 gliders, all serial numbers, certificated in any category, with a freewheel clutch part number (P/N) 12AK with a serial number (S/N) starting with ''12-'' installed.

Note 1 to paragraph (c): Stemme Service Bulletin Doc. No. P062–980058, Revision 1, dated December 14, 2021, contains guidance for identifying the S/N of a P/N 12AK freewheel clutch.

(d) Subject

Joint Aircraft System Component (JASC) Code 7100, Powerplant System.

(e) Unsafe Condition

This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as unintended slipping of the freewheel clutch with overheating (burnishing) of the friction pads inside of the clutch. The unsafe condition, if not addressed, could result in a loss of thrust and consequent loss of glider control.

(f) Required Action and Compliance

(1) Before further flight after the effective date of this AD, remove the freewheel clutch from service.

(2) As of the effective date of this AD, do not install a freewheel clutch P/N 12AK with an S/N starting with ''12-'' on any glider.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (h)(1) of this AD and email to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(h) Related Information

(1) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2021–0278–E, dated December 15, 2021, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1175.

(3) For service information identified in this AD, contact Stemme AG, Flugplatzstrasse F2, Nr. 6–7, D–15344 Strausberg, Germany; phone: +49 (0) 3341 3612–0; fax: +49 (0) 3341 3612–30; email: *airworthiness@stemme.de;* website: *https://www.stemme.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(i) Material Incorporated by Reference

None.

Issued on January 4, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–00348 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1003; Project Identifier AD–2021–01141–R; Amendment 39–21899; AD 2022–02–02]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Inc. (Type Certificate Previously Held by Bell Helicopter Textron Inc.) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–15–

51, which applied to Bell Textron Inc. (type certificate previously held by Bell Helicopter Textron Inc.) Model 204B, 205A, 205A–1, 205B, and 212 helicopters. AD 2021–15–51 required removing certain main rotor hub strap pins (pins) from service and prohibited installing them on any helicopter. Since the FAA issued AD 2021–15–51, it was determined that a defective pin could also be installed on Bell Textron Inc. Model 210 helicopters. This AD continues the required actions in AD 2021–15–51 and expands the applicability to add Model 210 helicopters. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 16, 2022.

ADDRESSES: For service information identified in this final rule, contact Bell Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; email *productsupport@bellflight.com*; or at *https://www.bellflight.com/support/contact-support*. You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov*by searching for and locating Docket No. FAA–2021–1003; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: David Wilson, Aerospace Engineer, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5786; email *david.wilson@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued Emergency AD 2021–15–51 on July 6, 2021, and it published as a Final rule; request for comments on August 9, 2021 as Amendment 39–21678 (86 FR 43406) (AD 2021–15–51). AD 2021–15–51 applied to Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, and 212 helicopters with a pin part number (P/N) 204–012–104–005 with a serial number (S/N) prefix ''FNFS'' installed. AD 2021–15–51 was prompted by a fatal accident of a Model 212 helicopter in which a pin P/N 204–012–104–005 with an S/N prefix ''FNFS'' sheared off during flight, which resulted in the main rotor blade and the main rotor head detaching from the helicopter. The pin had accumulated only 20 total hours time-in-service (TIS). An inspection of a different Model 212 helicopter revealed that another pin installed, and made by the same manufacturer and with the same S/N prefix, was deformed; this pin had accumulated only 29 total hours TIS. Because an affected pin could also be installed on other helicopters, AD 2021–15–51 also applied to Model 204B, 205A, 205A–1, and 205B helicopters. Failure of a pin could result in the main rotor blade detaching from the helicopter and subsequent loss of control of the helicopter.

After AD 2021–15–51 was issued, it was determined that an affected pin could also be installed on Model 210 helicopters. Therefore, the FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–15–51. The NPRM published in the **Federal Register** on November 19, 2021 (86 FR 64832) and it proposed to continue to require all of the requirements of AD 2021–15–51 and add Model 210 helicopters to the applicability.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adoption of the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information

The FAA reviewed Bell Alert Service Bulletins (ASBs), each Revision A and dated July 22, 2021:

- ASB 204B–21–74 for Model 204B helicopters, S/Ns 2001 through 2070 and 2196 through 2199;
- ASB 205–21–117 for Model 205A and 205A–1 helicopters, S/Ns 30001 through 30065, 30067 through 30165, 30167 through 30187, 30189 through 30296, and 30298 through 30332;
- ASB 205B–21–71 for Model 205B helicopters, S/Ns 30066, 30166, 30188 and 30297;
- ASB 210–21–14 for all Model 210 helicopters, and
- ASB 212–21–165 for Model 212 helicopters, S/Ns 30501 through 30999, 31101 through 31311, 32101 through 32142, and 35001 through 35103.

The ASBs specify removing all P/N 204–012–104–005 pins with an S/N prefix ''FNFS'' before further flight. The ASBs also specify that, although the investigation is still in progress, removing these pins from service is required. The ASBs state that these pins may not have been manufactured in accordance with the engineering design requirements and may therefore shear as a result of this nonconformance.

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD affects 155 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Replacing up to four pins takes about 20 work-hours and parts cost about $1,756 for four pins for an estimated cost of up to $3,456 per helicopter, and up to $535,680 for the U.S. fleet.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or

develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2021–15–51, Amendment 39–21678 (86 FR 43406, August 9, 2021); and

■ b. Adding the following new airworthiness directive:

FAA–2021–1003 Bell Textron Inc. (Type Certificate Previously Held by Bell Helicopter Textron Inc.): Amendment 39–21899; Docket No. FAA–2021–1003; Project Identifier AD–2021–01141–R.

(a) Effective Date

This airworthiness directive (AD) is effective February 16, 2022.

(b) Affected ADs

This AD replaces AD 2021–15–51, Amendment 39–21678 (86 FR 43406, August 9, 2021) (AD 2021–15–51).

(c) Applicability

This AD applies to Bell Textron Inc. (type certificate previously held by Bell Helicopter Textron Inc.) Model 204B, 205A, 205A–1, 205B, 210, and 212 helicopters, certificated in any category, with an outboard main rotor hub strap pin (pin) part number 204–012–104–005 with a serial number prefix ''FNFS'' installed.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6200, Main Rotor System.

(e) Unsafe Condition

This AD was prompted by a fatal accident in which a pin sheared off during flight, which resulted in the main rotor blade and the main rotor head detaching from the helicopter. The FAA is issuing this AD to address this unsafe condition and prevent loss of control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) For Model 204B, 205A, 205A–1, 205B, and 212 helicopters:

(i) Before further flight from August 24, 2021 (the effective date of AD 2021–15–51), remove from service any pin that is identified in paragraph (c) of this AD.

(ii) After August 24, 2021 (the effective date of AD 2021–15–51), do not install any pin that is identified in paragraph (c) of this AD on any helicopter.

(2) For Model 210 helicopters:

(i) Before further flight after the effective date of this AD, remove from service any pin that is identified in paragraph (c) of this AD.

(ii) As of the effective date of this AD, do not install any pin that is identified in paragraph (c) of this AD on any helicopter.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, DSCO Branch, Compliance & Airworthiness Division, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the DSCO Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ASW-190-COS@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact David Wilson, Aerospace Engineer, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5786; email *david.wilson@faa.gov*.

(k) Material Incorporated by Reference

None.

Issued on January 4, 2022.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–00351 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 772, and 774

[Docket No. 220105–0004]

RIN 0694–AH56

Information Security Controls: Cybersecurity Items; Delay of Effective Date

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Interim final rule; delay of effective date.

SUMMARY: On October 21, 2021, the Bureau of Industry and Security (BIS) published an interim final rule that establishes new controls on certain cybersecurity items for National Security (NS) and Anti-terrorism (AT) reasons, along with a new License Exception, Authorized Cybersecurity Exports (ACE), that authorizes exports of these items to most destinations except in the circumstances described in that rule. That rule was published with a 45-day comment period, which ended on December 12, 2021, and a 90-day delayed effective date (January 19, 2022). This rule delays the effective date of the interim final rule by 45 days.

DATES: As of January 12, 2022, the effective date for the interim final rule published October 21, 2021, at 86 FR 58205, is delayed to March 7, 2022.

FOR FURTHER INFORMATION CONTACT: For questions regarding the Export Control Classification Numbers (ECCNs) included in this rule or License Exception ACE, contact Aaron Amundson at 202–482–0707 or email *Aaron.Amundson@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

In response to the interim final rule published on October 21, 2021 (86 FR 58205), which implements new controls on certain cybersecurity items for National Security (NS) and Anti-terrorism (AT) reasons, along with a new License Exception, Authorized Cybersecurity Exports (ACE), BIS received twelve comments before the end of the comment period on December 12, 2021. The submitted

comments are posted at *regulations.gov* under ID BIS–2020–0038. Based on issues raised by some of the public comments, BIS may consider some modifications for the final rule. Some of the comments described the necessary compliance measures that industry would have to complete to comply with the October 21, 2021 rule and, on that basis, requested that BIS delay the rule's effective date in order to allow industry sufficient time to update the requisite compliance procedures and for BIS to provide additional public guidance. BIS agrees that it is important to allow enough time for industry to implement the compliance measures and procedures necessary to comply with the published interim final rule, as well as for BIS to provide the public with additional guidance. Therefore, BIS is delaying the effective date of the October 21, 2021 interim final rule by 45 days, to March 7, 2022. This action does not extend or reopen the comment period for BIS's previous request for comments on the interim final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. Sections 4801–4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this action.

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–00448 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

30 CFR Part 1241

[Docket No. ONRR–2021–0002; DS63644000 DRT000000.CH7000 223D1113RT]

RIN 1012–AA31

2022 Civil Monetary Penalty Inflation Adjustments

AGENCY: Office of Natural Resources Revenue (''ONRR''), Interior.

ACTION: Final rule.

SUMMARY: ONRR is adjusting for inflation the civil monetary penalty (''CMP'') amounts it assesses under the Federal Oil and Gas Royalty Management Act of 1982 (''FOGRMA'').

DATES: This rule is effective on January 12, 2022.

FOR FURTHER INFORMATION CONTACT: For questions on procedural issues, contact Luis Aguilar, Regulatory Specialist, by telephone at (303) 231–3148 or email to *ONRR_RegulationsMailbox@onrr.gov.* For questions on technical issues, contact Michael Marchetti, Enforcement Program Manager, by telephone at (303) 231–3125 or email to *Michael.Marchetti@onrr.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. ONRR's Inflation-Adjusted Maximum Rates
III. Procedural Matters
A. Regulatory Planning and Review (Executive Orders 12866 and 13563)
B. Regulatory Flexibility Act
C. Small Business Regulatory Enforcement Fairness Act
D. Unfunded Mandates Reform Act
E. Takings (Executive Order 12630)
F. Federalism (Executive Order 13132)
G. Civil Justice Reform (Executive Order 12988)
H. Consultation With Indian Tribes (Executive Order 13175)
I. Paperwork Reduction Act
J. National Environmental Policy Act
K. Effects on the Energy Supply (Executive Order 13211)
L. Clarity of This Regulation
M. Administrative Procedure Act

I. Background

The Secretary of the Interior (''Secretary'') is authorized, under 30 U.S.C. 1719(a)–(d), to assess CMPs for royalty reporting and other violations. Pursuant to authority delegated to it by the Secretary, ONRR published regulations at 30 CFR part 1241 implementing the Secretary's CMP authority. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74) (the ''2015 Act'') (collectively referred to herein as the ''Inflation Adjustment Acts'') require Federal agencies to publish annual CMP inflation adjustments in the **Federal Register** by January 15th of each year.

The Inflation Adjustment Acts and Office of Management and Budget (''OMB'') Memorandum No. M–22–07, Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2021 (''OMB Memorandum'') specify that, for purposes of this rule, the annual inflation adjustments are based on the percent change between the Consumer Price Index for all Urban Consumers (''CPI–U'') published by the Department of Labor for October 2021 (October of the year in which ONRR's last CMP adjustment was published), and October 2020. The OMB Memorandum further specifies that the cost-of-living adjustment multiplier for 2022, not seasonally adjusted, is 1.06222 for CY 2022 (the October 2021 CPI–U (276.589) divided by the October 2020 CPI–U (260.388) = 1.06222). ONRR used this guidance to calculate required inflation adjustments. Pursuant to the Inflation Adjustment Acts and OMB Memorandum, any increases in CMPs are rounded to the nearest whole dollar and the new maximum penalty rates apply to CMPs assessed after the date the increase takes effect.

II. ONRR's Inflation-Adjusted Maximum Rates

This final rule increases the maximum CMP dollar amounts for each of the four violation categories identified in 30 U.S.C. 1719(a)–(d) and implemented by 30 CFR part 1241. The following table identifies the applicable ONRR regulations, the dollar amounts set forth in the regulations, and the adjusted amounts.

30 CFR citation	Current maximum penalty	2022 Inflation adjustment multiplier	2022 Adjusted maximum penalty
1241.52(a)(2)	$1,288	1.06222	$1,368
1241.52(b)	12,891	1.06222	13,693
1241.60(b)(1)	25,780	1.06222	27,384

30 CFR citation	Current maximum penalty	2022 Inflation adjustment multiplier	2022 Adjusted maximum penalty
1241.60(b)(2)	64,452	1.06222	68,462

III. Procedural Matters

A. Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order (''E.O.'') 12866 provides that the Office of Information and Regulatory Affairs (''OIRA'') in the OMB will review all significant rules. OIRA has determined that agency regulations intended only to implement the annual inflation adjustments are not significant, provided they are consistent with the OMB Memorandum. Because ONRR is only implementing the annual inflation adjustments in this final rule, this rule is not significant under E.O. 12866.

E.O. 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the United States' regulatory system to promote predictability, to reduce uncertainty, and to use the most innovative and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. ONRR developed this rule in a manner consistent with these requirements.

B. Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601, *et seq.,* because the rule only makes an adjustment for inflation. The 2015 Act requires agencies to adjust CMPs with an annual inflation adjustment. Therefore, the RFA does not apply to this rulemaking.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more;

(b) Will not cause a major increase in costs or prices for consumers; individual industries; Federal, State, local government agencies; or geographic regions; and

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. This rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. Therefore, ONRR is not required to provide a statement containing the information that the Unfunded Mandates Reform Act (2 U.S.C. 1531, *et seq.*) requires because this rule is not an unfunded mandate.

E. Takings (E.O. 12630)

This rule does not result in a taking of private property or otherwise have takings implications under E.O. 12630. Therefore, this rule does not require a takings implication assessment.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a), which requires that ONRR review all regulations to eliminate errors and ambiguity and to write them to minimize litigation; and

(b) Meets the criteria of section 3(b)(2), which requires that ONRR write all regulations in clear language, using clear legal standards.

H. Consultation With Indian Tribal Governments (E.O. 13175)

The Department of the Interior (''DOI'') strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. Under the DOI's consultation policy and the criteria in E.O. 13175, ONRR evaluated this rule and determined that it will have no substantial, direct effects on Federally recognized Indian Tribes and does not require consultation.

I. Paperwork Reduction Act

This rule:

(a) Does not contain any new information collection requirements; and

(b) Does not require a submission to OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). *See* 5 CFR 1320.4(a)(2).

J. National Environmental Policy Act of 1969 (''NEPA'')

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. ONRR is not required to provide a detailed statement under NEPA because this rule qualifies for categorical exclusion under 43 CFR 46.210(i) in that this rule is ''. . . of an administrative, financial, legal, technical, or procedural nature . . . .'' ONRR also has determined that this rule is not involved in any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211 and, therefore, does not require a Statement of Energy Effects.

L. Clarity of This Regulation

ONRR is required by E.O. 12866 (section 1(b)(12)), E.O. 12988 (section 3(b)(1)(B)), and E.O. 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule ONRR publishes must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible;

If you feel that ONRR has not met these requirements, send your

comments to Luis Aguilar, Regulatory Specialist at *ONRR_RegulationsMailbox@onrr.gov.* Your comments should be as specific as possible. For example, you should identify the number of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

M. Administrative Procedure Act (APA)

The Inflation Adjustment Acts require agencies to publish annual inflation adjustments by January 15 of each year, notwithstanding section 553 of the APA. OMB has interpreted this direction to mean that the usual APA public procedure for rulemaking—which includes public notice of a proposed rule, an opportunity for public comment, and a delay in the effective date of a final rule—is not required when agencies issue regulations to implement the annual adjustments to CMPs required by the 2015 Act. *See* OMB Memorandum, M–22–07, at page 3–4. Accordingly, ONRR is issuing the 2022 annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**.

Kimbra G. Davis,

Director for the Office of Natural Resources Revenue.

List of Subjects in 30 CFR Part 1241

Administrative practice and procedure, Penalties.

Administrative practice and procedure, Coal, Geothermal energy, Indian—lands, Mineral royalties, Natural gas, Oil and gas exploration, Penalties, Public lands—mineral resources.

Authority and Issuance

For the reasons discussed in the preamble, ONRR amends 30 CFR part 1241 as set forth below:

PART 1241—PENALTIES

■ 1. The authority citation for part 1241 continues to read as follows:

Authority: 25 U.S.C. 396 *et seq.,* 396a *et seq.,* 2101 *et seq.;* 30 U.S.C. 181 *et seq.,* 351 *et seq.,* 1001 *et seq.,* 1701 *et seq.;* 43 U.S.C. 1301 *et seq.,* 1331 *et seq.,* 1801 *et seq.*

§ 1241.52 [Amended]

■ 2. Amend § 1241.52:

■ a. In paragraph (a)(2), by removing ''$1,288'' and adding in its place ''$1,368''.

■ b. In paragraph (b) introductory text, by removing ''$12,891'' and adding in its place ''$13,693''.

§ 1241.60 [Amended]

■ 3. Amend § 1241.60:

■ a. In paragraph (b)(1) introductory text, by removing ''$25,780'' and adding in its place ''$27,384''.

■ b. In paragraph (b)(2), by removing ''$64,452'' and adding in its place ''$68,462''.

[FR Doc. 2022–00165 Filed 1–11–22; 8:45 am]

BILLING CODE 4335–30–P

POSTAL SERVICE

39 CFR Part 111

Plus One Permanent Product

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: On November 10, 2021, the Postal Service (USPS®) filed a notice of intent to implement Plus One as a permanent product with the Postal Regulatory Commission (PRC), effective January 9, 2022. This final rule contains the revisions to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to adopt Plus One mailpiece as a permanent product.

DATES: *Effective date:* January 9, 2022.

FOR FURTHER INFORMATION CONTACT: Elke Reuning-Elliott at (202) 268–4068 or Jacqueline Erwin at (202) 268–2158.

SUPPLEMENTARY INFORMATION: On November 10, 2021, the Postal Service filed a request to add Plus One as a new permanent product offering to USPS Marketing Mail saturation letters as a new optional feature. The Postal Service conducted a two-year market test of Plus One, beginning September 2019.

Plus One is an advertising card mailed as an add-on mailpiece with a USPS Marketing Mail letters marriage mail envelope. The host mailpiece must be mailed as a commercial automation USPS Marketing Mail saturation marriage mail letter, with a minimum of 90 percent of the mailing being saturation sorted. The remaining 10 percent must be USPS Marketing Mail high density and/or high density plus letters. All mailpieces must be entered at the destinating sectional center facility, SCF, and the Plus One add-on card must be part of the same mailing as the host piece, addressed to the same delivery points.

On January 4, 2022, the PRC favorably reviewed the addition of Plus One as a permanent Market Dominant product proposed by the Postal Service. The price and DMM revisions are scheduled to become effective on January 9, 2022. Final product information is available under Docket No. MC2022–20 (Order No. 6081) on the Postal Regulatory Commission's website at *www.prc.gov.*

* * * * *

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations. See* 39 CFR 111.1.

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401–404, 414, 416, 3001–3018, 3201–3220, 3401–3406, 3621, 3622, 3626, 3629, 3631–3633, 3641, 3681–3685, and 5001.

■ 2. Revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

200 Commercial Letters, Flats, and Parcels Design Standards

* * * * *

204 Barcode Standards

* * * * *

3.0 Standards for Barcoded Tray Labels, Sack Labels, and Container Labels

* * * * *

3.2 Specifications for Barcoded Tray and Sack Labels

* * * * *

3.2.4 3-Digit Content Identifier Numbers

Exhibit 3.2.4 3-Digit Content Identifier Numbers

CLASS AND MAILING

* * * * *

[*Revise Exhibit 3.2.4; to read as follows:*]

USPS MARKETING MAIL

ECR Letters—Barcoded

saturation price—(including Plus One) high density or high density plus price—(including Plus One)

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

602 Addressing

* * * * *

[*Add new section 11.0 to 602; to read as follows:*]

11.0 Commercial Plus One Mailpieces

11.1 General

11.1.1 Definition

The commercial mail Plus One product is a bundled offering consisting of a host mailpiece and a Plus One card. Both the host mailpiece and the Plus One card must meet the applicable basic standards of a USPS Marketing mail saturation letter in 245.6.0, be entered at a destination sectional center facility (DSCF), and meet automation standards with a correct mailing address and intelligent mail barcode, (IMb). The Plus One mailpiece (card) must meet the following additional standards:

- Have at least a six-month relationship with the host mailer.
- Be addressed to the same delivery points as the host mailpiece.
- Be sorted and presented separately from the host piece.
- Must not exceed 6 inches long by 9.5 inches high.
- Must be at least 0.009 inches thick, card stock.
- Must have ''Plus One'' marking directly below Permit indicia.

11.1.2 Mail Preparation

Each Plus One mailing must be trayed and labeled according to 245.6.7. Palletized mailings must be prepared according to 705.8.10.3.

11.1.3 Documentation

When requested by USPS, Plus One mailpiece mailers must provide standardized documentation according to 203.3.0, to establish that the applicable distribution standards are met. Spoilage of host pieces may affect eligibility to mail Plus One pieces in the following manner:

a. File must show that at least 90% of host pieces are saturation mail, the remainder may be high density or high density plus.

b. The total number of Plus One pieces must be less than or equal to the number of host pieces.

11.1.4 Extra Services

Items mailed with Plus One mailpieces may not be combined with any extra service.

* * * * *

Notice 123 (Price List)

[*Revise prices as applicable.*]

* * * * *

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–00396 Filed 1–7–22; 11:15 am]

BILLING CODE P

POSTAL SERVICE

39 CFR Parts 233 and 273

Inspection Service Authority; Civil Monetary Penalty Inflation Adjustment

AGENCY: Postal Service™.

ACTION: Interim final rule.

SUMMARY: This document updates postal regulations by implementing inflation adjustments to civil monetary penalties that may be imposed under consumer protection and mailability provisions enforced by the Postal Service pursuant to the Deceptive Mail Prevention and Enforcement Act and the Postal Accountability and Enhancement Act, as well as the civil monetary penalty that may be imposed by the Postal Service for false claims and statements under the Program Fraud Civil Remedies Act. These adjustments are required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. This document includes the adjustments for 2022 for the statutory civil monetary penalties subject to the 2015 Act and all necessary updates authorized by the 2015 Act for regulatory civil monetary penalties.

DATES: Effective January 12, 2022.

FOR FURTHER INFORMATION CONTACT: Louis DiRienzo, (202) 268–3028, *ljdirienzo@uspis.gov.*

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), Public Law 114–74, 129 Stat. 584, amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (1990 Act), Public Law 101–410, 104 Stat. 890 (28 U.S.C. 2461 note), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Section 3 of the 1990 Act specifically includes the Postal Service in the definition of ''agency'' subject to its provisions.

Beginning in 2017, the 2015 Act requires the Postal Service to make an annual adjustment for inflation to civil penalties that meet the definition of ''civil monetary penalty'' under the 1990 Act. The Postal Service must make the annual adjustment for inflation and publish the adjustment in the **Federal Register** by January 15 of each year. The Postal Service has not completed the annual adjustments for the civil monetary penalty that may be imposed under the Program Fraud Civil Remedies Act. In order to satisfy the annual adjustment requirement, the Postal Service is making all annual adjustments at this time. Each penalty will be adjusted as instructed by the Office of Management and Budget (OMB) based on the Consumer Price Index (CPI–U) from the most recent October. OMB has furnished detailed instructions regarding the annual adjustment for 2022 in memorandum M–22–07, *Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (December 15, 2021), *https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-07.pdf.* This year, OMB has advised that an adjustment multiplier of 1.06222 will be used. The new penalty amount must be rounded to the nearest dollar.

The 2015 Act allows the interim final rule and annual inflation adjustments to be published without prior public notice or opportunity for public comment.

Adjustments to Postal Service Civil Monetary Penalties

Civil monetary penalties may be assessed for postal offenses under sections 106 and 108 of the Deceptive Mail Prevention and Enforcement Act, Public Law 106–168, 113 Stat. 1811, 1814 (*see,* 39 U.S.C. 3012(a), (c)(1), (d), and 3017 (g)(2), (h)(1)(A)); and section 1008 of the Postal Accountability and Enhancement Act, Public Law 109–435, 120 Stat. 3259–3261 (*see,* 39 U.S.C. 3018 (c)(1)(A)). The statutory civil monetary penalties subject to the 2015 Act and the amount of each penalty after implementation of the annual adjustment for inflation are as follows:

39 U.S.C. 3012(a)—False Representations and Lottery Orders

Under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may issue administrative orders prohibiting persons from using the mail to obtain money through false representations or lotteries. Persons who evade, attempt to evade, or fail to comply with an order to stop such prohibited practices may be liable to the

United States for a civil penalty under 39 U.S.C. 3012(a). The regulations implemented pursuant to this section currently impose a $74,825 penalty for each mailing less than 50,000 pieces, $149,647 for each mailing of 50,000 to 100,000 pieces, and $14,966 for each additional 10,000 pieces above 100,000 not to exceed $2,992,956. The new penalties will be as follows: A $79,481 penalty for each mailing less than 50,000 pieces, $158,958 for each mailing of 50,000 to 100,000 pieces, and $15,897 for each additional 10,000 pieces above 100,000 not to exceed $3,179,178.

39 U.S.C. 3012(c)(1)—False Representation and Lottery Penalties in Lieu of or as Part of an Order

In lieu of or as part of an order issued under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may assess a civil penalty. Currently, the amount of this penalty, set in the implementing regulations to 39 U.S.C. 3012(c)(1), is $37,412 for each mailing that is less than 50,000 pieces, $74,825 for each mailing of 50,000 to 100,000 pieces, and an additional $7,482 for each additional 10,000 pieces above 100,000 not to exceed $1,496,478. The new penalties will be $39,740 for each mailing that is less than 50,000 pieces, $79,481 for each mailing of 50,000 to 100,000 pieces, and an additional $7,948 for each additional 10,000 pieces above 100,000 not to exceed $1,589,589.

39 U.S.C. 3012(d)—Misleading References to the United States Government; Sweepstakes and Deceptive Mailings

Persons may be liable to the United States for a civil penalty under 39 U.S.C. 3012(d) for sending certain deceptive mail matter described in 39 U.S.C. 3001((h)–(k), including:

- Solicitations making false claims of Federal Government connection or approval;
- Certain solicitations for the purchase of a product or service that may be obtained without cost from the Federal Government;
- Solicitations containing improperly prepared ''facsimile checks''; and
- Certain solicitations for ''skill contests'' and ''sweepstakes'' sent to individuals who, in accordance with 39 U.S.C. 3017(d), have requested that such materials not be mailed to them.

Currently, under the implementing regulations, this penalty is not to exceed $14,966 for each mailing. The new penalty will be $15,897.

39 U.S.C. 3017(g)(2)—Commercial Use of Lists of Persons Electing Not To Receive Skill Contest or Sweepstakes Mailings

Under 39 U.S.C. 3017(g)(2), the Postal Service may impose a civil penalty against a person who provides information for commercial use about individuals who, in accordance with 39 U.S.C. 3017(d), have elected not to receive certain sweepstakes and contest information. Currently, this civil penalty may not exceed $2,992,956 per violation, pursuant to the implementing regulations. The new penalty may not exceed $3,179,178 per violation.

39 U.S.C. 3017(h)(1)(A)—Reckless Mailing of Skill Contest or Sweepstakes Matter

Currently, under 39 U.S.C. 3017(h)(1)(A) and its implementing regulations, any promoter who recklessly mails nonmailable skill contest or sweepstakes matter may be liable to the United States in the amount of $14,966 per violation for each mailing to an individual. The new penalty is $15,897 per violation.

39 U.S.C. 3018(c)(1)(A)—Hazardous Material

Under 39 U.S.C. 3018(c)(1)(A), the Postal Service may impose a civil penalty payable into the Treasury of the United States on a person who knowingly mails nonmailable hazardous materials or fails to follow postal laws on mailing hazardous materials. Currently, this civil penalty is at least $324, but not more than $129,032 for each violation, pursuant to the implementing regulations. The new penalty is at least $344, but not more than $137,060 for each violation.

Adjustments to Regulatory Postal Service Civil Monetary Penalties

In October 1986, Congress enacted the Program Fraud Civil Remedies Act, 31 U.S.C. 3801–3812. The Program Fraud Civil Remedies Act established an administrative remedy against any person who makes, or causes to be made, a false claim or written statement to certain Federal agencies. The Act requires each covered agency to promulgate rules and regulations necessary to implement its provisions. The Postal Service's implementing regulations are found in part 273 of title 39, Code of Federal Regulations. The Program Fraud Civil Remedies Act established a maximum penalty of $5,000 for each violation. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. 2461 note, required all Federal agencies to (1) adjust the penalty amount to 2016 inflation levels with an initial ''catch-up'' inflation adjustment; and (2) make subsequent annual adjustments for inflation. This rule incorporates the initial ''catch-up'' adjustment to 2016 inflation levels and the annual adjustments for 2017 through 2022, and applies those adjustments cumulatively to the civil monetary penalties that the Program Fraud Civil Remedies Act imposes. The adjustment factors are as follows: 2016—2.15628; 2017—1.01636; 2018—1.02041; 2019—1.02522; 2020—1.01764; 2021—1.01182; 2022—1.06222.

After applying all adjustments, the new penalty amount is $12,537.

List of Subjects

39 CFR Part 233

Administrative practice and procedure, Banks, Banking, Credit, Crime, Infants and children, Law enforcement, Penalties, Privacy, Seizures and forfeitures.

39 CFR Part 273

Administrative practice and procedure, Claims, Fraud, Penalties.

For the reasons set out in the preamble, the Postal Service amends 39 CFR parts 233 and 273 as follows:

PART 233—INSPECTION SERVICE AUTHORITY

■ 1. The authority citation for part 233 continues to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005(e)(1), 3012, 3017, 3018; 12 U.S.C. 3401–3422; 18 U.S.C. 981, 983, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 104–208, 110 Stat. 3009; Secs. 106 and 108, Pub. L. 106–168, 113 Stat. 1806 (39 U.S.C. 3012, 3017); Pub. L. 114–74, 129 Stat. 584.

§ 233.12 [Amended]

■ 2. In § 233.12:

■ a. In paragraph (a), remove ''$74,825'' and add in its place ''$79,481'', remove ''$149,647'' and add in its place ''$158,958'', remove ''$14,966'' and add in its place ''$15,897'', and remove ''$2,992,956'' and add in its place ''$3,179,178''.

■ b. In paragraph (b), remove ''$37,412'' and add in its place ''$39,740'', remove ''$74,825'' and add in its place ''$79,481'', remove ''$7,482'' and add in its place ''$7,948'', and remove ''$1,496,478'' and add in its place ''$1,589,589''.

■ c. In paragraph (c)(4), remove ''$14,966'' and add in its place ''$15,897''.

■ d. In paragraph (d), remove ''$2,992,956'' and add in its place ''$3,179,178''.

■ e. In paragraph (e), remove ''$14,966'' and add in its place ''$15,897''.
■ f. In paragraph (f), remove ''$324'' and add in its place ''$344'' and remove ''$129,032'' and add in its place ''$137,060''.

PART 273—ADMINISTRATION OF PROGRAM FRAUD CIVIL REMEDIES ACT

■ 3. The authority citation for part 273 continues to read as follows:

Authority: 31 U.S.C. Chapter 38; 39 U.S.C. 401.

■ 4. In § 273.3, in paragraph (a)(1)(iv), add a sentence to the end of the paragraph to read as follows:

§ 273.3 Liability for false claims and statements.

* * * * *

(a) * * *

(1) * * *

(iv) * * * As adjusted under Public Law 114–74, the penalty is $12,537 per claim.

* * * * *

Joshua Hofer,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–00373 Filed 1–11–22; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 19

[FRL–5906.6–01–OECA]

Civil Monetary Penalty Inflation Adjustment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating this final rule to adjust the level of the maximum (and minimum) statutory civil monetary penalty amounts under the statutes the EPA administers. This action is mandated by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended through the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (''the 2015 Act''). The 2015 Act prescribes a formula for annually adjusting the statutory maximum (and minimum) amount of civil monetary penalties to reflect inflation, maintain the deterrent effect of statutory civil monetary penalties, and promote compliance with the law. The rule does not establish specific civil monetary penalty amounts the EPA may seek in particular cases, as appropriate given the facts of particular cases and applicable agency penalty policies. The EPA's civil penalty policies, which guide enforcement personnel on how to exercise the EPA's discretion within statutory penalty authorities, take into account a number of fact-specific considerations, *e.g.,* the seriousness of the violation, the violator's good faith efforts to comply, any economic benefit gained by the violator as a result of its noncompliance, and a violator's ability to pay.

DATES: This final rule is effective January 12, 2022.

FOR FURTHER INFORMATION CONTACT: David Smith-Watts, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, Mail Code 2241A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone number: (202) 564–4083; *smith-watts.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since 1996, Federal agencies have been required to issue regulations adjusting for inflation the statutory civil monetary penalties [1] that can be imposed under the laws administered by that agency. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 (DCIA), required agencies to review their statutory civil monetary penalties every four years, and to adjust the statutory civil monetary penalty amounts for inflation if the increase met the DCIA's adjustment methodology. In accordance with the DCIA, the EPA reviewed and, as appropriate, adjusted the civil monetary penalty levels under each of the statutes the agency implements in 1996 (61 FR 69360), 2004 (69 FR 7121), 2008 (73 FR 75340), and 2013 (78 FR 66643).

The 2015 Act [2] required each Federal agency to adjust the level of statutory civil monetary penalties under the laws implemented by that agency with an initial ''catch-up'' adjustment through an interim final rulemaking. The 2015 Act also required Federal agencies, beginning on January 15, 2017, to make subsequent annual adjustments for inflation. Section 4 of the 2015 Act requires each Federal agency to publish these adjustments by January 15 of each year. The purpose of the 2015 Act is to maintain the deterrent effect of civil monetary penalties by translating originally enacted statutory civil penalty amounts to today's dollars and rounding statutory civil penalties to the nearest dollar.

As required by the 2015 Act, the EPA issued a catch-up rule on July 1, 2016, which was effective August 1, 2016 (81 FR 43091). The EPA has made five annual adjustments since then: On January 12, 2017, effective on January 15, 2017 (82 FR 3633); on January 10, 2018, effective on January 15, 2018 (83 FR 1190); on February 6, 2019, effective February 6, 2019 (84 FR 2056), and issued a subsequent correction on February 25, 2019 (84 FR 5955); on January 13, 2020, effective the same day (85 FR 1751); and on December 23, 2020, effective the same day (85 FR 83818). This rule implements the sixth annual adjustment mandated by the 2015 Act.

The 2015 Act provides a formula for calculating the adjustments. Each statutory maximum and minimum [3] civil monetary penalty, as currently adjusted, is multiplied by the cost-of-living adjustment multiplier, which is the percentage by which the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October 2021 exceeds the CPI–U for the month of October 2020.[4]

With this rule, the new statutory maximum and minimum penalty levels listed in the third column of Table 1 of 40 CFR 19.4 will apply to all civil monetary penalties assessed on or after January 12, 2022, for violations that occurred after November 2, 2015, the

[1] The Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 28 U.S.C. 2461 note, defines ''civil monetary penalty'' as any penalty, fine, or other sanction that—(1)(i) is for a specific monetary amount as provided by Federal law; or (ii) has a maximum amount provided for by Federal law; and (2) is assessed or enforced by an agency pursuant to Federal law; and (3) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

[2] The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701 of Pub. L.114–74) was signed into law on November 2, 2015, and further amended the Federal Civil Penalties Inflation Adjustment Act of 1990.

[3] Under Section 3(2)(A) of the 2015 Act, ''civil monetary penalty'' means ''a specific monetary amount as provided by Federal law''; or ''has a maximum amount provided for by Federal law.'' EPA-administered statutes generally refer to statutory maximum penalties, with the following exceptions: Section 311(b)(7)(D) of the Clean Water Act, 33 U.S.C. 1321(b)(7)(D), refers to a minimum penalty of ''not less than $100,000 . . .''; Section 104B(d)(1) of the Marine Protection, Research, and Sanctuaries Act, 33 U.S.C. 1414b(d)(1), refers to an exact penalty of $600 ''[f]or each dry ton (or equivalent) of sewage sludge or industrial waste dumped or transported by the person in violation of this subsection in calendar year 1992 . . .''; and Section 325(d)(1) of the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. 11045(d)(1), refers to an exact civil penalty of $25,000 for each frivolous trade secret claim.

[4] Current and historical CPI–U's can be found on the Bureau of Labor Statistics' website here: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202110.pdf.*

date the 2015 Act was enacted. The former maximum and minimum statutory civil monetary penalty levels, which are in the fourth column of Table 1 to 40 CFR 19.4, will now apply only to violations that occurred after November 2, 2015, where the penalties were assessed on or after December 23, 2020, but before January 12, 2022. The statutory civil monetary penalty levels that apply to violations that occurred on or before November 2, 2015, are codified at Table 2 to 40 CFR 19.4. The fifth column of Table 1 and the seventh column of Table 2 display the statutory civil monetary penalty levels as originally enacted.

The formula for determining the cost-of-living or inflation adjustment to statutory civil monetary penalties consists of the following steps:

Step 1: The cost-of-living adjustment multiplier for 2022 is the percentage by which the CPI–U of October 2021 (276.589) exceeds the CPI–U for the month of October 2020 (260.388), which is 1.06222.[5] Multiply 1.06222 by the current penalty amount. This is the raw adjusted penalty value.

Step 2: Round the raw adjusted penalty value. Section 5 of the 2015 Act states that any adjustment shall be rounded to the nearest multiple of $1. The result is the final penalty value for the year.

II. The 2015 Act Requires Federal Agencies To Publish Annual Penalty Inflation Adjustments Notwithstanding Section 553 of the Administrative Procedure Act

Pursuant to section 4 of the 2015 Act, each Federal agency is required to publish adjustments no later than January 15 each year. In accordance with section 553 of the Administrative Procedure Act (APA), most rules are subject to notice and comment and are effective no earlier than 30 days after publication in the **Federal Register**. However, section 4(b)(2) of the 2015 Act provides that each agency shall make the annual inflation adjustments ''notwithstanding section 553'' of the APA. Consistent with the language of the 2015 Act, this rule is not subject to notice and an opportunity for public comment and will be effective on January 12, 2022.

III. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was therefore not submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This rule merely increases the level of statutory civil monetary penalties that can be imposed in the context of a Federal civil administrative enforcement action or civil judicial case for violations of EPA-administered statutes and their implementing regulations.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. Because the 2015 Act directs Federal agencies to publish this rule notwithstanding section 553 of the APA, this rule is not subject to notice and comment requirements or the RFA.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action is required by the 2015 Act, without the exercise of any policy discretion by the EPA. This action also imposes no enforceable duty on any state, local or tribal governments or the private sector. Because the calculation of any increase is formula-driven pursuant to the 2015 Act, the EPA has no policy discretion to vary the amount of the adjustment.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175.

This rule merely reconciles the real value of current statutory civil monetary penalty levels to reflect and keep pace with the levels originally set by Congress when the statutes were enacted or amended. The calculation of the increases is formula-driven and prescribed by statute, and the EPA has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, this rule will not have a substantial direct effect on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

The rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. Rather, this action is mandated by the 2015 Act, which prescribes a formula for adjusting statutory civil penalties on an annual basis to reflect inflation.

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[5] Section 5(b) of the 2015 Act provides that the term ''cost-of-living adjustment'' means the percentage (if any) for each civil monetary penalty by which—

(1) the Consumer Price Index for the month of October preceding the date of the adjustment, exceeds

(2) the Consumer Price Index for the month of October 1 year before the month of October referred to in paragraph (2).

Because the CPI–U for October 2021 is 276.589 and the CPI–U for October 2020 is 260.388, the cost-of-living multiplier is 1.06222 (276.589 divided by 260.388).

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA finds that the APA's notice and comment rulemaking procedures are unnecessary because the 2015 Act directs Federal agencies to publish their annual penalty inflation adjustments ''notwithstanding section 553 [of the APA].''

List of Subjects in 40 CFR Part 19

Environmental protection, Administrative practice and procedure, Penalties.

Michael S. Regan,
Administrator.

For the reasons set out in the preamble, the EPA amends title 40, chapter I, part 19 of the Code of Federal Regulations as follows:

PART 19—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

■ 1. The authority citation for part 19 continues to read as follows:

Authority: Pub. L. 101–410, Oct. 5, 1990, 104 Stat. 890, as amended by Pub. L. 104–134, title III, sec. 31001(s)(1), Apr. 26, 1996, 110 Stat. 1321–373; Pub. L. 105–362, title XIII, sec. 1301(a), Nov. 10, 1998, 112 Stat. 3293; Pub. L. 114–74, title VII, sec. 701(b), Nov. 2, 2015, 129 Stat. 599.

■ 2. Revise § 19.2 to read as follows:

§ 19.2 Effective date.

(a) The statutory civil monetary penalty levels set forth in the third column of Table 1 of § 19.4 apply to all violations which occur or occurred after November 2, 2015, where the penalties are assessed on or after January 12, 2022. The statutory civil monetary penalty levels set forth in the fourth column of Table 1 of § 19.4 apply to all violations which occurred after November 2, 2015, where the penalties were assessed on or after December 23, 2020, but before January 12, 2022.

(b) The statutory monetary penalty levels in the third column of table 2 to § 19.4 apply to all violations which occurred after December 6, 2013 through November 2, 2015, and to violations occurring after November 2, 2015, where penalties were assessed before August 1, 2016. The statutory civil monetary penalty levels set forth in the fourth column of table 2 of § 19.4 apply to all violations which occurred after January 12, 2009 through December 6, 2013. The statutory civil monetary penalty levels set forth in the fifth column of table 2 of § 19.4 apply to all violations which occurred after March 15, 2004 through January 12, 2009. The statutory civil monetary penalty levels set forth in the sixth column of table 2 of § 19.4 apply to all violations which occurred after January 30, 1997 through March 15, 2004.

■ 3. In § 19.4, revise the section heading, introductory text, and table 1 of § 19.4 to read as follows:

§ 19.4 Statutory civil monetary penalties, as adjusted for inflation, and tables.

Table 1 of this section sets out the statutory civil monetary penalty provisions of statutes administered by the EPA, with the third column setting out the latest operative statutory civil monetary penalty levels for violations that occur or occurred after November 2, 2015, where penalties are assessed on or after January 12, 2022. The fourth column displays the operative statutory civil monetary penalty levels where penalties were assessed on or after December 23, 2020, but before January 12, 2022. Table 2 of this section sets out the statutory civil monetary penalty provision of statutes administered by the EPA, with the operative statutory civil monetary penalty levels, as adjusted for inflation, for violations that occurred on or before November 2, 2015, and for violations that occurred after November 2, 2015, where penalties were assessed before August 1, 2016.

TABLE 1 OF § 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

U.S. Code citation	Environmental statute	Statutory civil monetary penalties for violations that occur or occurred after November 2, 2015, where penalties are assessed on or after 1/12/2022	Statutory civil monetary penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after December 23, 2020, but before 1/12/2022	Statutory civil monetary penalties, as enacted
7 U.S.C. 136*l*(a)(1)	FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA).	$21,805	$20,528	$5,000
7 U.S.C. 136*l*(a)(2) [1]	FIFRA	3,198/2,061/3,198	3,011/1,940/3,011	1,000/500/1,000
15 U.S.C. 2615(a)(1)	TOXIC SUBSTANCES CONTROL ACT (TSCA).	43,611	41,056	25,000
15 U.S.C. 2647(a)	TSCA	12,537	11,803	5,000
15 U.S.C. 2647(g)	TSCA	10,360	9,753	5,000
31 U.S.C. 3802(a)(1)	PROGRAM FRAUD CIVIL REMEDIES ACT (PFCRA).	12,537	11,803	5,000
31 U.S.C. 3802(a)(2)	PFCRA	12,537	11,803	5,000
33 U.S.C. 1319(d)	CLEAN WATER ACT (CWA)	59,973	56,460	25,000
33 U.S.C. 1319(g)(2)(A)	CWA	23,989/59,973	22,584/56,460	10,000/25,000
33 U.S.C. 1319(g)(2)(B)	CWA	23,989/299,857	22,584/282,293	10,000/125,000
33 U.S.C. 1321(b)(6)(B)(i)	CWA	20,719/51,796	19,505/48,762	10,000/25,000
33 U.S.C. 1321(b)(6)(B)(ii)	CWA	20,719/258,978	19,505/243,808	10,000/125,000
33 U.S.C. 1321(b)(7)(A)	CWA	51,796/2,072	48,762/1,951	25,000/1,000
33 U.S.C. 1321(b)(7)(B)	CWA	51,796	48,762	25,000
33 U.S.C. 1321(b)(7)(C)	CWA	51,796	48,762	25,000
33 U.S.C. 1321(b)(7)(D)	CWA	207,183/6,215	195,047/5,851	100,000/3,000
33 U.S.C. 1414b(d)(1)(A)	MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT (MPRSA).	1,380	1,299	600
33 U.S.C. 1415(a)	MPRSA	218,048/287,632	205,276/270,784	50,000/125,000
33 U.S.C. 1901 note (*see* 1409(a)(2)(A))	CERTAIN ALASKAN CRUISE SHIP OPERATIONS (CACSO).	15,897/39,740	14,966/37,412	10,000/25,000
33 U.S.C. 1901 note (*see* 1409(a)(2)(B))	CACSO	15,897/198,698	14,966/187,059	10,000/125,000
33 U.S.C. 1901 note (*see* 1409(b)(1))	CACSO	39,740	37,412	25,000

TABLE 1 OF § 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code citation	Environmental statute	Statutory civil monetary penalties for violations that occur or occurred after November 2, 2015, where penalties are assessed on or after 1/12/2022	Statutory civil monetary penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after December 23, 2020, but before 1/12/2022	Statutory civil monetary penalties, as enacted
33 U.S.C. 1908(b)(1)	ACT TO PREVENT POLLUTION FROM SHIPS (APPS).	81,540	76,764	25,000
33 U.S.C. 1908(b)(2)	APPS	16,307	15,352	5,000
42 U.S.C. 300g–3(b)	SAFE DRINKING WATER ACT (SDWA)	62,689	59,017	25,000
42 U.S.C. 300g–3(g)(3)(A)	SDWA	62,689	59,017	25,000
42 U.S.C. 300g–3(g)(3)(B)	SDWA	12,537/43,678	11,803/41,120	5,000/25,000
42 U.S.C. 300g–3(g)(3)(C)	SDWA	43,678	41,120	25,000
42 U.S.C. 300h–2(b)(1)	SDWA	62,689	59,017	25,000
42 U.S.C. 300h–2(c)(1)	SDWA	25,076/313,448	23,607/295,088	10,000/125,000
42 U.S.C. 300h–2(c)(2)	SDWA	12,537/313,448	11,803/295,088	5,000/125,000
42 U.S.C. 300h–3(c)	SDWA	21,805/46,517	20,528/43,792	5,000/10,000
42 U.S.C. 300i(b)	SDWA	26,209	24,674	15,000
42 U.S.C. 300i–1(c)	SDWA	152,557/1,525,582	143,621/1,436,220	100,000/1,000,000
42 U.S.C. 300j(e)(2)	SDWA	10,902	10,263	2,500
42 U.S.C. 300j–4(c)	SDWA	62,689	59,017	25,000
42 U.S.C. 300j–6(b)(2)	SDWA	43,678	41,120	25,000
42 U.S.C. 300j–23(d)	SDWA	11,506/115,054	10,832/108,315	5,000/50,000
42 U.S.C. 4852d(b)(5)	RESIDENTIAL LEAD-BASED PAINT HAZARD REDUCTION ACT OF 1992.	19,507	18,364	10,000
42 U.S.C. 4910(a)(2)	NOISE CONTROL ACT OF 1972	41,219	38,805	10,000
42 U.S.C. 6928(a)(3)	RESOURCE CONSERVATION AND RECOVERY ACT (RCRA).	109,024	102,638	25,000
42 U.S.C. 6928(c)	RCRA	65,666	61,820	25,000
42 U.S.C. 6928(g)	RCRA	81,540	76,764	25,000
42 U.S.C. 6928(h)(2)	RCRA	65,666	61,820	25,000
42 U.S.C. 6934(e)	RCRA	16,307	15,352	5,000
42 U.S.C. 6973(b)	RCRA	16,307	15,352	5,000
42 U.S.C. 6991e(a)(3)	RCRA	65,666	61,820	25,000
42 U.S.C. 6991e(d)(1)	RCRA	26,269	24,730	10,000
42 U.S.C. 6991e(d)(2)	RCRA	26,269	24,730	10,000
42 U.S.C. 7413(b)	CLEAN AIR ACT (CAA)	109,024	102,638	25,000
42 U.S.C. 7413(d)(1)	CAA	51,796/414,364	48,762/390,092	25,000/200,000
42 U.S.C. 7413(d)(3)	CAA	10,360	9,753	5,000
42 U.S.C. 7524(a)	CAA	51,796/5,179	48,762/4,876	25,000/2,500
42 U.S.C. 7524(c)(1)	CAA	414,364	390,092	200,000
42 U.S.C. 7545(d)(1)	CAA	51,796	48,762	25,000
42 U.S.C. 9604(e)(5)(B)	COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT (CERCLA).	62,689	59,017	25,000
42 U.S.C. 9606(b)(1)	CERCLA	62,689	59,017	25,000
42 U.S.C. 9609(a)(1)	CERCLA	62,689	59,017	25,000
42 U.S.C. 9609(b)	CERCLA	62,689/188,069	59,017/177,053	25,000/75,000
42 U.S.C. 9609(c)	CERCLA	62,689/188,069	59,017/177,053	25,000/75,000
42 U.S.C. 11045(a)	EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT (EPCRA).	62,689	59,017	25,000
42 U.S.C. 11045(b)(1)(A)	EPCRA	62,689	59,017	25,000
42 U.S.C. 11045(b)(2)	EPCRA	62,689/188,069	59,017/177,053	25,000/75,000
42 U.S.C. 11045(b)(3)	EPCRA	62,689/188,069	59,017/177,053	25,000/75,000
42 U.S.C. 11045(c)(1)	EPCRA	62,689	59,017	25,000
42 U.S.C. 11045(c)(2)	EPCRA	25,076	23,607	10,000
42 U.S.C. 11045(d)(1)	EPCRA	62,689	59,017	25,000
42 U.S.C. 14304(a)(1)	MERCURY-CONTAINING AND RECHARGEABLE BATTERY MANAGEMENT ACT (BATTERY ACT).	17,474	16,450	10,000
42 U.S.C. 14304(g)	BATTERY ACT	17,474	16,450	10,000

[1] Note that 7 U.S.C. 136*l*(a)(2) contains three separate statutory maximum civil penalty provisions. The first mention of $1,000 and the $500 statutory maximum civil penalty amount were originally enacted in 1978 (Pub. L. 95–396), and the second mention of $1,000 was enacted in 1972 (Pub. L. 92–516).

* * * * *

[FR Doc. 2022–00349 Filed 1–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2021–0863; FRL–9250–01–OAR]

Findings of Failure To Submit State Implementation Plan Revisions in Response to the 2015 Findings of Substantial Inadequacy and SIP Calls To Amend Provisions Applying To Excess Emissions During Periods of Startup, Shutdown, and Malfunction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to find that 12 States and local air pollution control agencies failed to submit State Implementation Plan (SIP) revisions required by the Clean Air Act (CAA) in a timely manner to address EPA's 2015 findings of substantial inadequacy and ''SIP calls'' for provisions applying to excess emissions during periods of startup, shutdown, and malfunction (SSM). This action triggers certain CAA deadlines for the EPA to impose sanctions if a State does not submit a complete SIP revision addressing the outstanding requirements and to promulgate a Federal Implementation Plan (FIP) if the EPA does not approve the State's submission as a SIP revision.

DATES: This action is effective February 11, 2022.

FOR FURTHER INFORMATION CONTACT: General questions concerning this notice should be addressed to, Erin Lowder, Office of Air Quality Planning and Standards, Air Quality Policy Division, 109 T.W. Alexander Drive, Research Triangle Park, NC 27711; by telephone (919) 541–5421; or by email at *lowder.erin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. How is the preamble organized?

The information presented in this preamble is organized as follows:

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B. Notice and Comment Under the Administrative Procedure Act (APA)

Section 553(b)(3)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this final agency action without prior proposal and opportunity for comment because no significant EPA judgment is involved in making findings of failure to submit SIPs, or elements of SIPs, required by the Clean Air Act (CAA), where states have made no submissions to meet the requirement. As is discussed in further detail later, pursuant to CAA section 110(k)(1)(B), the EPA ''shall determine'' no later than 6 months after the date by which a state is required to submit a SIP whether a state has made a submission that meets the minimum completeness criteria established pursuant to CAA section 110(k)(1)(A). EPA exercises no significant judgment in making a determination that a state failed to make a submission and subsequently issuing a finding of failure to submit. Thus, notice and public procedures are unnecessary to take this action. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

C. How can I get copies of this document and other related information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2021–0863. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA/DC, William Jefferson Clinton Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Office of Air and Radiation Docket and Information Center is (202) 566–1742. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

D. Where do I go if I have specific air agency questions?

For questions related to specific air agencies mentioned in this notice, please contact the appropriate EPA Regional Office:

Regional offices	Air agencies
EPA Region 1: Mr. John Rogan, Chief, Air Program Branch, EPA Region 1, 5 Post Office Square, Boston, MA 02109. *rogan.john@epa.gov*.	Rhode Island.
EPA Region 3: Mr. Mike Gordon, Chief, Planning and Implementation Branch, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. *gordon.mike@epa.gov*.	District of Columbia.

Regional offices	Air agencies
EPA Region 4: Ms. Lynorae Benjamin, Chief, Air Planning and Implementation Branch, EPA Region 4, 61 Forsyth Street SW, Atlanta, GA 30303. *benjamin.lynorae@epa.gov*.	Alabama; North Carolina—Forsyth; Tennessee—Shelby (Memphis).
EPA Region 5: Mr. Doug Aburano, Manager, Air Program Branch, EPA Region 5, 77 West Jackson Boulevard, Chicago, IL 60604. *aburano.douglas@epa.gov*.	Illinois; Ohio.
EPA Region 6: Mr. Guy Donaldson, Chief, Air Program Branch, EPA Region 6, 1201 Elm Street, Dallas, TX 75270. *donaldson.guy@epa.gov*.	Arkansas.
EPA Region 8: Mr. Scott Jackson, Chief, Air Quality Planning Branch, EPA Region 8, Mailcode 8ARD–QP, 1595 Wynkoop Street, Denver, CO 80202. *jackson.scott@epa.gov*.	South Dakota.
EPA Region 9: Ms. Doris Lo, Manager, Rules Office, Air and Radiation Division, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. *lo.doris@epa.gov*.	California—San Joaquin Valley Air Pollution Control District (APCD).
EPA Region 10: Ms. Debra Suzuki, Chief, Air Program Branch, EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101. *suzuki.debra@epa.gov*.	Washington—Energy Facility Site Evaluation Council (EFSEC); Washington—Southwest Clean Air Agency (SWCAA).

II. Background

On June 12, 2015, the EPA finalized an action (2015 SSM SIP Action), which clarified, restated, and updated EPA's national policy regarding SSM provisions in SIPs (2015 Policy).[1] The 2015 Policy explained the EPA's interpretation of certain CAA requirements, affirming that SSM exemption provisions (*e.g.,* automatic exemptions, discretionary exemptions, and overly broad enforcement discretion provisions) and affirmative defense SIP provisions are generally viewed as inconsistent with CAA requirements. At the same time, pursuant to CAA section 110(k)(5), the EPA issued findings of substantial inadequacy for SIP provisions applying to excess emissions during SSM periods for 36 states that were applicable in 45 statewide and local jurisdictions (air agencies).[2] As part of the 2015 SSM SIP Action, the EPA also issued a ''SIP call'' (2015 SIP Call) to each of those 45 air agencies. The 2015 SIP Call required air agencies to adopt and submit revisions to the EPA to correct identified SSM-related deficiencies in their SIPs by November 22, 2016. The 2015 SSM SIP Action also responded to a petition for rulemaking alleging specific deficiencies related to SSM provisions in existing SIPs. On July 27, 2015, the 2015 SSM SIP Action was challenged in the United States Court of Appeals for the District of Columbia Circuit.[3]

In 2017, the EPA requested that the pending litigation on the final 2015 SSM SIP Action be held in abeyance to allow the new administration time to review the action. In 2020, Regions 4, 6, and 7 took final actions that were inconsistent with the 2015 Policy and the EPA withdrew the corresponding SIP calls previously issued to Texas, North Carolina, and Iowa. These state-specific actions are the subject of pending litigation.[4] Moreover, in alignment with the SIP call withdrawals for Texas, North Carolina, and Iowa, the EPA issued a Memorandum in October 2020 (2020 Memorandum), which established a new national policy that permitted the inclusion of certain provisions governing SSM periods in SIPs, including those related to exemptions and affirmative defenses. Importantly, the 2020 Memorandum was not a regulatory action and did not alter or withdraw the 2015 SIP Call for any of the 45 air agencies identified in the 2015 SSM SIP Action. The 2020 Memorandum did, however, indicate the EPA's intent at the time to review the remaining SIP calls that were issued in the 2015 SSM SIP Action to determine whether the EPA should maintain, modify, or withdraw particular SIP calls through future agency actions.

On September 30, 2021, the EPA issued a Memorandum (2021 Memorandum) that announced a withdrawal of the 2020 Memorandum and EPA's intent to return to the 2015 Policy and implement it fully. As previously articulated in the 2015 Policy, the 2021 Memorandum states that SSM exemption provisions and affirmative defense provisions included in SIPs will generally be viewed as inconsistent with CAA requirements.

As part of the reinstatement of the 2015 Policy, the EPA intends to implement the pending SIP calls, which remain in place from the 2015 SSM SIP Action. Pursuant to CAA section 110(k)(1)(B), the EPA must determine no later than 6 months after the date by which a state is required to submit a SIP whether a state has made a submission that meets the minimum completeness criteria established pursuant to CAA section 110(k)(1)(A). These criteria are set forth at 40 CFR part 51, appendix V. The EPA refers to the determination that a state has not submitted a SIP submission that meets the minimum completeness criteria, or has not submitted a SIP at all, as a ''finding of failure to submit.''

For the 2015 SIP Call, as previously discussed, SIP submissions were due by November 22, 2016. The EPA's determinations of whether air agencies made submittals were therefore due on May 22, 2017. The EPA has neither made such determinations nor issued findings of failure to submit. Accordingly, the EPA is now issuing findings of failure to submit to the 12 air agencies that, as of the date of this action, had not submitted SIPs responding to the SIP call: Alabama, Arkansas, California—San Joaquin Valley Air Pollution Control District (APCD), District of Columbia, Illinois, Ohio, North Carolina—Forsyth County, Rhode Island, South Dakota, Tennessee—Shelby County, Washington—Energy Facility Site Evaluation Council (EFSEC), and Washington—Southwest Clean Air Agency (SWCAA). The EPA also notes that on September 8, 2021, a group of non-governmental organizations filed suit in the Northern District of

[1] State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls To Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown and Malfunction, 80 FR 33840 (June 12, 2015).

[2] For convenience, the EPA refers to ''air agencies'' in this action collectively when meaning to refer in general to states, the District of Columbia, and local air permitting authorities that are currently administering, or may in the future administer, EPA-approved implementation plans.

[3] *Environ. Comm. Fl. Elec. Power* v. *EPA, et al.,* No. 15–1239 (D.C. Cir.) (and consolidated cases).

[4] *Sierra Club, et al.* v. *EPA, et al.,* No. 20–1115 (D.C. Cir. Apr. 7, 2020); *Sierra Club, et al.* v. *EPA, et al.,* No. 20–1229 (D.C. Cir. June 29, 2020); *Sierra Club, et al.* v. *EPA, et al.,* No. 21–1022 (D.C. Cir. January 2021).

California alleging that the EPA is in violation of its mandatory duty to issue findings of failure to submit for those states that have not yet responded to the 2015 SIP Call.[5]

III. Consequences of Findings of Failure To Submit

If the EPA finds that a state has failed to make the required SIP submittal or that a submitted SIP is incomplete, then CAA section 179(a) establishes specific consequences, after a period of time, including the imposition of mandatory sanctions under CAA section 179(b) for the affected areas or states. The two applicable sanctions enumerated in CAA section 179(b) are: (1) The 2-to-1 emission offset requirement for all new and modified major sources subject to the nonattainment NSR program, and (2) restrictions on highway funding. Additionally, a finding that a state has failed to submit a complete SIP triggers an obligation under CAA section 110(c) for the EPA to promulgate a FIP no later than 2 years after issuance of the finding of failure to submit if the affected state has not submitted, and the EPA has not approved, the required SIP submittal.

With respect to mandatory sanctions, if the EPA has not affirmatively determined that a state has made the required complete SIP submittal within 18 months[6] of the effective date of this final action, then, pursuant to CAA section 179(a) and (b) and 40 CFR 52.31, the offset sanction identified in CAA section 179(b)(2) will apply in the affected nonattainment area or state. If the EPA has not affirmatively determined that the state has made the required complete SIP submittal within 6 months after the offset sanction is imposed, then the highway funding sanction will apply in the affected nonattainment area(s), in accordance with CAA section 179(b)(1) and 40 CFR 52.31.[7] The sanctions will not take effect if, within 18 months after the effective date of these findings, the EPA affirmatively determines that the state has made a complete SIP submittal addressing the deficiency for which the finding was made. Additionally, if the state makes the required SIP submittal and the EPA takes final action to approve the submittal within 2 years of the effective date of these findings, the EPA is not required to promulgate a FIP.

[5] *Sierra Club et al.* v. *Regan et al.,* No. 4:21–cv–06956 (N.D. Cal. Sept 8, 2021).

[6] C.A.A. 110(k)(5).

[7] Such highway sanctions would only apply in nonattainment areas. If a state jurisdictional area does not contain any nonattainment areas, then the highway sanctions would not apply in that state.

IV. Findings of Failure To Submit for Air Agencies That Failed To Make a SIP Submittal in Response to EPA's 2015 SIP Call for Provisions Applying to Excess Emissions During SSM Periods

Based on a review of SIP submittals received and deemed complete as of the date of signature of this action, the EPA finds that 12 air agencies have failed to submit SIP revisions in response to the 2015 SSM SIP Call that were statutorily due no later than November 22, 2016. These affected air agencies are Alabama, Arkansas, California—San Joaquin Valley APCD, District of Columbia, Illinois, Ohio, North Carolina—Forsyth County, Rhode Island, South Dakota, Tennessee—Shelby County, Washington—EFSEC, and Washington—SWCAA.

V. Environmental Justice Considerations

The purpose of this action is to make findings that the named air agencies failed to provide the identified SIP submissions to the EPA that are required under the CAA. As such, this action, in and of itself, does not adversely affect the level of protection provided for human health or the environment. Moreover, it is intended that the actions and deadlines resulting from this notice will promote greater protection for U.S. citizens, including minority, low-income, or indigenous populations, by ensuring that air agencies meet their statutory obligation to develop and submit SIPs to ensure that areas make progress toward reducing excess emissions during periods of SSM.

VI. Statutory and Executive Order Reviews

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

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

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the PRA. This final action does not establish any new information collection requirement apart from what is already required by law. This action relates to the requirement in the CAA for states to submit SIPs in response to findings of substantial inadequacy under section 110(k)(5).

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The action is a finding that the named air agencies have not made the necessary SIP submission in response to findings of substantial inadequacy under section 110(k)(5) of the CAA.

E. Unfunded Mandates Reform Act of 1995 (UMRA)

This action does not contain any unfunded mandate as described in UMRA 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments, or the private sector.

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. This action finds that several air agencies have failed to submit SIP revisions in response to findings of substantial inadequacy under section 110(k)(5) of the CAA. No tribe is subject to the requirement to submit an implementation plan under the findings of inadequacy relevant to this action. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it is a finding that several air agencies failed to submit SIP revisions

in response to findings of substantial inadequacy under section 110(k)(5) of the CAA and does not directly or disproportionately affect children.

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

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

J. National Technology Transfer and Advancement Act (NTTAA)

This final action does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. In finding that several air agencies have failed to submit SIP revisions in response to findings of substantial inadequacy under section 110(k)(5) of the CAA, this action does not directly affect the level of protection provided to human health or the environment.

L. Congressional Review Act (CRA)

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

M. Judicial Review

Section 307(b)(1) of the CAA governs judicial review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the United States Court of Appeals for the District of Columbia Circuit: (i) When the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator,'' or (ii) when such action is locally or regionally applicable, but ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.'' For locally or regionally applicable final actions, the CAA reserves the EPA complete discretion whether to invoke the exception in (ii).

This final action is ''nationally applicable'' within the meaning of CAA section 307(b)(1). In the alternative, to the extent a court finds this final action to be locally or regionally applicable, the Administrator is exercising the complete discretion afforded to him under the CAA to make and publish a finding that this action is based on a determination of ''nationwide scope or effect'' within the meaning of CAA section 307(b)(1).[8] This final action consists of findings of failure to submit required SIPs from areas within 10 states and the District of Columbia, located in 8 of the 10 EPA regions, and in 8 different federal judicial circuits.[9] This final action is also based on a common core of factual findings concerning the receipt and completeness of the relevant SIP submittals. For these reasons, this final action is nationally applicable or, alternatively, the Administrator is exercising the complete discretion afforded to him by the CAA and hereby finds that this final action is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1) and is hereby publishing that finding in the **Federal Register**.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the District of Columbia Circuit within 60 days from the date this final action is published in the **Federal Register**. Filing a petition for reconsideration by the Administrator of this final action does not affect the finality of the action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action.

Janet G. McCabe,

Deputy Administrator.

[FR Doc. 2022–00138 Filed 1–11–22; 8:45 am]

BILLING CODE 6560–50–P

[8] In deciding whether to invoke the exception by making and publishing a finding that this final action is based on a determination of nationwide scope or effect, the Administrator has also taken into account a number of policy considerations, including his judgment balancing the benefit of obtaining the D.C. Circuit's authoritative centralized review versus allowing development of the issue in other contexts and the best use of Agency resources.

[9] In the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator's determination that the ''nationwide scope or effect'' exception applies would be appropriate for any action that has a scope or effect beyond a single judicial circuit. See H.R. Rep. No. 95–294 at 323, 324, reprinted in 1977 U.S.C.C.A.N. 1402–03.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0438; FRL–8773–02–R9]

Limited Approval and Limited Disapproval of California Air Quality Implementation Plan Revisions; Amador Air District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a limited approval and limited disapproval of a revision to the Amador Air District's (AAD or ''District'') portion of the California State Implementation Plan (SIP). This revision governs the District's issuance of permits for stationary sources, and focuses on the preconstruction review and permitting of major sources and major modifications under part D of title I of the Clean Air Act (CAA or ''Act''). Under the authority of the CAA, this action simultaneously approves a local rule that regulates these emission sources and directs the District to correct rule deficiencies.

DATES: This rule is effective February 11, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket No. EPA–R09–OAR–2021–0438. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Amber Batchelder, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; by phone: (415) 947–4174, or by email to *batchelder.amber@epa.gov.*

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

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I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On August 23, 2021 (86 FR 47046), the EPA proposed a limited approval and limited disapproval of the following rule that was submitted for incorporation into the California SIP.

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Adopted	Submitted [1]
AAD	400	NSR Requirements for New and Modified Major Sources in Nonattainment Areas.	08/20/19	11/05/19

We proposed a limited approval because we determined that this rule improves the SIP and is largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions do not fully satisfy the relevant requirements for preconstruction review and permitting under section 110 and part D of the Act. First, Section 4.5 of Rule 400 allows the District to approve interprecursor trading (IPT) of ozone precursors to satisfy emission offset requirements, provided certain conditions are satisfied. However, on January 29, 2021, the D.C. Circuit Court of Appeals in *Sierra Club* v. *EPA,* 984 F.3d 1055, issued a decision holding that the CAA does not allow IPT for ozone precursors and vacating the provisions in the EPA's Nonattainment New Source Review (NSR) regulations allowing IPT for ozone precursors. In light of the Court's decision, the provision in Section 4.5 allowing for IPT for ozone precursors is no longer permissible. Second, Section 9.1(b)(iii) of Rule 400 fails to reference Section 7.4 (Relaxation in Enforceable Limitations). This apparent typographical error creates a deficiency in Section 9.1(b)(iii) of the rule, because it suggests that the source and the District need not adhere to the general requirements for establishing Plant-wide Applicability Limitations (PALs) in Section 9.4, which are required by 40 CFR 51.165(f)(4). Third, due to an apparent typographical error, Section 9.5 of the rule does not require the District to implement the public participation provisions of Section 8 for purposes of processing a request for a PAL to be established, renewed or increased in accordance with 40 CFR 51.165(f)(5). Therefore, the provisions of Section 9.5 are deficient. This error also causes a related deficiency in Sections 9.4(a)(ii), 9.8(b)(iii), 9.10(a), and 9.11(c), because these rule sections cross-reference Section 9.5, which refers to the wrong section of the rule for public participation requirements. Fourth, Section 9.10(d)(i) references Section 9.5 when it should reference Section 9.6. This error appears typographical in nature. However, this error creates a deficiency because it does not provide the correct reference for how to perform the emissions level calculation in accordance with 40 CFR 51.165(f)(10)(iv)(A). Fifth, Section 9.12(a)(iii) includes a reference to Section 7.12 of the rule (which does not exist), instead of Section 9.12. This apparent typographical error creates a deficiency in Section 9.12(a)(iii), because it does not include the requirement to comply with the provisions of Section 9.12 in accordance with 40 CFR 51.165(f)(12)(i)(C).[2]

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, no comments were submitted on our proposal.

III. EPA Action

No comments were submitted on our proposal. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is finalizing a limited approval of the submitted rule. This action incorporates the submitted rule into the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3) and 301(a), the EPA is simultaneously finalizing a limited disapproval of the rule.

As a result, the EPA must promulgate a federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months.

In addition, the offset sanction in CAA section 179(b)(2) will be imposed 18 months after the effective date of this action, and the highway funding sanction in CAA section 179(b)(1) six months after the offset sanction is imposed. Sanctions will not be imposed if the EPA determines that a subsequent SIP submission corrects the identified deficiencies before the applicable deadline.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the rule listed in Table 1 of this preamble. The EPA has made, and will continue to make, these documents available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

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

[1] The submittal was transmitted to the EPA via a letter from the California Air Resources Board dated October 31, 2019.

[2] We note that the EPA recently adopted a rule known as the NSR Error Corrections Rule, effective August 18, 2021, which corrected minor, inadvertent, and non-substantive errors in 40 CFR parts 51 and 52, which govern NSR permitting programs, and updated the regulatory text to reflect statutory changes and certain court decisions vacating elements of the regulatory text, but did not change the requirements within these programs. See 86 FR 37918 (July 19, 2021). States have discretion as to when to make the changes in this rule and may choose to combine them with other SIP submittals. See 86 FR 37918, 37923–24. Accordingly, this recent rulemaking does not affect our final action.

B. Paperwork Reduction Act (PRA)

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

C. Regulatory Flexibility Act (RFA)

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

D. Unfunded Mandates Reform Act (UMRA)

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

E. Executive Order 13132: Federalism

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

F. Executive Order 13175: Coordination With Indian Tribal Governments

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

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

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

L. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 14, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: January 6, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(568) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(568) The following new regulation was submitted on November 5, 2019 by the Governor's designee as an attachment to a letter dated October 31, 2019.

(i) *Incorporation by reference.* (A) Amador Air District.

(*1*) Rule 400, ''NSR Requirements for New and Modified Major Sources in Nonattainment Areas,'' adopted on August 20, 2019.

(B) [Reserved]

(ii) [Reserved]

* * * * *

[FR Doc. 2022–00385 Filed 1–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2021–0540; FRL–9201–02–R5]

Air Plan Approval; Wisconsin; Redesignation of the Rhinelander Sulfur Dioxide Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is redesignating the Rhinelander nonattainment area, which consists of a portion of Oneida County (Crescent Township, Newbold Township, Pine Lake Township, Pelican Township, and the City of Rhinelander), to attainment for the 2010 primary, health-based 1-hour sulfur dioxide (SO_2) National Ambient Air Quality Standard (NAAQS). EPA is also approving Wisconsin's SO_2 maintenance plan for

the Rhinelander area. Wisconsin submitted the request for approval of the Rhinelander area's redesignation and maintenance plan on July 28, 2021. EPA approved Wisconsin's attainment plan for the Rhinelander area on October 22, 2021, with an effective date of December 31, 2021. EPA proposed to approve this action on November 17, 2021, and received no adverse comments.

DATES: This final rule is effective on January 12, 2022.

ADDRESSES: EPA has established a docket for this *action* under Docket ID No. EPA–R05–OAR–2021–0540. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Abigail Teener, Environmental Engineer, at (312) 353–7314 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Abigail Teener, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–7314, *teener.abigail@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

On November 17, 2021, EPA proposed to approve the redesignation of the Rhinelander SO_2 nonattainment area to attainment of the 2010 primary, health-based 1-hour SO_2 NAAQS and to approve Wisconsin's SO_2 maintenance plan for the area (86 FR 64110). An explanation of the Clean Air Act (CAA) requirements, a detailed analysis of the revisions, and EPA's reasons for proposing approval were provided in the notice of proposed rulemaking and will not be restated here. In the notice of proposed rulemaking, EPA noted that the redesignation would not be finalized until Wisconsin's attainment plan for the Rhinelander area was approved and effective. EPA approved Wisconsin's plan on October 22, 2021, with an effective date of December 31, 2021.

II. Public Comments

The public comment period for this proposed rule ended on December 17, 2021. EPA received no adverse comments on the proposal.

III. Final Action

In accordance with Wisconsin's July 28, 2021, request, EPA is redesignating the Rhinelander nonattainment area from nonattainment to attainment of the 2010 SO_2 NAAQS. EPA finds that Wisconsin has demonstrated that the area is attaining the 2010 SO_2 NAAQS and that the improvement in air quality is due to permanent and enforceable SO_2 emission reductions in the area. EPA is also approving Wisconsin's maintenance plan, which is designed to ensure that the area will continue to maintain the SO_2 NAAQS.

In accordance with 5 U.S.C. 553(d) of the Administrative Procedure Act (APA), EPA finds there is good cause for this action to become effective immediately upon publication. The immediate effective date for this action is authorized under both 5 U.S.C. 553(d)(1).

Section 553(d)(1) of the APA provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction.'' The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when the agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. EPA has determined that this rule relieves a restriction because this rule relieves sources in the area of Nonattainment New Source Review (NNSR) permitting requirements; instead, upon the effective date of this action, sources will be subject to less restrictive Prevention of Significant Deterioration (PSD) permitting requirements. For this reason, EPA finds good cause under 5 U.S.C. 553(d)(1) for this action to become effective on the date of publication of this action.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a state implementation plan (SIP) submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 14, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: January 5, 2022.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends 40 CFR parts 52 and 81 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.2575 is amended by removing paragraph (b) introductory text and adding paragraph (c) to read as follows:

§ 52.2575 Control strategy: Sulfur dioxide.

* * * * *

(c) Approval-On July 28, 2021, Wisconsin submitted a request to redesignate the Rhinelander area, which consists of a portion of Oneida County (Crescent Township, Newbold Township, Pine Lake Township, Pelican Township, and the City of Rhinelander), to attainment of the 2010 primary 1-hour sulfur dioxide standard. As part of the redesignation request, the State submitted a maintenance plan as required by section 175A of the Clean Air Act (CAA). Elements of the section 175 maintenance plan include a contingency plan and an obligation to submit a subsequent maintenance plan revision in eight years as required by the CAA.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. Section 81.350 is amended by revising the entry for ''Rhinelander, WI'' in the table entitled ''Wisconsin-2010 Sulfur Dioxide NAAQS [Primary]'' to read as follows:

§ 81.350 Wisconsin.

* * * * *

WISCONSIN—2010 SULFUR DIOXIDE NAAQS

[Primary]

Designated area [1]	Designation	
	Date [2]	Type
* * * * *	*	*
Rhinelander, WI	January 12, 2022	Attainment.
Oneida County (part)		
City of Rhinelander, Crescent Town, Newbold Town, Pine Lake Town, and Pelican Town.		
* * * * *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is April 9, 2018, unless otherwise noted.

* * * * *

[FR Doc. 2022–00347 Filed 1–11–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 220105–0005]

RIN 0648–BK68

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Amendment 21

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

ACTION: Final rule.

SUMMARY: NMFS implements the measures included in Amendment 21 to the Atlantic Sea Scallop Fishery Management Plan as adopted and submitted by the New England Fishery Management Council. This action allows for more controlled access to the scallop resource by the limited access and limited access general category fleets and increases monitoring to a growing directed scallop fishery in Federal waters, including the Northern Gulf of Maine Management Area. These management measures are intended to promote conservation of the scallop resource in the Northern Gulf of Maine Management Area and to manage total removals from the area by all fishery components. Amendment 21 also expands flexibility in the limited access general category individual fishing quota fishery to reduce impacts of potential decreases in ex-vessel price and increases in operating costs.

DATES: Effective March 31, 2022.

ADDRESSES: The Council has prepared a draft Environmental Assessment (EA) for this action that describes the measures contained in Amendment 21 to the Atlantic Sea Scallop Fishery Management Plan (FMP) and other considered alternatives and analyzes the impacts of these measures and alternatives. The Council submitted a draft of the amendment to NMFS that includes the draft EA, a description of the Council's preferred alternatives, the Council's rationale for selecting each alternative, and a Regulatory Impact Review (RIR). Copies of supporting documents used by the New England Fishery Management Council, including the EA and RIR, are available from: Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950 and accessible via the internet in documents available at: *https://www.nefmc.org/library/amendment-21.*

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this rule may be submitted to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by using the search function and entering either the title of the collection or the OMB Control Number 0648–0546.

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Policy Analyst, (978) 281–9233.

SUPPLEMENTARY INFORMATION:

Background

On December 3, 2021, pursuant to section 304(a)(3) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), NMFS approved Amendment 21 to the Atlantic Sea Scallop FMP in its entirety as recommended by the New England Fishery Management Council. The Council developed this action, and the measures described in this rule, to adjust the Northern Gulf of Maine (NGOM) Management Program to allow more controlled access by the limited access and limited access general category (LAGC) components, increase monitoring to support a growing directed scallop fishery in Federal waters, and adjust the LAGC individual fishing quota (IFQ) program to support overall economic performance while allowing for continued participation in the general category fishery at varying levels.

This final rule implements Amendment 21, which:

- Accounts for biomass in the NGOM as part of the overfishing limit (OFL) and the acceptable biological catch (ABC) to be consistent with other portions of scallop resource management;
- Develops landing limits for all permit categories in the NGOM and establishes an 800,000-lb (362,874-kg) NGOM Set-Aside trigger for the NGOM directed fishery, with a sharing agreement for access by all permit categories for allocation above the trigger. Allocation above the trigger will be split 5 percent for the NGOM fleet and 95 percent for limited access and LAGC IFQ fleets;
  - The NGOM Set-Aside supports a directed LAGC fishery (including NGOM and LAGC IFQ permitted vessels) at a possession limit of 200 lb (90.7 kg) per vessel per day.
  - The Council will determine how allocation above the NGOM Set-Aside trigger could be harvested by the limited access and LAGC IFQ components in a subsequent specifications package or framework adjustment.
- Expands the scallop industry-funded observer program to monitor directed scallop fishing in the NGOM by using a portion of the NGOM allocation to off-set monitoring costs;
- Allocates 25,000 lb (11,340 kg) of the NGOM allocation to increase the overall Scallop Research Set-Aside (RSA) and support Scallop RSA compensation fishing;
- Increases the LAGC IFQ possession limit from 600 lb (272 kg) to 800 lb (363 kg) per trip only for access area trips;
- Prorates the daily observer compensation rate in 12-hour increments for observed LAGC IFQ trips longer than 1 day; and
- Allows for temporary transfers of IFQ from limited access vessels with IFQ to LAGC IFQ-only vessels.

The Magnuson-Stevens Act requires NMFS to approve, partially approve, or disapprove measures proposed by the Council based on whether the measures are consistent with an FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law.

NMFS published a Notice of Availability (NOA) announcing its review of the Amendment on September 8, 2021 (86 FR 50320). The public comment period on the NOA ended on November 8, 2021. NMFS published a proposed rule for Amendment 21 on October 5, 2021 (86 FR 54903). The public comment period for the proposed rule ended on November 4, 2021.

Accounting for the NGOM as Part of the Acceptable Biological Catch and Annual Catch Limit

Amendment 21 modifies the annual catch limit (ACL) flowchart to account for the scallop biomass in the NGOM as part of the legal limits in the fishery by adding biomass from the area into calculations of the OFL and ABC. This action moves the accounting of the NGOM ACL from only within the OFL into the OFL and ABC/ACL for the entire fishery (Figure 1). By including exploitable scallop biomass from the NGOM as part of the scallop OFL and ABC, the ACL and sub-ACLs for the limited access and LAGC IFQ, and the limited access annual catch target (ACT) will increase. The observer set-aside will also increase with the NGOM as part of the OFL/ABC. The ABC/ACL will be reduced by the NGOM Set-Aside value, along with the Research and Observer Set-Asides and incidental catch (Figure 1). The Council will set specifications for the NGOM though future specifications actions.

The Council will use the following approach to include the NGOM in the ACL flowchart:

1. Exploitable biomass from surveyed areas of the NGOM will be estimated;

2. The contribution to the OFL will be calculated at the fishing mortality (F) rate equal to the estimate of F at Maximum Sustainable Yield (F_{MSY}) for Georges Bank from the most recent research or management track assessment, unless direct estimates of F_{MSY} for the Gulf of Maine are available; and

3. Combining OFL values from areas on Georges Bank/Mid Atlantic and the NGOM could be done in a single model (*e.g.,* add the NGOM to the Scallop Area Management Simulator model), or as separate calculations. The method will, in part, be determined by the available data.

Incorporating the NGOM into the ACL flowchart will have no impact on limited access days-at-sea (DAS), or any other fishery allocation that is part of the annual projected landings (APL).

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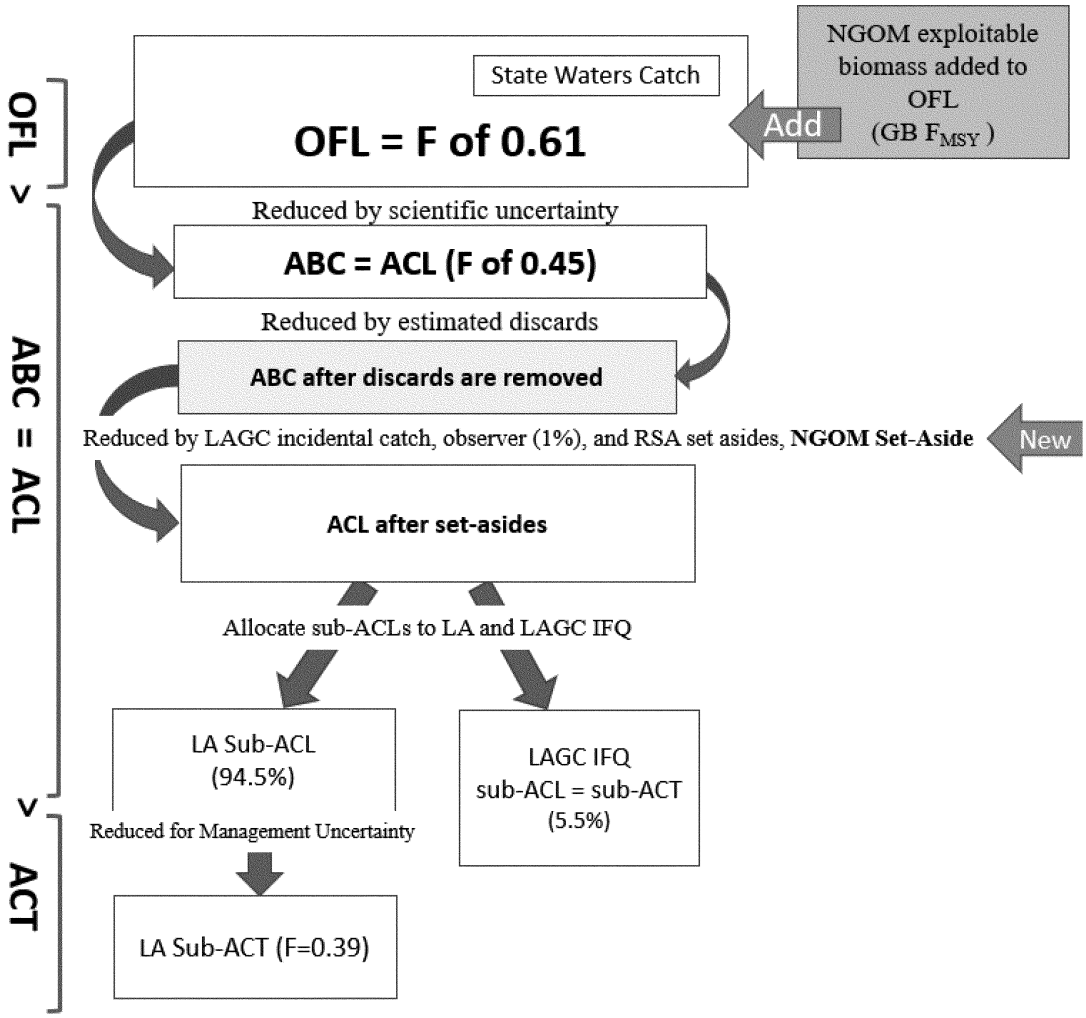

Figure 1 -- Example of Scallop Legal Limits (OFL, ABC, and ACL) with the NGOM Incorporated into Estimates of the OFL and ABC.

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Creating the NGOM Total Allowable Limit

Amendment 21 requires that the Council set an overall total allowable limit (TAL) for the NGOM management area for all permit categories. If NGOM survey data are available, the NGOM TAL will be developed using a projection method to estimate exploitable biomass in upcoming fishing years. The allowable landings will be set by applying an F rate ranging from F=0.15 to F=0.25 to exploitable biomass in open areas of the NGOM, as specified by the Council. Modifying the F rate used to set the NGOM TAL could be adjusted in a future specification or framework action. A portion of the NGOM TAL will be added to the fishery-wide RSA (described below). In addition, one percent of the NGOM's contribution to the fishery-wide ABC will be removed from the NGOM TAL to off-set monitoring costs (described below).

NGOM Set-Aside and NGOM Annual Projected Landings

The remaining portion of NGOM TAL after contributions to the fishery-wide observer and RSAs are removed will then be allocated to the NGOM Set-Aside up to the NGOM Set-Aside trigger (800,000 lb (362,874 kg)). The NGOM Set-Aside supports a directed LAGC

fishery (including NGOM and LAGC IFQ permitted vessels) in the NGOM Management Area at a possession limit of 200 lb (91 kg) per vessel per day. If there is additional allocation available above the 800,000-lb (362,874-kg) trigger, the allocation above the trigger will be shared between the NGOM Set-Aside (5 percent of the allocation above the trigger) and the NGOM APL (95 percent of the allocation above the trigger). The NGOM APL will then be added to the overall APL to increase allocations for the limited access and LAGC IFQ fleets. If there is allocation above the NGOM Set-Aside trigger, the Council will determine the methods of how the NGOM APL could be harvested by the limited access and LAGC IFQ components in a subsequent specifications package or framework adjustment.

The trip limit for LAGC vessels fishing the NGOM Set-Aside (*i.e.,* NGOM and IFQ vessels) will be 200 lb (90.7 kg) per vessel per day. Landings from LAGC IFQ vessels fishing the NGOM Set-Aside will be deducted from their IFQ as well as from the NGOM Set-Aside. LAGC vessels with incidental catch permits (LAGC Category C) will be permitted to land up to 40 lb (18 kg) per day while fishing on non-scallop trips in the NGOM, if the area is open for LAGC vessels fishing against the NGOM Set-Aside. Scallop landings by vessels with LAGC incidental permits will not count against the NGOM Set-Aside. Incidental catch from the area will be tracked as part of the final year-end catch accounting.

For catch accounting purposes, all landings from the NGOM will be included in the review of year-end catch data.

NGOM Accountability Measures

Any overage of NGOM Set-Aside or NGOM APL allocations fished inside the NGOM Management Area will be subject to a pound-for-pound payback in a subsequent fishing year after an overage is determined. If reliable data are available to calculate an overage (Year 1), NMFS may implement these accountability measures (AM) in the following fishing year (Year 2) through the rulemaking process for updated fishery specifications. If reliable data are not available in time for the start of the following fishing year, then the AMs will be implemented 2 years after the overage occurred (Year 3). Data may not be available by the start of the following fishing year because NMFS does not complete final catch accounting until June of the following fishing year. For example, if an overage occurred in fishing year 2021, NMFS would not have the final accounting data until June of fishing year 2022. The AMs could then be implemented at the April 1 start of fishing year 2023.

Expanding the Scallop Industry-Funded Observer Program to the NGOM

Amendment 21 expands the observer call-in requirement to all scallop vessels operating in the NGOM, including NGOM-permitted vessels. This expansion of the call-in requirement facilitates observer coverage in the NGOM Management Area.

This action removes one percent of the NGOM ABC from the NGOM TAL to offset monitoring costs for vessels fishing in this area. This allocation will be removed from the NGOM TAL before allocating to the NGOM set-aside. This allocation could be used to support monitoring of all permit categories that have access to the NGOM Management Area. The NGOM monitoring set-aside will be added to the fishery-wide observer set-aside that is calculated as one percent of the ABC.

The scallop observer program will be expanded to cover directed scallop trips in Federal waters in the NGOM Management Area. Scallop trips by LAGC vessels in the NGOM are currently not covered by the observer program. This expanded program will utilize the cumulative allocation of the NGOM observer set-aside and the observer set-aside to support observer coverage in the scallop fishery. All compensation allocation for all observed trips will come out of the same pool, and NMFS will administer a single scallop observer program. At a minimum, observer coverage levels for the NGOM Management Area will be set to meet Standardized Bycatch Reporting Methodology requirements.

The amount of daily compensation available for LAGC trips in the NGOM may vary from the daily compensation rate for LAGC IFQ vessels that have a higher trip limit. Vessels selected to carry an observer will be able to land the full amount of the daily observer compensation rate in addition to the NGOM trip limit. For example, if the daily compensation rate is set at 100 lb (45 kg), vessels with observers would be able to land 300 lb (136 kg) that trip.

NGOM Research Set-Aside

Amendment 21 sets aside 25,000 lb (11,340 kg) from the NGOM TAL to support RSA compensation fishing in the NGOM management area and increase the overall allocation available for the scallop RSA program. The total amount of RSA available will be the sum of the NGOM RSA and the existing 1.25 million-lb (566,990-kg) fishery-wide RSA (*i.e.,* 1.275 million lb (573,330 kg)).

RSA compensation fishing in the NGOM management area will be allowed. Although, NGOM RSA will be combined with the overall RSA, RSA compensation fishing in the NGOM will be capped at the available NGOM RSA, *i.e.,* 25,000 lb (11,340 kg). Any vessels that are awarded NGOM RSA compensation are required to declare into the area and fish exclusively within the NGOM Management Area. Compensation fishing in the NGOM Management Area could be done to support any research project awarded through the Scallop RSA. However, projects focusing on research in the NGOM will have the first opportunity to fish compensation allocation in the NGOM. NMFS would administer this process.

This action does not mandate that NGOM RSA be harvested strictly in the NGOM Management Area. Vessels allocated NGOM RSA will have an option to fish NGOM RSA in the NGOM or in any other area available to RSA compensation fishing.

Limited Access General Category Individual Fishing Quota Possession Limit

Amendment 21 increases the LAGC IFQ possession limit to 800 lb (363 kg) for access area trips and maintains the 600-lb (272-kg) possession limit for open area trips. The LAGC IFQ component has been subject to a possession limit since the program's inception through Amendment 11. Interest in increasing the 600-lb (272-kg) trip limit through this action is based on the continued increase of operating expenses, which are principally driven by fuel costs associated with longer steam times. For LAGC IFQ vessels that elect to do so, transiting farther offshore to fish access areas with higher landings per unit of effort and improved meat yield leads to increased trip costs due to higher fuel expenses associated with longer steam times. Increasing the access area possession limit will reduce the overall number of trips and combined steam time needed to harvest quota from offshore access areas, thereby reducing overall trip costs (*i.e.,* fuel) and operating expenses (*i.e.,* vessel maintenance) relative to the current 600-lb (272-kg) limit. Increasing the access area possession limit could offer LAGC IFQ vessels more flexibility with regard to timing access area trips around weather conditions, which could potentially improve safety in this component of the fishery.

Observer Compensation Available for LAGC IFQ Vessels

Amendment 21 will make LAGC IFQ vessels eligible for additional compensation when carrying an observer on board and fishing trips longer than 1 day (24 hours). The daily compensation rate, as determined by NMFS, will be prorated at 12-hour increments for trips exceeding 24 hours. The amount of compensation a vessel could receive on 1 trip would be capped at 2 days (48 hours) and vessels fishing longer than 48 hours will not receive additional compensation allocation. For example, if the observer compensation rate is 200 lb/day (90.7 kg/day) and an LAGC IFQ vessel carrying an observer departs on July 1 at 2200 and lands on July 3 at 0100, the length of the trip would equal 27 hours, or 1 day and 3 hours. In this example, the LAGC IFQ vessel would be eligible for 1 day plus 12 hours of compensation allocation, *i.e.,* 300 lb (136 kg). An LAGC IFQ vessel will be able to harvest the trip limit and the daily compensation rate on the observed trip, or the vessel could harvest any unfished compensation on a subsequent trip while adhering to the commercial possession limit.

Temporary Transfer of IFQ From Limited Access Vessels With IFQ (Combo Vessels) to LAGC IFQ-Only Vessels

Amendment 21 allows temporary transfers of IFQ from combo vessels to LAGC IFQ-only permits and maintains the existing prohibition on transferring quota to combo vessels. This action does not change how IFQ is allocated. Quota accumulation caps remain consistent with the limits established through Amendment 15 for LAGC IFQ-only permits, regardless of any additional quota that may become available through one-way, temporary transfers from combo vessels. An individual LAGC IFQ permit still may not hold more than 2.5 percent of the IFQ allocated to the LAGC IFQ component in a year and an ownership entity still may not hold more than 5 percent of the IFQ allocated to the LAGC IFQ component in a year. Allowing one-way, temporary transfers from combo vessels to LAGC IFQ-only permits increases the overall level of quota available to LAGC IFQ-only vessels, and it does not require changes to how allocations are estimated and distributed among the two fleets.

Specifications and Framework Adjustment Process

The regulations at 50 CFR part 648.55 list management measures that may be changed or implemented through specifications or framework actions. During the development of Amendment 21, the Council identified a list of specific issues that may be addressed through future specifications actions or framework adjustments. The existing scallop regulations do not need to be expanded to address concepts that the Council would like to adjust through a specifications package or a framework adjustment in the future. The Council's list included:

1. § 648.55(f)(25) Set-asides for funding research;

a. Contribution of RSA percentage and/or assigned pounds from the NGOM allocation.

2. § 648.55(f)(31) Modifications to provisions associated with observer set-asides; observer coverage; observer deployment; observer service provider; and/or the observer certification regulations;

a. Observer set-aside percentage from the NGOM Allocation.

3. § 648.55(f)(35) Adjustments to the Northern Gulf of Maine scallop fishery measures;

a. Partition the NGOM into multiple sub-areas with separate allocations;

b. Partition the NGOM Set-Aside is multiple seasons;

c. Modify the F rate used to set the NGOM TAL; and

d. Harvest methods of the NGOM APL by the IFQ and limited access boats.

4. § 648.55(f)(37) Increases or decreases in the LAGC possession limit;

a. Accounting for access area trips in the LAGC IFQ fishery.

5. § 648.55(f)(38) Adjustments to aspects of ACL management, including accountability measures;

a. Modify how the NGOM is accounted for in the calculation of OFL, ABC, and ACLs.

In addition, the Council clarified that it could develop options for electronic monitoring to replace at-sea monitors in a future framework based on existing language in these existing regulations:

1. § 648.55(f)(31) Modifications to provisions associated with observer set-asides; observer coverage; observer deployment; observer service provider; and/or the observer certification regulations;

2. § 648.11(g) *Industry-funded monitoring programs.* FMPs managed by the Council, including Atlantic Herring, Atlantic Salmon, Atlantic Sea Scallops, Deep-Sea Red Crab, Northeast Multispecies, and Northeast Skate Complex, may include industry-funded monitoring (IFM) programs to supplement existing monitoring required by the Standard Bycatch Reporting Methodology (SBRM), Endangered Species Act, and the Marine Mammal Protection Act. IFM programs may use observers, monitors, including at-sea monitors and portside samplers, and electronic monitoring to meet specified IFM coverage targets. The ability to meet IFM coverage targets may be constrained by the availability of Federal funding to pay NMFS cost responsibilities associated with IFM.

Regulatory Adjustments and Corrections Under Regional Administrator Authority

NMFS is making several changes consistent with section 305(d) of the Magnuson-Stevens Act, which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to an FMP are carried out in accordance with the FMP and the Magnuson-Stevens Act. These adjustments do not make any substantive changes to the implications of the current regulations. First, NMFS revises § 648.14(i) to more clearly define the prohibitions based on the scallop regulations at § 648 Subpart D. As a result, this rule includes revisions to the regulatory text that reorganize and condense references to possession limits and restrictions. The specific regulations being revised or removed are specified in Table 1.

Second, in §§ 648.2, 648.14(i), 648.52, 648.55, and 648.59, NMFS makes revisions to consistently reference the Scallop Access Area Program throughout the regulations. Third, in § 648.14(i)(x), NMFS clarifies the presumption related to where scallops are caught (*i.e.,* Federal/state waters), not whether a vessel has a Federal scallop permit. Fourth, NMFS updates §§ 648.14(i)(x)(3)(iv)(B) and 648.52(a)(1) with a corrected reference to § 648.10(f). Fifth, in § 648.52(b), (c), (d), (e), (f), NMFS adds headings for consistency across paragraphs. Sixth, in § 648.52(f), NMFS removes duplicative possession limit language for IFQ vessels. Seventh, in § 648.53(h)(3)(i)(A) and (B), NMFS clarifies that the IFQ accumulation cap applies to the annual IFQ allocation, not the IFQ sub-ACL. Eighth, in § 648.53(h)(5)(i) and (ii), NMFS clarifies that these regulations apply to IFQ permit holders regardless of whether the permit is in confirmation of permit history (CPH). Ninth, in § 648.59(b)(4), to promote safety at sea, at the request of the Council, NMFS will allow vessels to enter or exit a Scallop Access Area more than once per trip if there is a compelling safety reason.

Finally, due to the extensive regulatory changes in this action, we are updating references throughout the scallop regulations that will change based on these regulatory adjustments.

We have included a summary of all of the regulatory changes in this rule in Table 1.

TABLE 1—SUMMARY OF REGULATORY CHANGES TO 50 CFR PART 648

Section	Authority	Summary of changes
§§ 648.2, 648.14(i), 648.52, 648.55, 648.59	305(d)	Changing to consistently reference the Scallop Access Area Program throughout the regulations.
§ 648.14(i)(iii)	305(d)	Clarifying possession limits and restrictions which are already described in §§ 648.52 and 648.59.
§ 648.14(i)(x)	305(d)	Clarifying the presumption related to where scallops are caught (*i.e.,* Federal/state waters), not whether a vessel has a Federal scallop permit.
§ 648.14(i)(x)(3)(iii)(C) and (D)	305(d)	Clarifying possession limits and restrictions which are already described in § 648.52 for LAGC vessels in the NGOM are clearly stated later in the section specific to IFQ and NGOM vessels. Deleting to remove duplicative text.
§§ 648.14(i)(x)(3)(iv)(B), 648.52(a)(1)	305(d)	Updating with corrected reference to § 648.10(f).
§ 648.14(i)(x)(4)(i)(A)	305(d) and Amendment 21	Revising IFQ possession and landing regulations based on Amendment 21 measures. Clarify regulations by referencing IFQ possession limits for open and access areas in § 648.52(a).
§ 648.14(i)(x)(4)(i)(C)	Amendment 21	Updating NGOM landings and possession regulations with Amendment 21 language (*i.e.,* NGOM Set-Aside).
§ 648.14(i)(x)(4)(i)(D) and (G)	305(d)	Reducing duplicative language around possession and landing limits that are clearly stated later in § 648.52(a) and (c).
§ 648.14(i)(x)(5)(ii)	305(d)	Clarifying by cutting duplicative landings and possession prohibition, and referencing NGOM possession limit that is clearly stated in § 648.52(a).
§ 648.14(i)(x)(5)(iii)	Amendment 21	Updating NGOM regulations with Amendment 21 language (*i.e.,* NGOM Set-Aside).
§ 648.14(i)(x)(6)	305(d)	Clarifying regulations by removing duplicative landing and possession limit prohibition for incidental permits, and referencing incidental possession limit that is clearly stated in § 648.52.
§ 648.52(a)(1) and (2)	Amendment 21	Updating regulations with LAGC IFQ possession limits for open and access area trips.
§ 648.52(a)(2)	Amendment 21	Clarifying that default access area trips in fishing year 2022 will be subject to the 600-lb (272-kg) trip limit.
§ 648.52(b), (c), (d), (e), (f)	305(d)	Adding headings for consistency.
§ 648.52(a)(2)	Amendment 21	Making in-shell possession limit consistent with increased LAGC IFQ access area trip limit.
§ 648.52(b)	Amendment 21	Updating NGOM regulations with Amendment 21 language (*i.e.,* NGOM Set-Aside).
§ 648.52(f)	305(d)	Removing duplicative possession limit language for IFQ vessels.
§ 648.53(a)(3)(ii)	Amendment 21	Updating APL language to incorporate NGOM catch limit measures.
§ 648.53(a)(8)	Amendment 21	Adding language describing NGOM TAL and allocation structure.
§ 648.53(g)(1)	Amendment 21	Including NGOM contribution to observer set-aside.
§ 648.53(h)(3)(i)(A) and (B)	305(d)	Clarifying that the IFQ accumulation cap applies to the annual IFQ allocation, not the IFQ sub-ACL.
§ 648.53(h)(5)(i) and (ii)	305(d)	Clarifying that these regulations apply to IFQ permit holders regardless of whether permit is in CPH.
§ 648.53(h)(5)(i)(B)	Amendment 21	Specifying that temporary transfers from combo vessels to IFQ-only are allowed.
§ 648.53(h)(5)(ii)(A) and (iii)	Amendment 21	Clarifying that combo vessels are prohibited from permanently transferring or receiving IFQ.
§ 648.55(a)(1)	Amendment 21	Updating language to reflect NGOM catch limits.
§ 648.56(d)	Amendment 21	Including NGOM contribution to RSA.
§ 648.59(b)(4)	305(d)	Adjusting to promote safety at sea.

Comments and Responses

We received eight comment letters on this action. Six individuals commented in support of the action. One individual and Fisheries Survival Fund (FSF), which represents the significant majority of full-time Limited Access permit holders in the Atlantic scallop fishery, commented in opposition to some measures in Amendment 21.

Comment 1: A general category industry member commented that the IFQ possession limit should be increased to at least 1,000 lb (454 kg) because vessels must travel 3 to 12 hours to fish in open and access areas. He comments that increasing the trip limit to all areas would reduce risk to

vessels and reduce trip costs and the carbon footprint of the fleet.

Response: Amendment 21 increases the IFQ possession limit to 800 lb (363 kg) per trip for access area-only trips to address some of the issues raised by the commenter. The higher possession limit in access areas will reduce the number of trips and combined steam time needed to harvest quota from offshore access areas, thereby reducing overall trip costs (*i.e.,* fuel) and operating expenses (*i.e.,* vessel maintenance) relative to the current 600-lb (272 kg) limit. Increasing the access area possession limit to 800 lb (363 kg) could offer LAGC IFQ vessels more flexibility with regard to timing access area trips around weather conditions, which could potentially improve safety in this component of the fishery. In developing Amendment 21, the Council balanced the issues raised by the commenter and the Amendment's vision for the LAGC component, ''a fleet made up of relatively small vessels, with possession limits to maintain the historical character of this fleet and provide opportunities to various participants including vessels from smaller coastal communities.''

Comment 2: The same general category industry member commented that the Council should close the entire NGOM to limited access vessels because they decimate the available stock for the general category when they fish in the area.

Response: The purpose of Amendment 21, specific to the NGOM, is to allow for more controlled access by the limited access and LAGC components and increase monitoring in ways that support a growing directed scallop fishery in Federal waters. The 800,000-lb (362,874-kg) set aside supports some additional participation in the NGOM fishery by LAGC vessels without impacting the current harvest levels of existing participants. Amendment 21 provides the Council with the tools to control removals from the NGOM and better conserve the resource in the area. Further, it provides the mechanism to develop more controlled access to the NGOM by the limited access fleet once the allocation to the area exceeds the NGOM set-aside trigger. The Council considered limiting the cumulative maximum dredge width that could be fished in the NGOM, but ultimately found that there is no biological benefit to the resource in mandating smaller dredge sizes for the limited access fleet in the NGOM.

Comment 3: FSF commented that the NGOM set-aside amount of 800,000 lb (362,874 kg) developed in Amendment 21 does not provide ''orderly access'' to the limited access fleet because it would exclude limited access participants even during years of abundance. FSF continues that the recently-utilized 135,000-lb (61,235-kg) set-aside has already accommodated growth of the NGOM fishery, which was created to be a part-time dayboat fishery for vessels that predominately fish for other species (via Amendment 11). NGOM trips are set at 200 lb (90.7 kg); thus, under an 800,000-lb (362,874-kg) set-aside there would be 4,000 trips available, a number disproportionate to the size of the part-time NGOM scallop fishery.

Response: Using an 800,000-lb (362,874-kg) trigger for the NGOM set-aside supports increased fishing opportunities for all permit categories in the area and addresses the Council's vision of continued participation in the general category fishery at varying levels and providing opportunities to various participants, including vessels from smaller coastal communities, as stated in Amendment 11 and reaffirmed through this action.

There are a total of 427 LAGC permits that potentially could fish in the NGOM set-aside. In addition, there are 338 IFQ permits that could fish the NGOM set-aside (765 vessels total). In 2019, 110 NGOM permits were issued, and 41 vessels (a combination of NGOM and IFQ vessels) landed scallops from the area. An 800,000-lb (362,874-kg) trigger supports additional participation in the NGOM fishery by some of the remaining 724 vessels that could access this fishery without impacting the current harvest levels of existing participants.

Further, because the LAGC share of the NGOM total allowable catch has been harvested in about a month in recent years (*i.e.,* 2018–2021), setting a trigger value above recent allocation levels has the potential to lengthen the season for LAGC vessels and expand opportunities across more of the fishing year.

When the allocation to the NGOM is over this trigger, 5 percent will go to the NGOM set-aside, and 95 percent will go to the NGOM APL. This is intended to support access to the scallop resource in the area by limited access, LAGC IFQ, and LAGC NGOM vessels. Allocating 95 percent of the allocation over the trigger to the NGOM APL would quickly increase the share for the limited access and LAGC IFQ as the exploitable biomass in the area grows. This option would add to the existing allocations for the limited access and LAGC IFQ that come from Georges Bank and the Mid-Atlantic.

In 2017, the limited access fleet fished heavily in the NGOM on DAS. The limited access fleet landed an estimated 1,578,020 lb (715,778 kg) of scallops from March 1 through March 22. This shows that NGOM is capable of having biomass above the 800,000-lb (362,874-kg) trigger.

Comment 4: FSF commented that, since Amendment 11, set-aside has been set at levels that are consistent with NGOM vessels' participation in the fishery. For many years, the set-aside was 70,000 lb (31,751 kg) and in 2019, it was increased to 135,000 lb (61,235 kg). Amendment 21, however, would establish an annual set-aside of 800,000 lb (362,874 kg) for NGOM vessels. FSF comments that this is not consistent with historic allocations, nor is a set-aside of 800,000 lb (362,874 kg) consistent with either Amendment 21's Purpose and Need or its Goals and Objectives. Accordingly, FSF states that Amendment 21's allocation approach is arbitrary and capricious. Achievable access to the NGOM is important to the limited access fleet in the face of climate change and potential shifts in species abundance and distribution.

Response: NMFS disagrees that the allocation approach was arbitrary and that the allocation method is not consistent with the Purpose and Need or the Goals and Objectives of the Amendment. The purpose of Amendment 21, specific to the NGOM, is to allow for more controlled access by the limited access and LAGC components and increase monitoring in ways that support a growing directed scallop fishery in Federal waters. The need for this action is to promote conservation of the scallop resource in the NGOM and to manage total removals from the area by all fishery components. The Goals and Objectives specific to the NGOM are to:

1. Support a growing directed scallop fishery in Federal waters in the NGOM;
2. Allow for orderly access to the scallop resource in this area by the LAGC and limited access components; and
3. Establishing mechanisms to set allowable catches and accurately monitor catch and bycatch from the NGOM.

Amendment 11 allowed limited access vessels to access the NGOM on DAS. However, at the time, there had not been significant limited access fishing in the area for many years. In 2016, the limited access fleet began fishing in the area, landing 292,517 lb (132,683 kg) in 74 days before the area closed. In 2017, the limited access fleet returned to the NGOM landing 1,578,020 lb (715,778 kg) of scallops in 23 days before the area closed. It was this drastic increase in effort by the limited access fleet on DAS that led to

the Council's desire to have better controls on limited access removals from the NGOM to better conserve the resource in the area. Amendment 21 provides the Council with the tools to control removals from the NGOM and better conserve the resource in the area. Further, it provides the mechanism to develop more controlled access to the NGOM by the limited access fleet once the allocation to the area exceeds the NGOM set-aside trigger.

The 800,000-lb (362,874-kg) set-aside was not selected by the Council to be allocated only to the vessels that are accessing the NGOM currently. As stated above, there are a total of 427 LAGC permits and 338 IFQ permits that could fish the NGOM set-aside. In 2019, 110 NGOM permits were issued, and 41 vessels (NGOM and IFQ) landed scallops from the area. The 800,000-lb (362,874-kg) set aside supports some additional participation in the NGOM fishery by LAGC vessels without impacting the current harvest levels of existing participants.

Comment 5: FSF comments that the F rate being used to set the NGOM scallop allocation has no official Council sanction, nor is it subject to notice and comment rulemaking, as it should be. Nothing in Amendment 21 or its decision-making materials established this F range for the NGOM annual harvest setting. They comment that it does not appear that the Council considered either this F range or any methodology to set any F range for the NGOM as part of its Amendment 21 deliberations. Rather, at a meeting on February 27, 2020, the Scallop Committee passed a motion ''to apply a range of F rates for setting the NGOM total allowable landings (TAL) in allocation alternatives being considered in Amendment 21 as F = 0.15 to F = 0.25.'' From there, FSF argues the F rate was impermissibly taken as a given throughout the remainder of the Amendment 21 development process and is included in the Amendment 21 proposed rule as if it had Council sanction.

Response: NMFS disagrees that the F rate was impermissibly taken as a ''given.'' The motion in question specifically grants permission to apply F rates of F = 0.15 to F = 0.25 to the NGOM allocation alternatives. This motion carried 7–0–0 at the Scallop Oversight Committee. The rationale for this motion states, ''Recent framework actions have analyzed F rates from F = 0.15 up to F = 0.25. This could be a way to grow the biomass in the NGOM management area and support sustainable annual harvest. Modifying the F rate used to set the NGOM TAL could be adjusted in a future framework.'' This rationale is consistent with the need to promote conservation of the scallop resource in the NGOM. Further, Amendment 21 is clear that the Council can adjust the F rate for the NGOM in a future framework action to set specifications annually, making it subject to notice and comment rulemaking, annually. For future specifications-setting actions, the Council is in no way bound by these F rates considered for the allocation alternatives in Amendment 21.

Comment 6: FSF commented that the F rate for the NGOM was not included as part of the Amendment 21 analyses, and that Amendment 21's resulting economic analyses are therefore incomplete. The proposed rule states that Amendment 21 ''maximizes yields and economic benefits,'' but the supporting analyses do not provide any practical indication of its relative impacts on the NGOM and non-NGOM vessels, respectively.

FSF continues that, while the economic analyses compare the revenue generated by the LAGC and limited access fleets, respectively, with NGOM allocations of 100,000 lb (45,359 kg) to 6,000,000 lb (2,721,554 kg), these analyses do not integrate the F rate limit contained in Amendment 21 into the analyses. FSF comments that the F rate is a material element of the equation, and that an agency action is arbitrary and capricious if it fails to consider an important aspect of the problem.

Response: The NGOM is considered to be data poor relative to Georges Bank and the mid-Atlantic. The Gulf of Maine, and the NGOM management unit, have not been regularly surveyed for scallops. The NGOM is outside the areas covered by the stock assessment models (Georges Bank and the mid-Atlantic). The F rates considered in Amendment 21 were selected to promote conservation. Further, because the NGOM is currently considered data poor, during the discussion of the motion to include these F rates, the Committee agreed that being able to adjust fishing mortality rates in a future action will be important, especially if methods to setting harvest levels in the NGOM evolve/improve over time. Given this, and given that the F rates considered in the Amendment 21 allocation alternatives are adjustable during any specifications-setting framework, it is not necessary to directly compare F rates as part of the allocation alternatives.

The economic analysis does address the relative impacts on limited access and LAGC vessels. The economic impacts of this measure are likely to be mixed and dependent on the size of the NGOM allocation. When scallop biomass in the NGOM management area is relatively low, and catch rates are low, the impact on the limited access component could be negligible compared to No Action because these vessels would be unlikely to fish their DAS in the management area rather than on Georges Bank or in the mid-Atlantic. When the NGOM allocation is below the set-aside trigger, the limited access and LAGC IFQ components would not receive any additional allocation, which would also be the case under No Action.

Compared to No Action, the preferred alternative is expected to have a direct positive impact when the NGOM allocation is above the set-aside trigger because the limited access and LAGC IFQ components would receive 95 percent of the allocation above the trigger, have access to the area, and would not have to fish DAS when accessing the area. This allocation would be in addition to the allocations from Georges Bank and the mid-Atlantic that these permit holders receive each year. This is particularly important if the spatial extent of the scallop resource shifts in response to climate change. Further, because the preferred alternative would set landings limits for all components, there is a lower risk of harvest exceeding the allocation to the area compared to No Action.

Comment 7: FSF comments that if the F for the NGOM were set close to F = 0.39, a set-aside of 800,000 lb (362,874 kg) would still be largely exclusionary. Under Amendment 21, revenues for the limited access fleet would not equalize with the NGOM vessels until 1,688,888 lb (766,067 kg) of scallops are harvested from the NGOM. Conversely, under the 95 percent/5 percent split and a 500,000-lb (226,796-kg) NGOM set-aside, revenues would equalize between the two fleets at roughly 1,000,000 lb (453,592 kg).

Response: As stated above, in fishing year 2017, the limited access fleet harvested 1,578,020 lb (715,778 kg) from the NGOM in 23 days. The Council believes that these levels of harvest are possible again and developed Amendment 21 to account for scenarios where removals were more consistent with removals from other areas in Georges Bank and the mid-Atlantic (*i.e.,* millions of lb instead of hundreds of thousands of lb).

Comment 8: FSF commented that, the NGOM is part of the Atlantic sea scallop stock's range that must be managed as a unit under National Standard 3.

Response: The Council manages the scallop resource throughout its range. Under the Scallop FMP, target fishing

mortality rate and stock biomass are applied to the scallop resource, which spans from North Carolina to the U.S./Canada boundary. This represents the entire range of scallop stocks under Federal jurisdiction. Amendment 21 accounts for the scallop biomass in the NGOM as part of the legal limits in the fishery by adding biomass from the area into calculations of the OFL and ABC. Amendment 21 moves the accounting of the NGOM ACL from only within the OFL into the OFL and ABC/ACL for the entire fishery. The NGOM ACL will be set consistent with how the rest of the scallop fishery is managed, at the catch level equal to the F that has a 75-percent probability of remaining below the F associated with overfishing.

Comment 9: FSF comments that prorating the daily observer compensation rate in 12-hour increments for observed LAGC IFQ trips longer than 1 day threatens to reopen a loophole where IFQ vessels modify their behavior and fishing patterns to extend their trips to purposefully benefit from the additional compensation. Further, FSF comments that there is also no conservation benefit to the allocation contained in this proposed rule change, which is a known and documented detriment.

Response: NMFS disagrees. Aligning the amount that vessels can be compensated when carrying an observer with the length of a typical LAGC IFQ trip will reduce the risk of observer bias in the LAGC IFQ fishery. This is true in the current fishery that has a 600-lb (272-kg) trip limit and would hold true in the future with the larger 800-lb (363-kg) possession limit in access areas (*i.e.,* areas further offshore that take longer to access), which could result in longer trips. Currently, LAGC IFQ vessels are allowed 1 day of compensation for carrying an observer regardless of the length of a trip, but are required to assume the cost of having the observer on board even when a trip exceeds the 1-day limit. Prorating additional compensation in 12-hour increments over one 24-hour day and capping the amount of compensation that could be allocated on a single trip would make the level of compensation to a vessel more accurate with regard to the cost of carrying an observer on board for the full length of a trip and reduce the incentive for vessels to fish longer trips for the purpose of receiving additional compensation. Relieving vessels of the additional cost burden for trips of over 1 day will reduce the likelihood that fishing behavior will be different for observed trips versus unobserved trips. In addition, considering that observer data is a critical need for accurately characterizing the behavior of the LAGC IFQ component and for documenting interactions with protected species, non-target species, and discards, it is likely that reducing any potential observer bias would reduce uncertainty around the impacts of these interactions and improve observer data when analyzed by the Council in future specifications actions. Having less uncertainty in the data streams used to inform impacts of the scallop fishery would likely have conservation benefits to the fishery as a whole in the future.

Comment 10: FSF strongly supports the 95/5 percent split above the set aside.

Response: NMFS thanks FSF for the comment.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this Amendment and final rule are consistent with the Amendment 21, other provisions of the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866.

This final rule does not contain policies with federalism or ''takings'' implications, as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification.

During the development of preferred alternatives in Amendment 21, NMFS and the Council considered ways to reduce the regulatory burden and provide flexibility to the regulated community. The measures implemented by Amendment 21 related to NGOM allocations and the LAGC IFQ possession limit in access areas, along with other Amendment 21 actions, increase the economic benefits on small entities both in the short- and long-term. The action for the NGOM allocation adjusts landing limits and related research and observer set-asides based on annual scallop surveys in the NGOM area, leading to increased harvest and wider fishery participation in the future. However, there would be no change to the LAGC IFQ allocation when increasing the LAGC IFQ possession limit in access areas.

Overall, the preferred alternatives in Amendment 21 ensure that catch levels are sustainable, reduce the risk of overfishing, and maximize yield and economic benefits. The establishment of the NGOM Set-Aside and the increase to the LAGC IFQ access area possession limit are expected to have an immediate positive economic gain with potential for increased fishing participants/participation or effort, particularly in the NGOM area when there are more scallop fishing opportunities. The preferred alternatives in other actions of Amendment 21 also have overall positive economic effects benefitting both small and large entities.

As a result, a regulatory flexibility analysis is not required and none has been prepared.

This final rule contains a collection-of-information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). This rule revises the existing requirements for the collection of information OMB Control No. 0648–0546 by expanding the number of vessels required to carry observers and call-in to the observer program. Prior to Amendment 21, NGOM-permitted vessels were not required to carry observers. Amendment 21 would require that NGOM vessels call in to the observer program and, when selected, procure and carry an observer. Expanding the observer call-in requirement to directed scallop fishing in the NGOM means that monitoring requirements will be consistent for all scallop permit types across the entirety of the Atlantic sea scallop resource within the U.S. Exclusive Economic Zone. This change increases the number of respondents by 110 (512 respondents to 622 respondents). This results in an additional 933 burden hours (5,252 hours to 6,185 hours) and an additional $5,608 ($44,937 to $50,545) in total annual cost burden to the respondents. Public reporting burden for calling into the observer program is estimated to average 10 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Written comments and recommendations for this

information collection should be submitted on the following website: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by using the search function and entering either the title of the collection or the OMB Control Number 0648–0546.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: January 6, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.2, revise the definition of ''Open areas'' to read as follows:

§ 648.2 Definitions.

* * * * *

Open areas, with respect to the Atlantic sea scallop fishery, means any area that is not subject to restrictions of the Scallop Access Area Program specified in §§ 648.59 and 648.60, the Northern Gulf of Maine Management Area specified in § 648.62, Habitat Management Areas specified in § 648.370, Dedicated Habitat Research areas specified in § 648.371, the Frank R. Lautenberg Deep-Sea Coral Protection Area described in § 648.372, or the New England Deep-Sea Coral Protection Area in § 648.373.

* * * * *

■ 3. In § 648.14:

■ a. Revise paragraphs (i)(1)(iii) and (x), the paragraph (i)(2)(vi) subject heading, and paragraphs (i)(2)(vi)(C), (D), and (E);

■ b. Remove paragraphs (i)(3)(iii)(C) and (D);

■ c. Revise paragraph (i)(3)(iv)(B), (i)(3)(v)(C) and (D), and (i)(4)(i)(A);

■ d. Remove and reserve paragraph (i)(4)(i)(B);

■ e. Revise paragraph (i)(4)(i)(C);

■ f. Remove and reserve paragraph (i)(4)(i)(D);

■ g. Remove paragraphs (i)(4)(i)(G) and (H);

■ h. Revise paragraphs (i)(4)(ii)(A) and (B);

■ i. Remove and reserve paragraph (i)(5)(ii);

■ j. Revise paragraph (i)(5)(iii); and

■ l. Remove paragraph (i)(6).

The revisions read as follows:

§ 648.14 Prohibitions.

* * * * *

(i) * * *

(1) * * *

(iii) *Possession and landing.* Fish for, land, or possess on board a vessel per trip, or possess at any time prior to a transfer to another person for a commercial purpose, other than solely for transport on land in excess of any of the possession and/or landing limits described in §§ 648.52 and 648.59.

* * * * *

(x) *Presumption.* For purposes of this section, the following presumption applies: Scallops that are possessed or landed at or prior to the time when the scallops are received by a dealer, or scallops that are possessed by a dealer, are deemed to be harvested from the EEZ, unless the preponderance of evidence demonstrates that such scallops were harvested by a vessel fishing exclusively for scallops in state waters.

* * * * *

(2) * * *

(vi) *Scallop Rotational Area Management Program and Scallop Access Area Program requirements.*

* * * * *

(C) Fish for, possess, or land scallops in or from a Scallop Access Area in excess of the vessel's remaining specific allocation for that area as specified in § 648.59(b)(3) or the amount permitted to be landed from that area.

(D) Possess more than 50 bu (17.6 hL) of in-shell scallops outside the boundaries of a Scallop Access Area by a vessel that is declared into the Scallop Access Area Program as specified in § 648.59.

(E) Fish for, possess, or land scallops in or from any Scallop Access Area without an observer on board, unless the vessel owner, operator, or manager has received a waiver to carry an observer for the specified trip and area fished.

* * * * *

(3) * * *

(iv) * * *

(B) Fail to comply with any requirement for declaring in or out of the LAGC scallop fishery or other notification requirements specified in § 648.10(f).

* * * * *

(v) * * *

(C) Fish for or land per trip, or possess in excess of 40 lb (18.1 kg) of shucked scallops at any time in or from any Scallop Access Area specified at § 648.60, unless declared into the Scallop Access Area Program.

(D) Fish for, possess, or land scallops in or from any Scallop Access Area without an observer on board, unless the vessel owner, operator, or manager has received a waiver to carry an observer for the specified trip and area fished.

* * * * *

(4) * * *

(i) * * *

(A) Fish for or land per trip, or possess at any time, in excess of the possession and landing limits described in § 648.52(a).

* * * * *

(C) Declare into the NGOM scallop management area and fish against the NGOM Set-Aside after the effective date of a notification published in the **Federal Register** stating that after the NGOM Set-Aside has been harvested as specified in § 648.62, unless the vessel is fishing exclusively in state waters, declared a state-waters only NGOM trip, and is participating in an approved state waters exemption program as specified in § 648.54, or unless the vessel is participating in the scallop RSA program as specified in § 648.56.

* * * * *

(ii) * * *

(A) Have an ownership interest in vessels that collectively are allocated more than 5 percent of the total IFQ scallop APL as specified in § 648.53(a)(9).

(B) Have an IFQ allocation on an IFQ scallop vessel of more than 2.5 percent of the total IFQ scallop APL as specified in § 648.53(a)(9).

* * * * *

(5) * * *

(iii) Fish for, possess, or land scallops in state or Federal waters of the NGOM management area after the effective date of notification in the **Federal Register** that the LAGC share of the NGOM Set-Aside has been harvested as specified in § 648.62, unless the vessel is fishing exclusively in state waters, declared a state-waters only NGOM trip, and is participating in an approved state waters exemption program as specified in § 648.54, or unless the vessel is participating in the scallop RSA program as specified in § 648.56.

* * * * *

■ 4. In § 648.52, revise paragraphs (a) through (f) to read as follows:

§ 648.52 Possession and landing limits.

(a) *IFQ trips*—(1) *Open area trips.* A vessel issued an IFQ scallop permit that is declared into the IFQ scallop fishery in the open area, as specified in § 648.10(f), or on a properly declared NE multispecies, surfclam, or ocean quahog trip (or other fishery requiring a VMS declaration) and not fishing in a scallop access area, unless as specified in paragraph (g) of this section or exempted under the state waters exemption program described in § 648.54, may not possess or land, per trip, more than 600 lb (272 kg) of shucked scallops, or possess more than 75 bu (26.4 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 100 bu (35.2 hL) of in-shell scallops seaward of the VMS Demarcation Line on a properly declared IFQ scallop trip, or on a properly declared NE multispecies, surfclam, or ocean quahog trip, or other fishery requiring a VMS declaration, and not fishing in a scallop access area.

(2) *Access areas trips.* A vessel issued an IFQ scallop permit that is declared into the IFQ Scallop Access Area Program, as specified in § 648.10(f), may not possess or land, per trip, more than 800 lb (363 kg) of shucked scallops, or possess more than 100 bu (35.2 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 100 bu (35.2 hL) of in-shell scallops seaward of the VMS Demarcation Line on a properly declared IFQ scallop access area trip. Vessels fishing the 2022 default access area trips shall be subject to a 600-lb (272-kg) possession limit, as described in § 648.59(g)(3)(v).

(b) *NGOM trips.* A vessel issued an NGOM scallop permit, or an IFQ scallop permit that is declared into the NGOM scallop fishery and fishing against the NGOM Set-Aside as described in § 648.62, unless exempted under the state waters exemption program described under § 648.54, may not possess or land, per trip, more than 200 lb (90.7 kg) of shucked scallops, or possess more than 25 bu (8.81 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 50 bu (17.6 hL) of in-shell scallops seaward of the VMS demarcation line on a properly declared NGOM scallop fishery trip.

(c) *Incidental trips.* A vessel issued an Incidental scallop permit, or an IFQ scallop permit that is not declared into the IFQ scallop fishery or on a properly declared NE multispecies, surfclam, or ocean quahog trip or other fishery requiring a VMS declaration as required under § 648.10(f), unless exempted under the state waters exemption program described under § 648.54, may not possess or land, per trip, more than 40 lb (18.1 kg) of shucked scallops, or possess more than 5 bu (1.76 hL) of in-shell scallops shoreward of the VMS Demarcation Line. Such a vessel may land scallops only once in any calendar day. Such a vessel may possess up to 10 bu (3.52 hL) of in-shell scallops seaward of the VMS Demarcation Line.

(d) *Limited access vessel access area trips.* Owners or operators of vessels with a limited access scallop permit that have properly declared into the Scallop Access Area Program as described in § 648.59 are prohibited from fishing for or landing per trip, or possessing at any time, scallops in excess of any sea scallop possession and landing limit set by the Regional Administrator in accordance with § 648.59(b)(5).

(e) *Limited access vessel open area in-shell scallop possession limit.* Owners or operators of vessels issued limited access permits are prohibited from fishing for, possessing, or landing per trip more than 50 bu (17.6 hl) of in-shell scallops shoreward of the VMS Demarcation Line, unless when fishing under the state waters exemption specified under § 648.54.

(f) *Limited access vessel access area in-shell scallop possession limit.* A limited access vessel that is declared into the Scallop Area Access Program as described in § 648.59, may not possess more than 50 bu (17.6 hL) of in-shell scallops outside of the Access Areas described in § 648.60.

* * * * *

■ 5. In § 648.53:

■ a. Revise paragraphs (a)(3)(ii) and (a)(8);

■ b. Add paragraph (a)(9); and

■ c. Revise paragraphs (g)(1), (h)(3)(i)(A) and (B), (h)(5)(i), (h)(5)(ii)(A), and (h)(5)(iii).

The revisions and addition read as follows:

§ 648.53 Overfishing limit (OFL), acceptable biological catch (ABC), annual catch limits (ACL), annual catch targets (ACT), annual projected landings (APL), DAS allocations, individual fishing quotas (IFQ).

(a) * * *

(3) * * *

(ii) *APL.* The APL shall be equal to the combined projected landings by the limited access and LAGC IFQ, in open areas, access areas, and Northern Gulf of Maine management area after set-asides (RSA, NGOM, and observer) and incidental landings are accounted for, for a given fishing year. Projected scallop landings are calculated by estimating the landings that will come from open area, access area, and Northern Gulf of Maine effort combined for both limited access and LAGC IFQ fleets. These projected landings shall not exceed the overall ABC/ACL and ACT, as described in paragraph (a) of this section.

* * * * *

(8) *Northern Gulf of Maine Total Allowable Landings (TAL).* The NGOM TAL is the landings available for harvest from the NGOM Management Area. The TAL shall be set by applying a fishing mortality rate of F = 0.15 to F = 0.25 to exploitable biomass estimated from open areas of the NGOM.

(i) *NGOM Observer Set-Aside.* The NGOM TAL shall be reduced by 1 percent to off-set monitoring costs for vessels fishing in this area. The NGOM monitoring set-aside would be added to the fishery-wide observer set-aside, as described in paragraph (g) of this section.

(ii) *NGOM Research Set-Aside.* The NGOM TAL shall be reduced by 25,000 lb (11,340 kg) to be added to the fishery-wide research set-aside, as described in § 648.56(d).

(iii) *Northern Gulf of Maine Set-Aside.* The NGOM Set-Aside shall be the portion of the NGOM TAL that is available for harvest by the LAGC IFQ and NGOM fleets at 200 lb (90.7 kg) per trip per day as set through specifications. After the observer and research set-asides are removed, the first 800,000 lb (362,874 kg) of the NGOM TAL shall be allocated to the NGOM Set-Aside. For all allocation above 800,000 lb (362,874 kg), 5 percent shall go to the NGOM Set-Aside, and 95 percent shall go to the NGOM Annual Projected Landings.

(iv) *NGOM APL.* The NGOM APL shall be the portion of the NGOM TAL that is available for harvest for the limited access and LAGC IFQ fleets set through specifications after the observer and research set-asides are removed and the first 800,000 lb (362,874 kg) of the NGOM TAL are allocated to the NGOM Set-Aside. For all allocation above 800,000 lb (362,874 kg), 5 percent shall go to the NGOM set-aside, and 95 percent shall go to the NGOM APL. The method in which the limited access and LAGC IFQ components will access the NGOM APL will be determined in future specifications.

(9) *Scallop fishery catch limits.* The following catch limits will be effective for the 2021 and 2022 fishing years:

TABLE 1 TO PARAGRAPH (a)(9)—SCALLOP FISHERY CATCH LIMITS

Catch limits	2021 (mt)	2022 (mt) [1]
OFL	45,392	41,926
ABC/ACL (discards removed)	30,517	28,074
Incidental Catch	23	23
RSA	567	567
Observer Set-Aside	305	281
ACL for fishery	29,622	27,203
Limited Access ACL	27,993	25,707
LAGC Total ACL	1,629	1,496
LAGC IFQ ACL (5 percent of ACL)	1,481	1,360
Limited Access with LAGC IFQ ACL (0.5 percent of ACL)	148	136
Limited Access ACT	24,260	22,279
APL (after set-asides removed)	17,269	(1)
Limited Access APL (94.5 percent of APL)	16,319	(1)
Total IFQ Annual Allocation (5.5 percent of APL) [2]	950	712
LAGC IFQ Annual Allocation (5 percent of APL) [2]	863	648
Limited Access with LAGC IFQ Annual Allocation (0.5 percent of APL) [2]	86	65

[1] The catch limits for the 2022 fishing year are subject to change through a future specifications action or framework adjustment. This includes the setting of an APL for 2022 that will be based on the 2021 annual scallop surveys. The 2022 default allocations for the limited access component are defined for DAS in paragraph (b)(3) of this section and for access areas in § 648.59(b)(3)(i)(B).

[2] As specified in paragraph (a)(6)(iii)(B) of this section, the 2022 IFQ annual allocations are set at 75 percent of the 2021 IFQ Annual Allocations.

* * * * *

(g) * * *

(1) To help defray the cost of carrying an observer, 1 percent of the ABC/ACL defined in paragraph (a)(3) of this section and 1 percent of the NGOM ABC/ACL shall be set aside to be used by vessels that are assigned to take an at-sea observer on a trip. This observer set-aside is specified through the specifications or framework adjustment process defined in § 648.55.

* * * * *

(h) * * *

(3) * * *

(i) * * *

(A) Unless otherwise specified in paragraphs (h)(3)(i)(B) and (C) of this section, a vessel issued an IFQ scallop permit or confirmation of permit history shall not be issued more than 2.5 percent of the IFQ-only annual allocation to the IFQ scallop vessels as described in paragraph (a)(6) of this section.

(B) A vessel may be initially issued more than 2.5 percent of the IFQ-only annual allocation allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section, if the initial determination of its contribution factor specified in accordance with § 648.4(a)(2)(ii)(E) and paragraph (h)(2)(ii) of this section, results in an IFQ that exceeds 2.5 percent of the IFQ-only annual allocation to the IFQ scallop vessels as described in paragraph (a)(6) of this section. A vessel that is allocated an IFQ that exceeds 2.5 percent of the IFQ-only annual allocation to the IFQ scallop vessels as described in paragraph (a)(6) of this section, in accordance with this paragraph (h)(3)(i)(B), may not receive IFQ through an IFQ transfer, as specified in paragraph (h)(5) of this section. All scallops that have been allocated as part of the original IFQ allocation or transferred to a vessel during a given fishing year shall be counted towards the vessel cap.

* * * * *

(5) * * *

(i) *Temporary IFQ transfers*—(A) *IFQ-only vessels.* Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may temporarily transfer (*e.g.,* lease) its entire IFQ allocation, or a portion of its IFQ allocation, to another IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit. Temporary IFQ transfers shall be effective only for the fishing year in which the temporary transfer is requested and processed. IFQ can be temporarily transferred more than once (*i.e.,* re-transferred). For example, if a vessel temporarily transfers IFQ to a vessel, the transferee vessel may re-transfer any portion of that IFQ to another vessel. There is no limit on how many times IFQ can be re-transferred in a fishing year. The Regional Administrator has final approval authority for all temporary IFQ transfer requests.

(B) *Limited access vessels with LAGC IFQ.* Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of a limited access vessel with LAGC IFQ (and/or a limited access permit with LAGC IFQ in confirmation of permit history) may temporarily transfer (*e.g.,* lease) its entire IFQ allocation, or a portion of its IFQ allocation, to an IFQ-only scallop vessel that does not have a limited access permit. Temporary IFQ transfers shall be effective only for the fishing year in which the temporary transfer is requested and processed. IFQ can be temporarily transferred more than once (*i.e.,* re-transferred). The Regional Administrator has final approval authority for all temporary IFQ transfer requests.

* * * * *

(ii) * * *

(A) Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may transfer IFQ permanently to or from another IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit. Any such transfer cannot be limited in duration and is permanent as to the transferee, unless the IFQ is subsequently permanently transferred to another IFQ scallop vessel. IFQ may be permanently transferred to a vessel and then be re-transferred (temporarily transferred (*i.e.,* leased) or permanently transferred) by such vessel to another vessel in the same fishing year. There is no limit on how many times IFQ can be re-transferred in a fishing year. Limited access vessels with LAGC IFQ permits

are prohibited from permanently transferring or receiving IFQ.

* * * * *

(iii) *IFQ transfer restrictions.* The owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may transfer that vessel's IFQ to another IFQ scallop vessel, regardless of whether or not the vessel has fished under its IFQ in the same fishing year. Requests for IFQ transfers cannot be less than 100 lb (46.4 kg), unless that the transfer reflects the total IFQ amount remaining on the transferor's vessel, or the entire IFQ allocation. IFQ may be temporarily or permanently transferred to a vessel and then temporarily re-transferred (*i.e.,* leased) or permanently re-transferred by such vessel to another vessel in the same fishing year. There is no restriction on how many times IFQ can be re-transferred. A transfer of an IFQ may not result in the sum of the IFQs on the receiving vessel exceeding 2.5 percent of the allocation to IFQ-only scallop vessels. A transfer of an IFQ, whether temporary or permanent, may not result in the transferee having a total ownership of, or interest in, general category scallop allocation that exceeds 5 percent of the allocation to IFQ-only scallop vessels. Limited access scallop vessels that are also issued an IFQ scallop permit may not permanently transfer or receive IFQ. Further, they may not temporarily receive IFQ.

* * * * *

■ 6. In § 648.55, revise paragraph (a)(1) and paragraph (f) introductory text to read as follows:

§ 648.55 Specifications and framework adjustments to management measures.

(a) * * *

(1) The Scallop Plan Development Team (PDT) shall meet at least every 2 years to assess the status of the scallop resource and to develop and recommend the following specifications for a period of up to 2 years, as well as second or third-year default measures, for consideration by the New England Fishery Management Council's Atlantic Sea Scallop Oversight Committee and Advisory Panel: OFL, overall ABC/ACL, sub-ACLs, sub-ACTs, DAS open area allocations, possession limits, modifications to rotational area management (*e.g.,* schedule, rotational closures and openings, seasonal restrictions, modifications to boundaries, etc.), access area limited access poundage allocations and LAGC IFQ fleet-wide trip allocations, annual incidental catch target TAC, and NGOM TAL.

* * * * *

(f) *Framework adjustments.* The Council may at any time initiate a framework adjustment to add or adjust management measures within the Scallop FMP if it finds that action is necessary to meet or be consistent with the goals and objectives of the FMP. The Council shall develop and analyze appropriate management actions over the span of at least two Council meetings. To address interactions between the scallop fishery and sea turtles and other protected species, such adjustments may include proactive measures including, but not limited to, the timing of Sea Scallop Access Area openings, seasonal closures, gear modifications, increased observer coverage, and additional research. The Council shall provide the public with advance notice of the availability of both the proposals and the analyses, and opportunity to comment on them prior to and at the second Council meeting. The Council's recommendation on adjustments or additions to management measures may include specifications measures specified in paragraph (a) of this section, which must satisfy the criteria set forth § 648.53(a) in order to prevent overfishing of the available biomass of scallops and ensure that OY is achieved on a continuing basis. Other measures that may be changed or implemented through framework action include:

* * * * *

■ 7. In § 648.56, revise paragraph (d) to read as follows:

§ 648.56 Scallop research.

* * * * *

(d) Available RSA allocation shall be 1.275 million lb (578 mt) annually, which shall be deducted from the ABC/ACL specified in § 648.53(a) prior to setting ACLs for the limited access and LAGC fleets, as specified in § 648.53(a)(3) and (4), respectively. Approved RSA projects shall be allocated an amount of scallop allocation that can be harvested in open areas, available access areas, and the NGOM. The specific access areas that are open to RSA harvest and the amount of NGOM allocation to be landed through RSA harvest shall be specified through the framework process as identified in § 648.59(e)(1). In a year in which a framework adjustment is under review by the Council and/or NMFS, NMFS shall make RSA awards prior to approval of the framework, if practicable, based on total scallop allocation needed to fund each research project. Recipients may begin compensation fishing in open areas prior to approval of the framework, or wait until NMFS approval of the framework to begin compensation fishing within approved access areas.

* * * * *

■ 8. In § 648.59, revise the section heading and paragraphs (a) introductory text, (a)(3), (b)(4), (g)(3)(i), and (g)(4)(ii) to read as follows:

§ 648.59 Scallop Rotational Area Management Program and Scallop Access Area Program requirements.

(a) The Scallop Rotational Area Management Program consists of Scallop Rotational Areas, as defined in § 648.2. Guidelines for this area rotation program (*i.e.,* when to close an area and reopen it to scallop fishing) are provided in § 648.55(a)(6). Whether a rotational area is open or closed to scallop fishing in a given year, and the appropriate level of access by limited access and LAGC IFQ vessels, are specified through the specifications or framework adjustment processes defined in § 648.55. When a rotational area is open to the scallop fishery, it is called an Access Area and scallop vessels fishing in the area are subject to the Scallop Access Area Program Requirements specified in this section. Areas not defined as Scallop Rotational Areas specified in § 648.60, Habitat Management Areas specified in § 648.370, or areas closed to scallop fishing under other FMPs, are governed by other management measures and restrictions in this part and are referred to as Open Areas.

* * * * *

(3) *Transiting a Scallop Access Area.* Any sea scallop vessel that has not declared a trip into the Scallop Access Area Program may enter a Scallop Access Area, and possess scallops not caught in the Scallop Access Areas, for transiting purposes only, provided the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2. Any scallop vessel that has declared a trip into the Scallop Area Access Program may not enter or be in another Scallop Access Area on the same trip except such vessel may transit another Scallop Access Area provided its gear is stowed and not available for immediate use as defined in § 648.2, or there is a compelling safety reason to be in such areas without such gear being stowed. A vessel may only transit the Closed Area II Scallop Rotational Area, as defined in § 648.60(d), if there is a compelling safety reason for transiting the area and the vessel's fishing gear is

stowed and not available for immediate use as defined in § 648.2.

(b) * * *

(4) *Area fished.* While on a Scallop Access Area trip, a vessel may not fish for, possess, or land scallops in or from areas outside the Scallop Access Area in which the vessel operator has declared the vessel will fish during that trip, and may not enter or exit the specific declared Scallop Access Area more than once per trip unless there is a compelling safety reason. A vessel on a Scallop Access Area trip may not enter or be in another Scallop Access Area on the same trip except such vessel may transit another Scallop Access Area as provided for under paragraph (a)(3) of this section.

* * * * *

(g) * * *

(3) * * *

(i) An LAGC scallop vessel authorized to fish in the Scallop Rotational Areas specified in § 648.60 or in paragraph (g)(3)(iv) of this section may land scallops, subject to the possession limit specified in § 648.52(a)(2), unless the Regional Administrator has issued a notice that the number of LAGC IFQ access area trips have been or are projected to be taken. All LAGC IFQ access area trips must be taken in the fishing year that they are allocated (*i.e.,* there are no carryover trips). The total number of LAGC IFQ trips in an Access Area is specified in the specifications or framework adjustment processes defined in § 648.55.

* * * * *

(4) * * *

(ii) *Other species.* Unless issued an LAGC IFQ scallop permit and fishing under an approved NE multispecies SAP under NE multispecies DAS, an LAGC IFQ vessel fishing in the Closed Area I, Closed Area II, Closed Area II Extension, and Nantucket Lightship Rotational Areas specified in § 648.60, and the Nantucket Lightship North Scallop Access Area specified in paragraph (g)(3)(iv) of this section is prohibited from possessing any species of fish other than scallops and monkfish, as specified in § 648.94(c)(8)(i). Such a vessel may fish in an approved SAP under § 648.85 and under multispecies DAS in the scallop access area, provided that it has not declared into the Scallop Access Area Program. Such a vessel is prohibited from fishing for, possessing, or landing scallops.

[FR Doc. 2022–00367 Filed 1–11–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 220105–0003]

RIN 0648–BL05

Fisheries of the Northeastern United States; Atlantic Mackerel; 2022 Interim Action

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

ACTION: Temporary rule; interim measures; request for comments.

SUMMARY: This temporary rule implements interim specifications for the 2022 fishing year to address new assessment information regarding the status of the Atlantic mackerel stock. This action is intended to reduce potential Atlantic mackerel overfishing based on new 2021 assessment findings while a rebuilding plan is being developed.

DATES: Effective January 7, 2022, through July 11, 2022. Comments must be received by February 11, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0137 by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2021–0137 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

The supporting documents for the action are available upon request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 N State Street, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Aly Pitts, Fishery Management Specialist, (978) 281–9352.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council (Council) manages the Atlantic mackerel fishery under the Mackerel, Squid, and Butterfish (MSB) Fishery Management Plan (FMP). Section 305(c) of the Magnuson-Stevens Act allows the Secretary to implement interim measures to reduce or address overfishing. In situations such as this, in which the Mid-Atlantic Council has begun the development of a rebuilding plan, section 304(e)(6) allows the Council to request the Secretary to implement interim measures to reduce overfishing, even if such measures are not sufficient themselves to stop overfishing, until such measures can be replaced by the rebuilding plan. As further described below, NMFS implements this action to adjust the domestic annual harvest (DAH, or commercial quota) from the previously implemented amount of 17,312 metric tons (mt) to 4,963 mt in order to minimize overfishing while the Council responds to the most recent stock assessment information and completes work on a revised rebuilding plan. This revised DAH takes into account new information on Canadian harvest and U.S. recreational landings.

The 2017 stock assessment indicated that Atlantic mackerel was overfished and subject to overfishing. To end overfishing and rebuild the species, the Council adopted a rebuilding plan under Framework Adjustment 13 to the Mackerel, Squid, and Butterfish FMP (84 FR 58053; October 30, 2019). The rebuilding plan became effective in November 2019 and set Atlantic mackerel catch levels to prevent overfishing and rebuild the stock by 2023 based on the strength of a larger than average year class from 2015. However, shortly after the rebuilding program was implemented, updated information, including a Canadian stock assessment, suggested that more recent recruitment was lower than expected when specifications were set in the original rebuilding plan. In response, the Council maintained, and we implemented, the overall 2019 acceptable biological catch (ABC) (29,184 mt) and DAH (17,312 mt) through 2023 instead of increasing catch levels based on expected rebuilding progress as a precautionary measure to help the species continue to rebuild as

planned. On July 22, 2021, we published a final rule in the **Federal Register** (86 FR 38586), implementing the previously approved 2021–2022 Atlantic mackerel specifications to maintain the 2020 specifications.

At its July 2021 meeting, the Council's Scientific and Statistical Committee (SSC) reviewed the 2021 management track assessment results from the Northeast Fisheries Science Center, which concluded that Atlantic mackerel remains overfished, overfishing is occurring, and the 2015 recruitment has not been as productive as expected. Based on this information, the SSC recommended that measures be implemented to eliminate or minimize additional catch for the rest of 2021 and 2022. At its August 2021 meeting, the Council requested that NMFS take action to reduce potential mackerel overfishing while it develops a rebuilding plan for this species during the 2022 fishing year. In response to the Council's request and to address concerns over 2021 catch, we recently published an in-season action reducing the mackerel possession limit to 5,000 lb (2,268 kg) for the remainder of 2021 (86 FR 57376; October 15, 2021) to minimize landings and overfishing based on the latest scientific information. We have also projected that the U.S. commercial fishery is expected to land over 5,400 mt of Atlantic mackerel during 2021. Therefore, taking into account new estimates of Canadian landings and U.S. recreational harvest, this rule will adjust the commercial 2022 DAH to 4,963 mt so that total catch in 2022 is similar to 2021.

Interim Atlantic Mackerel Specifications for 2022

Based on the recommendations of the SSC, the MSB Monitoring Committee, and the Council, this action sets the 2022 Atlantic mackerel specifications, specifically the DAH to 4,963 mt. These specifications also maintain the 129-mt river herring and shad catch cap. There is an Atlantic mackerel stock assessment update scheduled for 2022 that will inform future ABC specifications.

This temporary rule has an effective period limited by the Magnuson-Stevens Act to 180 days, with a potential extension of an additional 186 days. The Council has begun development of a revised rebuilding plan which it intends to be implemented by January 1, 2023. However, if the expected rulemaking implementing the rebuilding plan is not in place before the expiration of this rule (180 days following publication), an extension of the interim measures for 186 days will be considered.

Justification for Interim Measures

Section 305(c) of the Magnuson-Stevens Act (16 U.S.C. 1855(c)) authorizes the Secretary of Commerce to implement interim measures to address overfishing. This action meets the 305(c) requirements for interim measures because it is necessary to minimize overfishing on the Atlantic mackerel stock that remains overfished while the Council develops a new rebuilding program for the stock.

While some changes resulting from the 2021 stock assessment were expected, the magnitude of the shift in the perception of stock status necessitating changes to the catch limits was not, and could not have been, foreseen. The assessment results only recently became available, after the Council took final action on, and we implemented, the 2022 specifications. Based on this new information, and only two years after the implementation of the original rebuilding program for mackerel, the Council must develop a new rebuilding plan to incorporate the most recent scientific information. However, given that the new information only recently became available, the Council could not complete an action to develop a new rebuilding plan and adjust specifications in time for the fishing year. Because of unforeseen specification adjustments necessary to address the recent stock assessment, the Council requested that NMFS take action to reduce potential additional Atlantic mackerel harvest in 2022 via a reduction in the commercial quota while the Council modifies Atlantic mackerel rebuilding for 2023. Delayed implementation of these measures increases the risk and magnitude of overfishing for 2022 by allowing the current 17,312 mt commercial catch rather than 4,963 mt, implemented by this rule.

These interim measures are intended to minimize overfishing in the Atlantic mackerel fishery and additional negative impacts to the already overfished fishery resource. Therefore, avoiding the serious conservation and management problem of subjecting the overfished Atlantic mackerel stock to continued overfishing conditions due to reasonably unforeseen circumstances justifies these interim measures, and outweighs the benefit of advance notice and comment.

Renewal of Interim Regulations

The Magnuson-Stevens Act limits NMFS' authority to implement interim measures for an initial period of 180 days, with a potential extension up to an additional 186 days, if warranted. The public has an opportunity to comment on the specification measures in this temporary rule (see **ADDRESSES**). After considering public comments on this rule, NMFS may extend the interim measures for one additional period of not more than 186 days to maintain the interim measures until permanent rulemaking can be implemented.

Classification

NMFS issues this action pursuant to section 305(c) of the Magnuson-Stevens Act. This action is required by 50 CFR part 648, which was issued pursuant to section 304(b).

The Assistant Administrator for Fisheries, NOAA, finds that it would be unnecessary and contrary to the public interest to provide for prior notice and an opportunity for public comment, pursuant to 5 U.S.C. 553(b)(B). This action reduces the allowable Atlantic mackerel catch based on new assessment information that recently became available. This adjustment is allowed pursuant to section 305(c) of the Magnuson-Stevens Act in order to minimize overfishing while the Council responds to the new, updated information. A delay would be contrary to the public interest for the Atlantic mackerel fishery. Implementing a reduced DAH was anticipated and discussed during development and implementation of the original specifications action (86 FR 38586, June 22, 2021), as well as at the August and October 2021 Council meetings. Fishery stakeholders are anticipating action to reduce mackerel harvest in 2022, and they will have the opportunity to comment on this action in response to the current public notice.

Where the public has had an opportunity to review the development of the Council motion to reduce Atlantic mackerel catch for 2022 based on the best available science (the purpose of this action), the value of a delay in its effectiveness would be outweighed by the need to implement this adjustment as quickly as possible. Failure to implement this action as quickly as possible for the 2022 fishing year could result in 2022 catch that could have potential negative biological impacts, as well as the potential to result in lower catch limits in the future than would otherwise be required by the new rebuilding plan. The Atlantic mackerel fishery is active in November-February. Given the high-volume nature of the fishery and the reduced DAH, it is likely that the fishery will exceed the DAH. A delay would be contrary to the public interest while we take action to reduce potential mackerel overfishing while the

Council responds to recent scientific information and develops a rebuilding plan and new specifications for this species. For the same reasons, the Assistant Administrator finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay of effectiveness period for this. This rule should be effective as close to January 1, 2022, as possible, to fully realize the intended benefits to this high-volume fishery that is most active during the November-February months.

This action is being taken pursuant to the 305(c) emergency action and interim measures provision of the Magnuson-Stevens Act and is exempt from OMB review.

This temporary rule is has been determined to be not significant for purposes of Executive Order 12866.

This rule does not duplicate, conflict, or overlap with any existing Federal rules.

This action would not establish any new reporting or record-keeping requirements.

This interim rule contains no information collection requirements under the Paperwork Reduction Act of 1995

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

Dated: January 6, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2022–00402 Filed 1–7–22; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 8
Wednesday, January 12, 2022

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1172; Project Identifier MCAI–2021–00939–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus SAS Model A300 series airplanes Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). This proposed AD was prompted by reports of cracking in the main landing gear (MLG) support rib 5 lower flange. This proposed AD would require a one-time detailed inspection (DET) of the affected area, and applicable corrective actions, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 28, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1172.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1172; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1172; Project Identifier MCAI–2021–00939–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0190, dated August 17, 2021 (EASA AD 2021–0190) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus SAS Model A300, A300–600, and A300–600ST airplanes. Model A300–600ST airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by reports of cracking in the MLG support rib 5 lower flange, inboard and outboard of rib 5, on the right-hand and left-hand

sides. The cracking was found during routine maintenance checks on airplanes that do not have Airbus modification 11912 embodied and on which fastener hole spot facing modifications had been embodied in the affected area. The FAA is proposing this AD to address cracking of the MLG support rib 5 lower flange. This condition, if not detected and corrected, could affect the structural integrity of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0190 specifies procedures for a DET of the affected area, a one-time fluorescent penetrant inspection (FPI) around some fastener holes in the affected area, and applicable corrective action(s) including crack repair. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0190 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0190 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0190 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0190 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0190. Service information required by EASA AD 2021–0190 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1172 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 124 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
23 work-hours × $85 per hour = $1,955	$0	$1,955	$242,420

The FAA estimates the following costs to replace any cracked rib that would be required based on the results of any required actions and repair status. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 1,500 work-hours × $85 per hour = $127,500	$620,000	Up to $747,500.

The FAA has received no definitive data on which to base the cost estimates for the repair specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Airbus SAS: Docket No. FAA–2021–1172; Project Identifier MCAI–2021–00939–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 28, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus SAS airplanes, certificated in any category, without Airbus modification 11912 and identified in figure 1 to paragraph (c) of this AD.

Figure 1 to paragraph (c): *Affected airplanes by MSN*

Model	Manufacturer Serial Number (MSN)
A300 B2-1A, B2-1C, B2K-3C, B2-203, B4-2C, B4-103, and B4-203 airplanes	075, 080, 090, 107, 126, 139, 141, 151, 154, 157, 173, 175, 183, 203, 210, 212, 227, 235, 239, 255, 256, 261, 274, 277, 292, 299, and 302
A300 B4-601, B4-603, B4-620, and B4-622 airplanes A300 B4-605R and B4-622R airplanes A300 C4-605R Variant F airplanes A300 F4-605R and F4-622R airplanes	358, 361, 365, 380, 388, 401, 405, 408, 417, 464, 477, 479, 518, 521, 530, 532, 536, 543, 546, 553, 555, 557, 559, 561, 572, 575, 579, 581, 584, 602, 603, 607, 608, 611, 613, 617, 618, 621, 623, 625, 626, 630, 632, 633, 637, 641, 643, 657, 659, 664, 666, 668, 670, 677, 679, 683, 688, 696, 701, 703, 707, 709, 711, 713, 715, 717, 722, 723, 724, 725, 726, 727, 728, 729, 730, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 748, 749, 750, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 766, 768, 769, 770, 771, 772, 773, 774, 775, 777, 778, 779, 780, 781, 783, 789, 790, and 791

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of cracking in the main landing gear (MLG) support rib 5 lower flange, inboard and outboard of Rib 5, on the right-hand and left-hand sides. The FAA is issuing this AD to address cracking of the MLG support rib 5 lower flange. This condition, if not detected and corrected, could affect the structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0190, dated August 17, 2021 (EASA AD 2021–0190).

(h) Exceptions to EASA AD 2021–0190

(1) Where EASA AD 2021–0190 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (3) of EASA AD 2021–0190 specifies to ''accomplish those instructions accordingly'' if any crack is detected, for this AD if any crack is detected, the crack must be repaired before further flight using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) The ''Remarks'' section of EASA AD 2021–0190 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA DOA. If

approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information referenced in EASA AD 2021–0190 contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(j) Related Information

(1) For EASA AD 2021–0190, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1172.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

Issued on December 29, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–28510 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1174; Project Identifier MCAI–2021–00246–R]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020–23–07, which applies to certain Leonardo S.p.a. Model AB139 and AW139 helicopters. AD 2020–23–07 requires removing certain life raft reservoirs (reservoirs) from service, inspecting the reservoirs and actuator cables, and depending on the inspection results, replacing the reservoir or adjusting the actuator cable. Since the FAA issued AD 2020–23–07, additional serial-numbered reservoirs were identified as also being affected by the unsafe condition. This proposed AD would retain certain requirements of AD 2020–23–07, expand the required actions to include additional serial-numbered reservoirs, and update applicable service information. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 28, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://customerportal.leonardocompany.com/en-US/.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1174; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1174; Project Identifier MCAI–2021–00246–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email

Darren.Gassetto@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2020–23–07, Amendment 39–21323 (85 FR 73610, November 19, 2020) (AD 2020–23–07), for Leonardo S.p.a. Model AB139 and AW139 helicopters with emergency flotation kit part number (P/N) 4G9560F00111 (15 passengers) or 4G9560F00211 (18 passengers) installed. AD 2020–23–07 requires for helicopters with certain serial-numbered right-hand (RH) or left-hand (LH) reservoirs installed, within 25 hours time-in-service (TIS) removing each affected reservoir from service. For helicopters with certain serial-numbered RH or LH reservoirs installed, AD 2020–23–07 requires, within 25 TIS or before the reservoir accumulates 55 hours TIS since first installation on a helicopter, whichever occurs later, inspecting the valve pull rod of each reservoir and depending on the inspection results, replacing the reservoir before further flight. For helicopters with certain other serial-numbered RH or LH reservoirs installed, AD 2020–23–07 requires within 25 hours TIS, inspecting the actuator cable of each reservoir and depending on the inspection results, adjusting the actuator cable before further flight. Finally, AD 2020–23–07 prohibits installing certain serial-numbered reservoirs with certain part numbers on any helicopter and prohibits installing certain other serial-numbered reservoirs with certain part numbers on any helicopter unless the actuator cable of the reservoir has been inspected, and if required, the actuator cable adjusted.

AD 2020–23–07 was prompted by EASA AD 2020–0185, dated August 19, 2020 (EASA AD 2020–0185), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Leonardo S.p.A. Helicopters, formerly Finmeccanica S.p.A, AgustaWestland S.p.A., Agusta S.p.A.; and AgustaWestland Philadelphia Corporation, formerly Agusta Aerospace Corporation, Model AB139 and AW139 helicopters, all serial numbers, if equipped with emergency flotation kit P/N 4G9560F00111 (15 passengers) or P/N 4G9560F00211 (18 passengers). EASA advised of an inadvertent emergency life raft activation and deployment event that occurred on a Model AW139 helicopter during flight. EASA advised that following the deployment, the life raft separated from the helicopter and was lost at sea. EASA stated that investigation is on-going into the cause of this event and that Model AB139 helicopters are subject to the same unsafe condition due to design similarity to the AW139 helicopters. This condition, if not addressed, could result in further unintended activation and deployment of the life raft in flight and separation with possible impact on the rotors, resulting in reduced control of the helicopter.

Accordingly, EASA AD 2020–0185 required for some helicopters, replacement of affected reservoirs and, for other helicopters, inspections of the valve pull rod and the actuator cable of the life raft and, depending on findings, accomplishment of the applicable corrective actions. EASA AD 2020–0185 also prohibited re-installation of an affected reservoir on any helicopter.

Actions Since AD 2020–23–07 Was Issued

Since the FAA issued AD 2020–23–07, EASA issued AD 2021–0054, dated February 25, 2021 (EASA AD 2021–0054), which supersedes EASA AD 2020–0185. EASA advises that additional serial-numbered reservoirs are affected by the same unsafe condition. EASA also advises Leonardo Helicopters issued Alert Service Bulletin (ASB) No. 139–662, dated February 15, 2021 (ASB 139–662), which includes a Table listing the serial numbers of the additional batch of affected reservoirs and provides additional replacement and inspection instructions. Furthermore, EASA advises some of the affected reservoirs could become serviceable after an inspection and after these reservoirs are re-identified and marked with an ''R.'' Accordingly, EASA AD 2021–0054 retains the requirements of EASA AD 2020–0185, expands the batch of affected reservoirs to include the additional affected reservoirs, and includes the updated service information.

After AD 2020–23–07 was issued, the FAA determined the total number of affected helicopters stated in the Cost of Compliance paragraph in AD 2020–23–07 was estimated as the total number of U.S. registered Leonardo S.p.a. Model AB139 and AW139 helicopters. However, the FAA revised the Cost of Compliance paragraph in this proposed AD to the total number of helicopters that the type certificate holder estimated as having an affected emergency flotation kit installed. The FAA has also updated the cost information for the parts cost estimates.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other products of the same type designs.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Leonardo Helicopters ASB No. 139–648, dated August 10, 2020 (referred to as ''ASB 139–648 First Issue'') and ASB No. 139–648, Revision A, dated February 15, 2021 (ASB 139–648 Rev A). ASB 139–648 First Issue specifies procedures to replace certain reservoirs and return them to the supplier, inspect the valve pull rod by measuring the actuator cable between the face of the pull rod and the back of the valve cap, inspect the actuator cable by verifying the presence of a clearance between the sphere at the end of the actuator cable and the activation system, and adjust the actuator cable. ASB 139–648 Rev A specifies the same procedures as ASB 139–648 First Issue, except ASB 139–648 Rev A includes a Note clarifying that LH and RH reservoirs with S/Ns marked (or recorded on the component Log Card) with the suffix ''R'' after the S/N are not affected by Part I of ASB 139–648 Rev A, even if they have an S/N listed in Table 1 of ASB 139–648 Rev A.

The FAA also reviewed ASB 139–662, which specifies additional serial-numbered reservoirs that are affected by the same unsafe condition. ASB 139–662 also provides additional actuator cable inspection procedures for these affected reservoirs.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Proposed AD Requirements in This NPRM

This proposed AD would retain all of the requirements of AD 2020–23–07 and would expand the required actions to include the additional serial-numbered reservoirs identified in ASB 139–662. This proposed AD would also allow alternative service information to be used for specific portions of certain inspections and corrective action. This

proposed AD would add an exemption from certain required actions for reservoirs marked with an ''R'' after the S/N.

Differences Between This Proposed AD and EASA AD 2021–0054

EASA AD 2021–0054 uses flight hours (FH) for certain compliance times, whereas this proposed AD would use hours TIS. EASA AD 2021–0054 specifies the compliance time for certain serial-numbered reservoirs to be replaced is within 25 FH after August 26, 2020 (the effective date of EASA AD 2020–0185), whereas this proposed AD would require certain serial-numbered reservoirs to be removed from service within 25 hours TIS after December 4, 2020 (the effective date of AD 2020–23–07). EASA AD 2021–0054 specifies the compliance time for certain serial-numbered reservoirs to be replaced is within 25 FH after March 4, 2021 (the effective date of EASA AD 2021–0054), whereas this proposed AD would require certain serial-numbered reservoirs to be removed from service within 25 hours TIS after the effective date of this AD.

EASA AD 2021–0054 specifies the compliance time to inspect the valve pull rod for certain helicopters is after replacement of the affected reservoir and within 5 FH after the serviceable reservoir exceeds 50 FH since installation, whereas this proposed AD would require the valve pull rod inspection for certain helicopters within 25 hours TIS or before the reservoir accumulates 55 total hours TIS since first installation on a helicopter, whichever occurs later after December 4, 2020 (the effective date of AD 2020–23–07).

EASA AD 2021–0054 specifies the compliance time to inspect the actuator cable for certain helicopters is before next flight after the replacement of the affected reservoir and for certain other helicopters within 25 FH after August 26, 2020 (the effective date of EASA AD 2020–0185), whereas this proposed AD would require the actuator cable inspection for certain helicopters within 25 hours TIS after December 4, 2020 (the effective date of AD 2020–23–07).

EASA AD 2021–0054 requires returning removed reservoirs to the supplier, whereas this proposed AD would require removing certain reservoirs from service and replacing other reservoirs instead.

Costs of Compliance

The FAA estimates that this AD affects 15 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates that operators may incur the following costs in order to comply with this AD.

Replacing a reservoir would take about 1 work-hour and parts would cost up to $3,710 for an estimated cost of up to $3,795 per reservoir.

Inspecting the valve pull rod of a reservoir would take about 1 work-hour for an estimated cost of $85 per reservoir and up to $ 2,550 for the U.S. fleet.

Inspecting an actuator cable would take about 0.25 work-hours for an estimated cost of $21 per inspection and up to $630 for the U.S. fleet.

If required, adjusting an actuator cable would take about 0.75 work-hour for an estimated cost of $64 per cable.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2020–23–07, Amendment 39–21323 (85 FR 73610, November 19, 2020); and

■ b. Adding the following new airworthiness directive:

Leonardo S.p.a.: Docket No. FAA–2021–1174; Project Identifier MCAI–2021–00246–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by February 28, 2022.

(b) Affected ADs

This AD replaces AD 2020–23–07, Amendment 39–21323 (85 FR 73610, November 19, 2020) (AD 2020–23–07).

(c) Applicability

This AD applies to Leonardo S.p.a. Model AB139 and AW139 helicopters, certificated in any category, with emergency flotation kit part number (P/N) 4G9560F00111 (15 passengers) or 4G9560F00211 (18 passengers) installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 2560, Emergency Equipment, and 2564, Life Raft.

(e) Unsafe Condition

This AD was prompted by the inadvertent activation and deployment of an emergency life raft while the helicopter was in flight. The FAA is issuing this AD to prevent the unintended deployment of a life raft (raft). The unsafe condition, if not addressed, could result in the deployment of a raft during flight, separation of the raft with possible impact on the rotors, and subsequent reduced control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) For helicopters with a right-hand (RH) or left-hand (LH) life raft reservoir (reservoir) P/N 3G2560V01951 or P/N 3G2560V01251 and with a serial number (S/N) listed in

Table 1 of Leonardo Helicopters Alert Service Bulletin (ASB) No. 139–648, dated August 10, 2020 (referred to as ''ASB 139–648 First Issue''), within 25 hours time-in-service (TIS) after December 4, 2020 (the effective date of AD 2020–23–07), remove each affected reservoir from service. Any reservoir with the letter ''R'' after the S/N is excluded from this requirement.

(2) For helicopters with a RH or LH reservoir P/N 3G2560V01951 or P/N 3G2560V01251 and with an S/N listed in Table 1 of Leonardo Helicopters ASB No. 139–662, dated February 15, 2021 (ASB 139–662) within 25 hours TIS after the effective date of this AD, remove each affected reservoir from service. Any reservoir with the letter ''R'' after the S/N is excluded from this requirement.

(3) For helicopters with a RH or LH reservoir P/N 3G2560V01951 or P/N 3G2560V01251 and with an S/N not listed in Table 1 of ASB 139–648 First Issue or Table 1 of ASB 139–662 installed, within 25 hours TIS or before the reservoir accumulates 55 total hours TIS since first installation on a helicopter, whichever occurs later after December 4, 2020 (the effective date of AD 2020–23–07), inspect the valve pull rod of each reservoir by following the Accomplishment Instructions, Part II, paragraphs 3. through 5.1, of ASB 139–648 First Issue. Any reservoir with the letter ''R'' after the S/N is included in this requirement. If the measurement of the actuator cable between the face of the pull rod and the back of the valve cap exceeds 68.5 mm, before further flight, replace the reservoir. As an alternative to using the specified portions of ASB 139–648 First Issue, you may accomplish the valve pull rod inspection by following the Accomplishment Instructions, Part II, paragraphs 3. through 5.1, of Leonardo Helicopters ASB No. 139–648, Revision A, dated February 15, 2021 (ASB 139–648 Rev A).

Note 1 to paragraph (g)(3): An actuator cable, which is referenced in paragraphs (g)(3) and (4) of this AD, is also known as an actuation cable.

(4) For helicopters with a RH or LH reservoir P/N 3G2560V01951 or P/N 3G2560V01251 and with an S/N not listed in Table 1 of ASB 139–648 First Issue or Table 1 of ASB 139–662 installed, within 25 hours TIS after December 4, 2020 (the effective date of AD 2020–23–07), inspect the actuator cable of each reservoir by following the Accomplishment Instructions, Part III, paragraphs 3. through 5.1, of ASB 139–648 First Issue. Any reservoir with the letter ''R'' after the S/N in included in this requirement. If the clearance between the sphere at the end of the actuator cable and the activation system exceeds 5.0 +0.00/−2.0 mm, before further flight, adjust the actuator cable by following Annex A of ASB 139–648 First Issue. As an alternative to using the specified portions of ASB 139–648 First Issue, you may accomplish the actuator cable inspection and corrective action by following:

(i) The Accomplishment Instructions, Part III, paragraphs 3. through 5.1, and Annex A, as applicable, of ASB 139–648 Rev A, or

(ii) The Accomplishment Instructions, paragraphs 4 through 4.3.1, and Annex A, as applicable, of ASB 139–662.

(5) As of the effective date of this AD, do not install reservoir P/N 3G2560V01951 or P/N 3G2560V01251 with an S/N listed in Table 1 of ASB 139–648 First Issue, Table 1 of ASB 139–648 Rev A, or Table 1 of ASB 139–662 on any helicopter. Any reservoir with the letter ''R'' after the S/N is excluded from this requirement.

(6) As of the effective date of this AD, do not install a reservoir P/N 3G2560V01951 or P/N 3G2560V01251 with an S/N other than an S/N listed in Table 1 of ASB 139–648 First Issue, Table 1 of ASB 139–648 Rev A, or Table 1 of ASB 139–662, on any helicopter unless you have complied with the requirements in paragraphs (g)(3) and (4) of this AD, as applicable to your helicopter.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.*

(2) For service information identified in this AD, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://customerportal.leonardocompany.com/en-US/.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2021–0054, dated February 25, 2021. You may view the EASA AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2021–1174.

Issued on January 3, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–00057 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2021–OESE–0152]

Proposed Priorities, Requirement, Definitions, and Selection Criteria—Full-Service Community Schools Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Proposed priorities, requirement, definitions, and selection criteria.

SUMMARY: The Department of Education (Department) proposes priorities, requirement, definitions, and selection criteria under the Full-Service Community Schools (FSCS) program, Assistance Listing Number 84.215J. The Department is taking this action to support the successful implementation of this critical program and build additional evidence to share with the field. The Department may use these priorities, requirement, definitions, and selection criteria for competitions in FY 2022 and later years.

DATES: We must receive your comments on or before February 11, 2022.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about the proposed priorities, requirement, selection criteria, and definitions, address them to Elson Nash, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E246, Washington, DC 20202.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only

information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Elson Nash, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E246, Washington, DC 20202. Telephone: (202) 260–2655. Email: *FSCS@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: Community schools serve as centers of the community, connecting students and families to vital resources that can help them thrive. Importantly, community schools expand learning and enrichment opportunities for both students and parents alike, and promote family and community engagement in education, which ultimately can bolster students' success.

This document reflects full-service community schools program improvements based on lessons learned over the last decade, including addressing the increased mental and behavioral health needs among school community members, to improve program implementation and evaluation.

The community schools field has been successful over the years expanding community schools.[1] Practitioners and policy makers at the local, state, and national levels have embraced the community schools approach to address critical needs of children, recognizing that academic opportunities and success can be impacted by factors such as neighborhood poverty, access to health and social services, including mental and behavioral health services and supports, and family stressors. Evidence-based community school approaches can help mitigate the impact of these factors in ways that support student success.[2]

Through proposed priorities and an enhanced application requirement, the Department hopes to encourage applications to include a plan to successfully implement the ''pillars of a full-service community school'' (as defined in this document). In addition, the Department seeks to continuously improve program implementation quality at the site level. The Department also seeks to codify and enhance the definitions, and selection criteria to coincide with improvements to the overall purpose and structure of the FSCS program. Lastly, to continue to build the evidence to support program quality and improvement, we propose to include a priority that allows for a national evaluation of the program.

We invite you to submit comments regarding the proposed priorities, requirement, definitions, and selection criteria. To ensure that your comments have maximum effect in developing the notice of final priorities, requirement, definitions, and selection criteria, we urge you to identify clearly the specific proposed priority, requirement, definition, or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities, requirement, definitions, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice by accessing *Regulations.gov.* Due to the COVID–19 pandemic, the Department buildings are currently not open to the public. However, upon reopening, you may also inspect the comments in person at 400 Maryland Avenue SW, Room 3E246, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern Time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed priorities, requirement, definitions, and selection criteria. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Purpose of Program: The FSCS program provides support for the planning, implementation, and operation of full-service community schools that improve the coordination, integration, accessibility, and effectiveness of services for children and families, particularly for children attending schools with concentrated poverty, including rural schools. The FSCS program is authorized under Title IV through Community Support for School Success, sections 4621–4623 and 4625(a) of the Elementary and Secondary Education Act, as amended (ESEA).

Program Authority: 20 U.S.C. 7271–7273, 7275.

Proposed Priorities

This document contains the following five proposed priorities:

Proposed Priority 1—Capacity Building and Development Grants;

Proposed Priority 2—Multi-Local Educational Agency Grants;

Proposed Priority 3—State Scaling Grants;

Proposed Priority 4—Participation in the National Evaluation; and

Proposed Priority 5—Evidence-Based Integrated Student Supports.

Background: Over the last five years, the FSCS program experienced rapid growth as grantees expanded program implementation to multiple schools and districts. Grantees adopted varied approaches to size and scope, with a range of experiences and outcomes. Those grantees with the most success provided clear guidance to the schools and partners on program implementation, staff training, support for teachers, and continuous improvement. This was particularly true with the 2016 study by the Gardner Center[3] on the implementation of the community school approach by the 2014 FSCS grantee Oakland Unified School District. In Oakland, across 33 schools, school staff, school leadership, and community partners focused on four competencies when addressing the needs of students: Comprehensiveness, collaboration, coherence, and commitment. The results included reductions in suspensions and chronic absenteeism and improved academic engagement.

Proposed priorities 1 through 3 would allow the Department to award grants to projects at different stages of development, from capacity-building to scaling full- service community schools approaches where the community and education leadership are ready to scale. These stages represent points of entry at

[1] Harkavy, I. (2017). John Dewey and the Community School Idea. In L. Benson. *Knowledge for Social Change: Bacon, Dewey and the Revolutionary Transformation of Research Universities in the Twenty-First Century* (pp.42–67), Philadelphia, Temple University Press.

[2] Brookings Institution's Task Force for the Next Generation Community Schools (2021). Addressing inequality in education with a next generation of community schools: A blueprint for mayors, states, and the federal government.

[3] Fehrer, K., & Leos-Urbel, J. (2016). ''We're One Team'': Examining Community School Implementation Strategies in Oakland. Education Sciences, 6(4), 26. MDPI AG. Retrieved from *https://dx.doi.org/10.3390/educsci6030026.*

the local, district, region, and state level to strategically scale the community school approach based on the readiness of the consortium applying for the grant.

Although scaling the approach is important, equally important is retaining high quality implementation and fidelity to the approach which includes the pillars of full-service community schools. The four pillars of full- service community schools (as defined in this notice) are integrated student supports, expanded learning opportunities, active family and community engagements, and collaborative leadership and practices.

There is some evidence that implementing all pillars of full-service community schools is associated with a range of positive outcomes for students and families.[4] As the field continues to evolve, it is important to expand this body of evidence with additional, rigorously designed evaluations. Of the studies that assess the effects of community schools using a randomized controlled trial or quasi-experimental design, all examined the effects of a single community school, the effects of multiple community schools within a single city/metropolitan area, or the effects within 1–2 states.[5]

Key opportunities for next steps include rigorous evaluation of community schools across a wide range of cities and states. The Department proposes Priority 4 to provide the option to institute the first ever national evaluation of the FSCS program.

The Department proposes Priority 5 to support high quality initiative design and implementation. A body of research demonstrates that evidence-based integrated student support models positively impact students' school progress, attendance, and mathematics achievement.[6] These models offer a process for connecting students to personalized, comprehensive services in a systematic manner. Incorporation of a proven integrated student support model would enhance the impact of the FSCS program on students. Under this proposed priority, we include the four tiers of evidence outlined in ESEA, and the Department may choose which tier or tiers to use in a notice inviting applications for FSCS grants.

Proposed Priority 1—Capacity Building and Development Grants. Projects that propose to conduct initial development and coordination activities that leverage the findings of their needs assessment to develop the infrastructure, activities, and partnerships to implement and sustain full- service community schools in two or more schools through extensive community engagement and gathering data on initial outcomes.

Proposed Priority 2—Multi-Local Educational Agency (LEA) Grants. Projects that propose to implement full-service community schools in two or more LEAs within the same state.

Proposed Priority 3—FSCS State Scaling Grants.[7]

Projects in partnership with an SEA that propose to initiate, support, and expand full-service community schools in six or more LEAs across the state where there is a commitment to sustain the program beyond two years after the term of the grant.

Proposed Priority 4—Participation in the National Evaluation.

Projects in which the applicant agrees to:

(1) Carry out the FSCS grant in a manner consistent with a randomized controlled trial evaluation design developed by the Department and its national evaluator;

(2) Propose at least four schools to potentially receive grant funding in the national evaluation. The proposed schools can be elementary, middle, and/or high schools.

Note: From among the proposed schools, applicants may designate one group of two or more schools that serve the same grade levels as ''highest need,'' and if the applicant receives a grant, the national evaluation will ensure that at least one of the schools in the group receives FSCS funding.

(3) Not currently be fully implementing all four pillars of full-service community schools (as defined in this notice) in any of the schools proposed for the grant;

(4) Consent to the evaluator's random assignment of approximately one-half of the schools proposed by the applicant to receive funding and begin implementing the FSCS approach; and the other half of schools to not receive funding from any FSCS grant for three years following random assignment;

(5) Not promote or begin using grant funds for the implementation of the FSCS approach in any proposed schools until the grantee receives notification from the national evaluator about the random assignment of its schools to receive FSCS grant funding or not; and

(6) Cooperate, consistent with applicable privacy requirements, with evaluation data collection activities, including: Surveys of grantee directors, principals of both groups of proposed schools (those randomly assigned to receive grant funding and schools assigned to not receive grant funding), and a representative sample of parents/guardians of students attending the two groups of grantee schools; and provision of district administrative records on educators (*e.g.,* credentials, experience) and students (*e.g.,* academic assessment scores, course taking and credit accumulation, attendance) in the two groups of grantee schools. These data collections will be carried out at multiple points over the grant period.

Proposed Priority 5—Evidence-Based Integrated Student Supports.

Projects that propose adoption of an evidence-based model to provide integrated student supports in their implementation at one or more of the following tiers:

(a) Demonstrates a rationale;
(b) Promising evidence;
(c) Moderate evidence; or
(d) Strong evidence.

Types of Priorities: When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an

[4] Maier, A., J. Daniel, J. Oakes, and L. Lam. ''Community Schools as an Effective School Improvement Strategy: A Review of the Evidence.'' Palo Alto, CA: Learning Policy Institute, 2017.

[5] For example, see:

Adams, C. (2010). ''Improving Conditions for Learning in High Poverty Elementary Schools: Evidence from the Tulsa Area Community Schools Initiative (TACSI).'' Norman, OK: University of Oklahoma.

Durham, R.E., and Connoly, F.(2016). ''Baltimore Community Schools: Promise & Progress.'' Baltimore, MD: Baltimore Education Research Consortium, 2016.

Somers, M., and Haider, Z. (2017). ''Using Integrated Student Support to Keep Kids in School. A Quasi-Experimental Evaluation of Communities In Schools, New York, NY: MDRC.

Johnston, W., Engberg, J., Opper, I., Sontag-Padilla, L. and Xenakis, L. (2020). ''Illustrating the Promise of Community Schools: An Assessment of the Impact of the New York City Community Schools Initiative.'' Sponsored by the New York Mayor's Office of Economic Opportunity. Santa Monica, CA: RAND Corporation.

Olson, L.S.(2014). ''A First Look at Community Schools in Baltimore.'' Baltimore, MD: Baltimore Education Research Consortium.

Somers, M.A, and Haider, Z.(2017). ''Using Integrated Student Supports to Keep Kids in School: A Quasi-Experimental Evaluation of Communities in Schools.'' New York: MDRC.

[6] Moore, K.A., Lantos, H., Jones, R., Schindler, A., Belford, J., & Sacks, V. (2017). Making the Grade: A Progress Report and Next Steps for Integrated Student Supports. Child Trends. (*childtrends.org*). Maier, A., Daniel, J., Oakes, J., and Lam, L. (2017). Community Schools as an Effective School Improvement Strategy: A Review of the Evidence. (*learningpolicyinstitute.org*).

[7] DC, HI, and PR may apply for Statewide grants.

application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirement

Background: To enhance the quality of implementation of full-service community schools the Department proposes that each application address the four pillars of full-service community schools. The four pillars are: (1) Integrated student supports that address out-of-school barriers to learning through partnerships with social and health service agencies and providers; (2) expanded and enriched learning time and opportunities; (3) active family and community engagement; and (4) collaborative leadership and practices that build a culture of professional learning, collective trust, and shared responsibility.

The Department proposes this application requirement to be used in conjunction with those set out in Section 4625(a) of the ESEA. The proposed application requirement is intended to: (1) Assist applicants with creating and clearly presenting elements of high-quality full-service community schools; (2) emphasize the critical role and direct involvement of school partners, including community based organizations, families, educators, and staff, in identifying and implementing solutions needed to improve educational opportunities and academic outcomes; (3) ensure that applicants have a clear knowledge of the assets and needs in the schools and communities to be served as demonstrated by the applicant's initial needs assessment and plan; and (4) communicate to families that the combination of supports, rich learning environment and collaboration with school leadership will create the best conditions to meet the needs of their child. The Department expects that the proposed requirement will not only improve the application and review process but also improve program outcomes.

Through each of the FSCS competitions over the last ten years, the program recognized the need for applications to more clearly represent information such as presentation of services, demonstration of needs, and connection to the classroom. These improvements will help increase the likelihood that the proposed project addresses all identified needs and connects the services and community assets to the schools. It will also help peer reviewers' evaluation of services, partners, and collaborations with school leadership.

Proposed Application Requirement

The Department proposes the following application requirement for this program. We may apply this requirement in any year in which this program is in effect.

Proposed Application Requirement: An applicant must, in addition to providing the information and assurances required by Section 4625(a) of the ESEA, provide the following:

In addressing the application requirements set out in Section 4625(a) of the ESEA, applicants must address the essential pillars of full-service community schools (as defined in this notice).

Projects must describe the pillars of full-service community schools that they have in place or how they will establish these pillars, or how they will implement these supports with partners, including community-based organization, and collaborating with school leadership and staff.

Proposed Definitions

Background: To ensure a common understanding of the proposed priorities, requirement, and selection criteria, we propose the following definitions that are critical to the policy and statutory purposes of the FSCS program. We propose these definitions to clarify expectations for eligible entities applying for FSCS program grants and to ensure that the review process for applications for FSCS grants remains as transparent as possible.

Proposed Definitions: The Department proposes the following definitions for this program. We may apply one or more of these definitions in any year in which this program is in effect.

Pillars of Full-Service Community Schools means all of the following:

(A) Integrated student supports at a community school that provide in- and out-of-school support for students, address well-being, and address out-of-school barriers to learning through partnerships with social and health service agencies, including mental and behavioral health agencies and providers, and coordinated by a community school coordinator, which may include—

(i) Medical, dental, vision care, and mental and behavioral health services, including mental health literacy for students and staff; and

(ii) Individuals to assist with housing, transportation, nutrition, citizenship preparation, or criminal justice issues and other services.

(B) Expanded and enriched learning time and opportunities, through evidence-based strategies, including before-school, after-school, during-school, weekend, and summer programs that provide additional academic instruction, individualized academic support, enrichment activities, or learning opportunities, for students at a community school that—

(i) May emphasize real-world project based learning in which students can apply their learning to contexts that are relevant and engaging; and

(ii) May include art, music, drama, creative writing, hands-on experience with engineering or science (including computer science), career and technical education, tutoring that is aligned with classroom success and homework help, and recreational programs that enhance and are consistent with the school's curriculum.

(C) Active family and community engagement that—

(i) Brings parents and families of students at the community school and in the community into the school as partners in students' education, including meaningfully involving parents and families in the community school's decision-making processes;

(ii) Makes the community school a hub for services, activities, and programs, for students, families, and members of the neighborhood that the community school serves;

(iii) Provides adults with desired educational opportunities; and

(iv) Provides centralized supports for families and communities in community schools, which may include English as a second language classes, citizenship preparation, computer skills, art, housing assistance, child abuse and neglect prevention supports, health and mental health literacy programs, digital literacy training, or other programs that bring community members into a school building for meetings, events, or programming.

(D) Collaborative leadership and practices that build a culture of professional learning, collective trust, and shared responsibility for each community school using strategies that—

(i) Shall, at a minimum, include a school-based leadership team, a community school coordinator, and a community-wide leadership team; and

(ii) May include other leadership or governance teams, community school steering committees, or other community coalitions, educator learning communities, and other staff to manage the multiple, complex joint work of school and community organizations.

Broadly representative consortium means stakeholders representing broad groups of people working together for the best interest of children; such stakeholders may include, but are not limited to schools, nonprofits, government, philanthropy, and the business community.

History of effectiveness means an eligible entity demonstrating the ability to successfully implement programs and policies. Such programs and policies must include but shall not be limited to successfully implementing with other organizations grants, policies, and programs for students from high need schools (as defined in ESEA section 2221).

Proposed Selection Criteria

Background: Since the original FSCS grant competition in FY 2008, the Department has held four additional competitions (FY 2010, 2014, 2018, and 2019). Our experience with administering these competitions, including feedback from peer reviewers, applicants, funded grantees, and experts, demonstrates the need to use program-specific selection criteria to evaluate specific program elements.

Proposed Selection Criteria: The Department proposes the following selection criteria for evaluating an application under this program. We may apply one or more of these criteria in any year in which this program is in effect. In the notice inviting applications or the application package or both we will announce the maximum possible points assigned to each criterion.

(a) The extent to which the design of the proposed project reflects relevant and evidence-based findings from existing literature, and includes a high-quality plan for project implementation integrating the four pillars of full-service community schools and the use of appropriate evaluation methods to ensure successful achievement of project objectives.

(b) The extent to which the applicant will ensure that a diversity of perspectives is brought to bear in the design and operation of the proposed project, including those of families, educators and staff, beneficiaries of services, school leadership, and community leadership.

(c) The extent to which the grantee has plans for a full-time coordinator at each school, includes a plan to sustain the position beyond the grant period, and a description of how this position will serve to integrate, coordinate, and deliver pipeline services at each school.

(d) The extent to which the grantee has a consortium broadly representative of community stakeholders and needs.

(e) The extent to which the applicant demonstrates a history of effectiveness.

Final Priority, Requirement, Definitions and Selection Criteria: We will announce the final priorities, requirement, definitions, and selection criteria in a notice in the **Federal Register**. We will determine the final priorities, requirement, definitions, and selection criteria after considering responses to this document and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, and selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use these priorities, requirement, definitions, and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule).

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify).

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations.

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing the proposed priorities, requirement, definitions, and selection criteria only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the

potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Paperwork Reduction Act

The proposed priorities, requirement, definitions, and selection criteria contain information collection requirements that are approved by OMB under OMB control number 1894–0006; the proposed priorities, requirement, definitions, and selection criteria do not affect the currently approved data collection.

Regulatory Flexibility Act Certification

The Secretary certifies that this proposed regulatory action would not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The small entities that this proposed regulatory action would affect are LEAs, including charter schools that operate as LEAs under State law; institutions of higher education; public or private nonprofit organizations; and Indian Tribes or Tribal organizations. We believe that the costs imposed on an applicant by the proposed priorities, requirement, definitions, and selection criteria would be limited to paperwork burden related to preparing an application and that the benefits of these proposed priorities, requirement, definitions, and selection criteria would outweigh any costs incurred by the applicant.

Participation in the FSCS program is voluntary. For this reason, the proposed priorities, requirement, definitions, and selection criteria would impose no burden on small entities unless they applied for funding under the program. We expect that in determining whether to apply for FSCS program funds, an eligible entity would evaluate the requirements of preparing an application and any associated costs and weigh them against the benefits likely to be achieved by receiving an FSCS program grant. An eligible entity will probably apply only if it determines that the likely benefits exceed the costs of preparing an application.

We believe that the proposed priorities, requirements, definitions, and selection criteria would not impose any additional burden on a small entity applying for a grant than the entity would face in the absence of the proposed action. That is, the length of the applications those entities would submit in the absence of the proposed regulatory action and the time needed to prepare an application would likely be the same.

This proposed regulatory action would not have a significant economic impact on a small entity once it receives a grant because it would be able to meet the costs of compliance using the funds provided under this program. We invite comments from small eligible entities as to whether they believe this proposed regulatory action would have a significant economic impact on them and, if so, request evidence to support that belief.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or another accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs, delegated the authority to perform the functions and duties of the Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2022–00453 Filed 1–11–22; 8:45 am]

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Notices

Federal Register

Vol. 87, No. 8

Wednesday, January 12, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Recommendation

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Assembly of the Administrative Conference of the United States adopted five recommendations at its virtual Seventy-sixth Plenary Session: (a) Public Access to Agency Adjudicative Proceedings, (b) Public Availability of Inoperative Agency Guidance Documents, (c) Technical Reform of the Congressional Review Act, (d) Regulation of Representatives in Agency Adjudicative Proceedings, and (e) Quality Assurance Systems in Agency Adjudication.

FOR FURTHER INFORMATION CONTACT: For Recommendation 2021–6, Jeremy Graboyes; for Recommendation 2021–7, Todd Rubin; for Recommendation 2021–8, Kazia Nowacki; for Recommendation 2021–9, Gavin Young; and for Recommendation 2021–10, Matthew A. Gluth. For each of these recommendations the address and telephone number are: Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036; Telephone 202–480–2080.

SUPPLEMENTARY INFORMATION: The Administrative Conference Act, 5 U.S.C. 591–596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations to agencies, the President, Congress, and the Judicial Conference of the United States for procedural improvements (5 U.S.C. 594(1)). For further information about the Conference and its activities, see *www.acus.gov.*

The Assembly of the Conference met during its Seventy-sixth Plenary Session on December 16, 2021, to consider five proposed recommendations. All five were adopted.

Recommendation 2021–6, *Public Access to Agency Adjudicative Proceedings.* This recommendation identifies best practices regarding when and how federal agencies provide public access to adjudicative proceedings. Within the legal framework established by federal law, it identifies factors agencies should consider when determining whether to open or close particular proceedings. It also offers best practices to promote public access to proceedings that agencies open to the public and recommends that agencies make the policies governing public access readily available.

Recommendation 2021–7 *Public Availability of Inoperative Agency Guidance Documents.* This recommendation provides best practices for maintaining public access to agency guidance documents that are no longer in effect—that is, inoperative. It identifies factors agencies should consider in deciding whether to include certain types of inoperative guidance documents on their websites, outlines steps agencies can take to make it easier for the public to find inoperative guidance documents, and identifies ways that agencies can label and explain the significance of inoperative guidance documents.

Recommendation 2021–8 *Technical Reform of the Congressional Review Act.* This recommendation offers technical reforms of the Congressional Review Act (CRA) to clarify certain of its procedural aspects and reduce administrative burdens on executive-branch agencies and congressional offices. Specifically, it recommends (1) requiring electronic rather than paper submission of the materials agencies must transmit to Congress, (2) making it easier to ascertain key dates and time periods relevant to review of agency rules under the CRA, and (3) formalizing the procedure by which members of Congress initiate congressional review of rules that agencies conclude are not covered by the CRA.

Recommendation 2021–9, *Regulation of Representatives in Agency Adjudicative Proceedings.* This recommendation recommends that agencies consider adopting rules governing attorney and non-attorney representatives in order to promote accessibility, fairness, integrity, and efficiency in agency adjudicative proceedings. It provides guidance on the topics that rules might cover and recommends that agencies consider whether greater harmonization of different bodies of rules is desirable and ensure that their rules are readily accessible on their websites.

Recommendation 2021–10, *Quality Assurance Systems in Agency Adjudication.* This recommendation identifies best practices for promoting fairness, accuracy, timeliness, and consistency in agency adjudications through the use of quality assurance systems. It provides guidance to agencies on the selection, role, and institutional placement of quality-assurance personnel. It also identifies specific considerations for the timing of and process for quality-assurance review; outlines different methodologies for identifying and correcting quality issues; and addresses how agencies might use electronic case management, data analytics, and artificial intelligence for quality-assurance purposes.

The Conference based its recommendations on research reports and prior history that are posted at: *https://www.acus.gov/meetings-and-events/event/76th-plenary-session-virtual.*

Authority: 5 U.S.C. 595.

Dated: January 7, 2022.

Shawne C. McGibbon,

General Counsel.

Appendix—Recommendation of the Administrative Conference of the United States

Administrative Conference Recommendation 2021–6

Public Access to Agency Adjudicative Proceedings

Adopted December 16, 2021

Agencies adjudicate millions of cases each year. The matters they adjudicate are diverse, as are the processes they use to do so. Some processes are trial-like; others are informal. Some are adversarial; others are non-adversarial. Agencies conduct many different types of proceedings in the course of adjudicating cases, such as investigatory hearings, prehearing and scheduling conferences, settlement conferences, evidentiary hearings, and appellate

arguments.[1] Members of the public—participants' family and friends, media representatives, representatives of non-governmental organizations, researchers, and others—may seek to observe adjudicative proceedings for any number of reasons.

Agencies must determine whether and how to allow public access to the proceedings they conduct. Federal statutes govern how agencies manage public access in some contexts. The Government in the Sunshine Act[2] and certain statutes specific to particular programs and agencies require that agencies open or close adjudicative proceedings or certain portions thereof to public observation.[3] Agencies may need to transcribe or record certain adjudicative proceedings and may be required, under the Federal Advisory Committee Act[4] or other laws, to make such records publicly available.[5] Conversely, the Privacy Act[6] and other laws and executive-branch policies may require agencies to protect sensitive interests and information.

On top of these legal requirements, many agencies have adopted their own policies regarding public access to adjudicative proceedings.[7] Settling on a sound policy for determining which proceedings should be open to public observation can require balancing different, and sometimes conflicting, interests. Proceedings open to public observation promote transparency, public accountability, and public understanding of agency decision making. Openness encourages fair process for private parties and promotes accurate and efficient decision making by subjecting arguments and evidence to public scrutiny. And many participants, especially self-represented parties, people with disabilities, and children, benefit from having a family member, friend, personal care attendant, case worker, or other supportive member of the public present at their proceedings.[8]

As with any legal proceeding, however, there can be drawbacks to opening adjudicative proceedings to the public. Many adjudications involve sensitive information that would be publicly disclosed in an open proceeding. Public disclosure of unverified information or unproven allegations may result in unwarranted reputational harm to private parties. Just as open proceedings allow family members and other supportive members of the public to accompany participants, they also allow in those who would intimidate or harass. Openness may also affect the dynamic of agency proceedings, leaving them vulnerable to disruption or leading them to become unduly adversarial or protracted. There can also be administrative costs associated with facilitating in-person or remote observation of adjudicative proceedings by members of the public, providing advance public notice of open proceedings, and providing access to transcripts and recordings of open proceedings. These costs may be warranted in some circumstances but not others.

This Recommendation recognizes that agency adjudicative proceedings vary widely in their purpose, complexity, and governing law and the degree of public interest they attract. It also recognizes that not all agencies can bring the same resources to bear in addressing public access to their adjudicative proceedings. In offering these best practices, the Administrative Conference encourages agencies to develop policies that, in addition to complying with all relevant legal requirements for public access, recognize the benefits of public access for members of the public, private parties, agencies, and other participants and account for countervailing interests, such as privacy and confidentiality.

Recommendation

Policies for Public Access to Agency Adjudicative Proceedings

1. Agencies should promulgate and publish procedural regulations governing public access to their adjudicative proceedings in the **Federal Register** and codify them in the *Code of Federal Regulations.* In formulating these regulations, agencies, in addition to adhering to any legal requirements for public access, should consider the benefits of public access and countervailing interests, such as privacy and confidentiality, as elaborated in Paragraph 6. These regulations should include the following:

a. A list of proceedings that should be categorically or presumptively open or closed, and standards for determining when adjudicators may or must depart from such presumption in individual cases (see Paragraphs 5–7);

b. The manners in which members of the public can observe open proceedings, for example by attending in person (*e.g.,* at an agency hearing room) or by remote means (*e.g.,* online or by telephone) (see Paragraphs 8–14);

c. Requirements, if any, for advance public notice of proceedings, whether open or closed (see Paragraphs 11–14); and

d. The public availability of and means of accessing transcripts and audio and video recordings of proceedings (see Paragraphs 15–17).

2. In conjunction with such regulations, agencies should develop guidelines that set forth, in plain language, the following information for proceedings that are open to the public:

a. The manner in which agencies will communicate the schedule of upcoming proceedings to the public;

b. The location at and manner in which members of the public can observe proceedings;

c. The registration process, if any, required for members of the public to observe proceedings and how they should register;

d. The agency official whom members of the public should contact if they have questions about observing proceedings;

e. Any instructions for accessing agency or non-agency facilities where proceedings are held;

f. Any requirements for conduct by public observers (*e.g.,* regarding the possession and use of electronic devices);

g. Any protocols for facilitating media coverage; and

h. Any policies for managing proceedings that attract high levels of public interest.

3. Agencies should also consider whether presumptively closed proceedings may be open to select members of the public, such as family members or caregivers, and, if so, develop guidelines for such situations that address, as relevant, the information in Paragraph 2.

4. Agencies should provide access to the regulations described in Paragraph 1, the guidelines described in Paragraphs 2 and 3, and any other information about public access to adjudicative proceedings, in an appropriate location on their websites.

Standards and Procedures for Determining Which Adjudicative Proceedings Are Open or Closed

5. Agencies ordinarily should presume that evidentiary hearings and appellate proceedings (including oral arguments) are open to public observation. Agencies may choose to close such proceedings, in whole or in part, to the extent consistent with applicable law and if there is substantial justification to do so. Substantial justification may exist, for example, when the need to protect one or more of the following interests can reasonably be considered to outweigh the public interest in openness:

a. National security;

[1] This Recommendation applies however adjudicative proceedings are conducted, including virtually or by telephone or video teleconferencing.

[2] 5 U.S.C. 552b.

[3] Members of the public have, in some instances, asserted a right under the First Amendment to access certain agency adjudicative proceedings. *See* Jeremy Graboyes & Mark Thomson, Public Access to Agency Adjudicative Proceedings 10–12 (Nov. 22, 2021). Courts have reached different conclusions on whether and in what circumstances such a right exists for administrative proceedings. *Compare Detroit Free Press* v. *Ashcroft,* 303 F.3d 681, 700 (6th Cir. 2002), with *N. Jersey Media Grp., Inc.* v. *Ashcroft,* 308 F.3d 198, 212–213 (3d Cir. 2002). Agencies should be aware of such opinions when establishing policies on public access and responding to requests for public access to adjudicative proceedings they conduct.

[4] 5 U.S.C. app. 2, 11. Although the Federal Advisory Committee Act principally governs the operation of advisory committees, section 11 of the Act requires agencies to ''make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings.'' *Id.* § 11(a). ''Agency proceedings'' means agency processes for rulemaking, adjudication, and licensing. *Id.* § 11(b).

[5] The Administrative Conference has recommended that agencies consider providing access on their websites to supporting adjudicative materials issued and filed in adjudicative proceedings. Admin. Conf. of the U.S., Recommendation 2017–1, *Adjudication Materials on Agency Websites,* 82 FR 31039 (July 5, 2017). Online disclosure of transcripts and recordings of adjudicative proceedings and real-time broadcast of open proceedings can save staff time or money through a reduction in the volume of Freedom of Information Act (FOIA) requests or printing costs, or an increase in the speed with which agency staff will be able to respond to remaining FOIA requests.

[6] 5 U.S.C. 552a.

[7] *See* Graboyes & Thomson, *supra* note 3.

[8] Although family members, friends, personal care attendants, care workers, or other supportive members of the public may wish to attend an adjudicative proceeding as a public observer, such individuals may, in some circumstances, assist or provide support for a party or other participant by serving, for example, as a legal guardian, representative, or interpreter. Individuals who serve in such a role are not considered public observers for purposes of this Recommendation.

b. Law enforcement interests;
c. Confidentiality of business information;
d. Personal privacy interests;
e. The interests of minors and juveniles; and
f. Other interests protected by statute or regulation.

6. Agencies should consider whether types of adjudicative proceedings other than evidentiary hearings and appellate proceedings (such as investigatory hearings and prehearing conferences), which are typically closed, should be open to public observation. In doing so, agencies, in addition to adhering to any legal requirements for public access, should consider the following:

a. Whether public access would promote important policy objectives such as transparency, fairness to parties, accurate and efficient development of records for decision making, or public participation in agency decision making;

b. Whether public access would impede important policy objectives such as encouraging candor, achieving consensus, deciding cases and resolving disputes in an efficient manner, preventing intimidation or harassment of participants, avoiding unwarranted reputational harm to participants, or protecting national security, law enforcement interests, confidentiality of business information, personal privacy interests, the interests of minors and juveniles, and other interests protected by statute or regulation;

c. Whether such proceedings or the broader adjudication process of which the proceeding at issue is a part typically include opportunities for public access;

d. Whether there is often public interest in observing such proceedings; and

e. Whether matters to be discussed at such proceedings ordinarily involve issues of broad public interest or the interests of persons beyond the parties.

7. Agencies should adopt processes for departing from or considering requests to depart from a presumption of open or closed proceedings in particular cases. Agencies should consider addressing the following topics in the procedural regulations described in Paragraph 1:

a. How parties to a case can request that proceedings that are presumptively open to public observation be closed or that proceedings that are presumptively closed to public observation be open to particular individuals or the general public;

b. How non-parties to a case can request access, for themselves or the general public, to proceedings that are presumptively closed to public observation;

c. How parties and non-parties can respond or object to requests regarding public access made in subparagraphs (a) or (b);

d. Under what circumstances adjudicators or other agency officials can, on their own motion, close proceedings that are presumptively open to public observation or open proceedings that are presumptively closed to public observation;

e. Whether and how adjudicators or other agency officials must document and notify participants about decisions regarding public access; and

f. Who, if anyone, can appeal decisions regarding public access and, if so, when, to whom, and how they may do so.

Manner of Public Observation of Open Adjudicative Proceedings

8. When adjudicators conduct open proceedings in public hearing rooms, members of the public should have the opportunity to observe the proceedings from the rooms in which they are conducted, subject to reasonable security protocols, resource and space constraints, and concerns about disruptions.

9. Agencies should provide all or select members of the public, such as family members or caregivers, the opportunity to observe open adjudicative proceedings remotely. Agencies should provide remote access in a way that is appropriate for a particular proceeding, such as by providing a dial-in number to select members of the public, such as family members or caregivers, on request, or by livestreaming audio or video of the proceedings to the general public online. Agencies should structure remote access in a way that avoids disruptions, such as by ensuring that public observers cannot unmute themselves or use chat, screen-sharing, document-annotation, and file-sharing functions common in internet-based videoconferencing software.

10. Agencies should consider whether interested members of the public are likely to encounter any barriers to accessing open adjudicative proceedings and, if so, take steps to remedy them. For example, measures may be needed to accommodate people with disabilities, people for whom it may be difficult to make arrangements to travel to locations where proceedings are conducted, and people who do not have access to electronic devices or private internet services necessary to observe proceedings remotely. Agencies may also need to adjust security protocols at the facilities where proceedings are conducted to facilitate in-person attendance while still accounting for reasonable security needs.

Advance Public Notice of Adjudicative Proceedings

11. Agencies should provide advance public notice of open adjudicative proceedings and consider whether to provide advance public notice of closed proceedings, so that the public is aware of such proceedings and can request access to them as specified in Paragraph 7(b). Agencies that determine that advance public notice would be beneficial should consider (a) the best places and publications for providing such notice, (b) the information provided in the notice, and (c) the timing of the notice. Agencies that regularly conduct open proceedings should also consider maintaining a schedule of and information about upcoming proceedings in an appropriate location on their websites.

12. To determine the best places and publications for providing advance public notice of adjudicative proceedings, agencies should consider their needs and available resources and the individuals, communities, and organizations that are likely to be interested in or affected by such proceedings. Places and publications where agencies might provide public notice of proceedings include:

a. The **Federal Register**;
b. A press release, digest, newsletter, or blog post published by the agency;
c. An agency events calendar;
d. Social media;
e. A newspaper or other media outlet that members of the public who may be interested in observing the proceeding are likely to monitor;
f. A physical location that potentially interested members of the public are likely to see (*e.g.,* a bulletin board at a jobsite or agency office);
g. An email sent to persons who have subscribed to a mailing list or otherwise opted to receive updates about a particular adjudication; and
h. A communication sent directly to members of the public, communities, and organizations who may be interested in observing the proceeding.

13. Agencies should include the following information in any public notice for an open adjudicative proceeding, as applicable:

a. The name and docket number or other identifying information for the proceeding;
b. The date and time of the proceeding;
c. The ways that members of the public can observe the proceeding, along with the directions, if any, for registering or requesting access to the proceeding and, for in-person observers, instructions for accessing the facility where the proceeding will take place, including any security or public health protocols and disability accommodations;
d. A brief summary of the proceeding's purpose; and
e. Contact information for a person who can answer questions about the proceeding.

14. Agencies should determine the appropriate timing for providing and updating public notice of adjudicative proceedings given the nature of their programs and the proceeding at issue. More advance notice may be warranted, for example, if significant public interest in an open proceeding is likely and interested members of the public will need to travel to observe it in person.

Public Access to Transcripts and Recordings of Adjudicative Proceedings

15. Consistent with applicable legal requirements, agencies should consider how they make transcripts and recordings of adjudicative proceedings available to interested members of the public. In addition to providing public access to such materials on their websites, an agency might also, as appropriate:

a. Make transcripts and recordings available for public inspection in a reading room, docket office, or other agency facility;
b. Make transcripts and recordings available for public inspection on another public website, such as a public video sharing website; or
c. Provide, or arrange for court reporters working under contract with the government to provide, copies of transcripts and recordings on request for a fee that is no more than the actual cost of duplication, though the agency may charge a reasonable, additional fee for expedited processing.

16. Agencies should take steps to redact any information that is protected by law or policy from public disclosure before providing public access to transcripts and recordings.

17. Agencies should ensure that transcripts and recordings of open proceedings are available for public inspection in a timely manner.

Administrative Conference Recommendation 2021–7

Public Availability of Inoperative Agency Guidance Documents

Adopted December 16, 2021

Agencies issue guidance documents to help explain their programs and policies, announce their interpretation of laws, and communicate other important information to regulated entities, regulatory beneficiaries, and the broader public.[1] The Administrative Conference has issued several recent recommendations regarding guidance documents.[2] Among them was Recommendation 2019–3, *Public Availability of Agency Guidance Documents,* which encourages agencies to facilitate public access to guidance documents on their websites.

Over time, a given guidance document may no longer reflect an agency's position. An agency may rescind the document in whole or in part by announcing that it no longer reflects the agency's position. Even without being rescinded in whole or in part, a guidance document may be superseded in whole or in part by later statutory, regulatory, or judicial developments, or it may fall into disuse in whole or in part. The present Recommendation terms these documents ''inoperative guidance documents.''

Some inoperative guidance documents will be of interest to the public because they disclose how an agency's legal interpretations have changed [3] or how policies or programs have changed over time.[4] But if these documents are not posted on an agency's website, they will be either inaccessible (except through a Freedom of Information Act (FOIA) request), in the case of documents not published in the **Federal Register**, or not as accessible as they should be, in the case of documents that were noticed in the **Federal Register**.[5]

Three statutes require agencies to make some inoperative guidance documents publicly available. The Federal Records Act requires agencies to post on their websites materials that are of ''general interest or use to the public.'' [6] FOIA calls upon agencies to publish notices in the **Federal Register** when they have rescinded or partially rescinded certain guidance documents that are addressed to the public generally rather than to specific individuals or organizations.[7] The E-Government Act requires agencies, in certain circumstances, to publish these rescission and partial rescission notices on their websites.[8] Many agencies have also issued regulations pertaining to the public availability of their inoperative guidance documents.

The Office of Management and Budget's 2007 *Final Bulletin for Agency Good Guidance Practices* imposes additional requirements on agencies relating to inoperative guidance documents. It directs all agencies other than independent regulatory agencies to maintain a list on their websites identifying significant guidance documents that have been revised or withdrawn in the past year. It also encourages agencies to stamp or otherwise prominently identify as ''superseded'' those significant guidance documents that have become inoperative but which remain available for historical purposes.[9]

Recommendation 2019–3, though concerned primarily with operative guidance documents, makes several recommendations relating to the posting of inoperative guidance documents. In summary, it recommends that agencies (1) mark posted guidance documents to indicate whether they are current or were withdrawn or rescinded and (2) in the case of rescinded or withdrawn documents, note their rescission or withdrawal date and provide links to any successor documents.

Recommendation 2019–3 reserved the question, however, of which inoperative guidance documents agencies should publish online. This Recommendation takes up that issue, building on the principles Recommendation 2019–3 set forth for operative documents by extending them, as appropriate, to inoperative guidance documents. Specifically, it advises agencies to develop written procedures for publishing inoperative guidance documents, devise effective strategies for labeling and organizing these documents on their websites, and deploy other means of disseminating information about these documents.[10] The Recommendation also encourages agencies to provide clear cross-references or links between inoperative guidance documents and any operative guidance documents replacing or modifying them.

This Recommendation, like Recommendation 2019–3, accounts for differences across agencies in terms of the number of guidance documents they issue, how they use guidance documents, and their resources and capacities for managing online access to these documents.[11] Accordingly, although it is likely that agencies following this Recommendation will make some of their inoperative guidance documents more readily available to the public, this Recommendation should not be understood as necessarily advising agencies to post the full universe of their inoperative guidance documents online.

This Recommendation is limited to guidance documents that agencies determine are inoperative after the date of this Recommendation. Agencies may, of course, choose to apply it retroactively to existing inoperative guidance documents.

Recommendation

Establishing Written Procedures Governing the Public Availability of Inoperative Guidance Documents

1. Each agency should develop and publish on its website written procedures governing the public availability of inoperative guidance documents and should consider doing the following in its procedures:

a. Explaining what it considers to be inoperative guidance documents for purposes of its procedures instituted under this Recommendation;

b. Identifying which one or more of the following kinds of inoperative guidance documents are covered by its procedures: Rescinded guidance documents, partially rescinded guidance documents, superseded guidance documents, partially superseded guidance documents, or guidance documents that have fallen into disuse in whole or in part;

c. Identifying, within the kinds of inoperative guidance documents covered by its procedures, which categories of inoperative guidance documents will be published on its website and otherwise made publicly available, taking into consideration the categories articulated in Paragraph 2 below;

d. Explaining how it will include links or cross-references between any related inoperative and operative guidance documents;

[1] Guidance documents include what the Administrative Procedure Act calls ''interpretive rules'' and ''general statements of policy.'' 5 U.S.C. 553(b). They may also include other materials considered to be guidance documents under other, separate definitions adopted by government agencies. *See* Admin. Conf. of the U.S., Recommendation 2019–3, *Public Availability of Agency Guidance Documents,* 84 FR 38931, 38931 (Aug. 8, 2019).

[2] *See, e.g.,* Recommendation 2019–3, *supra* note 1; Admin. Conf. of the U.S., Recommendation 2019–1, *Agency Guidance Through Interpretive Rules,* 84 FR 38927 (Aug. 8, 2019); Admin. Conf. of the U.S., Recommendation 2017–5, *Agency Guidance Through Policy Statements,* 82 FR 61734 (Dec. 29, 2017); Admin. Conf. of the U.S., Recommendation 2014–3, *Guidance in the Rulemaking Process,* 79 FR 35992 (June 25, 2014).

[3] *See* Blake Emerson & Ronald Levin, Agency Guidance Through Interpretive Rules: Research and Analysis (May 28, 2019) (report to the Admin. Conf. of the U.S.).

[4] *See* Nicholas R. Parrillo, Agency Guidance Through Policy Statements: An Institutional Perspective (Oct. 12, 2017) (report to the Admin. Conf. of the U.S.).

[5] *See* Recommendation 2019–3, *supra* note 1.

[6] *See* 44 U.S.C. 3102(2).

[7] *See* 5 U.S.C. 552(a)(1); *Nat'l Org. of Veterans' Advocs., Inc.* v. *Sec'y of Veterans Affairs,* 981 F.3d 1360, 1375 (Fed. Cir. 2020).

[8] *See* E-Government Act of 2002 § 206, 44 U.S.C. 3501 note (Federal Management and Promotion of Electronic Government Services).

[9] *See* Office of Mgmt. & Budget, Exec. Office of the President, OMB Bull. No. 07–02, Final Bulletin for Agency Good Guidance Practices (2007).

[10] Several paragraphs of this Recommendation directly or indirectly apply the paragraphs of Recommendation 2019–3 to inoperative guidance documents. Compare Paragraph 1 of this Recommendation with Recommendation 2019–3, ¶ 1; Paragraph 3 with Recommendation 2019–3, ¶¶ 4, 7, 9; Paragraph 4 with Recommendation 2019–3, ¶ 8; and Paragraph 6 with Recommendation 2019–3, ¶ 11.

[11] *See* Todd Rubin, Public Availability of Inoperative Agency Guidance Documents (Nov. 22, 2021) (report to the Admin. Conf. of the U.S.); Cary Coglianese, Public Availability of Agency Guidance Documents (May 15, 2019) (report to the Admin. Conf. of the U.S.).

e. Specifying how long inoperative guidance documents will be retained on its website;

f. Specifying whether some types of previously unpublished operative guidance documents will be posted on its website and otherwise made publicly available when they become inoperative and, if so, under what circumstances;

g. Providing for how inoperative guidance documents will be organized on its website to facilitate searching and public access;

h. Identifying, as provided in Paragraph 4 below, what labels and explanations it will use to communicate clearly the inoperative status of guidance documents; and

i. Indicating whether any of the procedures should be applied retroactively.

Determining Which Categories of Inoperative Guidance Documents To Publish Online and Otherwise Make Publicly Available

2. Each agency should consider publishing on its website and otherwise making publicly available one or more of the following categories of inoperative guidance documents:

a. Inoperative guidance documents whose operative versions it made publicly available;

b. Inoperative guidance documents that, if they were operative, would be made publicly available under its current policies;

c. Inoperative guidance documents that have been replaced or amended by currently operative guidance documents;

d. Inoperative guidance documents that expressed policies or legal interpretations that remain relevant to understanding current law or policy;

e. Inoperative guidance documents that generated reliance interests when they were operative;

f. Inoperative guidance documents that generate—or, when they were operative, generated—numerous unique inquiries from the public;

g. Inoperative guidance documents that are—or, when operative, were—the subject of attention in the general media or specialized publications relevant to the agency, or have been cited frequently in other agency documents, such as permits, licenses, grants, loans, contracts, or briefs;

h. Inoperative guidance documents that, when originally being formulated, generated a high level of public participation; and

i. Inoperative guidance documents that, when operative or originally being formulated, had been published in the *Unified Agenda of Federal Regulatory and Deregulatory Actions* or were considered ''significant guidance documents'' under the Office of Management and Budget's *Final Bulletin for Agency Good Guidance Practices.*

Organizing and Labeling Inoperative Guidance Documents Available Online

3. Each agency should organize its inoperative guidance documents on its website to make it easy for members of the public to find them and relate them to any successor guidance documents. The agency should consider one or more of the following approaches:

a. Assigning a unique guidance identification number to each inoperative guidance document, if this number had not already been assigned when the document was operative;

b. Creating a table that is indexed, tagged, or sortable and is dedicated exclusively to displaying entries for inoperative guidance documents, with links to these documents;

c. Providing a search function that enables retrieval of inoperative guidance documents;

d. Using a method, such as a pull-down menu, that allows the public to view inoperative guidance documents and see that they are inoperative; and

e. Including links or notations within inoperative guidance documents, pointing to any successor operative guidance documents.

4. Each agency should label inoperative guidance documents on its website to ensure that the public can readily understand the inoperative status of those guidance documents. The agency should consider adopting one or more of the following methods for publicly labeling its guidance documents as inoperative and then using the selected method or methods consistently:

a. Including a watermark that displays ''rescinded,'' ''partially rescinded,'' ''superseded,'' ''partially superseded,'' ''not in use,'' or similar terminology as appropriate across each page of an inoperative guidance document;

b. Including words such as ''rescinded,'' ''partially rescinded,'' ''superseded,'' ''partially superseded,'' ''not in use,'' or similar terminology as appropriate within a table in which links to inoperative guidance documents appear;

c. Using an appropriate method, including redline versions or lists of changes, to communicate changes made to a guidance document that has been partially rescinded or superseded;

d. Including a prominent stamp at the top of an inoperative guidance document noting that the document is inoperative and indicating the date it became inoperative;

e. Providing cross-references, using links or notations, from an inoperative guidance document to any successor versions of the guidance document, and vice versa; and

f. Publishing a notice of rescission or partial rescission of a guidance document on the agency's website and providing links to this notice in the inoperative guidance document.

Using Means in Addition to Agency Websites To Notify the Public When a Guidance Document Has Become Inoperative

5. At a minimum, each agency should notify the public that a guidance document has become inoperative in the same way that it notified the public that the operative version of the guidance document was issued or in the same way it would notify the public that an operative version of the guidance document has been issued under the agency's current policies.

6. Each agency should consider using one or more of the following methods to notify the public when a guidance document has become inoperative:

a. Publishing this notification in the **Federal Register** even when not required to do so by law;

b. Sending this notification over an agency listserv or to a similar mailing list to which the public can subscribe;

c. Providing this notification during virtual meetings, in-person meetings, or webinars involving the public; and

d. Publishing this notification in a press release.

7. In disseminating notifications as indicated in Paragraph 6, each agency should consider including cross-references to any successor guidance documents.

Administrative Conference Recommendation 2021–8

Technical Reform of the Congressional Review Act

Adopted December 16, 2021

The Congressional Review Act (CRA) [1] allows Congress to enact joint resolutions overturning rules issued by federal agencies. It also establishes special, fast-track procedures governing such resolutions. This Recommendation aims to address certain technical flaws in the Act and how it is presently administered.

The Hand-Delivery Requirement

The CRA provides that, before a rule can take effect, an agency must submit a report (an 801(a) report) to each house of Congress and the Comptroller General, who heads the Government Accountability Office (GAO). Receipt of the 801(a) report by each house of Congress and the Comptroller General also triggers the CRA's special, fast-track procedures.

The CRA says nothing about how agencies must deliver 801(a) reports to Congress or the Comptroller General. Congressional rules, however, currently require that 801(a) reports be hand-delivered to both chambers of Congress. Although the House allows members to electronically submit certain legislative documents and the Comptroller General permits agencies to electronically submit 801(a) reports, electronic submission is not generally regarded by Congress as an acceptable means of submitting 801(a) reports to Congress.

The hand-delivery requirement has been the subject of persistent criticism on the grounds that it is inefficient and outdated and results in exorbitant costs to federal agencies. Recent events have also shown that it is sometimes impracticable. For example, staffing disruptions related to the COVID–19 pandemic have, in some instances, meant that agencies had difficulty delivering 801(a) reports by hand and congressional officials have not been present in the Capitol to receive 801(a) reports via hand-delivery.

Time Periods for Introducing and Acting on Resolutions Under the CRA

Another source of persistent criticism of the CRA concerns the time periods during which members of Congress may introduce and act on joint resolutions overturning agencies' rules. Under the CRA, Congress's receipt of an 801(a) report begins a period of 60 days, excluding days when either chamber adjourns for more than three days, during

[1] 5 U.S.C. 801–08.

which any member of either chamber may introduce a joint resolution disapproving the rule.[2] Only rules submitted during this period, sometimes called the ''introduction period,'' are eligible for the CRA's special, fast-track procedures.

Calculating the introduction period can be confusing because it runs only on ''days of continuous session''—that is, on every calendar day *except* those falling in periods when, pursuant to a concurrent resolution, at least one chamber adjourns for more than three days. As a practical matter, there is seldom a difference between 60 days of continuous session and 60 calendar days because recent Congresses have made regular use of *pro forma* sessions to avoid adjournments of more than three days. Nevertheless, having to calculate the introduction period according to days of continuous session rather than calendar days can mislead people unfamiliar with the concept of days of continuous session or with recent Congresses' uses of *pro forma* sessions. Moreover, because modern Congresses invoke *pro forma* sessions in a way that negates almost any practical difference between days of continuous session and calendar days, the CRA's use of days of continuous session to calculate the introduction period accomplishes little beyond complicating the process of ascertaining the period's end date.

The introduction period is not the only complicated timing provision in the CRA. Another—sometimes called the ''lookback period''—provides that if, within 60 days of session in the Senate or 60 legislative days in the House after Congress receives a rule, Congress adjourns its annual session *sine die* (*i.e.,* for an indefinite period), the periods to submit and act on a disapproval resolution ''reset'' in their entirety in the next session of Congress.[3] In that next session, the reset period begins on the 15th day of the session in the Senate and the 15th legislative day in the House. The lookback period thus ensures that Congress has the full periods contemplated by the CRA to disapprove a rule, even if the rule is submitted near the end of a session of Congress.

The lookback period is anomalous and difficult to ascertain for several reasons. Whereas most of the time periods set forth in the CRA are calculated in calendar days, the lookback period is calculated using Senate session days and House legislative days—terms of art with which most people are unfamiliar.[4] The lookback period is also unpredictable because House legislative and Senate session days do not always correspond to each other, and the chambers regularly modify their anticipated calendar of session or legislative days, often with little advance notice. In addition, using legislative and session days to calculate the lookback period means interested members of Congress can strategically lengthen or shorten the period, either by having legislative or session days extend for multiple calendar days or cramming several legislative or session days into a single calendar day. Perhaps most troublesome: Whereas most time periods under the CRA are calculated prospectively—that is, by counting forward from an established starting date—the lookback period is calculated retrospectively—that is, by counting backward from an end date that is not known until Congress adjourns *sine die*. The lookback period's retrospective quality makes it effectively impossible to calculate in real time because the date on which the lookback period begins is only knowable once the period has closed. For those and other reasons, the public, members of Congress, congressional staff, and agencies sometimes struggle to anticipate when the CRA's lookback period will commence, or determine when it did commence, during a given session of Congress.[5]

Complicating matters still further, the CRA's key dates do not necessarily align in ways that make sense. For instance, the CRA expressly provides that the introduction and lookback periods commence when an 801(a) report is submitted to Congress. But other, related CRA time periods—such as the periods for discharging a joint resolution from committee (the discharge period) and for fast-tracking a rule through the Senate (the Senate action period)—commence running only after Congress receives the report *and* the rule is published in the **Federal Register**. This can lead to anomalous situations. Members of Congress might, for instance, timely introduce joint resolutions of disapproval under the CRA and yet be unable to avail themselves of the CRA's fast-track procedures.

At present, problems with synchronizing related CRA time windows are addressed primarily through interpretations from the Senate and House Parliamentarians. For example, the Senate Parliamentarian has interpreted the lookback and introduction periods to commence only after the 801(a) report has been submitted to Congress *and* the rule has been published in the **Federal Register**, thereby harmonizing the starting dates for those periods with the starting dates for the discharge and Senate action periods.

But relying on the Parliamentarians' interpretations creates its own problems. Chief among them is that the interpretations are not always easily accessible by the public. Although some of the Parliamentarians' interpretations are publicly available, many are not. Indeed, the formal rulings of the Senate Parliamentarian have not been published in decades. In the case of the interpretations that are collected and published, moreover, most members of the public are either unaware of the interpretations' existence or unsure how to access them.

Initiating CRA Review of Actions for Which Agencies Do Not Submit 801(a) Reports

Still another criticism of the CRA concerns what Congress should do to enable CRA review of agency actions for which agencies do not submit 801(a) reports. The CRA itself does not say what to do in those situations, even though studies show they arise frequently.

Absent statutory text addressing the subject, Congress has adopted a process through which it initiates review of such agency actions by requesting an opinion from the GAO. That process begins when members of Congress or committees request a GAO opinion on whether an agency action qualifies as a ''rule'' under the CRA. If GAO concludes that it does, a member or a committee provides for publication of the GAO opinion in the *Congressional Record*. Publication in the *Congressional Record* is then deemed to be the date that triggers the time periods for CRA review of the agency action.

Although that process has worked tolerably well as a response to the problem of unreported rules, it lacks a clear basis in the CRA's text. There are also aspects of it that warrant revisiting. For example, there is no time limit for using the current, de facto procedure, meaning Congress might use it to subject a decades-old action to CRA review.[6]

* * * * *

This Recommendation provides targeted, technical reforms to address many of the criticisms just identified—including criticisms of the hand-delivery requirement, criticisms prompted by the confusion surrounding key dates under CRA, and criticisms of the process for initiating CRA review of agency actions for which agencies do not submit 801(a) reports.

Recommendation

Requiring Electronic Submission of Reports Required by 5 U.S.C. 801(a)(1)(A)

1. Congress should amend 5 U.S.C. 801(a)(1)(A) to provide that the reports required by that provision (801(a) reports) be submitted to Congress and the Government Accountability Office (GAO) electronically rather than by hard copy.

2. In the event Congress does not enact the amendment described in Paragraph 1, both houses of Congress should modify their rules or policies to require electronic submission of 801(a) reports.

3. In the event that Congress, in some manner, mandates electronic submission of

[2] *Id.* 802(a).

[3] *Id.* 801(d)(1).

[4] A Senate session day is ''[a] calendar day on which [the Senate] convenes and then adjourns or recesses until a later calendar day,'' while a House legislative day commences when the House convenes and continues until the House adjourns. *See* Richard S. Beth & Valerie Heitshusen, Cong. Rsch. Serv., R42977, Sessions, Adjournments, and Recesses of Congress 2, 6 (2016), *available at https://crsreports.congress.gov/product/pdf/R/R42977.*

[5] In recent years, the lookback period has tended to commence between mid-July and early August, with the precise date varying from year to year. *See* Jesse M. Cross, Technical Reform of the Congressional Review Act 35 (Oct. 8, 2021) (draft report to the Admin. Conf. of the U.S.). In setting a commencement date for the lookback period, Congress may wish to consider the relationship between the CRA and what are sometimes called midnight rules (that is, rules published in the final months of an administration). *See* Admin. Conf. of the U.S., Recommendation 2012–2, *Midnight Rules,* 77 FR 47802 (Aug. 10, 2012).

[6] The role proposed for GAO in Paragraph 7 is applicable solely for purposes of triggering the expedited congressional review procedures under 5 U.S.C. 802; it does not have any impact on when a rule is effectuated under 5 U.S.C. 801. *Cf.* Bowsher v. Synar, 478 U.S. 714 (1986).

801(a) reports, it should establish procedures governing how agencies may electronically submit 801(a) reports.

Simplifying and Clarifying the Procedures for Determining Relevant Dates Under 5 U.S.C. 801 and 802

4. Congress should simplify 5 U.S.C. 801(d)(1) by setting a fixed month and day after which, each year, rules submitted to Congress under the Congressional Review Act (CRA) will be subject to the CRA's review process during the following session of Congress.

5. Congress should amend 5 U.S.C. 802(a), which establishes the period during which joint resolutions of disapproval under the CRA may be introduced, to either:

a. Eliminate the requirement that joint resolutions be introduced during a particular period;

b. Align the dates on which the period commences and ends with the period during which the Senate may act on a proposed joint resolution of disapproval submitted under the CRA; or

c. Align the date on which the period commences with the period during which the Senate may so act and provide that such period ends a fixed number of calendar days from such commencement.

6. Congress should review and, where appropriate, enact Parliamentarian interpretations that bear on calculating deadlines under the CRA, either as statutory law or as formal rules of the houses. If Congress does not enact those interpretations into statutory law, it should ensure that they are published in a manner that is accessible to the public.

Initiating Review of Agency Actions for Which Agencies Do Not Submit 801(a) Reports

7. If Congress continues the practice of requesting an opinion from the GAO on whether an agency action, for which the agency did not submit an 801(a) report, qualifies as a ''rule'' under the CRA to initiate the expedited process for congressional review outlined in 5 U.S.C. 802, it should provide a transparent mechanism for doing so. To that end, Congress should amend Chapter 8 of title 5 of the *United States Code* to enact the process it currently relies on to initiate CRA review (while clarifying that such amendment is solely for purposes of implementing 5 U.S.C. 802). Under such process:

a. Any member of Congress or committee may request the opinion of the GAO on whether an agency action qualifies as a ''rule'' under the CRA;

b. After soliciting views from the agency, GAO responds by issuing an opinion as to whether the agency action in question qualifies as a ''rule'';

c. If GAO concludes that the action amounts to a rule under the CRA, any member of Congress or committee may provide for publication of the GAO opinion in the *Congressional Record;* and

d. Publication of the GAO opinion in the *Congressional Record* is the date that triggers the time periods for CRA review of the agency rule.

8. If Congress amends the CRA to enact the procedure described in Paragraph 7, it should impose time limits within which the steps in Paragraph 7 must be taken.

Administrative Conference Recommendation 2021–9

Regulation of Representatives in Agency Adjudicative Proceedings

Adopted December 16, 2021

Many agencies have adopted rules governing the participation and conduct of attorneys and non-attorneys who represent parties in adjudicative proceedings. These rules may address a wide array of topics, including who can represent parties in adjudications, how representatives must conduct themselves, and how the agency enforces rules of conduct.[1] Some agencies have drafted their own rules. Others have adopted rules developed by state bar associations or the American Bar Association's (ABA) *Model Rules of Professional Conduct.* Agencies provide public access to their rules in different ways, including publishing them in the **Federal Register** and *Code of Federal Regulations* and posting them on their websites. Some agencies have provided explanatory materials to help representatives, parties, and the public understand how the rules operate.

Agency authority to set qualifications for who may serve as a representative depends on whether the potential representative is an attorney or non-attorney. For attorneys, the generally applicable Agency Practice Act provides, with some exceptions, that ''any individual who is a member in good standing of the bar of the highest court of a State may represent a person before an agency,''[2] though some statutes authorize agencies to impose additional qualification requirements. Agencies generally have greater discretion under the Administrative Procedure Act and agency- or program-specific statutes to determine whether persons who are not attorneys may act as representatives and, if they may, to establish the qualifications for doing so.

As a general matter, agencies have legal authority to establish rules governing the conduct of representatives and to take actions against representatives found to have violated such rules.[3] Courts have consistently found such authority inherent in agencies' general rulemaking power or their power to protect the integrity of their processes.[4] Agencies' disciplinary authority is not limitless, however, and agencies must determine what their governing statutes allow.

Agencies that adopt rules governing representatives will need to make a number of decisions as they decide the type of rules to adopt and how they will apply those rules. They must determine whether the rules will apply only to attorney representatives or will also apply to other representatives. They must decide whether to borrow language from rules drafted by other entities (state bars, ABA) or to draft their own rules. They must determine the particular conduct that the rules will regulate and whether to apply the same rules to attorneys and non-attorneys. And if they decide to adopt rules governing who may practice before the agency, they must ensure that they comply with the Agency Practice Act for rules applied to attorneys and determine the qualification standards, if any, they will establish for non-attorneys.

Once agencies have decided to adopt rules, they also must determine how to enforce those rules. Agencies may enforce rules in various ways, ranging from reminders or warnings to more serious actions, including disqualifying a representative from appearing in the current adjudication or future adjudications or imposing a monetary penalty. Agencies must determine that they have the legal authority to undertake any such actions. Agencies also must determine whether to implement a program for reciprocal discipline, which involves imposing discipline on a representative found to have engaged in misconduct by another jurisdiction, or for referral procedures, which involve reporting attorneys' misconduct to another jurisdiction for purposes of taking possible disciplinary action.

Agencies that have adopted rules must ensure that representatives, parties, and the public can easily access the rules. Agencies also must decide whether to provide additional explanatory materials and, if so, ensure that those are also easily accessible.

This Recommendation recognizes that agency adjudicative proceedings vary widely in their purpose, complexity, and governing law. Some processes are trial-like; others are informal. Some are adversarial; others are non-adversarial. Given the extensive variation in agencies' needs and available resources, this Recommendation focuses primarily on setting forth the various options agencies should consider in deciding whether to adopt rules and deciding on the content of those rules. It takes no position on whether agencies should allow non-attorney representatives. For agencies that decide to adopt rules for attorneys and, if they elect to do so, for non-attorneys, the Recommendation offers best practices for seeking to ensure that those rules are disseminated widely and that representatives, parties, and the public can understand the rules and how agencies go about enforcing them.

Although the Recommendation does not endorse harmonization of rules for its own sake, it does urge agencies to consider whether achieving greater uniformity among different adjudicative components within the agency or even across adjudicative components of multiple agencies might prove valuable for representatives who practice before a variety of components or agencies. It also recommends that the Administrative

[1] *See* George M. Cohen, Regulation of Representatives in Agency Adjudicative Proceedings (Dec. 3, 2021) (report to the Admin. Conf. of the U.S.).

[2] 5 U.S.C. 500(b).

[3] *See, e.g.,* 5 U.S.C. 301.

[4] *See, e.g., Checkovsky* v. *SEC,* 23 F.3d 452, 456 (D.C. Cir. 1994); *Davy* v. *SEC,* 792 F.2d 1418, 1421 (9th Cir. 1986); *Polydoroff* v. *ICC,* 773 F.2d 372, 374 (D.C. Cir. 1985); *Touche Ross & Co.* v. *SEC,* 609 F.2d 570, 580–82 (2d Cir. 1979); *Koden* v. *U.S. DOJ,* 564 F.2d 228, 233 (7th Cir. 1977).

Conference's Office of the Chairman consider preparing model rules that agencies can use when drafting their own rules.

Recommendation

Adoption of Rules Governing Participation and Conduct

1. For federal agency adjudication systems in which parties are represented—either by attorneys or non-attorney representatives—agencies should consider adopting rules governing the participation and conduct of representatives in adjudicative proceedings to promote the accessibility, fairness, integrity, and efficiency of adjudicative proceedings.

Rules of Conduct

2. Agencies should consider whether to adopt or reference rules promulgated by other authorities or professional organizations or instead draft their own rules. Agencies should ensure that the rules are appropriate for the adjudicative proceedings they conduct and consider whether any modifications to adopted rules should be included. Agencies should consider whether any rules applicable to attorneys should be applied to non-attorneys and whether they should be modified before doing so.

3. Possible topics that agencies might consider in their rules include representatives' actions that are likely to occur during a particular adjudication and actions that might occur outside a particular adjudication but that might still adversely affect the conduct of agency adjudications. Topics agencies might consider include the following:

a. Engaging in conduct that disrupts or is intended to disrupt an adjudication;

b. Making unauthorized ex parte contacts with agency officials;

c. Engaging in representation of a client that conflicts with other interests, including representation of another client, or the attorney's personal interests;

d. Filing frivolous claims or asserting frivolous defenses;

e. Engaging in conduct that is prejudicial to the administration of justice, including conduct not limited to that occurring during an adjudication;

f. Failing to provide competent representation;

g. Improperly withdrawing from client representation;

h. Unreasonably delaying the conduct of an adjudication;

i. Making a material intentional false statement;

j. Improperly seeking to influence the conduct of a judge or official;

k. Being convicted of a crime or being subject to an official finding of a civil violation that reflects adversely on the attorney's fitness to represent clients before the agency; and

l. Knowingly disobeying or attempting to disobey agency rules (including conduct rules) or adjudicators' directions, or knowingly assisting others in doing so.

4. Agencies should consider whether divergence among rules governing different types of adjudicative proceedings would create needless complexity in practicing before the agency. This might entail harmonizing rules among different components of the agency. It might also involve harmonization of style or language across rules as well as cross-referencing of other rules of the agency. Agencies should also consider whether to harmonize rules across agencies, especially in cases in which the same representatives commonly appear before a group of agencies (*e.g.,* financial agencies).

Agency Action in Response to Allegations of a Violation of Rules

5. Agencies should specify in their rules how they will respond to an allegation of a violation of their conduct rules, and they should publish these rules consistent with Paragraphs 9 through 12. Among other topics, agencies should address:

a. Who can make a complaint and how to make it;

b. How notice of a complaint should be provided to the representative who is the subject of the complaint;

c. Who adjudicates the complaint;

d. The procedure for adjudicating the complaint, including any rules governing the submission of evidence and the making of arguments;

e. The manner in which a decision will be issued, including any applicable timeline for issuing a decision;

f. Procedures for appealing a decision;

g. Who is responsible for enforcing the decision within the agency and communicating the decision to other relevant authorities; and

h. The process for identifying and dismissing complaints that are frivolous, repetitive, meant to harass, or meant primarily to delay agency action, including any consequences for persons filing such complaints.

Agency Action in Response to a Violation of Rules

6. Rules should address what actions an agency may take in the case of a violation of the rules consistent with their authority to do so, including informal warnings short of sanctions and the range of available sanctions.

7. For rules applicable to attorneys, agencies should consider whether to adopt any reciprocal disciplinary procedures or referral procedures.

Who Can Practice Before Agencies

8. Agencies should, in compliance with the Agency Practice Act (5 U.S.C. 500), only establish additional rules governing which attorney representatives can practice before the agencies if authorized to do so by separate statute. With respect to non-attorneys, agencies should determine what rules, if any, they will establish to govern who can practice before the agencies.

Transparency

9. Agencies should publish their rules governing representatives' conduct in the **Federal Register** and codify them in the *Code of Federal Regulations.*

10. When agencies adopt rules promulgated by another entity, which may in some instances be copyrighted, they should ensure that the rules are reasonably available to the public such as by providing links on the agencies' websites or other mechanisms for easily accessing those rules.

11. Agencies should also publish their rules governing representatives' conduct on a single web page or in a single document on their websites and clearly label them using a term such as ''Rules of Conduct for Representatives.'' The agency should indicate clearly whether the rules apply only to attorneys, non-attorneys, or both.

12. On the web page or in the document described in Paragraph 11, agencies should also publish information concerning qualifications for representatives (including for non-attorneys as applicable), how to file a complaint, and a summary of the disciplinary process.

13. On the web page or in the document described in Paragraph 11, agencies should consider providing comments, illustrations, and other explanatory materials to help clarify how the rules work in practice.

14. Agencies should consider publishing disciplinary actions, or summaries of them, on the web page or in the document described in Paragraph 11 so as to promote transparency regarding the types of conduct that lead to disciplinary action. When necessary to preserve recognized privacy interests, the agency may consider redacting information about particular cases or periodically providing summary reports describing the rules violated, the nature of the misconduct, and any actions taken.

Model Rules

15. ACUS's Office of the Chairman should consider promulgating model rules of conduct that would address the topics in this Recommendation. The model rules should account for variation in agency practice and afford agencies the flexibility to determine which rules apply to their adjudicative proceedings. In doing so, the Office of the Chairman should seek the input of a diverse array of agency officials and members of the public, including representatives who appear before agencies, and the American Bar Association.

Administrative Conference Recommendation 2021–10

Quality Assurance Systems in Agency Adjudication

Adopted December 16, 2021

A quality assurance system is an internal review mechanism that agencies use to detect and remedy both problems in individual adjudications and systemic problems in agency adjudicative programs. Through well-designed and well-implemented quality assurance systems, agencies can proactively identify both problems in individual cases and systemic problems, including misapplied legal standards, inconsistent applications of the law by different adjudicators, procedural violations, and systemic barriers to participation in adjudicatory proceedings (such as denials of reasonable accommodation). Identifying such problems enables agencies to ensure adherence to their own policies and improve the fairness (and perception of fairness), accuracy, inter-

decisional consistency, timeliness, and efficiency of their adjudicative programs.[1]

In 1973, the Administrative Conference recommended the use of quality assurance systems to evaluate the accuracy, timeliness, and fairness of adjudication of claims for public benefits or compensation.[2] Since then, many agencies, including those that adjudicate other types of matters, have implemented or considered implementing quality assurance systems, often to supplement other internal review mechanisms such as agency appellate systems.[3] Unlike agencies' appellate systems, quality assurance systems are not primarily concerned with error correction in individual cases, and they may assess numerous adjudicatory characteristics that are not typically subject to appellate review, such as effective case management. Nor are they avenues for collateral attack on individual adjudicatory dispositions. Also, quality assurance systems are distinct from agencies' procedures that deal with allegation of judicial misconduct. This Recommendation accounts for these developments and provides further guidance for agencies that may wish to implement new or to improve existing quality assurance systems.

How agencies structure their quality assurance systems can have important consequences for their success. For example, quality assurance systems that overemphasize timeliness as a measure of quality may overlook problems of decisional accuracy. Quality assurance personnel must have the expertise and judgment necessary to accurately and impartially perform their responsibilities. Quality assurance personnel must use methods for selecting and reviewing cases that allow them to effectively identify case-specific and systemic problems. Agencies must determine how they will use information collected through quality assurance systems to correct problems that threaten the fairness (and perception of fairness), accuracy, inter-decisional consistency, timeliness, and efficiency of their adjudicative programs. Agencies also must design quality assurance systems to comply with all applicable requirements, such as the statutory prohibition against rating the job performance of or granting any monetary or honorary award to an administrative law judge.[4]

There are many methods of quality review that agencies can use, independently or in combination, depending upon the needs and goals of their adjudicative programs. For example, agencies can adopt a peer review process by which adjudicators review other adjudicators' decisions and provide feedback before decisions are issued. Agencies can prepare and circulate regular reports for internal use that describe systemic trends identified by quality assurance personnel. Agencies can also use information from quality assurance systems to identify training needs and clarify or improve policies.

Agencies, particularly those with large caseloads, may also benefit from using data captured in electronic case management systems. Through advanced data analytics and artificial intelligence techniques (*e.g.,* machine-learning algorithms), agencies can use such data to rapidly and efficiently identify anomalies and systemic trends.[5]

This Recommendation recognizes that agencies have different quality assurance needs and available resources. What works best for one agency may not work for another. What quality assurance techniques agencies may use may also be constrained by law. Agencies must take into account their own unique circumstances when implementing the best practices that follow.

Recommendation

Review and Development of Quality Assurance Standards

1. Agencies with adjudicative programs that do not have quality assurance systems—that is, practices for assessing and improving the quality of decisions in adjudicative programs—should consider developing such systems to promote fairness, the perception of fairness, accuracy, inter-decisional consistency, timeliness, efficiency, and other goals relevant to their adjudicative programs.

2. Agencies with adjudicative programs that have quality assurance systems should review them in light of the recommendations below.

3. Agencies' quality assurance systems should assess whether decisions and decision-making processes:

a. Promote fairness and the appearance of fairness;

b. Accurately determine the facts of the individual matters;

c. Correctly apply the law to the facts of the individual matters;

d. Comply with all applicable requirements;

e. Are completed in a timely and efficient manner; and

f. Are consistent across all adjudications of the same type.

4. Agencies should consider both reviews that address decisions' likely outcomes before reviewing tribunals, and reviews of adjudicators' decisional reasoning, which address policy compliance, consistency, and fairness.

5. A quality assurance system should review the work of adjudicators and all related personnel who have important roles in the adjudication of cases, such as attorneys who assist in drafting decisions, interpreters who assist in hearings, and staff who assist in developing evidence.

6. Analyzing decisions of agency appellate and judicial review bodies may help quality assurance personnel assess whether the adjudicatory process is meeting the goals outlined in Paragraph 3. But agencies should not rely solely on such decisions to set and assess standards of quality because appealed cases may not be representative of all adjudications.

Quality Assurance Personnel

7. Agencies should ensure that quality assurance personnel can perform their functions in a manner that is, and is perceived as, impartial, including being able to perform such functions without pressure, interference, or expectation of employment consequences from the personnel whose work they review.

8. Agencies should ensure that quality assurance personnel understand all applicable substantive and procedural requirements and have the expertise necessary to review the work of all personnel who have important roles in adjudicating cases.

9. Agencies should ensure that quality assurance personnel have sufficient time to fully and fairly perform their assigned functions.

10. Agencies should consider whether quality assurance systems should be staffed by permanent or temporary personnel, or some combination of the two. Personnel who perform quality assurance functions on a permanent basis may gain more experience and institutional knowledge over time than will personnel who perform on a temporary basis. Personnel who perform quality assurance on a temporary basis, however, may be more likely to contribute different experiences and new perspectives.

Timing of and Process for Quality Assurance Review

11. Agencies should consider at what points in the adjudication process quality assurance review should occur. In some cases, review that occurs before adjudicators issue their decisions, or during a period when agency appellate review is available, could allow errors to be corrected before decisions take effect. However, agencies should take care that pre-disposition review does not interfere with adjudicators' qualified decisional independence and comports with applicable restrictions governing ex parte communications, internal separation of decisional and adversarial personnel, and decision making based on an exclusive record.

12. Agencies should consider implementing peer review programs in which adjudicators can provide feedback to other adjudicators.

13. Agencies should consider a layered approach to quality assurance that employs more than one methodology. As resources allow, this may include formal quality assessments and informal peer review on an individual basis, sampling and targeted case selection on a systemic basis, and case management systems with automated adjudication support tools.

14. In selecting cases for quality assurance review, agencies should consider the following methods:

a. Review of every case, which may be useful for agencies that adjudicate a small

[1] Daniel E. Ho, David Marcus & Gerald K. Ray, Quality Assurance Systems in Agency Adjudication (Nov. 30, 2021) (report to the Admin. Conf. of the U.S.).

[2] Admin. Conf. of the U.S., Recommendation 73–3, *Quality Assurance Systems in the Adjudication of Claims of Entitlement to Benefits or Compensation,* 38 FR 16840 (June 27, 1973).

[3] Admin. Conf. of the U.S., Recommendation 2020–3, *Agency Appellate Systems,* 86 FR 6618 (Jan. 22, 2021).

[4] *See, e.g.,* 5 U.S.C. 4301; 5 CFR 930.206.

[5] Admin. Conf. of the U.S., Statement #20, *Agency Use of Artificial Intelligence,* 86 FR 6616 (Jan. 22, 2021); Admin. Conf. of the U.S., Recommendation 2018–3, *Electronic Case Management in Federal Administrative Adjudication,* 83 FR 30686 (June 29, 2018).

number of cases but impractical for agencies that adjudicate a high volume of cases;

b. Random sampling, which can be more efficient for agencies that decide a high volume of cases but may cause quality assurance personnel to spend too much time reviewing cases that are unlikely to present issues of concern;

c. Stratified random sampling, a type of random sampling that over-samples cases based on chosen characteristics, which may help quality assurance personnel focus on specific legal issues or factual circumstances associated with known problems, but may systematically miss certain types of problems; and

d. Targeted selection of cases, which allows agencies to directly select decisions that contain specific case characteristics and may help agencies study known problems but may miss identifying other possible problems.

Data Collection and Analysis

15. Agencies, particularly those with large caseloads, should consider what data would be useful and how data could be used for quality assurance purposes. Agencies should ensure that, for each case, an electronic case management or other system includes the following information:

a. The identities of adjudicators and any personnel who assisted in evaluating evidence, writing decisions, or performing other case-processing tasks;

b. The procedural history of the case, including any actions and outcomes on administrative or judicial review;

c. The issues presented in the case and how they were resolved; and

d. Any other data the agency determines to be helpful.

16. Agencies should regularly evaluate their electronic case management or other systems to ensure they are collecting the data necessary to assess and improve the quality of decisions in their programs.

17. Agencies, particularly those with large caseloads, should consider whether to use data analytics and artificial intelligence (AI) tools to help quality assurance personnel identify potential errors or other quality issues. Agencies should ensure that they have the technical capacity, expertise, and data infrastructure necessary to build and deploy such tools; that any data analytics or AI tools the agencies use support, but do not displace, evaluation and judgment by quality assurance personnel; and that such systems comply with legal requirements for privacy and security and do not create or exacerbate harmful biases.

Use of Quality Assurance Data and Findings

18. Agencies should not use information gathered through quality assurance systems in ways that could improperly influence decision making or personnel matters.

19. Agencies should provide, consistent with Paragraph 11, individualized feedback for adjudicators and other personnel who assist in evaluating evidence, writing decisions, or performing other case-processing tasks within a reasonable amount of time and include any relevant positive and negative feedback.

20. Agencies should establish regular communications mechanisms to facilitate the dissemination of various types of quality assurance information within the agency. Agencies should:

a. Communicate information about systemic recurring or emerging problems identified by quality assurance systems to all personnel who participate in the decision-making process and to training personnel;

b. Communicate, as appropriate, with agency rule-writers and operations support personnel to allow them to consider whether recurring problems identified by quality assurance systems should be addressed or clarified by rules, operational guidance, or decision support tools; and

c. Consider whether to communicate information to appellate adjudicators or other agency officials who are authorized to remedy problems identified by quality assurance systems in issued decisions.

Public Disclosure and Transparency

21. Agencies should provide access on their websites to all rules and any associated explanatory materials that apply to quality assurance systems, including standards for evaluating the quality of agency decisions and decision-making processes.

22. Agencies should consider whether to publicly disclose data in case management systems in a de-identified form (*i.e.,* with all personally identifiable information removed) to enable continued research by individuals outside of the agency.

Assessment and Oversight

23. Agencies with quality assurance systems should assess periodically whether those systems achieve the goals they were intended to accomplish, including by affirmatively soliciting feedback from the public, adjudicators, and other agency personnel concerning the functioning of their quality assurance systems.

[FR Doc. 2022–00463 Filed 1–11–22; 8:45 am]

BILLING CODE 6110–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the New Mexico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the New Mexico Advisory Committee (Committee) will hold a meeting via videoconference on Tuesday, January 25, 2022, from 12:00 p.m. to 1:00 p.m. Mountain Time for the purpose of selecting the Committee's first project topic.

DATES: The meeting will be held on:

- Tuesday, January 25, 2022, from 12:00 p.m. to 1:00 p.m. MT.

Public Registration Link: https://tinyurl.com/2p96f52c.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO), at *bpeery@usccr.gov* or (202) 701–1376.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the public registration link listed above. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 300 N Los Angeles St., Suite 2010, Los Angeles, CA 90012 or emailed to Brooke Peery at *bpeery@usccr.gov*.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlGAAQ*.

Please click on the ''Meeting Details'' and ''Documents'' links. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or street address.

Agenda

I. Welcome & Roll Call

II. Approval of Minutes

III. Discussion

IV. Public Comment

V. Adjournment

Dated: January 7, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–00466 Filed 1–11–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Chemical Weapons Convention Declaration and Report Handbook and Forms & Chemical Weapons Convention Regulations (CWCR)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 14, 2022.

ADDRESSES: Interested persons are invited to submit comments by email to Mark Crace, IC Liaison, Bureau of Industry and Security, at *mark.crace@bis.doc.gov* or to *PRAcomments@doc.gov*). Please reference OMB Control Number 0694–0091 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Mark Crace, IC Liaison, Bureau of Industry and Security, phone 202–482–8093 or by email at *mark.crace@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Chemical Weapons Convention ((CWC or Convention) is a multilateral arms control and non-proliferation treaty that seeks to achieve an international ban on chemical weapons (CW). The CWC prohibits, inter alia, the use, development, production, acquisition, stockpiling, retention, and direct or indirect transfer of chemical weapons. Furthermore, each State Party to the Convention is required to make initial and annual declarations on certain facilities which produce, process, consume, transfer, or import/export toxic chemicals and their precursors as specified in three lists or schedules of chemicals contained in the Convention's Annex on Chemicals. In addition to traditional CW agents, the Schedules include chemicals that have both large-scale commercial uses and CW applications (referred to as ''dual-use chemicals''). Information is also required on facilities which produce a broad class of chemicals referred to as ''Unscheduled Discrete Organic Chemicals,'' or ''UDOCs.'' Finally, information is also required from facilities subject to inspection by the Organization for the Prohibition of Chemical Weapons (OPCW). This information is in addition to information provided in initial and annual declarations.

II. Method of Collection

Electronic or paper.

III. Data

OMB Control Number: 0694–0091.

Form Number(s): Form 1–1, Form, 1–2, Form 1–2A, Form 1–2B.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 779.

Estimated Time per Response: 10 minutes to 12 hours.

Estimated Total Annual Burden Hours: 14,813.

Estimated Total Annual Cost to Public: 51,300.

Respondent's Obligation: Mandatory.

Legal Authority: Executive Order 13128 authorizes the Department of Commerce (DOC) to issue regulations necessary to implement the Act and U.S. obligations under Article VI and related provisions of the Convention.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–00392 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Southeast Region Vessel Monitoring System (VMS) and Related Requirements

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to the Office of Management and Budget (OMB).

DATES: To ensure consideration, comments regarding this proposed

information collection must be received on or before March 14, 2022.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0554 in the subject line of your comments. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Carolyn Sramek, Investigative Support Program Manager, National Marine Fisheries Service (NMFS), Office of Law Enforcement, Southeast Division, 263 13th Avenue South, St. Petersburg, FL 33701, (727) 824–5346, *Carolyn.Sramek@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The NMFS, Office of Law Enforcement, Southeast Enforcement Division is submitting this request for an extension of a currently approved information collection.

The Magnuson-Stevens Fishery Conservation and Management Act authorizes the Gulf of Mexico Fishery Management Council (Gulf Council) and South Atlantic Fishery Management Council (South Atlantic Council) to prepare and amend fishery management plans for any fishery in Federal waters under their respective jurisdictions. NMFS and the Gulf Council manage the reef fish fishery in the Gulf of Mexico (Gulf) under the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico. NMFS and the South Atlantic Council manage the fishery for rock shrimp in the South Atlantic under the FMP for the Shrimp Fishery in the South Atlantic Region. The vessel monitoring system (VMS) regulations for the Gulf reef fish fishery and the South Atlantic rock shrimp fishery may be found at 50 CFR 622.28 and 622.205, respectively.

The FMPs and the implementing regulations contain several specific management areas where fishing is restricted or prohibited to protect habitat or spawning aggregations, or to control fishing pressure. Unlike size, bag, and trip limits, where the catch can be monitored on shore when a vessel returns to port, area restrictions require at-sea enforcement. However, at-sea enforcement of offshore areas is difficult due to the distance from shore and the limited number of patrol vessels, resulting in a need to improve enforceability of area fishing restrictions through remote sensing methods. In addition, all fishing gears are subject to some area fishing restrictions. Because of the sizes of these areas and the distances from shore, the effectiveness of enforcement through over flights and at-sea interception is limited. An electronic VMS allows a more effective means to monitor vessels for intrusions into restricted areas.

The VMS provides effort data and significantly aids in enforcement of areas closed to fishing. All position reports are treated in accordance with NMFS existing guidelines for confidential data. As a condition of authorized fishing for or possession of Gulf reef fish or South Atlantic rock shrimp in or from Federal waters, vessel owners or operators subject to VMS requirements must allow NMFS, the United States Coast Guard, and their authorized officers and designees, access to the vessel's position data obtained from the VMS.

The information collected on the ''Vessel Monitoring System Installation and Activation Certification for the Reef Fish Fishery of the Gulf of Mexico'' form provides NMFS assurance that vessels are compliant with the requirements to install and activate an approved VMS unit. Information collected on the ''Vessel Monitoring System Mobile Transceiver Unit (MTU) Power-Down Exemption Request for Vessels in the Gulf of Mexico Reef Fish Fishery'' form provides information that allows NMFS to exempt a vessel from their the VMS reporting requirement under specific criteria.

II. Method of Collection

Information about VMS unit installation and activation and power-down exemption requests are currently collected via paper form; trip declarations and timed position reports are submitted via VMS satellite transmission.

III. Data

OMB Control Number: 0648–0544.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,027.

Estimated Time per Response: VMS unit installation, 5 hours; installation and activation checklist, 20 minutes; power-down exemption request, 5 minutes; transmission of fishing activity report, 1 minute; and annual maintenance, 2 hours.

Estimated Total Annual Burden Hours: 2,499 hours.

Estimated Total Annual Cost to Public: $1,466,255 in start-up, transfer, operations, and maintenance costs.

Respondent's Obligation: Submission of the Installation and Activation certification is and mandatory. Transmission of fishing activity report is mandatory. Submission of a Powerdown Exemption Authorization request is required to obtain or retain benefits.

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

IV. Request for Comments

We are soliciting public comments to permit the Agency to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Agency, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this information collection. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–00405 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB715]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel and Mackerel, Squid, and Butterfish Advisory Panel will hold a joint public webinar meeting.

DATES: The meeting will be held on Tuesday, February 15, 2022, from 2:30 p.m. until 4 p.m.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the calendar prior to the meeting at *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel will meet via webinar jointly with the Mackerel, Squid, and Butterfish Advisory Panel. The purpose of this meeting is to review and provide feedback on sea turtle trawl bycatch issues and the ongoing research on mitigation measures in the Greater Atlantic Region. Fisheries bycatch is a primary threat to endangered and threatened sea turtles and occurs at high levels in trawl fisheries such as croaker, longfin squid, and summer flounder. NMFS and other partners have been investigating mitigation measures such as gear modifications called Turtle Excluder Devices (TEDs) or limited tow durations to reduce mortality of incidentally bycaught sea turtles.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00424 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB712]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Coastal Pelagic Species Management Team will hold two public meetings.

DATES: The meetings will be held Wednesday, February 2, 2022, from 10 a.m. to 4 p.m. Pacific Standard Time or until business for the day has been completed, and Tuesday, February 8, 2022, from 10 a.m. to 4 p.m. Pacific Standard Time or until business for the day has been completed.

ADDRESSES: These meetings will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer, Pacific Council; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The primary purpose of these online meetings is to discuss and potentially develop work products for the Pacific Council's April and June 2022 meetings. Topics will include Coastal Pelagic Species (CPS) Fishery Management Plan (FMP) revisions to remove the Active and Monitored management categories, FMP housekeeping updates, and the scope of Phase 2 of the essential fish habitat review. Other items on the Pacific Council's April and June agendas may be discussed as well. Meeting agendas will be available on the Pacific Council's website in advance of the meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00422 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB714]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ad Hoc Marine Planning Committee will hold a public meeting.

DATES: The meeting will be held Tuesday February 1, 2022, from 10 a.m. to 4 p.m. Pacific Standard Time or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer, Pacific Council; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The primary purpose of this online meeting is to discuss and development of a policy guidance document for Council consideration at its March 2022 meeting. Other marine planning topics or emerging issues may be discussed such as upcoming comment opportunities on offshore wind energy planning projects and consideration of the NOAA Aquaculture Opportunity Area Atlas for the Southern California Bight. The meeting agenda will be available on the Pacific Council's website in advance of the meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00423 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB685]

New England Fishery Management Council; Public Meeting; Correction

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

ACTION: Notice of addendum to a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public joint meeting of its Habitat Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, January 18, 2022 at 9 a.m.

ADDRESSES: All meeting participants and interested parties can register to join the webinar at *https://attendee.gotowebinar.com/register/6570510383641205518.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The original notice published on January 6, 2022 (87 FR 762). This correction notice adds the following additional agenda item:

The committee plans to discuss a clam industry request for secretarial emergency action related to the Great South Channel Habitat Management Area, as well as a related meeting between New England Fishery Management Council and Mid-Atlantic Fishery Management Council leadership.

All other information that was previously published remains unchanged.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00420 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB706]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Scallop Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Friday, January 28, 2022, at 9 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/5780878516104199952.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will receive an update on the implementation timeline for Framework Adjustment 34 and Amendment 21. They plan to review 2022 scallop workload based on priorities approved by the Council at its December meeting and discuss potential timelines for completing each task. The committee will review a draft scoping document that will be used to assess: (1) The need for a leasing program, and (2) what should the leasing program consider. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00426 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB703]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 77 Highly Migratory Species (HMS) Hammerhead Sharks Post Data Workshop Webinar 2.

SUMMARY: The SEDAR 77 assessment of the Atlantic stocks of hammerhead sharks will consist of a stock identification (ID) process, data webinars/workshop, a series of assessment webinars, and a review workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 77 HMS Hammerhead Sharks Post Data Workshop Webinar 2 has been scheduled for Monday, January 31, 2022, from 12 p.m. until 3 p.m. ET.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Registration is available online at: *https://attendee.gotowebinar.com/register/1719527754187205645.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 77 HMS Hammerhead Shark Post Data Workshop Webinar 2 are as follows:

Discuss any data issues or concerns remaining from the workshop. Finalize all decisions required for the data workshop report.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00421 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB716]

Caribbean Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Caribbean Fishery Management Council (CFMC) will hold the 177th public meeting to address the items contained in the tentative agenda included in the **SUPPLEMENTARY INFORMATION**. The meeting will be an in-person/virtual hybrid meeting.

DATES: The 177th CFMC public meeting will be held on February 9, 2022, from 9 a.m. to 4:15 p.m. AST.

ADDRESSES: The meeting will be held at the Courtyard by Marriott Isla Verde Beach Resort, 7012 Boca de Cangrejos Avenue, Carolina, Puerto Rico 00979. See **SUPPLEMENTARY INFORMATION** for joining the meeting virtually.

FOR FURTHER INFORMATION CONTACT: Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903; telephone: (787) 398–3717.

SUPPLEMENTARY INFORMATION: You may join the 177th CFMC public meeting (virtual) via Zoom, from a computer, tablet or smartphone by entering the following address:

Join Zoom Meeting: https://us02web.zoom.us/j/83060685915?pwd=VmVsc1orSUtKck8xYk1XOXNDY1ErZz09.

Meeting ID: 830 6068 5915.

Passcode: 995658.

One tap mobile:

+17879451488,,83060685915#,,,,,,0#,,995658# Puerto Rico

+17879667727,,83060685915#,,,,,,0#,,995658# Puerto Rico

Dial by your location:

+1 787 945 1488 Puerto Rico

+1 787 966 7727 Puerto Rico

+1 939 945 0244 Puerto Rico

Meeting ID: 830 6068 5915.

Passcode: 995658.

In case there are problems and we cannot reconnect via Zoom, the meeting will continue using GoToMeeting.

You can join the meeting from your computer, tablet or smartphone. *https://global.gotomeeting.com/join/971749317.* You can also dial in using your phone: United States: +1 (408) 650–3123 Access Code: 971–749–317.

The following items included in the tentative agenda will be discussed:

9 a.m.–9:30 a.m.

—Welcome—Marcos Hanke, CFMC Chair
—Roll call
—Executive Director's Report

Panel I—Marine Protected Areas (MPAs): Legal, Scientific and Educational Aspects—Graciela García-Moliner, Chair

9:30 a.m.–9:45 a.m.

—Legal Aspects of Federal MPAs in Magnuson Stevens Act—Jocelyn D'Ambrosio, NOAA Office of General Counsel

9:45 a.m.–10 a.m.

—Inventory of U.S. Caribbean MPAs Diana Beltrán, URI

10 a.m.–10:15 a.m.

—Past, Present and Future Studies on MPAs in the U.S. Caribbean—SEFSC

10:15 a.m.–10:30 a.m.

—CFMC's MPAs and Connectivity—Graciela García-Moliner and Miguel Canals, UPRM

10:30 a.m.–10:45 a.m.

—Area-Based Management of Blue Water Fisheries: Current Knowledge and Research Needs—Mark Fitchett, Western Pacific Fishery Management Council

10:45 a.m.–11 a.m.

—Outreach and Education on MPAs—Alida Ortíz, CFMC Outreach and Education Advisory Panel Chair

11 a.m.–12 p.m.

—Discussion and Recommendations

12 p.m.–1 p.m.

—Lunch Break

Panel II—Marine Protected Areas: Governance and Industry Perspectives—Julian Magras, Chair

1 p.m.–1:45 p.m.

—Inventory of State MPAs:
  —St. Croix, USVI—Mavel Maldonado, CFMC St. Croix Liaison
  —St. Thomas, USVI—Nikole Greaux, CFMC St. Thomas/St. John Liaison
  —Puerto Rico—Wilson Santiago, CFMC Puerto Rico Liaison

1:45 p.m.–2:30 p.m.

—Fishery Industry Perspectives:
  —Julian Magras—District Advisory Panel (DAP) Chair, St. Thomas/St. John, USVI
  —Edward Schuster—DAP Chair St. Croix, USVI
  —Nelson Crespo—DAP Chair Puerto Rico

2:30 p.m.–3:15 p.m.

—Governance: Mechanisms for Implementing and Monitoring MPAs
  —Puerto Rico—Damaris Delgado or Designee, Puerto Rico Department of Natural and Environmental Resources
  —USVI—Nicole Angeli, or Designee, USVI Division of Fish and Wildlife
  —Federal Government—María López-Mercer, NOAA Fisheries, Southeast Regional Office

3:15 p.m.–4:15 p.m.

—Discussion and Recommendations

4:15 p.m.

—Adjourn

Note (1): Other than starting time and dates of the meetings, the established times for addressing items on the agenda may be adjusted as necessary to accommodate the timely completion of discussion relevant to the agenda items. To further accommodate discussion and completion of all items on the agenda, the meeting may be extended from, or completed prior to the date established in this notice. Changes in the agenda will be posted to the CFMC website, Facebook, Twitter and Instagram as practicable.

Note (2): Financial disclosure forms are available for inspection at this meeting, as per 50 CFR part 601.

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on February 9, 2022, at 9 a.m. AST, and will end on February 9, 2022 at 4:15 p.m. AST. Other than the start time on the first day of the meeting, interested parties should be aware that discussions may start earlier or later than indicated in the agenda, at the discretion of the Chair.

Special Accommodations

Simultaneous interpretation will be provided.

For simultaneous interpretation English-Spanish-English follow your Zoom screen instructions. You will be asked which language you prefer when you join the meeting.

For any additional information on this public virtual meeting, please contact Diana Martino, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone: (787) 226–8849.

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

Dated: January 7, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–00425 Filed 1–11–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

[Docket ID DoD–2022–OS–0003]

Privacy Act of 1974; System of Records

AGENCY: Department of Defense (DoD).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the DoD is adding a new system of records, titled ''Office of Military Commissions (OMC) Victim and Witness Assistance Program Records,'' DGC 22. The system will be used to maintain the necessary information for victims, victim family members (VFMs), and witnesses to travel to Guantanamo Bay, Cuba (GTMO). The information will also be used to obtain clearance for victims and VFMs to travel to military installations for the purpose of viewing Closed Circuit Television of the GTMO trials.

DATES: This new system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before February 11, 2022. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Alva C. Foster, Office of Information Counsel, DoD General Counsel (Legal Counsel), 1600 Defense Pentagon, Room 3B688, Washington, DC 20301, *alva.c.foster.civ@mail.mil* or by phone at (571) 286–0254.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Military Commissions (OMC) Victim and Witness Assistance Program Records, DGC 22, system of records provides OMC the necessary means to process and track the clearances and travel of victims, VFMs and witnesses as required by the Regulation for Trial by Military Commission (2011 Edition). It is also the means established by the Deputy Secretary of Defense Memorandum dated October 17, 2008, which authorizes VFM travel to GTMO.

The DoD notices for systems of records subject to the Privacy Act of 1974, as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Privacy, Civil Liberties, and FOIA Division (PCLFD) website at *https://dpcld.defense.gov/privacy.*

II. Privacy Act

Under the Privacy Act, a ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, the DoD has provided a report of this system of records to OMB and to Congress.

Dated: January 7, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Office of Military Commissions (OMC) Victim and Witness Assistance Program Records, DGC 22.

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

Office of Military Commissions, 1600 Defense Pentagon, Washington, DC 20301–1600.

SYSTEM MANAGER(S):

Director, Victim and Witness Assistance Program, Office of the Chief Prosecutor, Office of Military Commissions, 1610 Defense Pentagon, Washington, DC 20301–1610.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 10607, Victims' Rights and Restitution Act (VRRA); 18 U.S.C. 3771, Crime Victims' Rights Act (CVRA); DoD Directive 1030.01, Victim and Witness Assistance; DoD Instruction 1030.2, Victim and Witness Assistance Procedures; and E.O. 9397 (SSN), as amended.

PURPOSE(S) OF THE SYSTEM:

A. Allow the Office of Military Commissions to communicate directly with the victims, victim family members (VFMs), and witnesses to obtain the credentials which enable them to attend portions of the trials in Guantanamo Bay, Cuba (GTMO). All of these individuals travel on military aircraft.

B. Facilitate obtaining victim impact information for use by the trial authorities.

C. Allow access to military installations by victims and VFMs for the purpose of viewing the GTMO proceedings while remaining in the United States, as authorized by the President of the United States.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

A. All individuals who have suffered direct harm or loss as the result of an offense as defined in the 10 U.S.C. Chapter 47A (the Military Commissions Act of 2009), and for which an individual subject to trial by a military commission has been charged. Individuals include, but are not limited to, victim families of the September 11, 2001 attack on the United States and the October 12, 2000 attack on the USS Cole.

B. Case in chief witnesses and sentencing witnesses, and prosecution and defense witnesses of any case referred to this military commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information collected includes full name, Social Security Number (SSN), alien registration number, immigration certification number and petition number, mailing address, home telephone number(s) and email address(s), citizenship, passport information, driver's license number, gender, race/ethnicity, date of birth, place of birth, weight, height, hair color, eye color, security clearance information, name of the deceased or injured, relationship to the victim, case name, requests to view closed circuit television broadcasts of hearings, travel-related information (emergency point of contact information, physician's information), military status and grade, whether or not the person has been convicted of a felony, and statements for the court from family members on how their loss affected them.

RECORD SOURCE CATEGORIES:

The individuals: Victims, family members, and witnesses.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government when necessary to accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent. Specifically, to the Department of Justice, Director for Victims of Overseas Terrorism for the purpose of facilitating victim assistance. Department of Justice victim specialists will be detailed as necessary to assist the Department of Defense, Office of Military Commissions Victim Witness Liaison to run the victim assistance program.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

I. To another Federal, State or local agency for the purpose of comparing to the agency's system of records or to non-Federal records, in coordination with an Office of Inspector General in conducting an audit, investigation, inspection, evaluation, or some other review as authorized by the Inspector General Act.

J. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

K. To the Victim Liaison for a U.S. Federal District Court for the purpose of facilitating communications about the proceedings, in the event a military commissions case is transferred to such court.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper records and electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Individual's name, email address, and name of the deceased or injured persons.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Disposition pending (Treat system records as permanent until the National Archives and Records Administration approves the proposed retention and disposal schedule).

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

The records are maintained in a controlled facility. Access to the records is limited to person(s) responsible for servicing the record in performance of their official duties and who are properly screened and cleared for need-to-know. Physical entry is restricted by the use of combination and cipher locks, guards, and is accessible only to authorized personnel. Paper records are stored in locked file cabinets. Access to the Victim and Witness Assistance Program (VWAP) SharePoint site is restricted by Common Access Card (CAC) and PIN.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to Office of the Secretary of Defense/Joint Staff Freedom of Information Act Requester Service Center, Office of Freedom of Information, 1155 Defense Pentagon, Washington, DC 20301–1155. Signed, written requests should include the individual's full name the name of the deceased or injured, and the name and number of this system of records notice. In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing initial Component determinations are contained in 32 CFR part 310, or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2022–00470 Filed 1–11–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Alaska Native Education Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2022 for the Alaska Native Education (ANE) program, Assistance Listing Number 84.356A. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: January 12, 2022.

Deadline for Transmittal of Applications: March 14, 2022.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979.* Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a Data Universal Numbering System (DUNS) number to the implementation of the Unique Entity Identifier (UEI). More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

FOR FURTHER INFORMATION CONTACT: Almita Reed, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E222, Washington, DC 20202. Telephone: (202) 260–1979. Email: *OESE.ASKANEP@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the ANE program is to support

innovative projects that recognize and address the unique educational needs of Alaska Natives. These projects must include the activities authorized under section 6304(a)(2) of the Elementary and Secondary Education Act of 1965, as amended (ESEA), and may include one or more of the activities authorized under section 6304(a)(3) of the ESEA, including, but not limited to, curriculum development, training and professional development, early childhood and parent outreach, and enrichment programs.

Background: The ANE program serves the unique educational needs of Alaska Natives and recognizes the roles of Alaska Native languages and cultures in the educational success and long-term well-being of Alaska Native students.

The Department encourages applicants to propose a broad array of activities to achieve these purposes, including activities that are consistent with the Administration's policy focus areas, such as promoting equity in student access to educational resources and opportunities. These activities may include supporting inclusive pedagogical practices in education preparation and professional development programs, and increasing the number and diversity of experienced effective educators, including those from the community that they serve.

Priorities: This notice contains one absolute priority. In accordance with 34 CFR 75.105(b)(2)(v), the absolute priority is from section 6304(a)(2)(A) and (B) of the ESEA.

Absolute Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

An applicant must address both parts of the absolute priority. An applicant must clearly identify in its application where the absolute priority is addressed.

This priority is:

Eligible applicants must design a project that—

1. Develops and implements plans, methods, strategies, and activities to improve the educational outcomes of Alaska Natives; and

2. Collects data to assist in the evaluation of the programs carried out under the ANE program.

Note: The construction of facilities that support the operation of ANE programs will be a permissible activity only if Congress specifically authorizes the use of FY 2022 funds for that purpose.

Definitions: The definitions for ''Alaska Native'' and ''Alaska Native organization'' are from section 6306 of the ESEA (20 U.S.C. 7546). The definitions for ''demonstrates a rationale,'' ''logic model,'' ''project component,'' and ''relevant outcome'' are from 34 CFR 77.1. The definition for ''Native'' is from section 3(b) of the Alaska Native Claims Settlement Act (43 U.S.C. 1602(b)). In addition, the definitions for ''experience operating programs that fulfill the purposes of the ANE program,'' ''official charter or sanction,'' and ''predominately governed by Alaska Natives'' are from the notice of final definitions and requirements—Alaska Native Program, published June 4, 2019, in the **Federal Register** (84 FR 25682) (NFR).

Alaska Native has the same meaning as the term Native has in section 3(b) of the Alaska Native Claims Settlement Act (43 U.S.C. 1602(b)) and includes the descendants of individuals so defined.

Alaska Native organization (ANO) means an organization that has or commits to acquire expertise in the education of Alaska Natives and is—

(a) An Indian Tribe, as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), that is an Indian Tribe located in Alaska;

(b) A Tribal organization, as defined in section 4 of such Act (25 U.S.C. 5304), that is a Tribal organization located in Alaska; or

(c) An organization listed in clauses (i) through (xii) of section 619(4)(B) of the Social Security Act (42 U.S.C. 619(4)(B)(i) through (xii)), or the successor of an entity so listed.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Experience operating programs that fulfill the purposes of the ANE program means that, within the past four years, the entity has received and satisfactorily administered, in compliance with applicable terms and conditions, a grant under the ANE program or another Federal or non-Federal program that focused on meeting the unique education needs of Alaska Native children and families in Alaska.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Native means a citizen of the United States who is a person of one-fourth degree or more Alaska Indian (including Tsimshian Indians not enrolled in the Metlaktla Indian Community) Eskimo, or Aleut blood, or combination thereof. The term includes any Native as so defined either or both of whose adoptive parents are not Natives. It also includes, in the absence of proof of a minimum blood quantum, any citizen of the United States who is regarded as an Alaska Native by the Native village or Native group of which he claims to be a member and whose father or mother is (or, if deceased, was) regarded as Native by any village or group. Any decision of the Secretary of the Interior regarding eligibility for enrollment shall be final.

Official charter or sanction means a signed letter or written agreement from an Alaska Native Tribe or ANO that is dated within 120 days prior to the date of the submission of the application and expressly (1) authorizes the applicant to conduct activities authorized under the ANE program and (2) describes the nature of those activities.

Predominately governed by Alaska Natives means that at least 80 percent of the entity's governing board (*i.e.,* the board elected or appointed to direct the policies of the organization) are Alaska Natives.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Application Requirements: The following requirements are from section 6304(a)(2) of the ESEA and from the NFR. In order to receive funding, an applicant must meet the following requirements.

(a) The applicant must provide a detailed description of the plans, methods, strategies, and activities it will develop and implement to improve the educational outcomes of Alaska Natives and how the applicant will develop and implement such plans, methods, strategies, and activities. (ESEA section 6304(a)(2))

(b) The applicant must provide a detailed description of the data it will collect to assist in the evaluation of the programs carried out under the ANE program, including data that address the

performance measures in section VI.5 (Performance Measures) of this notice; and how the applicant will collect such data. (ESEA section 6304(a)(2))

(c) Group Application Requirements:

An applicant that applies as part of a partnership must meet this requirement, in addition to the requirements in paragraphs (a) and (b) above.

(1) An ANO that applies for a grant in partnership with a State educational agency (SEA) or local educational agency (LEA) must serve as the fiscal agent for the project.

(2) Group applications under the ANE program must include a partnership agreement that includes a Memorandum of Understanding or a Memorandum of Agreement (MOU/MOA) between the members of the partnership identified and discussed in the grant application. Each MOU/MOA must—

(i) Be signed by all partners, and dated within 120 days prior to the date of the submission of the application;

(ii) Clearly outline the work to be completed by each partner that will participate in the grant in order to accomplish the goals and objectives of the project; and

(iii) Demonstrate an alignment between the activities, roles, and responsibilities described in the grant application for each of the partners in the partnership agreement. (NFR)

(d) Applicants Establishing Eligibility through a Charter or Sanction from an Alaska Native Tribe or ANO:

For an entity that does not meet the eligibility requirements for an ANO, established in section 6304(a)(1) and 6306(2) of the ESEA and the definitions in this notice, and that seeks to establish eligibility through a charter or sanction provided by an Alaska Native Tribe or ANO as required under section 6304(a)(1)(C)(ii) of the ESEA, the following documentation is required, in addition to the information in Application Requirements (a) through (c) above:

(1) Written documentation demonstrating that the entity is physically located in the State of Alaska.

(2) Written documentation demonstrating that the entity has experience operating programs that fulfill the purposes of the ANE program.

(3) Written documentation demonstrating that the entity is predominately governed by Alaska Natives (as defined in this notice), including the total number, names, and Tribal affiliations of members of the governing board.

(4) A copy of the official charter or sanction (as defined in this notice) provided to the entity by an Alaska Native Tribe or ANO. (NFR)

Statutory Hiring Preference: (a) Awards that are primarily for the benefit of Indians are subject to the provisions of section 7(b) of the Indian Self-Determination and Education Assistance Act (93 Pub. L. 638). That section requires that, to the greatest extent feasible, a grantee—

(1) Give to Indians preferences and opportunities for training and employment in connection with the administration of the grant; and

(2) Give to Indian organizations and to Indian-owned economic enterprises, as defined in section 3 of the Indian Financing Act of 1974 (25 U.S.C. 1452(e)), preference in the award of subcontracts in connection with the administration of the grant.

(b) For purposes of this requirement, an Indian is a member of any federally recognized Indian Tribe.

Program Authority: Title VI, part C of the ESEA (20 U.S.C. 7541–7546).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The NFR.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration's budget request for FY 2022 included $36,453,000 for this program. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process before the end of the current fiscal year if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2022 or in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $300,000–$1,500,000 for each 12-month budget period.

Estimated Average Size of Awards: $750,000 for each 12-month period.

Estimated Number of Awards: 48.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* (a) Alaska Native organizations with experience operating programs that fulfill the purposes of the ANE program;

(b) Alaska Native organizations that do not have experience operating programs that fulfill the purposes of the ANE program, but are in partnership with—

(i) An SEA or LEA; or

(ii) An Alaska Native organization that operates a program that fulfills the purposes of the ANE program; or

(c) An entity located in Alaska, and predominately governed by Alaska Natives, that does not meet the definition of an Alaska Native organization but—

(i) Has experience operating programs that fulfill the purposes of the ANE program; and

(ii) Is granted an official charter or sanction from at least one Alaska Native Tribe or Alaska Native organization to carry out programs that meet the purposes of the ANE program.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* No more than five percent of funds awarded for a grant under this program may be used for direct administrative costs (ESEA section 6305 and 20 U.S.C. 7545).

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/*

2021-27979, which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a DUNS number to the implementation of the UEI. More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the ANE program, your application may include business information that you consider proprietary. In 34 CFR 5.11, we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

4. *Funding Restrictions:* No more than five percent of funds awarded for a grant under this program may be used for direct administrative costs (ESEA section 6305 and 20 U.S.C. 7545).

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 30 pages and (2) use the following standards:

- A ''page'' is 8.5″; x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the résumés, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative. An applicant will not be disqualified if it exceeds the recommended page limit.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes the factors that reviewers will consider in determining the extent to which an applicant meets the criterion.

The selection criteria are as follows:

(a) *Need for project* (up to 10 points).

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers the following factors:

(1) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project (up to 5 points).

(2) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses (up to 5 points).

(b) *Quality of the project design* (up to 20 points).

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs (up to 10 points).

(2) The extent to which the proposed project demonstrates a rationale (as defined in this notice) (up to 10 points).

(c) *Quality of project services* (up to 30 points).

The Secretary considers the quality of the services to be provided by the proposed project.

(1) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (up to 10 points).

(2) In addition, the Secretary considers the extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice (up to 20 points).

(d) *Quality of project personnel* (up to 10 points).

The Secretary considers the quality of the personnel who will carry out the proposed project.

(1) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (up to 5 points).

(2) In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel (up to 5 points).

(e) *Quality of the management plan* (up to 20 points).

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (up to 10 points); and

(2) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project (up to 10 points).

(f) *Quality of the project evaluation* (up to 10 points).

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the extent to which the methods of evaluation will provide valid and reliable performance data on relevant outcomes.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3)(ii), the past performance of

the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General.* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of Department reporting under 34 CFR 75.110, we have established four performance measures for the ANE program: (1) The number of grantees who attain or exceed the targets for the outcome indicators for their projects that have been approved by the Secretary; (2) the percentage of Alaska Native children participating in early learning and preschool programs who consistently demonstrate school readiness in language and literacy as measured by the Revised Alaska Development Profile; (3) the percentage of Alaska Native students in schools served by the program who earn a high school diploma in four years; and (4) the number of Alaska Native programs that primarily focus on Alaska Native culture and language.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has

made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary Office of Elementary and Secondary Education.

[FR Doc. 2022–00411 Filed 1–11–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2445–028]

Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments; Green Mountain Power Corporation

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 2445–028.

c. *Date filed:* December 23, 2021.

d. *Applicant:* Green Mountain Power Corporation (GMP).

e. *Name of Project:* Center Rutland Hydroelectric Project (project).

f. *Location:* On Otter Creek in Rutland County, Vermont. The project does not occupy any federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John Greenan, PE, Green Mountain Power Corporation, 2152 Post Road, Rutland, VT 05701; Phone at (802) 770–2195, or email at *John.Greenan@greenmountainpower.com.*

i. *FERC Contact:* Taconya D. Goar at (202) 502–8394, or *Taconya.Goar@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* February 21, 2022.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. All filings must clearly identify the project name and docket number on the first page: Center Rutland Hydroelectric Project (P–2445–028).

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The existing Center Rutland Project consists of: (1) A 190-foot-long, 14-foot-high concrete and stone masonry gravity dam that includes: (i) A 174-foot-long spillway section with 2.3-foot-high wooden flashboards and a crest elevation of 507.1 feet mean seal level (msl) at the top of the flashboards; and (ii) a 16-foot-long non-overflow section; (2) an impoundment with a surface area of 13 acres and a storage capacity of 30 acre-feet at an elevation of 507.4 feet msl; (3) a forebay; (4) a concrete and marble masonry intake structure; (5) a 6-foot-diameter, 75-foot-long steel penstock; (6) a 40-foot-long, 33-foot-wide stone and marble masonry powerhouse containing one 275-kilowatt horizontal-shaft turbine-generator unit; (7) a substation; (8) an 80-foot-long, 12.47-kilovolt transmission line; (9) a 0.35-mile-long fiber optic cable for smart grid communications with the electric system; and (10) appurtenant facilities. The project creates an approximately 100-foot-long bypassed reach of Otter Creek.

The project includes a small off-street parking area (with 3 to 5 car spaces), signage, landscaping, and a marked footpath to Otter Creek.

The current license requires the project to operate in a run-of-river mode such that outflow from the project approximates inflow to the impoundment to protect aquatic resources in Otter Creek. The current

license also requires a minimum bypassed reach flow of 80 cubic feet per second or inflow to the impoundment, whichever is less, from June 1 through October 15 to protect aquatic resources in Otter Creek and aesthetic resources in the project area. The average annual generation of the project was approximately 541.7 megawatt-hours from 2014 through 2020.

The applicant proposes to: (1) Continue to operate the project in a run-of-river mode to protect aquatic resources; (2) continue to release a minimum bypassed reach flow of 80 cfs or inflow, whichever is less, from June 1 through October 15, to protect aquatic resources; (3) release a minimum bypassed reach flow of 40 cfs or inflow, whichever is less, from October 16 through May 31, to protect aquatic resources; and (4) implement a seasonal clearing restriction from April 15 through October 31, for trees that are 4 inches in diameter or greater, to protect the federally threatened northern long-eared bat. In addition, GMP states that the flashboards have not been in place since prior to 2012, and proposes to reinstall them.

o. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–2445). For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary)—February 2022
Request Additional Information—February 2022
Issue Scoping Document 1 for comments—May 2022
Request Additional Information (if necessary)—June 2022
Issue Acceptance Letter—June 2022
Issue Scoping Document 2—July 2022
Issue Notice of Ready for Environmental Analysis—July 2022

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: January 6, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00413 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–33–000]

Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline; Northern Natural Gas Company

Take notice that on December 27, 2021, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.213(b) and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA) and Northern's blanket certificate issued in Docket No. CP82–401–000, for authorization to replace an injection and withdrawal well at its Redfield Storage Field, located in Dallas County, Iowa. Northern purposes to (1) install and operate an injection and withdrawal well; (2) install a natural gas pipeline lateral; (3) install a water production line; and (4) abandon an existing injection and withdrawal well. Northern estimates that the cost of the Project is approximately $3.8 million. Northern states that the replacement injection and withdrawal well will have no impact on the Redfield storage field's certificated physical parameters, including total gas storage inventory, reservoir pressure, reservoir and buffer boundaries and certificated capacity. In addition, Northern states that there will be no impact to service of Northern's customers as a result of the proposed Project, all as more fully set forth in the application, which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this prior notice request should be directed to Michael T. Loeffler, Senior Director, Certificates and External Affairs for Northern, 1111 South 103rd Street, Omaha, NE 68124, at 402–398–7103, or by email to *mike.loeffler@nngco.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on March 7, 2022. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is March 7, 2022. A protest may also serve as a motion to intervene so long as the

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is March 7, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before March 7, 2022. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–33–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's *eFiling* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* New eFiling users must first create an account by clicking on ''*eRegister.*'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [6]

(2) You can file a paper copy of your submission by mailing it to the address below.[7] Your submission must reference the Project docket number CP22–33–000. Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail at: 1111 South 103rd Street, Omaha, NE 68124, or by email to (with a link to the document) at: *mike.loeffler@nngco.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

[6] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

[7] Hand-delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: January 6, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00408 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21–34–000]

Commission Information Collection Activities (FERC–500 and FERC–505); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on two currently approved information collections: FERC–500, Application for License/Relicense for Water Projects with More than 10 Megawatt (MW) Capacity; and FERC–505, Application for Small Hydropower Projects and Conduit Facilities including License/Relicense, Exemption, and Qualifying Conduit Facility Determinations, which will be submitted to the Office of Management and Budget (OMB) for a review of the information collection requirements.

DATES: Comments on the collections of information are due February 11, 2022.

ADDRESSES: Send written comments on FERC–500 and FERC–505 to OMB through *www.reginfo.gov/public/do/PRAMain,* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB control numbers 1902–0058 (FERC–500) and 1902–0115 (FERC–505) in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

Please submit copies of your comments (identified by Docket No. IC21–34–000) to the Commission as

noted below. Electronic filing through *http://www.ferc.gov,* is preferred.

• *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

• For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only, Addressed to:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (Including Courier) Delivery to:* Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain;* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collections.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov* and telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Titles: FERC–500 (Application for License/Relicense for Water Projects with More than 10 Megawatt (MW) Capacity) and FERC–505 (Application for Small Hydropower Projects and Conduit Facilities including License/Relicense, Exemption, and Qualifying Conduit Facility Determination).

OMB Control Nos.: 1902–0058 (FERC–500) and 1902–0115 (FERC–505).

Type of Request: Extension of currently approved information collections.

Abstract: Part I of the Federal Power Act (FPA) [1] authorizes the Commission to grant hydropower licenses and exemptions to citizens of the United States, or to any corporation organized under the laws of United States or any State thereof, or to any State or municipality. Holders of such licenses and exemptions construct, operate, and maintain dams, water conduits, reservoirs, power houses, transmission lines, or other project works necessary or convenient for the development and improvement of navigation and for the development, transmission, and utilization of power across, along, from, or in any of the streams or other bodies of water over which Congress has jurisdiction. This jurisdiction stems from Congressional authority to regulate commerce with foreign nations and among the several States, or upon any part of the public lands and reservations of the United States.

FERC–500 and FERC–505 comprise applications and other information collection activities implemented under numerous regulations. Some of the regulations are relevant to both FERC–500 and FERC–505, and others are relevant only to FERC–500 or FERC–505. Effective October 4, 2021,[2] information collection activities within FERC–500 are for projects with an installed capacity of more than 10 MW. Information collection activities within FERC–505 are for other smaller projects.

As required by OMB regulations at 5 CFR 1320.8(d), the Commission provided a 60-day notice of its renewal request in the **Federal Register** on October 28, 2021 (86 FR 59704). The public-comment period expired on December 27, 2021. No comments were received.

The following table lists information collection activities pertaining to applications and notices of intent. The table is organized as pairs of regulations that address, respectively, applicability and required contents of each activity.

TABLE 1—REGULATIONS AND INFORMATION COLLECTION ACTIVITIES: APPLICATIONS AND NOTICES OF INTENT

Title	18 CFR cites	FERC–500	FERC–505
Application for License for Major [3] Unconstructed Project and Major Modified Project	4.40 and 4.41	Yes	Yes
Application for License for Major Project—Existing Dam	4.50 and 4.51	Yes	Yes
Application for License for Minor [4] Water Power Projects and Major Water Power Projects 10 Megawatts or Less.	4.60 and 4.61	No	Yes
Application for License for Transmission Line Only	4.70 and 4.71	Yes	Yes
Application for a Preliminary Permit	4.80 and 4.81	Yes	Yes
Application for Exemption of Small Conduit Hydroelectric Facilities	4.90 and 4.92	No	Yes
Application for Case-Specific Exemption of Small Hydroelectric Power Projects of 10 Megawatts or Less.	4.101 and 4.107	No	Yes
Application for Amendment of License	4.200 and 4.201	Yes	Yes
Notice of Intent to Construct Qualifying Conduit Hydropower Facilities	4.400 and 4.401	No	Yes
Application Under the Integrated Licensing Process	5.1 and 5.18	Yes	Yes
Application for Transfer of License	9.1 and 9.2	Yes	Yes

Each of the ''contents'' regulations listed above requires information that assists the Commission in identifying the respondent and the type of proposed project. In addition, certain types of applications must include all [5] or some [6] of the following exhibits:

• Exhibit A is a description of the project.

• Exhibit B is a statement of project operation and resource utilization.

• Exhibit C is a proposed construction schedule for the project.

[1] 16 U.S.C. 791a–823g.

[2] Before October 4, 2021, FERC–500 applied only to projects with an installed capacity of more than 5 MW. On August 5, 2021, the Commission published a final rule that affected the paperwork burdens of FERC–500 by changing the regulatory threshold for certain licensing requirements from 5 MW to 10 MW. As a result, the regulatory threshold for FERC–500 is now projects with an installed capacity of more than 10 MW. *See* Final Rule, Docket RM20–21–000, 86 FR 42710 (Aug. 5, 2021).

[3] As defined at 18 CFR 4.30(b)(14) through 4.30(b)(16), a ''major'' project has a total installed generating capacity of more than 1.5 MW.

[4] As defined at 18 CFR 4.30(b)(17), a ''minor'' project has a total installed generating capacity of 1.5 MW or less.

[5] The following regulations require Exhibits A through G: 18 CFR 4.41, 4.51, 4.61, 4.71, 4.201(b)(1) and 4.201(b)(5).

[6] The following regulations do not require Exhibits B, C, or D: 18 CFR 4.92 and 4.107. The regulations at 18 CFR 4.201(b)(2) through (b)(4) do not require Exhibits A, B, C, or D. The regulations at 18 CFR 5.18 do not require Exhibit E.

• Exhibit D is a statement of project costs and financing.

• Exhibit E is an environmental report.

• Exhibit F consists of general design drawings of the principal project works described under Exhibit A and supporting information used as the basis of design.

• Exhibit G is a map of the project.

No exhibits are required in a Notice of Intent to Construct Qualifying Conduit Hydropower Facilities under 18 CFR 4.401. However, the Notice of Intent must include:

• Statements that the proposed project will use the hydroelectric potential of a non-federally owned conduit and that the proposed facility has not been licensed or exempted from the licensing requirements and Part I of the FPA;

• A description of the proposed facility;

• Project drawings;

• If applicable, the preliminary permit number for the proposed facility; and

• Verification in accordance with 18 CFR 4.401(g).

The following table lists information collection activities pertaining to matters other than applications and notices of intent:

TABLE 2—OTHER REGULATIONS AND INFORMATION COLLECTION ACTIVITIES

Title or description	18 CFR cite(s)	FERC–500	FERC–505
State and federal comprehensive plans	2.19	Yes	Yes
Acceptance for filing or rejection; information to be made available to the public; requests for additional studies.	4.32	Yes	Yes
Amendment of application; date of acceptance	4.35	Yes	Yes
Competing applications, deadlines for filing, notices of intent, and comparisons of plans of development.	4.36	Yes	Yes
Consultation requirements	4.38	Yes	Yes
Action on exemption applications	4.93	No	Yes
Integrated licensing process	5.2, 5.3, 5.4, 5.5, 5.6, 5.11, 5.13, 5.15, 5.16, 5.17, and 5.20, 5.21, 5.23, and 5.27.	Yes	Yes
Expedited licensing process for qualifying non-federal hydropower projects at existing nonpowered dams and for closed-loop pumped storage projects.	7.1, 7.2, 7.3, 7.4,.7.5, 7.6, 7.7, 7.8, and 7.9	Yes	Yes
Publication of license conditions relating to recreation and posting of project lands as to recreational use and availability of information.	8.1 and 8.2	Yes	Yes
Lease of Project Property	9.10	Yes	Yes
Procedures relating to takeover and relicensing of licensed projects.	16,1, 16.4, 16.6, 16.7, 16.8, 16.9, 16.10, 16.11, 16.12, 16.14, 16.19, 16.20, and 16.26.	Yes	Yes
Annual conveyance report	141.15	Yes	No
General requirements for qualifying cogeneration and small power production facilities.	292.203	No	Yes
Special requirements for hydroelectric small power production facilities located at a new dam or diversion.	292.208	No	Yes

Types of Respondents: Entities requesting Licenses, Relicenses, Exemptions, or Qualifying Conduit Facility Determinations, and certain entities in receipt of Commission Licenses and Exemptions.

Estimate of Annual Burden: The burdens are itemized in detail in the following table:

TABLE 3—ESTIMATED ANNUAL BURDENS

A. Type of response	B. Number of respondents and responses [7]	C. Average burden & cost [8] per response	D. Average annual burden hours & total annual cost (column B × column C)
FERC–500, Application for License/Relicense for Water Projects with Greater than 10 MW Capacity [9].	9	35,602.55 hrs.; $3,097,421.85	320,422.95 hrs.; $27,876,796.65.
FERC–500, Request for Authorization to Use Expedited Licensing Process.	5	40 hrs.; $3,480	200 hrs.; $17,400.
FERC–500, Annual Conveyance Reports	41	3 hrs.; $261	123 hrs.; $10,701.
FERC–500, Recreation Posting	432	0.5 hr.; $43.50	216 hrs.; $18,792.
Subtotals for FERC–500	487		320,961.95 hrs.; $27,923,689.65.
FERC–505, for Small Hydropower Projects and Conduit Facilities including License/Relicense, Exemption, and Qualifying Conduit Facility Determinations.	32	756.59 hrs.; $65,823.33	24,210.88 hrs.; $2,106,346.56.
FERC–505, Request for Authorization to Use Expedited Licensing Process.	5	40 hrs.; $3,480	200 hrs.; $17,400.
FERC–505, Recreation Posting	287	0.5 hr.; $43.50	143.5 hrs.; $12,484.50.
Sub-Totals for FERC–505	324		24,554.38 hrs.; $2,136,231.06.
Totals	811		345,516.33 hrs.; $30,059,920.71.

Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: January 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00354 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2628–066]

Alabama Power Company; Notice of Technical Teleconference

On January 20, 2022, Federal Energy Regulatory Commission (Commission) staff will host a technical teleconference to discuss details of the models used to evaluate alternative operating curves and downstream releases for relicensing Alabama Power Company's (Alabama Power) R.L. Harris Hydroelectric Project No. 2628 (Harris Project).

a. *Date and Time of Teleconference:* Thursday, January 20, 2022, from 2:00 p.m. to 4:30 p.m. Eastern Time.

b. *FERC Contact:* Sarah Salazar at 202–502–6863, or *sarah.salazar@ferc.gov.*

c. *Purpose of Teleconference:* On November 23, 2021, Alabama Power filed an application to relicense the Harris Project. The application includes analysis and proposals based on results of studies that involved the use of models, including the Hydrologic Engineering Center's River Analysis System (HEC–RAS) and Hydrologic Engineering Center's Reservoir System Simulation (HEC-ResSim). On December 23, 2021, Commission staff issued additional information requests (AIRs) regarding the models. Alabama Power representatives requested a teleconference so their modeling experts can address the AIRs.

d. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to attend and observe the technical teleconference. Attendees will be in listen-only mode, and will have an opportunity to ask questions pertaining to the models at the end of the teleconference. Please contact Allan Creamer at (202) 502–8365, or *allan.creamer@ferc.gov* by January 17, 2022, to RSVP for the teleconference. Details will be provided by Commission staff once attendance is confirmed. Commission staff will prepare a summary of the teleconference and issue it to the Commission's e-library under the Harris Project docket (P–2628).

Dated: January 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00356 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–32–000.
Applicants: Tenaska Gateway Partners, Ltd.
Description: Application for Authorization Under Section 203 of the Federal Power Act of Tenaska Gateway Partners, Ltd.
Filed Date: 1/5/22.
Accession Number: 20220105–5236.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: EC22–33–000.
Applicants: FirstEnergy Transmission, LLC.
Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of FirstEnergy Transmission, LLC, et al.
Filed Date: 1/5/22.
Accession Number: 20220105–5238.
Comment Date: 5 p.m. ET 1/26/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2488–023; ER13–1586–018; ER14–2871–017; ER15–463–016; ER15–621–016; ER15–622–016; ER16–72–012; ER16–182–012; ER16–902–009; ER17–47–009; ER17–48–010; ER18–47–008; ER18–2240–005; ER18–2241–005; ER19–426–005; ER19–427–005; ER19–1575–006; ER19–1660–005; ER19–1662–005; ER19–1667–005; ER20–71–005; ER20–72–005; ER20–75–005; ER20–76–007; ER20–77–005; ER20–79–005; ER21–1368–001; ER21–1369–002; ER21–1371–002; ER21–1373–003; ER21–1376–003; ER21–2782–001; ER22–149–001.
Applicants: Sagebrush Line, LLC, Sagebrush ESS, LLC, Sanborn Solar 1A, LLC, Edwards Solar 1A, LLC, Edwards Sanborn Storage II, LLC, Edwards Sanborn Storage I, LLC, Valley Center ESS, LLC, Voyager Wind IV Expansion, LLC, Painted Hills Wind Holdings, LLC, Oasis Plains Wind, LLC, Oasis Alta, LLC, Coachella Wind Holdings, LLC, Coachella Hills Wind, LLC, Terra-Gen VG Wind, LLC, Mojave 16/17/18 LLC, Mojave 3/4/5 LLC, Alta Oak Realty, LLC, LUZ Solar Partners IX, Ltd., LUZ Solar Partners VIII, Ltd., Garnet Wind, LLC, Yavi Energy, LLC, Voyager Wind II, LLC, Terra-Gen Mojave Windfarms, LLC, DifWind Farms LTD VI, Voyager Wind I, LLC, Cameron Ridge II, LLC, San Gorgonio Westwinds II—Windustries, LLC, Ridgetop Energy, LLC, Pacific Crest Power, LLC, San Gorgonio Westwinds II, LLC, Cameron Ridge, LLC, TGP Energy Management, LLC, Oasis Power Partners, LLC.
Description: Triennial Market Power Analysis for Southwest Region and Notice of Change in Status of Oasis Power Partners, LLC, et al.
Filed Date: 12/30/21.
Accession Number: 20211230–5331.
Comment Date: 5 p.m. ET 2/28/22.

Docket Numbers: ER20–2276–001.
Applicants: Moxie Freedom LLC.
Description: Notice of Non-Material Change in Status of Moxie Freedom LLC.
Filed Date: 1/6/22.
Accession Number: 20220106–5181.
Comment Date: 5 p.m. ET 1/27/22.

Docket Numbers: ER21–2652–002.
Applicants: Caddo Wind, LLC.
Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Caddo Wind, LLC.
Filed Date: 1/3/22.
Accession Number: 20220103–5494.
Comment Date: 5 p.m. ET 3/4/22.

Docket Numbers: ER22–774–000.
Applicants: PJM Interconnection, L.L.C.

[7] There is one response per respondent for each activity in this information collection.

[8] Commission staff estimates that the average industry hourly cost for this information collection is approximated by the current FERC 2021 average hourly costs for wages and benefits, *i.e.,* $87.00/hour.

[9] The previously reported 33 responses associated with Comprehensive Plans were incorrect and not consistent in how we have approached the number of respondents for this Information Collection. As a result, the total number of hours associated with the Comprehensive Plans requirement was moved to the total number of hours associated with the application process. The Commission does not break down pieces of this process (as it is all considered one application) and so this edit was made for consistency across the information collection.

Description: § 205(d) Rate Filing: Amendment to WMPA, SA No. 5665; Queue No. AF1–032 (amend) to be effective 5/28/2020.

Filed Date: 1/5/22.

Accession Number: 20220105–5201.

Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–775–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3875 White Rock Wind East GIA to be effective 12/8/2021.

Filed Date: 1/6/22.

Accession Number: 20220106–5048.

Comment Date: 5 p.m. ET 1/27/22.

Docket Numbers: ER22–776–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, Service Agreement No. 5841; Queue No. AF2–151 to be effective 10/9/2020.

Filed Date: 1/6/22.

Accession Number: 20220106–5067.

Comment Date: 5 p.m. ET 1/27/22.

Docket Numbers: ER22–777–000.

Applicants: Sky River LLC.

Description: § 205(d) Rate Filing: SR and NSRE Second Amended and Restated Shared Facilities Agreement to be effective 1/7/2022.

Filed Date: 1/6/22.

Accession Number: 20220106–5074.

Comment Date: 5 p.m. ET 1/27/22.

Docket Numbers: ER22–778–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement Nos. 386 and 388—E&P Agreements between APS and AES to be effective 3/8/2022.

Filed Date: 1/6/22.

Accession Number: 20220106–5105.

Comment Date: 5 p.m. ET 1/27/22.

Docket Numbers: ER22–779–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEC-New River NITSA SA No. 546 to be effective 1/1/2022.

Filed Date: 1/6/22.

Accession Number: 20220106–5126.

Comment Date: 5 p.m. ET 1/27/22.

Docket Numbers: ER22–780–000.

Applicants: Sky River LLC.

Description: § 205(d) Rate Filing: SR (Transmission) and Sky River Wind, LLC Shared Facilities Agreement to be effective 1/7/2022.

Filed Date: 1/6/22.

Accession Number: 20220106–5177.

Comment Date: 5 p.m. ET 1/27/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 6, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–00427 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–21–000.

Applicants: South Texas Electric Cooperative, Inc., San Bernard Electric Cooperative, Inc.

Description: Request of South Texas Electric Cooperative, Inc. and San Bernard Electric Cooperative, Inc. for Partial Waiver of Electric Utility Obligations Under PURPA to Purchase and Sell Energy From and To Qualifying Facilities.

Filed Date: 12/21/21.

Accession Number: 20211221–5277.

Comment Date: 5 p.m. ET 1/18/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1862–033; ER10–1865–014; ER10–1873–014; ER10–1875–014; ER10–1876–015; ER10–1878–014; ER10–1883–014; ER10–1884–014; ER10–1885–014; ER10–1888–014; ER10–1893–033; ER10–1934–033; ER10–1938–034; ER10–1941–014; ER10–1942–031; ER10–1947–015; ER10–2042–039; ER10–2985–037; ER10–3049–038; ER10–3051–038; ER11–4369–018; ER12–1987–012; ER12–2261–013; ER12–2645–007; ER13–1407–011; ER16–2218–019; ER17–696–019; ER19–1127–004; ER20–1699–002.

Applicants: Johanna Energy Center, LLC, Calpine King City Cogen, LLC, Calpine Energy Solutions, LLC, North American Power Business, LLC,CCFC Sutter Energy, LLC, Pastoria Energy Facility L.L.C., Russell City Energy Company, LLC,O.L.S. Energy-Agnews, Inc., North American Power and Gas, LLC, Champion Energy, LLC, Champion Energy Services, LLC, Champion Energy Marketing LLC, Calpine Energy Services, L.P., Otay Mesa Energy Center, LLC, Calpine Construction Finance Co., L.P., Calpine Gilroy Cogen, L.P., Calpine Power America—CA, LLC,CES Marketing IX, LLC,CES Marketing X, LLC, Creed Energy Center, LLC, Delta Energy Center, LLC, Geysers Power Company, LLC, Gilroy Energy Center, LLC, Goose Haven Energy Center, LLC, Los Esteros Critical Energy Facility, LLC, Los Medanos Energy Center LLC, Metcalf Energy Center, LLC, South Point Energy Center, LLC, Power Contract Financing, L.L.C.

Description: Updated Market Power Analysis (Southwest Region) for the indirect subsidiaries of Calpine Corporation.

Filed Date: 1/3/22.

Accession Number: 20220103–5491.

Comment Date: 5 p.m. ET 3/4/22.

Docket Numbers: ER10–3050–008; ER10–3053–008.

Applicants: Whitewater Hill Wind Partners, LLC, Cabazon Wind Partners, LLC.

Description: Triennial Market Power Analysis for Southwest Region of Cabazon Wind Partners, LLC, et al.

Filed Date: 1/3/22.

Accession Number: 20220103–5489.

Comment Date: 5 p.m. ET 3/4/22.

Docket Numbers: ER15–1332–008; ER10–2401–008; ER10–2402–008; ER10–2403–009; ER11–3414–009; ER13–1816–015; ER15–1333–008; ER17–1318–005; ER18–1188–004.

Applicants: Prairie Queen Wind Farm LLC, Redbed Plains Wind Farm LLC, Waverly Wind Farm LLC, Sustaining Power Solutions LLC, Blue Canyon Windpower VI LLC, Cloud County Wind Farm, LLC, Blue Canyon Windpower V LLC, Blue Canyon Windpower II LLC, Arbuckle Mountain Wind Farm LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Arbuckle Mountain Wind Farm LLC, et al.

Filed Date: 1/3/22.

Accession Number: 20220103–5493.

Comment Date: 5 p.m. ET 3/4/22.

Docket Numbers: ER22–136–001.

Applicants: Sagebrush Line, LLC.

Description: Compliance filing: Compliance Filing of Executed Facilities Use Agreements to be effective 12/27/2021.

Filed Date: 1/5/22.
Accession Number: 20220105–5170.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–613–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Amendment to Original WMPA, SA No. 6231; Queue No. AG2–392 to be effective 11/11/2021.
Filed Date: 1/5/22.
Accession Number: 20220105–5161.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–764–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 6273; Queue No. AG2–422 to be effective 12/7/2021.
Filed Date: 1/5/22.
Accession Number: 20220105–5050.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–765–000.
Applicants: Midcontinent Independent System Operator, Inc., Northern Indiana Public Service Company LLC.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–01–05_SA 3765 NIPSCO-Dunns Bridge Energy Storage E&P (J1333 J1334 J1335) to be effective 1/1/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5058.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–766–000.
Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Jersey Central Power & Light Company submits tariff filing per 35.13(a)(2)(iii: JCPL Submits IA No. 5947 to be effective 3/7/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5065.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–767–000.
Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Jersey Central Power & Light Company submits tariff filing per 35.13(a)(2)(iii: JCPL Submits IA No. 5948 to be effective 3/7/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5089.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–768–000.
Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Jersey Central Power & Light Company submits tariff filing per 35.13(a)(2)(iii: JCPL Submits IA No. 5946 to be effective 3/7/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5100.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–769–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: Tippsol (Tipperary Solar) LGIA Filing to be effective 12/20/2021.
Filed Date: 1/5/22.
Accession Number: 20220105–5104.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–770–000.
Applicants: Duke Energy Indiana, LLC.
Description: § 205(d) Rate Filing: DEI-Ameren—Rate Schedule No. 278—Construction Agreement to be effective 1/6/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5108.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–771–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: EKPC Fourth Amended and Restated Interconnection Agreement to be effective 12/23/2021.
Filed Date: 1/5/22.
Accession Number: 20220105–5125.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–772–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 205: BSM Capacity Accreditation Market Design to be effective 3/6/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5146.
Comment Date: 5 p.m. ET 1/26/22.

Docket Numbers: ER22–773–000.
Applicants: Mulligan Solar, LLC.
Description: Baseline eTariff Filing: Mulligan Solar LLC MBR Application Filing to be effective 3/7/2022.
Filed Date: 1/5/22.
Accession Number: 20220105–5147.
Comment Date: 5 p.m. ET 1/26/22.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH22–5–000.
Applicants: Starwood Energy Group Global, L.L.C.
Description: Starwood Energy Group Global, L.L.C., submits FERC 65–B Notice of Change in Fact to Waiver Notification.
Filed Date: 1/4/22.
Accession Number: 20220104–5193.
Comment Date: 5 p.m. ET 1/25/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00360 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–1–000]

Commission Information Collection Activities (FERC–725) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–725 (Certification of Electric Reliability Organization; Procedures for Electric Reliability Standards), which will be submitted to the Office of Management and Budget (OMB) for review. The Commission issued a 60-day notice on November 3, 2021 requesting public comments; no comments were received.

DATES: Comments on the collection of information are due February 11, 2022.

ADDRESSES: Send written comments on FERC–725 to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number (1902–0225) in the subject line of your comments. Comments should be sent

within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Please submit copies of your comments to the Commission. You may submit copies of your comments (identified by Docket No. IC22–1–000) by one of the following methods: Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (Including Courier) Delivery:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection. *FERC submissions* must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov/ferc-online/overview.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725, Certification of Electric Reliability Organization; Procedures for Electric Reliability Standards.

OMB Control No.: 1902–0225.

Type of Request: Three-year extension of the FERC–725 information collection requirements with no changes to the current reporting and recordkeeping requirements.

Abstract: The Commission issued a 60-day notice on November 3, 2021 (86 FR 60626) requesting public comments; no comments were received.

The FERC–725 contains the following information collection elements:

Self Assessment and ERO (Electric Reliability Organization) Application: The Commission requires the ERO to submit to FERC a performance assessment report every five years. The next assessment is due in 2024. Each Regional Entity submits a performance assessment report to the ERO.

Submitting an application to become the ERO is also part of this collection.[1]

Reliability Assessments: 18 CFR 39.11 requires the ERO to assess the reliability and adequacy of the Bulk-Power System in North America. Subsequently, the ERO must report to the Commission on its findings. Regional entities perform similar assessments within individual regions. Currently the ERO submits to FERC three assessments each year: Long term, winter, and summer. In addition, the North American Electric Reliability Corporation (NERC, the Commission-approved ERO) also submits various other assessments as needed.

Reliability Standards Development: Under section 215 of the Federal Power Act (FPA),[2] the ERO is charged with developing Reliability Standards. Regional Entities may also develop regional specific standards and have standard experts on staff to work with entities below the regional level.

Reliability Compliance: Reliability Standards are mandatory and enforceable upon approval by the Commission. In addition to the specific information collection requirements contained in each standard (cleared under other information collections), there are general compliance, monitoring and enforcement information collection requirements imposed on applicable entities. Audits, spot checks, self-certifications, exception data submittals, violation reporting, and mitigation plan confirmation are included in this area.

Stakeholder Survey: The ERO uses a stakeholder survey to solicit feedback from registered entities[3] in preparation for its five-year self-performance assessment. The Commission assumes that the ERO will perform another survey prior to the 2024 self-assessment.

Other Reporting: This category refers to all other reporting requirements imposed on the ERO or regional entities in order to comply with the Commission's regulations. For example, FERC may require NERC to submit a special reliability assessment or inquiry. This category captures these types of one-time filings required of NERC or the Regions. The Commission implements its responsibilities through 18 CFR part 39.

Type of Respondent: Electric Reliability Organization, Regional entities, and registered entities. *Estimate of Annual Burden:*[4] The Commission estimates the total annual burden and cost[5] for this information collection in the table below. For hourly cost (for wages and benefits), we estimate that 70% of the time is spent by Electrical Engineers (code 17–2071, at $72.15/hr.), 20% of the time is spent by Legal (code 23–0000, at $142.25/hr.), and 10% by Office and Administrative Support (code 43–0000, at $44.47/hr.). Therefore, we use the weighted hourly cost (for wages and benefits) of $83.40 (rounded) {or [(0.70) * ($72.15/hr.)] + [(0.20) * $142.25/hr.] + [(0.10) * $44.47/hr.]}.

[1] The Commission does not expect any new ERO applications to be submitted in the next five years and is not including any burden for this requirement in the burden estimate. FERC still seeks to renew the regulations pertaining to a new ERO application under this renewal but is expecting the burden to be zero for the foreseeable future. 18 CFR 39.3 contains the regulation pertaining to ERO applications.

[2] 16 U.S.C. 824o.

[3] A ''registered entity'' is an entity that is registered with the ERO. All Bulk-Power System owners, operators and users are required to register with the ERO. Registration is the basis for determining the Reliability Standards with which an entity must comply. See *http://www.nerc.com/page.php?cid=3%7C25* for more details.

[4] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1320.3.

[5] Costs (for wages and benefits) are based on wage figures from the Bureau of Labor Statistics (BLS) for May 2021 (at *https://www.bls.gov/oes/current/naics2_22.htm*) and benefits information (at *https://www.bls.gov/news.release/ecec.nr0.htm*).

FERC–725, CERTIFICATION OF ELECTRIC RELIABILITY ORGANIZATION; PROCEDURES FOR ELECTRIC RELIABILITY STANDARDS

Type of respondent	Type of reporting requirement	Number of respondents (A)	Annual number of responses per respondent (B)[6]	Total number of responses (A) × (B) = (C)	Average burden hours & cost ($) per response (rounded) (D)	Estimated total annual burden hrs. & cost ($) (rounded) (C) × (D)
Electric Reliability Organization (ERO).	Self-Assessment	1	.2	.2	4,160hrs.; $346,950	832 hrs.; $69,390.
	Reliability Assessments		5.0	5.0	10,400 hrs.; $867,360	52,000 hrs.; $4,336,800.
	Reliability Compliance		2	2	17,680 hrs.; $1,474,512.	35,360 hrs.; $2,949,024.
	Standards Development		1	1	20,800 hrs.; $1,734,720.	35,360 hrs.; $2,949,024.
	Other Reporting		1	1	4,160 hrs.; $346,944	4,160 hrs.; $346,944.
ERO, Sub-Total					*113,152 hrs.; $9,436,877..*	
Regional Entities	Self-Assessment	6	.2	1.2	4,160 hrs.; $346,944	4,992 hrs.; $416,332.8.
	Reliability Assessments		1	6	15,600 hrs.; $1,301,040.	93,600 hrs.; $7,806,240.
	Reliability Compliance		1	6	47,840 hrs.; $3,989,856.	287,040 hrs.; $23,939,136.
	Standards Development		1	6	4,680 hrs.; $390,312	28,080 hrs.; $2,341,872.
	Other Reporting		1	6	1,040 hrs.; $86,736	7,280 hrs.; $607,152.
Regional Entities, Sub-Total.					*420,992 hrs.; $35,110,732.6..*	
Registered Entities	Stakeholder Survey	estimated 1,496	.2	299.2	8 hrs.; $667.20	2,393.6 hrs.; $199,626.2.
	Reliability Compliance		1	1,496	400 hrs.; $33,360	598,400 hrs.; $49,906,186.
Registered Entities, Sub-Total.						*600,793.60 hrs.; $50,106,186.*
Total Burden Hrs. and Cost.						1,134,938 hrs.; $94,653,796.

As indicated in the table, there was a decrease from seven to six in the number of Regional Entities because the Florida Reliability Coordinating Council (FRCC) dissolved in July 2019. Other changes from previous estimates are based on new data in the proposed NERC 2022 Business Plan and Budget to reflect changes in the number of FTEs (full-time equivalent employees) working in applicable areas. Reviewing the NERC Compliance database, we determined the number of unique U.S. entities is 1,496 (compared to the previous value of 1,409). Lastly, in several instances, the amount of time an FTE devotes to a given function may have been increased or decreased.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: January 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00353 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

[6] In instances where the number of responses per respondent is ''1,'' the Commission Staff thinks that the actual number of responses varies and cannot be estimated accurately.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RC11–6–014]

Notice of Filing; North American Electric Reliability Corporation

Take notice that on November 17, 2021, the North American Electric Reliability Corporation submitted an annual report on the Find, Fix, Track and Compliance Exception programs, in accordance with the Federal Energy Regulatory Commission's (Commission) Orders.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using

[1] *See, North American Electric Reliability Corp.,* 138 FERC 61,193 (2012); *North American Electric Reliability Corp.,* 143 FERC 61,253 (2013); *North American Electric Reliability Corp.,* 148 FERC 61,214 (2014); *North American Electric Reliability Corp.,* Docket No. RC11–6–004 (Nov. 13, 2015) (delegated letter order).

the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 20, 2022.

Dated: January 6, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00409 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–773–000]

Mulligan Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Mulligan Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 26, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: January 6, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–00428 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15253–000]

Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications; Great Divide Energy Park LLC

On December 10, 2021, Great Divide Energy Park LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), to study the feasibility of the Great Divide Closed Loop Pumped Storage Hydro Project to be located near Jeffery City, in Fremont County, Wyoming. The proposed project would be located in part on federal lands administered by the U.S. Bureau of Land Management. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed pumped storage project would consist of the following new facilities: (1) A 5,062-foot-long earthen and/or roller compacted concrete embankment, creating a reservoir with a normal maximum water surface area of 8,900 feet and a storage capacity of 6,000 acre-feet; (2) a 4,093-foot-long, 18-foot diameter steel penstock that would convey water from the upper reservoir to the turbine/pump units in the powerhouse and to the lower reservoir; (3) a 760-foot-long, 200-foot-wide powerhouse located adjacent to the lower reservoir containing three 133–MW quaternary turbine/pump unit pairs for a combined capacity of approximately 399 megawatts; (4) a 5,371-foot-long earthen and/or roller compacted concrete embankment, creating a lower reservoir with a normal maximum water surface area of 7,850 feet and a storage capacity of 6,000 acre-feet; (5) gravel access roads to provide access to the upper or lower reservoirs from existing roads; (6) a 2.37 mile-long, 230 kilovolts (kV) transmission line; and (7) appurtenant facilities. The estimated annual generation of the Great Divide Closed Loop Pumped Storage Hydro Project would be approximately 1,861 gigawatt-hours, (GWhs).

Applicant Contact: Mr. Carl Borgquist, CEO Great Divide Energy Park LLC, 612 East Main St., Suite C,

P.O. Box 309, Bozeman, MT 59771; phone: (406) 585–3006; email: *carl@absarokaenergy.com.*

FERC Contact: Lauren Townson; phone: (202)-502–8572; email: *Lauren.townson@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 Days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–15253–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–15253) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 6, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00407 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–24–000]

Equitrans L.P.; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Truittsburg Well Conversion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Truittsburg Well Conversion Project involving construction and operation of facilities by Equitrans L.P. (Equitrans) in Clarion County, Pennsylvania. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on February 4, 2022. Comments may be submitted in written form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on December 13, 2022, you will need to file those comments in Docket No. CP22–24–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Equitrans provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (*www.ferc.gov*) under the Natural Gas Questions or Landowner Topics link.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.*

(1) You can file your comments electronically using the *eComment* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP22–24–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Summary of the Proposed Project

Equitrans is proposing to convert two observation wells into injection/withdrawal (I/W) wells in the existing Truittsburg Storage Field. Specifically, Equitrans is proposing to add approximately 1,119 feet of 4-inch-diameter natural gas pipeline to convert Truittsburg wells 2483 and 2484 from observation wells to I/W wells and install pigging [1] valves at the wellheads and associated piping. According to Equitrans, the purpose for the project is to transport gas from the wells to the main storage trunk line thereby increasing working gas capacity at the Truittsburg Storage Field.

The general location of the project facilities is shown in appendix 1.[2]

Land Requirements for Construction

The project would result in temporary impacts on 1.44 acres, with no permanent land impacts. Construction activities would require the use of 831 feet of existing permanent access roads and 1.44 acres of new pipeline right-of-way and temporary workspace.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- environmental justice;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary [3] and the Commission's natural gas environmental documents web page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[5] The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

[1] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary.'' For instructions on connecting to eLibrary, refer to the last page of this notice. At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[3] For instructions on connecting to eLibrary, refer to the last page of this notice.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Section 1501.8.

[5] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to *GasProjectAddressChange@ferc.gov* stating your request. You must include the docket number CP22–24–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

Or

(2) Return the attached ''Mailing List Update Form'' (appendix 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *https://www.ferc.gov/news-events/events* along with other related information.

Dated: January 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00359 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4644–016]

GR Catalyst Two, LLC; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process

a. *Type of Application:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 4644–016.

c. *Date filed:* November 30, 2021.

d. *Submitted by:* GR Catalyst Two, LLC (GR Catalyst).

e. *Name of Project:* Dahowa Hydroelectric Project.

f. *Location:* Located on the Batten Kill, a tributary of the Hudson River in Washington County, New York. The project does not occupy any federal land.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Ms. Celeste Fay, Director of Regulatory Affairs, GR Catalyst Two, LLC, c/o Gravity Renewables, Inc, P.O. Box 7580, Boulder, CO 80306, Phone: (303) 440–3378, Email: *Celeste@gravityrenewables.com.*

i. *FERC Contact:* Claire Rozdilski, Phone: (202) 502–8259, Email: *claire.rozdilski@ferc.gov.*

j. GR Catalyst filed its request to use the Traditional Licensing Process on November 30, 2021 and provided public notice of its request on the same date. In a letter dated January 6, 2022, the Director of the Division of Hydropower Licensing approved GR Catalyst's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the New York State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating GR Catalyst as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. GR Catalyst filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD may be viewed on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

o. The applicant states its unequivocal intent to submit an application for a new license for Project No. 4644. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by November 30, 2024.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: January 6, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00410 Filed 1–11–22; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12

CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 27, 2022.

A. Federal Reserve Bank of San Francisco (Sebastian Astrada, Director, Applications) 101 Market Street, San Francisco, California 94105–1579:

1. *Joaquin P.L.G. Cook, Chalan Pago-Ordot, Guam; to acquire control of voting shares of BankGuam Holding Company (BankGuam), by becoming trustee of the Voting Trust Agreement of BankGuam, which controls BankGuam, and thereby indirectly controls Bank of Guam, both of Hagatna, Guam, and with Martin D. Leon Guerrero, Martin Perez Leon Guerrero, William D. Leon Guerrero, Zita T. Leon Guerrero, the Jesus S. Leon Guerrero Family Trust, Eugenia A. Leon Guerrero, as trustee, Lourdes A. Leon Guerrero, the Felino B. Amistad and Fulgencia R. Amistad Trust, Felino A. Amistad, as trustee, Dominica LG Aguon, Pedro Perez Ada, Ada's Trust & Investments and the Ada's Family Trust, Pedro Perez Ada, Patricia Ann Perez Ada, and Teresa A. John, as co-executors and co-trustees, respectively, the John Family Living Trust, David James John and Teresa Ada John, as co-trustees, the Luis and Cynthia Camacho Living Trust, Cynthia Camacho, as trustee, all of Hagatna, Guam; Joe T. San Agustin, Dededo, Guam; Vincent Leon Guerrero, Mangilao, Guam; Patricia P. Ada, Tamuning, Guam; Agnes Leon Guerrero Winters and Tyler Reece Leon Guerrero Winters, both of Camarillo, California; Frances Perez Ada Purviance, El Dorado Hills, California; John S. San Agustin, San Francisco, California; Michelle M. Sablan, Santa Cruz, California; Carla Perez Ada, Sausalito, California; Maria Ada Bonnie, Minneapolis, Minnesota; the Ralph Guerrero Sablan and MaryAnne Gutierrez Sablan Living Trust, Hagatna, Guam, Mark J. Sablan, Hagatna, Guam, individually, and as co-trustee with Ralph Gregory Sablan, Agana Heights, Guam, individually, and as co-trustee; Michael S. Wu, Locust, New Jersey; James Wu, Shaker Heights, Ohio; and Rebecca S. Mann, Columbia, South Carolina;* as members of Voting Trust Agreement of BankGuam, a group acting in concert, to retain voting shares of BankGuam Holding Company, and thereby indirectly retain voting shares of Bank of Guam, both of Hagatna, Guam.

Board of Governors of the Federal Reserve System, January 7, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–00439 Filed 1–11–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 26, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *The First Amended and Restated Mark R. Peterson Bank Trust, the First Amended and Restated Susan P. Depass Bank Trust, the First Amended and Restated Chase R. Peterson Bank Trust, the First Amended and Restated Clair P. Peterson Bank Trust, the First Amended and Restated Cole M. Peterson Bank Trust, and the First Amended and Restated Aja M. Depass Bank Trust, Mark R. Peterson, as trustee, the Polly P. Peterson Trust, and the Polly P. Peterson IRA, Polly P. Peterson, as trustee and owner, respectively, all of Dakota Dunes, South Dakota;* to join the Peterson Family Control Group, a group acting concert, to retain voting shares of Liberty Financial Services, Inc., and thereby indirectly retain voting shares of Liberty National Bank, both of Sioux City, Iowa.

Board of Governors of the Federal Reserve System, January 6, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–00446 Filed 1–11–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0007; Docket No. 2022–0053; Sequence No. 3]

Information Collection; Subcontracting Plans

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on an extension concerning subcontracting plans. DoD, GSA, and NASA invite comments on: Whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to

be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through March 31, 2022. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by March 14, 2022.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit comments on this collection through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

Instructions: All items submitted must cite OMB Control No. 9000–0007, Subcontracting Plans. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0007, Subcontracting Plans.

B. Need and Uses

This clearance covers the information that offerors and contractors must submit to comply with the requirements in Federal Acquisition Regulation (FAR) 52.219–9, Small Business Subcontracting Plans, regarding subcontracting plans as follows:

1. Subcontracting plan. In accordance with section 8(d) of the Small Business Act (15 U.S.C. 637(d)), any contractor receiving a contract for more than the simplified acquisition threshold must agree in the contract that small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns will have the maximum practicable opportunity to participate in contract performance. Further, 15 U.S.C. 637(d) imposes the requirement that contractors receiving a contract that is expected to exceed, or a contract modification that causes a contract to exceed, $750,000 ($1.5 million for construction) and has subcontracting possibilities, shall submit an acceptable subcontracting plan that provides maximum practicable opportunities for small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Specific elements required to be included in the plan are specified in section 8(d) of the Small Business Act and implemented in FAR subpart 19.7 and the clause at FAR 52.219–9.

2. Summary Subcontract Report (SSR). In conjunction with the subcontracting plan requirements, contractors with subcontracting plans must submit an annual summary of subcontracts awarded as prime and subcontractors for each specific Federal Government agency. Contractors submit the information in a SSR through the Electronic Subcontracting Reporting System (eSRS). This is required for all contractors with subcontracting plans regardless of the type of plan (*i.e.,* commercial or individual).

3. Individual Subcontract Report (ISR). In conjunction with the subcontracting plan requirements, contractors with individual subcontracting plans must submit semi-annual reports of their small business subcontracting progress. Contractors submit the information through eSRS in an ISR, the electronic equivalent of the Standard Form (SF) 294, Subcontracting Report for Individual Contracts. Contracts that are not reported in the Federal Procurement Data System (FPDS) in accordance with FAR 4.606(c)(5) do not submit ISRs in eSRS; they will continue to use the SF 294 to submit the information to the agency.

4. Written explanation for not using a small business subcontractor as specified in the proposal or subcontracting plan. Section 1322 of the Small Business Jobs Act of 2010 (Jobs Act), Public Law 111–240, amends the Small Business Act (15 U.S.C. 637(d)(6)) to require as part of a subcontracting plan that a prime contractor make good faith effort to utilize a small business subcontractor during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. If a prime contractor does not utilize a small business subcontractor as described above, the prime contractor is required to explain, in writing, to the contracting officer the reasons why it is unable to do so.

C. Annual Burden

Respondents: 36,088.
Total Annual Responses: 55,016.
Total Burden Hours: 135,595.
Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0007, Subcontracting Plans.

William Clark,
Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2022–00415 Filed 1–11–22; 8:45 am]
BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10718]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to pilot the collection of race and ethnicity data on Part C and D enrollment forms. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by March 14, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10718 Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request; *Use:* The enrollment form is considered a ''model'' under Medicare regulations at §§ 422.2262 and 423.2262, for purposes of communication and marketing review and approval; therefore, MA and Part D plans are able to modify the language, content, format, or order of the enrollment form. The model enrollment form includes the minimal amount of information to process the enrollment, located in Section 1, and other limited information, in Section 2, that the sponsor is required (*i.e.,* race and ethnicity data, accessible format preference) or chooses to provide to the beneficiary (*i.e.,* premium payment information). The optional data elements, which aid the MA and Part D plans in processing the enrollment, is developed for efficiency for the plans. Plan sponsors can obtain information at the initial point of contact to help streamline the beneficiary's enrollment process. The optional questions include information, specific to the plan's business needs that serves to reduce overall burden and allow for timely processing of an enrollment request. All data elements in Section 2 are optional for the beneficiary to complete, but the plan will be required to have the questions on the enrollment forms. Plan enrollment will not be affected if the beneficiary does not complete this additional information.

With the long-term goal of collecting race and ethnicity data from all Medicare beneficiaries, CMS will focus initial efforts on beneficiaries who newly elect or change coverage in the Medicare Part C and D program. The detailed race and ethnicity categories collected through the demographic pilot on the enrollment form will be compliant with the 2011 HHS Data Collection Standards to provide granular information for plans and CMS to understand the diversity of the beneficiary population. The data will be used to: (1) Explore the response rate to race and ethnicity questions as a whole and how it intersects with beneficiary income and other demographics; (2) Conduct focus groups, to be approved in a separate PRA package, among non-responders to the race and ethnicity questions to understand how people who elect to not respond to the race and ethnicity questions perceive the addition of those questions on the form; (3) Continue to test CMS' race and ethnicity imputation models by adding additional race and ethnicity data to the data CMS already has; and (4) Determine the data necessary for sufficient samples sizes to conduct analyses of disaggregated race and ethnicity categories. As part of a broader health equity effort, CMS has interest in identifying patterns of differences across many key process and care outcomes by sociodemographic characteristics, including race and ethnicity. To best characterize these differences, self-reported *and* granular data are needed. Collecting these data will support efforts to continue to strengthen, for example, CMS OMH's stratified reporting efforts, which currently *do* consider quality indicators by race and ethnicity, but at present these data are *not* granular and *not* self-reported. In addition, this data will allow us to validate imputation methods CMS currently uses for race and ethnicity, to ensure that we do not rely on methodologies that unintentionally create or exacerbate disparities. To assess readiness for analysis of collected data (particularly with regard to considering sample sizes, especially of small groups), continual assessment will be required—simultaneously as enrollment happens—because readiness will depend partly on distribution of responses to these items by enrollees.

These categories are of great interest to CMS and will improve the accuracy of current data sets. We acknowledge that it may take several years of data collection to conduct other meaningful studies CMS intends to pursue that are not listed above. In addition to the aforementioned uses, CMS will ultimately use this information to: Track beneficiary enrollment, including tracking patterns in enrollment by race and ethnicity over time; to identify, monitor, and develop effective and efficient strategies and incentives to reduce and eliminate health and health care inequities; to validate existing race and ethnicity imputation methods; and to ensure that clinically appropriate and equitable care (in terms of payment, access, and quality) is consistently provided to all beneficiaries. *Form Number:* CMS–10718 (OMB control number: 0938–1378); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments, Federal Government, Private Sector (Business or other for-

profits and Not-for-profits); *Number of Respondents:* 80,539,628; *Number of Responses:* 80,539,628; *Total Annual Hours:* 8,567,975. (For questions regarding this collection contact Deme Umo at (410) 786–8854.).)

Dated: January 6, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–00375 Filed 1–11–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Success Sequence Qualitative Interviews (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), proposes interview data collection activities for the Success Sequence Interviews study.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OPRE/ACF/HHS proposes qualitative data collection as part of the Success Sequence Interviews study. The goal of this project is to understand complex decisions and circumstances of youth transitions to adulthood and explore the complexities around achieving the success sequence milestones of high school graduation, full-time employment, getting married, and having children. The data collected from the interviews will help ACF and the broader research field understand adults' perspectives and experiences related to the milestones, and will provide ACF's Family and Youth Services Bureau's Sexual Risk Avoidance Education grant program with greater insight into the program content and strategies related to the success sequence milestones and their ordering that could best resonate with youth. To support these efforts, we seek approval from the Office of Management and Budget to collect qualitative interview data from adults ages 30–35, recruiting from online research panels with participants across all U.S. regions. We propose the following data collection instruments:

(1) *Success Sequence Screener:* The screener will be administered by telephone. Information collected through the screener will be used to screen interview respondents into the study based on respondent demographics, household income, geographic location, and life milestones.

(2) *Success Sequence Interview Protocol:* We will administer an asynchronous interview with adults ages 30–35. Information collected through the interview protocol includes respondent life history focused on education, employment and work experience, family life, and financial status.

Respondents: A total of 225 interview respondents will be recruited from existing large national online panels of research participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden per response (in hours)	Total/annual burden (in hours)
(1) Success Sequence Screener	675	1	.083	56
(2) Success Sequence Interview Topic Guide	225	1	.75	169

Estimated Total Annual Burden Hours: 225.

Authority: Sec. 510. [42 U.S.C. 710].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–00366 Filed 1–11–22; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for Title VII, Part B of the Rehabilitation Act, Independent Living Services To Expand the Public Health Workforce

Title: Expanding the Public Health Workforce Within the Disability Networks: Independent Living Services.

Announcement Type: Initial.

Statutory Authority: The statutory authority for grants under this program announcement is Section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) and awards authorized under Title VII, Part B of the Rehabilitation Act of 1973 (29. U.S.C. 796f *et seq.*), Independent Living Services, shall be provided funding under this opportunity.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.369.

DATES: The deadline date for the submission of the Expanding the Public Health Workforce within the Disability Networks: Independent Living Services is 11:59 p.m. Eastern Time February 11, 2022.

I. Funding Opportunity Description

The Administration for Community Living (ACL) announced a new funding opportunity to expand the public health workforce within the disability

networks. Public health promotes and protects the health of people and the communities where they live, learn, work, and play. The disability networks funded by ACL play an essential role in that work. The disability networks consist of trusted organizations and programs that reach and provide services and supports to people with disabilities in every community throughout the nation, including those related to public health, such as health and wellness education and information, counseling, case management and guidance related to health and social needs, as well as how to access those supports. These networks have over 50 years of community experience and possess intimate knowledge of the public health and other resources available and the needs of older adults in their direct area.

As part of its ongoing COVID–19 response efforts, the Biden-Harris Administration is investing federal funds through the American Rescue Plan Act of 2021 (ARPA) [1] to recruit, hire, and train public health workers to respond to the pandemic and prepare for future public health challenges. Specifically, the Secretary of the U.S. Department of Health and Human Services (HHS) will ''carry out activities related to establishing, expanding, and sustaining a public health workforce . . . ,'' ARPA § 2501(a), and funds may be used to support costs, including wages and benefits, of a range of public health professionals including but not limited to social support professionals, community health workers, communication and policy experts and ''. . . other positions as may be required to prevent, prepare for, and respond to COVID–19 . . . ,'' ARPA § 2501(b)(1).

To help advance these efforts, ACL has created the Expanding the Public Health Workforce within the Disability Networks program. This program aims to increase the number of public health professionals within the disability networks to address the unique needs of people with disabilities through the support of wages and benefits for these professionals. Professionals supported through this program may provide a wide range of public health services and supports, including provision of culturally affirmative and linguistically accessible information, access assistance for vaccines and boosters, transition and diversion from high-risk congregate settings to community living, provision and connections to health and wellness programs, activities that address social isolation and social determinants of health, and other activities that support the public health and wellbeing of people with disabilities.

Designated state entities (DSEs)—the eligible entities for this opportunity—shall be provided funding to support wages and benefits for new staff or increase the full-time equivalent (FTE) of existing staff under this opportunity within the Part B Independent Living Services program. Award recipients are encouraged to make sub-awards to Part B funded CILs, Statewide Independent Living Councils (SILCs), and/or Part C funded CILs that receive Part B funding. Sub-awards may be allocated through an even distribution or based on information in the state plan for independent living, or other distribution based on need as determined by the chairperson of the SILC and the directors of the CILs in the State for the purposes of this funding. Although not required for funding, grantees are encouraged to explore options for funding to sustain the new FTE after the end of the grant. There is no cost sharing or matching requirement for this funding.

Award recipients will be required to submit annual progress reports in the form of a written summary on the number of full-time equivalents (FTEs) funded, type of public health professional(s) hired, and the activities they are engaged in to advance public health. To be eligible to receive this grant, the DSE must submit a Letter of Assurance to ACL containing all the assurances required (see ''Section III. Eligibility Criteria and Other Requirements'' and ''Section IV. Submission Information''). DSEs that do not submit a Letter of Assurance or otherwise indicate no desire to receive funds, will be excluded from receiving funds.

ACL may extend deadlines based on the need of the COVID–19 response, *e.g.,* to meet unanticipated issues related to COVID–19 and/or to allow impacted DSEs that missed the cut-off date to submit a Letter of Assurance for consideration. ACL intends to issue notices of award as soon as possible with an estimated start date of March 1, 2022. However, the actual award may be released earlier or later than that date. Because the total amount awarded to each grantee is contingent upon the total number of grantees applying for funding, grant awards will be issued after ACL receives responses from all eligible DSEs. Regardless of the date of award, the funding will be available until September 30, 2024. Grantees may use the funds over any period of time before this date but are encouraged to use the funding as soon as possible to have the greatest impact.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of new grants, evenly distributed to eligible entities.

2. Anticipated Total Funding per Budget Period

Awards made under this announcement will have an estimated start date of March 1, 2022 and an end date of September 30, 2024.

The total available funding for this opportunity is $4,480,000.

Eligible entities who do not complete assurance requirements below, or otherwise indicate no desire to receive funds, will be excluded from receiving funds. This will have the effect of increasing the amount of funds available for eventual recipients.

ACL will distribute the $4,480,000 evenly to all eligible entities to ensure a sufficient level of funding to provide substantive support for the public health workforce, which equates to a minimum award of $80,000. This figure is based on the current number of eligible entities and would rise if some eligible entities refuse or are deemed ineligible.

III. Eligibility Criteria and Other Requirements

1. Eligible Entities

The eligible entity for these awards is the designated state entity (DSE) for Part B Independent Living Services under Title VII of the Rehabilitation Act.

2. Match

Cost Sharing or Matching is not required.

3. Other Requirements

A. Letter of Assurance

A Letter of Assurance is required to be submitted by the eligible entity in order to receive an award. The Letter of Assurance must include the following:

1. Assurance that the award recipient is the DSE for Part B Independent Living Services.

2. Assurance that funds will be spent in ways consistent with the purpose of the funding to support the cost of wages and benefits for public health professionals, directly or through contract, such as:

- Case investigator,
- Contact tracer,
- Social support specialist,
- Community health worker,
- Public health nurse,
- Disease intervention specialist,

[1] American Rescue Plan Act of 2021, Public Law 117–2, 135 Stat 4 (Mar. 11, 2021).

- Epidemiologist,
- Program manager,
- Laboratory personnel,
- Informaticians,
- Communication and policy experts,
- Other positions as may be required to prevent, prepare for, and respond to COVID–19.

3. Plan for the distribution of funds within the state Part B funded independent living services program. Award recipients are encouraged to make sub-awards to Part B funded CILs, Statewide Independent Living Councils (SILCs), and/or Part C funded CILs that receive Part B funding. Sub-awards may be allocated through an even distribution or based on information in the state plan for independent living, or other distribution based on need as determined by the chairperson of the SILC and the directors of the CILs in the State for the purposes of this funding.

4. Assurance to provide semi-annual federal financial reports and annual program reports that include the number and type of full-time equivalents hired, and activities performed to advance public health.

B. DUNS Number

All grant applicants must obtain and keep current a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: *https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm.*

C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to *PHWF@acl.hhs.gov.*

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022. Letters of Assurance should be submitted electronically via email and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic and Submission Issues

Direct programmatic inquiries to *PHWF@acl.hhs.gov.*

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00398 Filed 1–11–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for Title VII, Part C of the Rehabilitation Act, Centers for Independent Living (CILs) To Expand the Public Health Workforce

Title: Expanding the Public Health Workforce within the Disability Networks: Centers for Independent Living.

Announcement Type: Initial.

Statutory Authority: The statutory authority for grants under this program announcement is Section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) and awards authorized under Part C of the Rehabilitation Act of 1973 (29. U.S.C. 796f *et seq.*), Centers for Independent Living, shall be provided funding under this opportunity.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.432.

DATES: The deadline date for the submission of the Expanding the Public Health Workforce within Disability Networks: Centers for Independent Living is 11:59 p.m. Eastern Time February 11, 2022.

I. Funding Opportunity Description

The Administration for Community Living (ACL) announced a new funding opportunity to expand the public health workforce within the disability networks. Public health promotes and protects the health of people and the communities where they live, learn, work, and play. The disability networks funded by the Administration for Community Living (ACL) play an essential role in that work. The disability networks consist of trusted organizations and programs that reach and provide services and supports to people with disabilities in every community throughout the nation, including those related to public health such as health and wellness education and information, counseling, case management and guidance related to health and social needs, as well as how to access those supports. These networks have over 50 years of community experience and possess intimate knowledge of the public health and other resources available and the needs of people with disabilities in their direct area.

As part of its ongoing COVID–19 response efforts, the Biden-Harris Administration is investing federal funds through the American Rescue Plan Act of 2021 (ARPA) [1] to recruit, hire, and train public health workers to respond to the pandemic and prepare for future public health challenges. Specifically, the Secretary of the U.S. Department of Health and Human Services (HHS) will ''carry out activities related to establishing, expanding, and sustaining a public health workforce. . . .'' ARPA § 2501(a), and funds may be used to support costs, including wages and benefits, of a range of public health professionals including but not limited to social support professionals, community health workers, communication and policy experts and ''. . . other positions as may be required to prevent, prepare for, and respond to COVID–19. . . .'' ARPA § 2501(b)(1).

To help advance these efforts, ACL has created the Expanding the Public Health Workforce within Disability Networks program. This program aims to increase through the support of wages and benefits the number of public health professionals within the disability networks to address the unique needs of individuals with disabilities. Public health professionals supported through this program may provide a wide range of public health services and supports, including provision of culturally affirmative and linguistically accessible information, access assistance for vaccines and boosters, transition and diversion from high-risk congregate settings to community living, provision and connections to health and wellness programs, activities that address social isolation and social determinants of health, and other activities that support the public health and wellbeing of people with disabilities.

Centers for Independent Living (CILs) under the Rehabilitation Act (Rehab Act)—the eligible entities for this opportunity—shall be provided funding to support new staff or increase the full-time equivalent (FTE) of existing staff under this opportunity to carry out public health services and supports. Although not required for funding, grantees are encouraged to explore options for funding to sustain the new

[1] American Rescue Plan Act of 2021, Public Law 117–2, 135 Stat 4 (Mar. 11, 2021).

FTE after the end of the grant. There is no cost sharing or matching requirement for this funding.

Award recipients will be required to submit annual progress reports in the form of a written summary on the number of full-time equivalents (FTEs) funded, type of public health professional(s) hired, and the activities they are engaged in to advance public health. To be eligible to receive this grant, the CIL must submit a Letter of Assurance to ACL containing all the assurances required, (see below, ''Section III. Eligibility Criteria and Other Requirements'' and ''Section IV. Submission Information''). CILs that do not submit a Letter of Assurance or otherwise indicate no desire to receive funds, will be excluded from receiving funds.

ACL may extend deadlines based on the need of the COVID–19 response, *e.g.,* to meet unanticipated issues related to COVID–19 and/or to allow impacted CILs that missed the cut-off date to submit a letter of assurance for consideration. ACL intends to issue notices of award as soon as possible with an estimated start date of March 1, 2022. However, the actual award may be released earlier or later than that date. Because the total amount awarded to each grantee is contingent upon the total number of grantees applying for funding, grant awards will be issued after ACL receives responses from all eligible CILs. Regardless of the date of award, the funding will be available until September 30, 2024. Grantees may use the funds over any period of time before this date but are encouraged to use the funding as soon as possible to have the greatest impact.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of new grants, evenly distributed to eligible entities.

2. Anticipated Total Funding per Budget Period

Awards made under this announcement will have an estimated start date of March 1, 2022 and an end date of September 30, 2024.

The total available funding for this opportunity is $38,297,600.

Eligible entities who do not complete assurance requirements below, or otherwise indicate no desire to receive funds will be excluded from receiving funds. This will have the effect of increasing the amount of funds available for eventual recipients.

ACL will distribute the $38,297,600 evenly to all eligible entities to ensure a sufficient level of funding to provide substantive support for the public health workforce, which equates to a minimum award of $104,069. This figure is based on the current number of eligible entities and would rise if some eligible entities refuse or are deemed ineligible.

III. Eligibility Criteria and Other Requirements

1. Eligible Entities

The eligible entity for these awards is designated by ACL as Centers for Independent Living under Part C of the Rehabilitation Act.

2. Match

Cost Sharing or Matching is not required.

3. Other Requirements

A. Letter of Assurance

A Letter of Assurance is required to be submitted by CILs in order to receive an award. The Letter of Assurance must include the following:

1. Assurance that the award recipient is an entity designated as a Part C funded CIL under the Rehab Act.

2. Assurance that funds will be spent in ways consistent with the purpose of the funding to support the cost of wages and benefits for public health professionals, directly or through contract such as:

- Case investigator,
- Contact tracer,
- Social support specialist,
- Community health worker,
- Public health nurse,
- Disease intervention specialist,
- Epidemiologist,
- Program manager,
- Laboratory personnel,
- Informaticians,
- Communication and policy experts,
- Other positions as may be required

to prevent, prepare for, and respond to COVID–19.

3. Assurance to provide semi-annual federal financial reports and annual program reports that include the number and type of full-time equivalents hired, and activities performed to advance public health.

B. DUNS Number

All grant applicants must obtain and keep current a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: *https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm.*

C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to *PHWF@acl.hhs.gov.*

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022. Letters of Assurance should be submitted electronically via email and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic and Submission Issues

Direct programmatic and submission inquiries to *PHWF@acl.hhs.gov.*

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00397 Filed 1–11–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for Subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act, State Councils on Developmental Disabilities To Expand the Public Health Workforce

Title: Expanding the Public Health Workforce within the Disability Networks: State Councils on Developmental Disabilities.

Announcement Type: Initial.

Statutory Authority: The statutory authority for grants under this program announcement is Section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) and awards authorized under Subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C 15021 *et seq.*), State Councils, shall be provided funding under this opportunity.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.620.

DATES: The deadline date for the submission of the Expanding the Public Health Workforce within Disability Networks: State Councils on Developmental Disabilities is 11:59 p.m. Eastern Time February 11, 2022.

I. Funding Opportunity Description

The Administration for Community Living (ACL) announced a new funding opportunity to expand the public health workforce within the disability networks. Public health promotes and protects the health of people and the communities where they live, learn, work, and play. The disability networks funded by the Administration for Community Living (ACL) play an essential role in that work. The disability networks consist of trusted organizations and programs that reach and provide services and supports to people with disabilities in every community throughout the nation, including those related to public health such as health and wellness education and information, counseling, case management and guidance related to health and social needs, as well as how to access those supports. These networks have over 50 years of community experience and possess intimate knowledge of the public health and other resources available and the needs of people with disabilities in their direct area.

As part of its ongoing COVID–19 response efforts, the Biden-Harris Administration is investing federal funds through the American Rescue Plan Act of 2021 (ARPA) [1] to recruit, hire, and train public health workers to respond to the pandemic and prepare for future public health challenges. Specifically, the Secretary of the U.S. Department of Health and Human Services (HHS) will ''carry out activities related to establishing, expanding, and sustaining a public health workforce. . . ,'' ARPA § 2501(a), and funds may be used to support costs, including wages and benefits, of a range of public health professionals including but not limited to social support professionals, community health workers, communication and policy experts and ''. . . other positions as may be required to prevent, prepare for, and respond to COVID–19. . . ,'' ARPA § 2501(b)(1).

To help advance these efforts, ACL has created the Expanding the Public Health Workforce within Disability Networks program. This program aims to increase through the support of wages and benefits the number of public health professionals within the disability networks to address the unique needs of individuals with disabilities. Public health professionals supported through this program may provide a wide range of public health services and supports, including provision of culturally affirmative and linguistically accessible information, access assistance for vaccines and boosters, transition and diversion from high-risk congregate settings to community living, provision and connections to health and wellness programs, activities that address social isolation and social determinants of health, and other activities that support the public health and wellbeing of people with disabilities.

State Councils on Developmental Disabilities (Councils)—the eligible entities for this opportunity—under the Developmental Disabilities Assistance and Bill of Rights Act (DD Act) shall be provided funding to support new staff or increase the full-time equivalent (FTE) of existing staff under this opportunity to carry out public health services and supports. Although not required for funding, grantees are encouraged to explore options for funding to sustain the new FTE after the end of the grant. There is no cost sharing or matching requirement for this funding.

Award recipients will be required to submit annual progress reports in the form of a written summary on the number of full-time equivalents (FTEs) funded, type of public health professional(s) hired, and the activities they are engaged in to advance public health. To be eligible to receive this grant, the Councils must submit a Letter of Assurance to ACL containing all the assurances required, (see below, ''Section III. Eligibility Criteria and Other Requirements'' and ''Section IV. Submission Information''). Councils that do not submit a Letter of Assurance or otherwise indicate no desire to receive funds, will be excluded from receiving funds.

ACL may extend deadlines based on the need of the COVID–19 response, *e.g.,* to meet unanticipated issues related to COVID–19 and/or to allow impacted Councils that missed the cut-off date to submit a letter of assurance for consideration. ACL intends to issue notices of award as soon as possible with an estimated start date of March 1, 2022. However, the actual award may be released earlier or later than that date. Because the total amount awarded to each grantee is contingent upon the total number of grantees applying for funding, grant awards will be issued after ACL receives responses from all eligible DDCs. Regardless of the date of award, the funding will be available until September 30, 2024. Grantees may use the funds over any period of time before this date but are encouraged to use the funding as soon as possible to have the greatest impact.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of new grants, evenly distributed to eligible entities.

2. Anticipated Total Funding per Budget Period

Awards made under this announcement will have an estimated start date of March 1, 2022 and an end date of September 30, 2024.

The total available funding for this opportunity is $4,480,000.

Eligible entities who do not complete assurance requirements below, or otherwise indicate no desire to receive funds will be excluded from receiving funds. This will have the effect of increasing the amount of funds available for eventual recipients. ACL will distribute the $4,480,000 evenly to all eligible entities to ensure a sufficient level of funding to provide substantive support for the public health workforce, which equates to a minimum award of $80,000. This figure is based on the current number of eligible entities and would rise if some eligible entities refuse or are deemed ineligible.

III. Eligibility Criteria and Other Requirements

1. Eligible Entities

The eligible entity for these awards is designated by ACL as State Developmental Disabilities Councils authorized under Subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act.

2. Match

Cost Sharing or Matching is not required.

3. Other Requirements

A. Letter of Assurance

A Letter of Assurance is required to be submitted by the eligible entity in order to receive an award. The Letter of Assurance must include the following:

1. Assurance that the award recipient is the agency or entity designated as the State DD Council in the state or territory under section 125 of the DD Act (42 U.S.C. 15025).

2. Assurance that funds will be spent in ways consistent with the purpose of

[1] American Rescue Plan Act of 2021, Public Law 117–2, 135 Stat 4 (Mar. 11, 2021).

the funding to support the cost of wages and benefits for public health professionals, directly or through contract such as:

- Case investigator,
- Contact tracer,
- Social support specialist,
- Community health worker,
- Public health nurse,
- Disease intervention specialist,
- Epidemiologist,
- Program manager,
- Laboratory personnel,
- Informaticians,
- Communication and policy experts,
- Other positions as may be required

to prevent, prepare for, and respond to COVID–19.

3. Assurance to provide semi-annual federal financial reports and annual program reports that include the number and type of full-time equivalents hired, and activities performed to advance public health.

B. DUNS Number

All grant applicants must obtain and keep current a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: *https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm.*

C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to *PHWF@acl.hhs.gov.*

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022 Letters of Assurance should be submitted electronically via email and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic and Submission Issues

Direct programmatic and submission inquiries to *PHWF@acl.hhs.gov.*

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00400 Filed 1–11–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Proposed Collection; Public Comment Request; of the No Wrong Door (NWD) System Management Tool OMB Control 0985–0062

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This IC Extension solicits comments on the information collection requirements relating to the Aging and Disability Resource Center/No Wrong Door System (ADRC/NWD). The statutory authority for ADRC/NWD is contained in Title IV of the Older Americans Act (OAA), as amended by the Older Americans Act Amendments of 2006.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by March 14, 2022.

ADDRESSES: Submit electronic comments on the collection of information to: *nowrongdoor@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Kristie Kulinski.

FOR FURTHER INFORMATION CONTACT: Kristie Kulinski, (202) 795–7379 or *kristie.kulinski@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

ACL, the Centers for Medicare and Medicaid Services (CMS), and the Veterans Health Administration (VHA) have partnered to support states' efforts in developing coordinated systems of access, or No Wrong Door (NWD) Systems, to make it easier for people to learn about and access long-term services and supports (LTSS). When seeking services and supports, individuals and caregivers often face multiple, fragmented processes that are complex and confusing. States' access systems have been built over time as programs and funding streams have been added, creating duplicative eligibility and intake processes that are difficult for individuals and their caregivers to use. To address these issues, the NWD System model supports state efforts to streamline access to LTSS options for all populations and provides the infrastructure to promote the collaboration of local service organizations, making service delivery more efficient and person-centered. Examples of coordinated efforts include processes where individuals are assessed once via a common or standardized data collection method

that captures a core set of individual level data relevant for determining the range of necessary LTSS.

The Federal vision for the NWD System gives states flexibility in determining how best to organize, structure and operate the various functions of their NWD System. States continue to integrate, in some cases restructure, and over time strengthen their existing programs in order to realize the joint ACL/CMS/VHA vision for a fully coordinated and integrated system of access. These efforts are supported by a variety of initiatives, including the VHA's Veteran Directed Care (VDC) program, an evidence-based self-directed program where person-centered counselors from aging and disability network agencies within a state's NWD System provide facilitated assessment and care planning, arrange fiscal management services, and provide ongoing counseling and support to Veterans, their families, and caregivers.

The NWD System Management Tool (NWD MT) provides a platform for data collection necessary to evaluate the four primary functions of a NWD System: State Governance and Administration, Public Outreach and Coordination with Key Referral Sources, Person Centered Counseling, and Streamlined Access to Public LTSS Programs. In addition, this tool will include data collection for the VDC program to collect qualitative and quantitative data elements necessary to evaluate the impact of the VDC program. The VDC Tool will track key performance measures and identify best practices and technical assistance needs.

The NWD MT and the VDC Tool will enable ACL and its partners to collect and analyze data elements necessary to assess the progress of the NWD System model, track performance measures, and identify gaps and best practices. These tools have been designed in close collaboration with states and are intended to simplify grant reporting requirements to reduce burden on local and state entities and will provide a consistent, streamlined and coordinated statewide approach to help states govern their NWD System and manage their programs efficiently.

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

Fifty-six lead NWD System state and territorial agencies will respond to the NWD MT bi-annually and it will take approximately half an hour to collect the data and an additional half hour to input the data into a web-based system. Additionally, an estimated 900 local agencies will take approximately two hours to collect and submit the data to their lead NWD System state agency. There may be several lead NWD System state and territorial agencies who will be submitting on behalf of their local agencies. Therefore, the approximate burden for the local level agencies may be thirty minutes less than anticipated. If all state and local agencies respond bi-annually, the national burden estimate for the NWD MT would be a total of 3,712 hours annually. This burden estimate is calculated based upon a sample of ADRC/NWD grantees. Each state entity submitting data will receive local-level data from designated NWD System entities. The estimated response burden includes time to review the instructions, gather existing information, and complete and review the data entries in a web-based system.

An estimated 275 VDC program entities will respond to the VDC Tool on a monthly-basis, all of which are also NWD local-level entities, for an annual burden of 1,650 hours. This burden estimate is calculated based upon information provided by current VDC program providers testing an abbreviated version of the VDC Tool. The NWD MT and the VDC Tool have been developed to increase ease and uniformity of reporting and improve the ability of ACL to manage and analyze data.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
NWD Management Tool data collection and entry—State Level	56	2	1.0	112
NWD Management Tool data collection and entry—Local Level	900	2	2.0	3,600
Veteran Directed Care Tool	275	12	0.5	1,650
Total	1,231			5,362

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00399 Filed 1–11–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000, Protection and Advocacy Systems To Expand the Public Health Workforce

Title: Expanding the Public Health Workforce within the Disability Networks: Protection and Advocacy Systems.

Announcement Type: Initial.

Statutory Authority: The statutory authority for grants under this program announcement is Section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) and awards authorized under Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C 15041 *et seq.*), Protection and Advocacy Systems, shall be provided funding under this opportunity.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.630.

DATES: The deadline date for the submission of the Expanding the Public Health Workforce within Disability Networks: Protection and Advocacy Systems is 11:59 p.m. Eastern Time February 11, 2022.

I. Funding Opportunity Description

The Administration for Community Living (ACL) announced a new funding opportunity to expand the public health workforce within the disability networks. Public health promotes and protects the health of people and the communities where they live, learn, work, and play. The disability networks funded by the Administration for Community Living (ACL) play an essential role in that work. The disability networks consist of trusted organizations and programs that reach and provide services and supports to people with disabilities in every community throughout the nation, including those related to public health

such as health and wellness education and information, counseling, case management and guidance related to health and social needs, as well as how to access those supports. These networks have over 50 years of community experience and possess intimate knowledge of the public health and other resources available and the needs of people with disabilities in their direct area.

As part of its ongoing COVID–19 response efforts, the Biden-Harris Administration is investing federal funds through the American Rescue Plan Act of 2021 (ARPA) [1] to recruit, hire, and train public health workers to respond to the pandemic and prepare for future public health challenges. Specifically, the Secretary of the U.S. Department of Health and Human Services (HHS) will ''carry out activities related to establishing, expanding, and sustaining a public health workforce . . . ,'' ARPA § 2501(a), and funds may be used to support costs, including wages and benefits, of a range of public health professionals including but not limited to social support professionals, community health workers, communication and policy experts and ''. . . other positions as may be required to prevent, prepare for, and respond to COVID–19 . . . ,'' ARPA § 2501(b)(1).

To help advance these efforts, ACL has created the Expanding the Public Health Workforce within Disability Networks program. This program aims to increase through the support of wages and benefits the number of public health professionals within the disability networks to address the unique needs of individuals with disabilities. Public health professionals supported through this program may provide a wide range of public health services and supports, including provision of culturally affirmative and linguistically accessible information, access assistance for vaccines and boosters, transition and diversion from high-risk congregate settings to community living, provision and connections to health and wellness programs, activities that address social isolation and social determinants of health, and other activities that support the public health and wellbeing of people with disabilities.

Protection and Advocacy Systems (P&As) under the Developmental Disabilities Assistance and Bill of Rights Act (DD Act)—the eligible entities for this opportunity—shall be provided funding to support new staff or increase the full-time equivalent (FTE) of existing staff under this opportunity to carry out public health services and supports. Although not required for funding, grantees are encouraged to explore options for funding to sustain the new FTE after the end of the grant. There is no cost sharing or matching requirement for this funding.

Award recipients will be required to submit annual progress reports in the form of a written summary on the number of full-time equivalents (FTEs) funded, type of public health professional(s) hired, and the activities they are engaged in to advance public health. To be eligible to receive this grant, the P&As must submit a Letter of Assurance to ACL containing all the assurances required, (see below, ''Section III. Eligibility Criteria and Other Requirements'' and ''Section IV. Submission Information''). P&As that do not submit a Letter of Assurance or otherwise indicate no desire to receive funds, will be excluded from receiving funds.

ACL may extend deadlines based on the need of the COVID–19 response, *e.g.,* to meet unanticipated issues related to COVID–19 and/or to allow impacted P&As that missed the cut-off date to submit a letter of assurance for consideration. ACL intends to issue notices of award as soon as possible with an estimated start date of March 1, 2022. However, the actual award may be released earlier or later than that date. Because the total amount awarded to each grantee is contingent upon the total number of grantees applying for funding, grant awards will be issued after ACL receives responses from all eligible P&As. Regardless of the date of award, the funding will be available until September 30, 2024. Grantees may use the funds over any period of time before this date but are encouraged to use the funding as soon as possible to have the greatest impact.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of new grants, evenly distributed to eligible entities.

2. Anticipated Total Funding per Budget Period

Awards made under this announcement will have an estimated start date of March 1, 2022 and an end date of September 30, 2024.

The total available funding for this opportunity is $6,384,000.

Eligible entities who do not complete assurance requirements below, or otherwise indicate no desire to receive funds will be excluded from receiving funds. This will have the effect of increasing the amount of funds available for eventual recipients.

ACL will distribute the $6,384,000 evenly to all eligible entities to ensure a sufficient level of funding to provide substantive support for the public health workforce, which equates to a minimum award of $112,000. This figure is based on the current number of eligible entities and would rise if some eligible entities refuse or are deemed ineligible.

III. Eligibility Criteria and Other Requirements

1. Eligible Entities

The eligible entity for these awards is designated by ACL as Protection and Advocacy Systems authorized under Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

2. Match

Cost Sharing or Matching is not required.

3. Other Requirements

A. Letter of Assurance

A Letter of Assurance is required to be submitted by the eligible entity in order to receive an award. The Letter of Assurance must include the following:

1. Assurance that the award recipient is the agency or entity designated as the Protection and Advocacy System in the state or territory under section 143 of the DD Act (42 U.S.C. 15042).

2. Assurance that funds will be spent in ways consistent with the purpose of the funding to support the cost of wages and benefits for public health professionals, directly or through contract such as:

- Case investigator,
- Contact tracer,
- Social support specialist,
- Community health worker,
- Public health nurse,
- Disease intervention specialist,
- Epidemiologist,
- Program manager,
- Laboratory personnel,
- Informaticians,
- Communication and policy experts,
- Other positions as may be required to prevent, prepare for, and respond to COVID–19.

3. Assurance to provide semi-annual federal financial reports and annual program reports that include the number and type of full-time equivalents hired, and activities performed to advance public health.

B. DUNS Number

All grant applicants must obtain and keep current a D–U–N–S number from

[1] American Rescue Plan Act of 2021, Public Law 117–2, 135 Stat 4 (Mar. 11, 2021).

Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: *https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm.*

C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to *PHWF@acl.hhs.gov.*

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022. Letters of Assurance should be submitted electronically via email and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic and Submission Issues

Direct programmatic and submission inquiries to *PHWF@acl.hhs.gov.*

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00401 Filed 1–11–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1817, FDA–2020–E–1818, and FDA–2020–E–1820]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** of November 1, 2021, for the determination of a regulatory review period for purposes of patent extension for the human biological product, ENHERTU. This document corrects that notice by adjusting the applicable regulatory review period for the testing phase and approval phase of the product, ENHERTU.

DATES: All due dates for submission of comments, redetermination requests, and submission of petitions for due diligence as well as the dates used to determine the regulatory review periods for the products noted above remain the same as originally published.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: On November 1, 2021, the Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** determining the regulatory review period for the human biological product ENHERTU. This correction to the notice adjusts the applicable regulatory review period of the product with the number of days occurring during the testing phase and the approval phase of the product ENHERTU.

Correction

In the **Federal Register** of November 1, 2021 (86 FR 60252), in FR Doc. 2021–23725, appearing on page 60253, in the third column, in section II., ''Determination of Regulatory Review Period,'' in the first two sentences, the following correction is made:

FDA has determined that the applicable regulatory review period for ENHERTU is 1,395 days. Of this time, 114 days occurred during the testing phase of the regulatory review period, while 1,281 days occurred during the approval phase.

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00404 Filed 1–11–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updates to the Bright Futures Periodicity Schedule

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Effective December 30, 2021, HRSA accepted recommended updates to the Bright Futures Periodicity Schedule, a HRSA-supported guideline for infants, children and adolescents for purposes of ensuring that non-grandfathered group and individual health insurance issuers provide coverage without cost sharing under the Public Health Service Act. The updates to the Bright Futures Periodicity Schedule are: A new category for sudden cardiac arrest and sudden cardiac death risk assessment, a new category for hepatitis B virus infection risk assessment, addition of suicide risk as an element of universal depression screening for children ages 12–21, and updated category title from ''Psychosocial/Behavioral Assessment'' to ''Behavioral/Social/Emotional Screening,'' with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added, with no associated recommended changes to clinical practice or health insurance coverage. Please see *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Savannah Kidd, M.S. MFT, HRSA/Maternal and Child Health Bureau by calling 301–287–2601 or by emailing at *SKidd@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Bright Futures program has been funded by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and recommend updates to the *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents,* a set of materials and tools that provide theory-based and evidence-driven guidance for all preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program's existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child's development.

Section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13), added by the Patient Protection and Affordable Care Act (Pub. L. 111–148), requires that non-grandfathered group health plans and health insurance issuers offering

group or individual health insurance coverage provide coverage without cost-sharing for certain preventive health services. Section 2713(a)(3) describes such services for infants, children, and adolescents as ''evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.'' HHS, along with the Departments of Treasury and Labor, issued an Interim Final Rule on July 19, 2010 (75 FR 41726–41760) that identified two specific resources as the comprehensive guidelines supported by HRSA for infants, children, and adolescents to be covered by insurance without cost sharing by non-grandfathered group health plans and health insurance issuers: (1) The Bright Futures Periodicity Schedule and (2) the Recommended Uniform Screening Panel of the Advisory Committee on Heritable Disorders in Newborns and Children. The Interim Final Rule provided that a future change to these comprehensive guidelines is considered to be issued for purposes of Section 2713 on the date on which it is accepted by the HRSA Administrator or, if applicable, adopted by the Secretary of HHS.

A public comment period was announced and occurred from September 13, 2021, through October 13, 2021 (86 FR 50894, September 13, 2021),[1] to allow public comment on the proposed recommended updates affecting clinical practice and health insurance coverage requirements. A total of 27 respondents gave 57 comments during the public comment period. The Bright Futures grantee, the American Academy of Pediatrics, received and considered the public comments. The annual report (Tab A) provides a description of the comments, including a detailed tabulation of each comment.

On December 30, 2021, the HRSA Administrator accepted the American Academy of Pediatrics' recommended several updates to the Bright Futures Periodicity Schedule. The Bright Futures recommendations included recommended clinical practice updates, along with revisions to the footnotes on the Bright Futures Periodicity Schedule that do not require changes to clinical practice or health insurance coverage. The updates to the Bright Futures Periodicity Schedule are: (1) A new category for sudden cardiac arrest and sudden cardiac death risk assessment, (2) a new category for hepatitis B virus infection risk assessment, (3) addition of suicide risk as an element of universal depression screening for children ages 12–21, and (4) updated category title from ''Psychosocial/Behavioral Assessment'' to ''Behavioral/Social/Emotional Screening,'' with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added with no associated recommended changes to clinical practice. In light of these updates, all non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must cover without cost-sharing the services and screenings listed on the updated Bright Futures Periodicity Schedule for plan years (in the individual market, policy years) that begin in 2023, which can be accessed at the following link: *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html*.

Diana Espinosa,

Acting Administrator.

[FR Doc. 2022–00461 Filed 1–11–22; 8:45 am]

BILLING CODE 4165–15–P

[1] *See https://www.federalregister.gov/documents/2021/09/13/2021-19630/opportunity-for-comments-on-proposed-updates-to-the-bright-futures-periodicity-schedule-as-part-of.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On December 30, 2021, HRSA approved updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines) that address health needs specific to women. The Guidelines are based on clinical recommendations from the Women's Preventive Services Initiative (WPSI), a coalition of experts and health professional organizations convened by the American College of Obstetricians and Gynecologist (ACOG) under a cooperative agreement awarded by HRSA. Under the Public Health Service Act and pertinent regulations, preventive care and screenings for women provided for in comprehensive guidelines supported by HRSA are required to be covered without cost sharing by group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. This 2021 update adds one additional service, Preventing Obesity in Midlife Women, and revises five services: Breastfeeding Services and Supplies, Contraception, Screening for Human Immunodeficiency Virus Infection, Counseling for Sexually Transmitted Infections, and Well-Woman Preventive Visits. This notice serves as an announcement of the decision to update the Guidelines as further described below. Please see *https://www.hrsa.gov/womens-guidelines/index.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The updated 2021 HRSA-supported Women's Preventive Services Guidelines, along with information related to their development and implementation, are available at *https://www.hrsa.gov/womens-guidelines/index.html.* A summary of information regarding the updates to the comprehensive guidelines supported by HRSA on December 30, 2021, is set out below.

Women's Preventive Services Guidelines

The first HRSA-supported Guidelines, based on recommendations of the Institute of Medicine, were established in 2011. The Guidelines were subsequently updated following review and recommendations by the ACOG under the WPSI cooperative agreement, awarded by HRSA in 2016. The purpose of WPSI is to improve adult women's health across the lifespan by engaging a coalition of experts and health professional organizations to recommend updates to the HRSA-supported Guidelines. Following such review and recommendations, HRSA decides whether or not to support, in whole or in part, the recommended updates to the Guidelines. In March 2021, HRSA awarded a subsequent cooperative agreement to ACOG to provide recommendations as appropriate over a 5-year period to update the HRSA-supported Guidelines. Under the cooperative agreement, ACOG, through the WPSI, engages in a process to consider and review new and existing Guidelines developed by a multidisciplinary group of women's health experts and professional organizations.

Under section 2713 of the Public Health Service Act, 42 U.S.C. 300gg–13, group health plans and issuers of non-grandfathered group and individual

health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Private health insurance companies must provide this coverage without cost-sharing in plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the recommendation or guideline is issued. A change to the Guidelines is considered to be issued on the date on which it is accepted by the HRSA Administrator.

Summary of the 2021 Updates Recommended by WPSI and Approved by HRSA

Breastfeeding Services and Supplies

WPSI recommends comprehensive lactation support services (including consultation, counseling, education by clinicians and peer support services, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding.

Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.

Contraception

WPSI recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve health outcomes. Contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (*e.g.,* management, evaluation, and changes, including the removal, continuation, and discontinuation of contraceptives).

WPSI recommends that the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care. The full range of contraceptives currently includes those listed in the FDA's Birth Control Guide: [1] (1) Sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), (7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate); and any additional contraceptives approved, granted, or cleared by the FDA.

Screening for HIV Infection

WPSI recommends all adolescent and adult women, ages 15 and older, receive a screening test for human immunodeficiency virus (HIV) at least once during their lifetime. Earlier or additional screening should be based on risk, and rescreening annually or more often may be appropriate beginning at age 13 for adolescent and adult women with an increased risk of HIV infection.

WPSI recommends risk assessment and prevention education for HIV infection beginning at age 13 and continuing as determined by risk.

A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in labor with an undocumented HIV status.

Counseling for Sexually Transmitted Infections

WPSI recommends behavioral counseling by a health care clinician or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

WPSI recommends that clinicians review a woman's sexual history and risk factors to identify those at increased risk for STIs. Risk factors include, but are not limited to, age younger than 25 years, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For those without identified risk factors, counseling to reduce the risk of STIs should be considered on an individual basis as determined by clinical judgment.

Well-Woman Preventive Visits

WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure the provision of all recommended preventive services. The primary purpose of well-woman visits is the delivery and coordination of recommended preventive services as determined by age and risk factors. These services may be completed at a single visit or as part of a series of visits that take place over time to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Well-women visits also include pre-pregnancy, prenatal, postpartum, and interpregnancy visits.

Preventing Obesity in Midlife Women

WPSI recommends counseling midlife women aged 40 to 60 years with normal or overweight body mass index (BMI) (18.5–29.9 kg/m2) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity.

Diana Espinosa,

Acting Administrator.

[FR Doc. 2022–00465 Filed 1–11–22; 8:45 am]

BILLING CODE 4165–15–P

[1] This refers to FDA's Birth Control Guide (*https://www.fda.gov/media/150299/download*) as posted on December 22, 2021 with the exception of sterilization surgery for men, which is beyond the scope of the WPSI.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–0036, ''Generic Clearance for the

Collection of Qualitative Feedback on Agency Service Delivery.'' This notice announces our intent to submit this previously approved information collection, which expires January 31, 2022, to OMB for approval of an extension and solicit comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by February 11, 2022.

Direct Your Comments To OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: *Evonne.Bennett@ihs.gov* or 301–443–4750.

SUPPLEMENTARY INFORMATION: The IHS is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995, as amended, and its implementing regulations. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3507 and 5 CFR 1320.10 concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Customer Service Satisfaction and Similar Surveys.

Type of Information Collection Request: Three year extension approval of this information collection.

OMB Control Number: 0917–0036.

Abstract: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback is information that provides useful insights on perceptions and opinions, but is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the agency's services will be unavailable.

The agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide remuneration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Current Actions: Extension of approval for a collection of information.

Type of Review: Extension.

Affected Public: Individuals and households, businesses and organizations, and Tribal governments.

Estimated Number of Respondents: 105,000.

Below are projected annual average estimates for the next three years:

Average Expected Annual Number of Activities: 100.

Average number of Respondents per Activity: 1,050.

Annual responses: 105,000.

Frequency of Response: Once per request.

Average minutes per response: 10.

Burden hours: 17,500.

There are no direct costs to respondents to report.

An agency may not conduct or sponsor, and a person is not required to

respond to, a collection of information unless it displays a currently valid OMB control number.

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Elizabeth A. Fowler,

Acting Deputy Director, Indian Health Service.

[FR Doc. 2022–00364 Filed 1–11–22; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Non-Pharmacological Clinical Trials.

Date: February 8, 2022.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Regina Tousignant Dolan-Sewell, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 4154, MSC 9606, Bethesda, MD 20852, *regina.dolan-sewell@nih.gov*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Service Ready Tools for Suicide Prevention.

Date: February 11, 2022.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MSC 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00431 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, February 14, 2022, 1:00 p.m. to 3:30 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892, which was published in the **Federal Register** on December 16, 2021, FR Doc 2021–27280, 86 FR 71512.

The meeting notice is amended to change the date of the meeting from February 14, 2022 to February 24, 2022. The meeting is closed to the public.

Dated: January 7, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00483 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Acquired Resistance to Therapy Network (ARTNet).

Date: February 16–17, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W124, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: David G. Ransom, Ph.D., Chief, Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W124, Rockville, Maryland 20850, 240–276–6351, *david.ransom@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–9: Contract Review Meeting.

Date: February 25, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609 Medical Center Drive, Room 7W236 Rockville, Maryland 20850 240–276–5256 *shuli.xia@nih.gov*

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–4: SBIR Contract Review Meeting.

Date: March 3–4, 2022.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850 (Telephone Conference Call),

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850, 240–276–7975, *chufanee@mail.nih.gov*,

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–8: Contract Review Meeting.

Date: March 4, 2022.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Shuli Xia, Ph.D., Scientific Review Officer Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, 240–276–5256 *shuli.xia@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Assay Validation of High-Quality Markers for Clinical Studies in Cancer (UH2/UH3).

Date: March 9, 2022.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Michael E. Lindquist, Ph.D., Scientific Review Officer, Research Programs, Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850, *mike.lindquist@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–2A: SBIR Contract Review Meeting.

Date: March 10, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609, Medical Center Drive, Room 7W264, Rockville, Maryland 20850, 240–276–7286, *salvucco@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–8: NCI Clinical and Translational Cancer Research.

Date: March 10–11, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Susan Lynn Spence, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850, 240–620–0819, *susan.spence@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–2B: SBIR Contract Review Meeting.

Date: March 11, 2022.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850, 240–276–7286, *salvucco@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–6: SBIR Contract Review Meeting.

Date: March 15–16, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W114, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W114, Rockville, Maryland 20850, 240–276–6371, *decluej@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Coordinating Center (U24) and Program (R01) on the Origins of Gastroesophageal Cancers.

Date: March 17, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850, 240–276–5085, *tandlea@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Pancreatic Cancer Detection Consortium U01/U24.

Date: March 17, 2022.

Time: 12:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: John Paul Cairns, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, 240–276–5415, *paul.cairns@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–7: SBIR Contract Review Meeting.

Date: March 18, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W260, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W260, Rockville, Maryland 20850, 240–276–5856, *nadeem.khan@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–5: SBIR Contract Review Meeting.

Date: March 23, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850, 240–276–7975, *chufanee@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–12: SBIR Contract Review Meeting.

Date: April 5, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Branch Chief, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850, 240–276–6442, *ahmads@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00433 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Geroscience-Based Chronic Wound Treatment.

Date: February 4, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–480–1266, *neuhuber@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 7, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00486 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Review of Data Analysis R03 Applications.

Date: February 9, 2022.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: NIDCR, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, Natl Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite #670, Bethesda, MD 20892, (301) 827–4639, *yun.mei@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00430 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: January 25, 2022.

Open: 10:00 a.m. to 2:15 p.m.

Agenda: Report of the Director, NIDCR and concept clearances.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Closed: 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn M. King, Ph.D., Director, Division of Extramural Research, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Room 960, Bethesda, MD 20892–4878, 301–594–5006, *Lynn.King@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00435 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Clinical Studies of Mental Illness (Collaborative R01).

Date: February 8, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Andrew Louden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20817, 301–435–1985, *loudenan@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Therapeutics and Drug Development.
Date: February 10–11, 2022.
Time: 9:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Maureen Shuh, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–4097, *maureen.shuh@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Intercellular Interactions.
Date: February 10, 2022.
Time: 11:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Thomas Y. Cho, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5144, MSC 7840, Bethesda, MD 20892, (301) 402–4179, *thomas.cho@nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Bioengineering, Technology and Surgical Sciences Study Section.
Date: February 14–15, 2022.
Time: 8:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Vector Biology Study Section.
Date: February 14–15, 2022.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, *zhengli@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.
Date: February 14–15, 2022.
Time: 10:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Alexei A. Yeliseev, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443–0552, *yeliseeva@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Gene and Drug Delivery Systems Study Section.
Date: February 15–16, 2022.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jain Krotz, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 672–8670, *jain.krotz@nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Basic Biology of Blood, Heart and Vasculature Study Section.
Date: February 15–16, 2022.
Time: 9:00 a.m. to 9:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Ashlee Lane, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–451–3849, *ashlee.tipton@nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.
Date: February 15–16, 2022.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–455–2364, *tatiana.cohen@nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.
Date: February 15–16, 2022.
Time: 9:30 a.m. to 8:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Chi-Wing Chow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800–A, Bethesda, MD 20892, (301) 402–3912, *chi-wing.chow@nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Pain and Itch Study Section.
Date: February 15–16, 2022.
Time: 10:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00434 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DFU Biomarkers RFA.
Date: February 25, 2022.
Time: 11:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 7, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00479 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Study Section.

Date: March 18, 2022.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Melissa H. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–R, Bethesda, MD 20892, (301) 827–7951, *nagelinmh2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00429 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; AD Models.

Date: January 11, 2022.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Greg Bissonette, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–402–1622, *bissonettegb@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 7, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00478 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Study Section.

Date: March 10–11, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–H, Bethesda, MD 20892, (301) 827–7969, *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 6, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00436 Filed 1–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on

proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communications Messages—(OMB No. 0930–0196)—Reinstatement

As the federal agency responsible for developing and disseminating authoritative knowledge about substance abuse prevention, addiction treatment, and mental health services and for mobilizing consumer support and increasing public understanding to overcome the stigma attached to addiction and mental illness, SAMHSA is responsible for development and dissemination of a wide range of education and information materials for both the general public and the professional communities. This submission is for generic approval and will provide for formative and qualitative evaluation activities to; (1) assess audience knowledge, attitudes, behavior and other characteristics for the planning and development of messages, communication strategies and public information programs; and (2) test these messages, strategies and program components in developmental form to assess audience comprehension, reactions, and perceptions. Information obtained from testing can then be used to improve materials and strategies while revisions are still affordable and possible. The annual burden associated with these activities is summarized below.

Activity	Number of respondents	Responses/ respondent	Hours per response	Total hours	Hourly wage rate ($) [1]	Total hour cost ($)
Individual In-depth Interviews:						
General Public	400	1	.75	300	$25.00	$7,500
Service Providers	200	1	.75	150	35.00	5,250
Focus Group Interviews:						
General Public	3,000	1	1.5	4,500	25.00	112,500
Service Providers	1,500	1	1.5	2,250	35.00	78,750
Telephone Interviews:.						
General Public	335	1	.08	27	25.00	675
Service Providers	165	1	.08	13	35.00	455
Self-Administered Questionnaires:						
General Public	2,680	1	.25	670	25.00	16,750
Service Providers	1,320	1	.25	330	35.00	11,550
Gatekeeper Reviews:						
General Public	1,200	1	.50	600	25.00	15,000
Service Providers	900	1	.50	450	35.00	15,750
Total	11,700			9,290		264,180

[1] The hourly wage of $25.00 for the general public was calculated based on weighted data from the 2019 NSDUH respondents' personal annual income. The $35 hourly wage rate for providers is an average across counselors and other service provider staff.

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov.* Written comments should be received by March 14, 2022.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–00432 Filed 1–11–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

New Zealand Beef Imports Approved for the Electronic Certification System

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that the export certification requirement for certain imports of beef from New Zealand subject to a tariff-rate quota will be accomplished through the Electronic Certification System (eCERT). All imports of beef from New Zealand that are subject to the tariff-rate quota must have a valid export certificate with a corresponding eCERT transmission at the time of entry, or withdrawal from warehouse, for consumption. The United States Government (USG) has approved the request from New Zealand to transition to eCERT as the method of transmission. The transition to eCERT will not change the tariff-rate quota filing process or requirements. Importers will continue to provide the export certificate numbers from New Zealand in the same manner as when currently filing entry summaries with U.S. Customs and Border Protection. The format of the export certificate numbers will remain the same for the corresponding eCERT transmissions.

DATES: The use of the eCERT process for certain New Zealand beef importations subject to a tariff-rate quota will be effective for beef entered, or withdrawn from a warehouse, for consumption on or after January 18, 2022.

FOR FURTHER INFORMATION CONTACT: Julia Peterson, Chief, Quota and Agriculture Branch, Trade Policy and Programs, Office of Trade, (202) 384–8905, or *HQQUOTA@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

There is an existing tariff-rate quota on certain beef from New Zealand pursuant to Additional U.S. Note 3 of Chapter 2 of the Harmonized Tariff Schedule of the United States (HTSUS). The tariff-rate quota for beef from New Zealand was established by section 6 of the Presidential Proclamation No. 6763 (December 23, 1994), as a result of the Uruguay Round Agreements, approved by Congress in section 101 of the Uruguay Round Agreements Act (19 U.S.C. 3511(a), Pub. L. 103–465, 108 Stat. 4814). Tariff-rate quotas permit a specified quantity of merchandise to be entered or withdrawn for consumption at a reduced duty rate during a specified period. Furthermore, section 2012.3 of title 15 of the Code of Federal Regulations (CFR) states that beef may only be entered as a product of an eligible country for a tariff-rate quota if the importer makes a declaration to U.S. Customs and Border Protection (CBP) that a valid export certificate is in effect with respect to the beef. In addition, the CBP regulations, at 19 CFR 132.15, set forth provisions relating to the requirement that an importer must possess a valid export certificate at the time of entry, or withdrawal from warehouse, for consumption, to claim the in-quota tariff rate of duty on entries of beef subject to the tariff-rate quota.

The Electronic Certification System (eCERT) is a system developed by CBP that uses electronic data transmissions of information normally associated with a required export document, such as a license or certificate, to facilitate the administration of quotas and ensure that the proper restraint levels are charged without being exceeded. New Zealand requested to participate in the eCERT process to comply with the United States' tariff-rate quota for beef exported from New Zealand for importation into the United States. CBP has coordinated with New Zealand to implement the eCERT process, and now New Zealand is ready to participate in this process by transmitting its export certificates to CBP via eCERT.

Foreign countries participating in eCERT transmit information via a global network service provider, which allows connectivity to CBP's automated electronic system for commercial trade processing, the Automated Commercial Environment (ACE). Specific data elements are transmitted to CBP by the importer of record (or an authorized customs broker) when filing an entry summary with CBP, and those data elements must match eCERT data from the foreign country before an importer may claim any applicable in-quota tariff rate of duty. An importer may claim an in-quota tariff rate when merchandise is entered, or withdrawn from warehouse, for consumption, only if the information transmitted by the importer matches the information transmitted by the foreign government. If there is no transmission by the foreign government upon entry, an importer must claim the higher over-quota tariff rate.[1] An importer may subsequently claim the in-quota tariff rate under certain limited conditions.[2]

This document announces that New Zealand will be implementing the eCERT process for transmitting export certificates for beef entries subject to the tariff-rate quota. Imported merchandise that is entered, or withdrawn from warehouse, for consumption on or after January 18, 2022, must match the eCERT transmission of an export certificate from New Zealand in order for an importer to claim the in-quota tariff rate. The transition to eCERT will not change the tariff-rate quota filing process or requirements. Importers will continue to provide the export certificate numbers from New Zealand in the same manner as when currently filing entry summaries with CBP. The format of the export certificate numbers will not change as a result of the transition to eCERT. CBP will reject entry summaries that claim an in-quota tariff rate when filed without a valid export certificate in eCERT.

Dated: January 7, 2022.

AnnMarie R. Highsmith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2022–00464 Filed 1–11–22; 8:45 am]

BILLING CODE P

[1] If there is no associated foreign government eCERT transmission available upon entry of the merchandise, an importer may enter the merchandise for consumption subject to the over-quota tariff rate or opt not to enter the merchandise for consumption at that time (*e.g.,* transfer the merchandise to a Customs bonded warehouse or foreign trade zone or export or destroy the merchandise).

[2] If an importer enters the merchandise for consumption subject to the over-quota tariff rate and the associated foreign government eCERT transmission becomes available afterwards, an importer may claim the in-quota rate of duty by filing a post summary correction (before liquidation) or a protest under 19 CFR part 174 (after liquidation). In either event, the in-quota rate of duty is allowable only if there are still quota amounts available within the original quota period.

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2022–0004]

Homeland Security Academic Advisory Council

AGENCY: The Department of Homeland Security (DHS), Office of Partnership and Engagement (OPE).

ACTION: Notice of reestablished Federal advisory committee.

SUMMARY: The Secretary of Homeland Security (Secretary) is reestablishing the Homeland Security Academic Advisory Council (HSAAC), a discretionary federal advisory committee. The primary purpose of the HSAAC will be to provide advice and recommendations to the Secretary and DHS senior leadership on matters related to homeland security and the academic community.

FOR FURTHER INFORMATION CONTACT: Acting Executive Director Traci Silas via email at *DHSAcademic@hq.dhs.gov* or via phone at 202–603–1142.

SUPPLEMENTARY INFORMATION: The HSAAC will consist of up to 30 members who are appointed by and serve at the pleasure of the Secretary of Homeland Security. Members are appointed as representative members, except that members from federal agencies are appointed as non-voting ex-officio members. To ensure a diverse, inclusive and balance membership, candidates include:

(a) Up to four members representing higher education associations.

(b) Up to two members representing higher education law enforcement, public safety, and emergency management associations.

(c) Up to two members representing four-year colleges and universities.

(d) Up to two members representing two-year community colleges.

(e) Up to two members representing Historically Black Colleges and Universities (HBCUs).

(f) Up to two members representing Hispanic serving institutions.

(g) Up to two members representing Tribal colleges.

(h) Up to two members representing the Asian American, Native American and Pacific Islander serving institutions.

(i) Up to four members representing K–12 school systems, to include schools, school systems, and state educational agencies.

(j) Up to two members representing Education Employee Associations/Labor Organizations.

(k) Up to one member from the DHS Science and Technology Center of Excellence.

(l) Up to one member from Cybersecurity and Infrastructure Security Agency (CISA) School Safety Task Force.

(m) Up to one member from the DHS Center for Prevention Programs and Partnership.

(n) Up to one member from US Secret Service National Threat Assessment Center.

(o) Up to one member from Federal Emergency Management Agency (FEMA) higher education initiatives.

(p) Up to one member from the DHS Office for Civil Right and Civil Liberties (CRCL).

(q) Up to one member from the Department of Education.

(r) Up to one member from the Department of State.

(s) Up to one member from the Department of Justice.

(t) Up to one member from the Department of Health and Human Services.

HSAAC is the sole advisory committee and public forum within DHS providing advice on matters relating to DHS's engagement with the academic community.

The HSAAC will operate in an advisory capacity only. The establishment of the HSAAC is necessary and in the public interest. This notice is provided in accordance with the Federal Advisory Committee Act (''FACA''), as amended, 5 U.S.C. App. The HSAAC will terminate two years from the date of its establishment, unless renewed by the Secretary.

Zarinah T. Silas,

Acting Executive Director and Acting Designated Federal Officer.

[FR Doc. 2022–00454 Filed 1–11–22; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request Extension From OMB of One Current Public Collection of Information: Law Enforcement Officers Safety Act and Retired Badge/Credential

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0071, that we will submit to OMB for an extension in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. This collection involves the submission of information from certain current and former TSA employees who are interested in a Law Enforcement Officers Safety Act of 2004 (LEOSA) Identification (ID) Card, a retired badge, and/or a retired credential.

DATES: Send your comments by March 14, 2022.

ADDRESSES: Comments may be emailed to *TSAPRA@tsa.dhs.gov* or delivered to the TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011.

FOR FURTHER INFORMATION: Christina A. Walsh at the above address, or by telephone (571) 227–2062.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

LEOSA

OMB Control Number 1652–0071; Law Enforcement Officers Safety Act and Retired Badge/Credential. Under 18 U.S.C. 926C, which codifies a portion of LEOSA,[1] a ''qualified retired law enforcement officer'' may carry a concealed firearm in any jurisdiction in the United States, regardless of State or local laws, with certain limitations and conditions. In accordance with LEOSA, the Department of Homeland Security (DHS) issued DHS Directive and Instruction Manual 257–01, *Law Enforcement Officers Safety Act* (Nov. 5, 2009). DHS Directive 257–01 requires DHS components to implement the provisions of LEOSA pertaining to qualified retired Law Enforcement Officers (LEOs) as cost-effectively and efficiently as possible consistent with the requirements and intent of the statute for LEOs formerly employed by DHS and predecessor agencies.

TSA subsequently issued TSA Management Directive (MD) 3500.1, *LEOSA Applicability and Eligibility* (Oct. 7, 2001), to implement the LEOSA statute and DHS directive. Under this MD, TSA issues photographic identification to retired LEOs who separated or retired from TSA in ''good standing'' and meet other qualification requirements identified in this MD.

Retired Badge/Credential

Under TSA MD 2800.11, *Badge and Credential Program,* a TSA employee retiring from Federal service is eligible to receive a ''retired badge and/or credential'' if the individual: (1) Was issued a badge and/or credential, (2) qualifies for a Federal annuity under the Civil Service Retirement System or the Federal Employees Retirement System, and (3) meets all of the other qualification requirements under the MD.[2]

If the employee is approved for a retired badge and/or credential, his or her badge and/or credential will be replicated by TSA and marked with the word ''RETIRED,'' to indicate that the retired employee no longer has the authority to perform specific official functions pursuant to law, statute, regulation, or DHS Directive. In the case of a retired LEO, the individual is prohibited from using the TSA retired credential as photographic identification for the purposes of the LEOSA.

Purpose and Description of Data Collection

Under TSA's current application process for these two programs,

[1] Public Law 108–277, 118 Stat. 865, July 22, 2004, codified in 18 U.S.C. 926B and 926C, as amended by the Law Enforcement Officers Safety Act Improvements Act of 2010 (Pub. L. 111–272, 124 Stat. 2855; Oct. 12, 2010) and National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239, 126 Stat. 1970; Jan. 2, 2013).

[2] These instructions are included in DHS Instruction: 121–01–002 (Issuance and Control of DHS Badges); DHS Instruction 121–01–008 (Issuance and Control of the DHS Credentials); and the associated Handbook for TSA MD 2800.11.

qualified applicants may apply for a LEOSA ID Card, a Retired Badge, and/or a Retired Credential, as applicable, either while still employed by TSA (shortly before separating or retiring) or after they have separated or retired (after they become private citizens, *i.e.,* are no longer employed by the Federal Government).

The LEOSA Identification Card Application (TSA Form 2825A) requires collection of identifying information, contact information, official title, separation date, and last known field office. Identifying information, such as the date of birth and social security number, are necessary to confirm the individual's identity and to process the individual through the National Crime Information Center database. Similarly, for purposes of a retired badge and/or credential, TSA Form 2808–R, *Retired Badge and/or Retired Credential Application,* requires collection of identifying information, contact information, TSA employment/position information (TSA component or Government agency), official title, and entry on duty date. This collection of information is necessary to confirm the identity of the individual, conduct the necessary qualification process to determine the individual's eligibility for a retired badge and/or credential, and to contact the individual if needed.

Based on current data, TSA estimates *183 TSA Forms 2825A* and *183 TSA Forms 2808–R* will be submitted, for a total of *366* respondents annually. It takes approximately 5 minutes (0.08333 hours) to complete either form, so the total annual hour burden to the public will be 366 x 0.08333 hours, or *30.5* hours.

Dated: January 6, 2022.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2022–00386 Filed 1–11–22; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2021–0136; FXES11130200000–212–FF02ENEH00]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for the New Mexico Meadow Jumping Mouse

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of our draft recovery plan for the New Mexico meadow jumping mouse (*Zapus hudsonius luteus*). This subspecies occurs in riparian habitats in New Mexico, Arizona, and southern Colorado, and was listed as endangered in 2014 under the Endangered Species Act. We request review and comment on this draft recovery plan from local, State, and Federal agencies; Tribes; nongovernmental organizations; and the public.

DATES: We must receive any comments on or before March 14, 2022. Comments submitted online at *http://www.regulations.gov* (see **ADDRESSES**) must be received by 11:59 p.m. Eastern Time on March 14, 2022.

ADDRESSES:

Obtaining Documents: You may obtain a copy of the draft recovery plan and species status assessment by the following methods:

- *Internet:* Go to one of the following sites:
  - *http://www.regulations.gov* in Docket No. FWS–R2–ES–2021–0136;
  - *http://ecos.fws.gov/ecp/species/7965;* or
  - *https://www.fws.gov/southwest/es/NewMexico/.*
- *U.S. mail:* Send a request to U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office (NMESFO), 2105 Osuna NE, Albuquerque, NM 87113.
- *Telephone:* 505–346–2525 or 800–299–0196.

Submitting Comments: Submit your comments in writing by one of the following methods:

- *Internet: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–R2–ES–2021–0136.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R2–ES–2021–0136; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For additional information about submitting comments, see Request for Public Comments and Public Availability of Comments under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shawn Sartorius, Field Supervisor, at 505–346–2525, or by email at *nmesfo@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (USFWS), announce the availability of our draft recovery plan for New Mexico meadow jumping mouse (*Zapus hudsonius luteus*), which we listed as endangered in 2014 (79 FR 33119) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The subspecies is endemic to New Mexico, Arizona, and a small area of southern Colorado. It nests in dry soils and uses dense riparian vegetation up to an elevation of about 9,500 feet. The draft recovery plan includes specific goals, objectives, and criteria that may help to inform our consideration of whether to reclassify the species as threatened (*i.e.,* ''downlist'') or remove the subspecies from the Federal List of Endangered and Threatened Wildlife (*i.e.,* ''delist''). We request review of and comment on the draft recovery plan from local, State, and Federal agencies; Tribes; nongovernmental organizations; and the public.

Recovery Planning and Implementation

Section 4(f) of the ESA requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species. Also pursuant to section 4(f) of the ESA, a recovery plan must, to the maximum extent practicable, include:

(1) A description of site-specific management actions as may be necessary to achieve the plan's goals for the conservation and survival of the species;

(2) Objective, measurable criteria that, when met, would support a determination under section 4(a)(1) that the species should be removed from the List of Endangered and Threatened Species; and

(3) Estimates of the time and costs required to carry out those measures needed to achieve the plan's goal and to achieve intermediate steps toward that goal.

In 2016 the USFWS revised its approach to recovery planning, and is now using a process termed recovery planning and implementation (RPI) (see *https://www.fws.gov/endangered/esa-library/pdf/RPI.pdf*). The RPI approach is intended to reduce the time needed to develop and implement recovery plans, increase recovery plan relevance over a longer timeframe, and add flexibility to recovery plans so they can be adjusted to new information or circumstances. Under RPI, a recovery plan addresses the statutorily required elements under section 4(f) of the Act, including site-specific management actions, objective and measurable recovery criteria, and the estimated time and cost to recovery. The RPI recovery plan is supported by two supplementary documents: A species status assessment (SSA), which describes the best

available scientific information related to the biological needs of the species and assessment of threats, and a recovery implementation strategy, which details the particular near-term activities needed to implement the recovery actions identified in the recovery plan. Under this approach, we can more nimbly incorporate new information on species biology or details of recovery implementation by updating these supplementary documents without concurrent revision of the entire recovery plan, unless changes to statutorily required elements are necessary.

Species Background

On June 10, 2014, we published a final rule (79 FR 33119) to list the New Mexico meadow jumping mouse as endangered. On March 16, 2016, we published a final rule (81 FR 14264) designating critical habitat for the subspecies. The New Mexico meadow jumping mouse is a small (181 to 233 millimeters (mm); 7.1 to 9.2 inches (in) in total length) dark brown rodent with an extremely long, bicolored tail (125.1 mm; 4.9 in), with a white underside and yellowish-brown sides. It is a true hibernator, hibernating from October through May, and is active from late May or early June into early October. The subspecies occurs within elevations ranging from approximately 1,372 m (4,500 ft) up to approximately 2,896 m (9,500 ft). It is a habitat specialist that requires dense riparian herbaceous vegetation with a minimum height of 61 cm (24 in) associated with seasonally available or perennial (persistent) flowing water, moist soils, and adjacent uplands that can support the vegetation characteristics needed for jumping mouse foraging, breeding, and hibernating.

Past and current habitat loss has resulted in the extirpation of historical populations and has reduced the size and increased the isolation of existing populations. The primary sources of current and anticipated future habitat loss include (1) livestock, elk, and feral horse grazing pressure that is incompatible with maintaining needed vegetation structure and diversity (*i.e.,* contributes to riparian herbaceous vegetation loss); (2) incompatible water management and use (*e.g.,* dams and water diversion and mowing along irrigation ditches); (3) lack of water due to drought (exacerbated by climate change); and (4) severe wildland fires that cause changes to riparian habitat (also exacerbated by climate change). Additional sources of habitat loss are likely to occur from post-fire scouring floods, stream incision resulting in disconnection of the floodplain from the stream channel, loss of beaver ponds, highway construction and maintenance, residential and commercial development, coalbed methane development, and unregulated recreation.

Recovery Criteria

The draft recovery criteria are summarized below. For a complete description of the rationale behind the objective, measurable criteria, the recovery strategy, site-specific management actions, and estimated time and costs associated with recovery, refer to the draft recovery plan for New Mexico meadow jumping mouse (see **ADDRESSES** for document availability).

The ultimate recovery goal is to delist the subspecies by ensuring the long-term viability in the wild. The New Mexico meadow jumping mouse currently is known to occur within thirteen 8th hydrological unit code (HUC8) subunits distributed across the subspecies' historical range in eastern Arizona, southern Colorado, and New Mexico. The thirteen HUC8s are within six geographical units (GUs) that contain the currently known populations. In the recovery plan, we define the following criteria for downlisting and delisting.

Downlisting Criteria

Criterion 1: Occupied riparian and adjacent upland New Mexico meadow jumping mouse habitat within each of 13 HUC8s are protected, maintained, and/or restored.

Criterion 2: Within an occupied HUC8, an overall stable or increasing New Mexico meadow jumping mouse estimate population trend is documented over an 8-year period.

Criterion 3: Threats to New Mexico meadow jumping mouse are decreasing or abated when the protection and expansion of occupied New Mexico meadow jumping mouse riparian functionally connected habitat and adjacent upland habitat meet Criteria 1 and 2.

Criterion 4: At least one HUC8 in each of the GUs has functional habitat and population(s) maintained as to meet criteria 1 and 2 above, to ensure genetic and ecological representation.

Delisting Criteria

Criterion 1: Occupied riparian and adjacent upland New Mexico meadow jumping mouse habitat within each of 16 HUC8s are protected, maintained, and/or restored.

Criterion 2: Within an occupied HUC8, an overall stable or increasing New Mexico meadow jumping mouse estimated population trend is documented over a 12-year period.

Criterion 3: Threats to New Mexico meadow jumping mouse are decreasing or abated when the protection and expansion of occupied New Mexico meadow jumping mouse riparian functionally connected habitat and adjacent upland habitat meet Criteria 1 and 2, and significant threats that include excessive grazing, ineffective water management and/or water diversions, stream degradation, and stream incision with flood plain disconnection are controlled or managed to the extent that they do not pose imminent or chronic downward pressures on the New Mexico meadow jumping mouse and its habitat.

Criterion 4: At least two HUC8s in each of the GUs have functional habitat and populations maintained as to meet criteria 1 and 2 above to ensure genetic and ecological representation.

Request for Public Comments

Section 4(f) of the ESA requires us to provide public notice and an opportunity for public review and comment during recovery plan development. It is also our policy to request peer review of recovery plans (59 FR 34270; July 1, 1994). In an appendix to the final recovery plan, we will summarize and respond to the issues raised during public comment and peer review. Substantive comments may or may not result in changes to the recovery plan. Comments regarding recovery plan implementation will be forwarded as appropriate to Federal agencies or other entities so that they can be taken into account during the course of implementation of recovery actions.

We invite written comments on this draft recovery plan. In particular, we are interested in additional information regarding the current threats to the species, ongoing beneficial management efforts, and the costs associated with implementing the recommended recovery actions. The species status assessment is accessible as a supporting document for the draft recovery plan, but we are not seeking comments on that document. We will consider all comments we receive by the date specified in **DATES**, above, prior to final approval of the plan.

Public Availability of Comments

All comments we receive, including names and addresses, will become part of the administrative record and will be available to the public. Before including your address, phone number, email address, or other personal identifying information in your comment, you

should be aware that your entire comment—including your personal identifying information—will be publicly available. While you may request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We developed our draft recovery plan and publish this notice under the authority of section 4(f) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Amy L. Lueders,

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2022–00362 Filed 1–11–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–ES–2021–N198; FXES11130500000–212–FF05E00000]

Endangered Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before March 14, 2022.

ADDRESSES: Use one of the following methods to request documents or submit comments. Requests and comments should specify the applicant name and application number (*e.g.,* PER0001234):

- *Email: permitsR5ES@fws.gov.*
- *U.S. Mail:* Abby Gelb, Ecological Services, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035.

FOR FURTHER INFORMATION CONTACT: Abby Gelb, 413–253–8212 (phone), or *permitsR5ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
PER0002181 ...	Paul L. Angermeier, dba USGS/Virginia Tech, Blacksburg, VA.	Candy darter (*Etheostoma osburni*).	Add: West Virginia	Electrofish, survey	Capture, collect	Amend.
PER0027548 ...	State University of New York—ESF, Syracuse, NY.	Piping plover (*Charadrius melodus*).	New York	Survey, band, biological samples, propagate.	Capture, collect, wound	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martin Miller,

Manager, Division of Endangered Species, Ecological Services, North Atlantic-Appalachian Region.

[FR Doc. 2022–00363 Filed 1–11–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[222A2100DD/AAKC001030/ A0A51010.999900]

Notice of Deadline for Submitting Completed Applications To Begin Participation in the Tribal Self-Governance Program in Fiscal Year 2023 or Calendar Year 2023

AGENCY: Office of Self-Governance, Interior.

ACTION: Notice of application deadline.

SUMMARY: In this notice, the Office of Self-Governance (OSG) establishes a March 1, 2022, deadline for Indian tribes/consortia to submit completed applications to begin participation in

the tribal self-governance program in fiscal year 2023 or calendar year 2023.

DATES: Completed application packages must be received by the Director, Office of Self-Governance, by March 1, 2022.

ADDRESSES: Application packages for inclusion in the applicant pool should be sent to Sharee M. Freeman, Director, Office of Self-Governance, Department of the Interior, Mail Stop 3624–MIB, 1849 C Street NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Vickie Hanvey, Office of Self Governance, Telephone (918) 931–0745 or Dr. Kenneth D. Reinfeld, Office of Self-Governance, Telephone (202) 821–7107.

SUPPLEMENTARY INFORMATION: Under the Tribal Self-Governance Act of 1994 (Pub. L. 103–413), as amended by the ''Practical Reforms and Other Goals to Reinforce the Effectiveness of Self-Governance and Self-Determination Act of 2019–2020'' or the ''PROGRESS for Indian Tribes Act'', Section 402(b)(1)(A), the Secretary, acting through the Director of the Office of Self-Governance, may select not more than 50 new Indian Tribes per year from those eligible tribes. The Act mandates that copies of the funding agreements be sent at least 90 days before the proposed effective date to each Tribe that is served by the Bureau of Indian Affairs' agency that is serving the Tribe that is a party to the funding agreement. Initial negotiations with a Tribe/consortium located in a region and/or agency which has not previously been involved with self-governance negotiations will take approximately 2 months from start to finish. Agreements for an October 1 to September 30 funding year need to be signed and submitted by July 1. Agreements for a January 1 to December 31 need to be signed and submitted by October 1.

Purpose of Notice

The regulations at 25 CFR 1000.10 to 1000.31 have been modified by Section 201 of the newly enacted ''Practical Reforms and Other Goals To Reinforce the Effectiveness of Self-Governance and Self-Determination'' (PROGRESS) Act as follows: Section 201. Definitions; reporting and audit requirements; application of programs.

To be eligible to participate in self-governance, an Indian Tribe shall:

(1) Successfully complete the planning phase described in subsection (d);

(2) request participation in self-governance by resolution or other official action by the Tribal governing body; and

(3) demonstrate for the 3 fiscal years preceding the date on which the Tribe requests participation, fiscal stability and financial management capability as evidenced by the Indian Tribe having no uncorrected significant and internal audit exceptions in the required annual audit of its self-determination or self-governance agreements with any Federal agency.

An Indian Tribe seeking to begin participation in self-governance shall complete the planning phase. The planning phase shall:

(A) Be conducted to the satisfaction of the Indian Tribe; and

(B) include:

(i) Legal and budgetary research; and

(ii) internal Tribal governing planning, training, and organizational preparation.

Applicants should be guided by the referenced requirements in preparing their applications to begin participation in the tribal self-governance program in fiscal year 2023 and calendar year 2023. Copies of these requirements may be obtained from the information contact person identified in this notice.

Tribes/consortia wishing to be considered for participation in the tribal self-governance program in fiscal year 2023 or calendar year 2023 must respond to this notice, except for those tribes/consortia which are one of the 137 tribal entities with signed self-governance agreements.

Information Collection

This information collection is authorized by OMB Control Number 1076–0143, Tribal Self-Governance Program, which expires June 30, 2022.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–00387 Filed 1–11–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[222A2100DD/AAKC001030/A0A51010.999900]

Proclaiming Certain Lands as Reservation for the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of reservation proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 9,302.93 acres, more or less, an addition to the reservation of the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

DATES: This proclamation was made on December 22, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene M. Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Box #44, Albuquerque, New Mexico 87104, *Sharlene.roundface@bia.gov,* (505) 563–3132.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according to the Act of June 18, 1934 (48 Stat. 984; 25 U.S.C. 5110) for the lands described below. The land was proclaimed to be the Figure Four parcel for the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota in Dunn County, and McKenzie County, North Dakota.

Figure Four Parcel, 310 34

Fifth Principal Meridian, North Dakota

T. 148 N., R. 95 W.,

Sec. 4, lots 1 thru 5, S½NW¼, and SW¼;

Sec. 5;

Sec. 6;

Sec. 7, lots 1 thru 4, NE¼, E½NW¼, E½SW¼, N½SE¼, and SW¼SE¼;

Sec. 8, N½SW¼, N½SE¼, and SE¼SE¼;

Sec. 9, lot 4, NE¼NW¼, and S½SW¼;

Sec. 17, SW¼NW¼, N½SW¼, and SE¼SW¼;

Sec. 18, lots 1, 3, and 4, NW¼NE¼, S½NE¼, E½NW¼, NE¼SE¼, and S½SE¼;

Sec. 19, lots 1 thru 4, N½NE¼, SW¼NE¼, E½NW¼, E½SW¼, and SE¼;

Sec. 20, SW¼SW¼;

Sec. 28, lots 3 and 4, E½SW¼, and SW¼SW¼;

Sec. 29, lot 1, W½NW¼, NW¼SW¼, SE¼SW¼, and S½SE¼, EXCEPT a tract of land described as follows: Beginning at the southwest corner of Section 29, thence north on the west line of Lot 1 a distance of 662.13 feet, thence N 89°53′25″ E on an assumed bearing a distance of 1,317.08 feet to the east line of Lot 1, thence S 0°08′33″ E on said east line of lot 1 for a distance of 261.6 feet, thence N 89°52′02″ E a distance of 300 feet, thence southeasterly to a point on the south line of section 29, said point being 658.35 feet easterly of the W1/16 corner common to sections 29 and 32, thence S 89°52′02″ W a distance of 658.35 feet to said W1/16 corner, thence continue S 89°52′02″ W on the section line a distance of 1,316.70 feet to the point of beginning;

Sec. 30, lots 4 and 5, E½NE¼, SE¼SW¼, NE¼SE¼, and SW¼SE¼, EXCEPT a tract more particularly described as follows: Beginning at the southeast corner of lot 5, thence north on the east line of lot 5 a distance of 455.08 feet,

thence westerly parallel to the south line of lot 5 a distance of 400 feet, thence southwesterly to a point on the south line of lot 5, said point being 732.95 feet westerly of the southeast corner of lot 5, thence east along the south line of lot 5 a distance of 732.95 feet, to the point of beginning;

Sec. 31, lot 3 and NE¼NW¼;

Sec. 32, lots 1 thru 3, EXCEPT Parcels A thru E;

Sec. 33: Lot 1 and N½NW¼.

T. 148 N., R. 96 W.,

Sec. 1, lots 1 thru 3, S½NE¼, and S½;

Sec. 2, SE¼NE¼ and NE¼SE¼;

Sec. 12;

Sec. 13, N½, E½SW¼, SW¼SW¼, and SE¼;

Sec. 14, SE¼SE¼;

Sec. 23, N½NE¼, SE¼NE¼, and S½SE¼;

Sec. 24, W½NE¼, W½, and SE¼;

Sec. 25, lots 1 and 2, N½NE¼, NW¼, N½SW¼, SW¼SW¼, N½SE¼, and SE¼SE¼;

Sec. 26, lots 5, 6, and 10, N½NE¼, and SE¼NE¼.

T. 149 N., R. 95 W.,

Sec. 25, lot 4;

Sec. 26, SE¼SE¼;

Sec. 33, S½;

Sec. 34, S½, EXCEPT all that portion of the S½SE¼ of said section 34, lying within a strip of land, said strip being 80 feet wide, lying 40 feet on each side of the following described center line: Beginning at a point on the east line of the said S½SE¼ of section 34, 305.2 feet from the southeast corner thereof, said point being on the centerline of the state highway as surveyed and staked over and across the said S½SE¼, section 34, thence S 25°31′ W 339.8 feet to the south line of the said S½SE¼, section 34, excepting all that portion lying within 33 feet of the section lines;

Sec. 35, E½ and SW¼, EXCEPT all that portion of the SW¼ of said section 35, lying within a strip of land, said strip being 80 feet wide, lying 40 feet on each side of the following described center line: Beginning at a point on the west line of the said SW¼ of section 35, 305.2 feet from the southwest corner thereof, said point being on the center line of the state highway as surveyed and staked over and across the said SW¼ of section 35, thence N 25°31′ E 315 feet, excepting all that portion lying within 33 feet of the section line.

The above described lands contain a total of 9,302.93 acres, more or less which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the lands described above, nor does it affect any valid existing easements for public roads, highways, public utilities, railroads and pipelines, or any other valid easements or rights-of-way or reservations of record.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–00388 Filed 1–11–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT910000 L18200000.XZ0000 223L1109AF.MO#4500159475]

Call for Nominations to the Missouri Basin and Western Montana Resource Advisory Councils

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of call for nominations.

SUMMARY: The purpose of this notice is to request public nominations for the Bureau of Land Management's (BLM) Missouri Basin and Western Montana Resource Advisory Councils (RACs) to fill existing vacancies, as well as for member terms that are scheduled to expire. The RACs provide advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within their geographic areas.

DATES: All nominations must be received no later than February 11, 2022.

ADDRESSES: Applications for the Missouri Basin RAC should be sent to Mark Jacobsen, BLM Eastern Montana/Dakotas District Office, 111 Garryowen Road, Miles City, MT 59301; (406) 233–2831; *mjacobse@blm.gov.*

Applications for the Western Montana RAC should be sent to David Abrams, BLM Butte Field Office, 106 North Parkmont, Butte, MT 59701; (406) 533–7617; *dabrams@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Ann Boucher, BLM Montana/Dakotas State Office, 5001 Southgate Drive, Billings, MT 59101, (406) 896–5011, *aboucher@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Ms. Boucher during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act directs the Secretary of the Interior to involve the public in planning and issues related to the management of lands administered by the BLM through the establishment of 10- to 15-member citizen-based advisory councils that are managed in accordance with the Federal Advisory Committee Act (FACA). As required by FACA, RAC membership must be balanced and representative of the various interests concerned with the management of the public lands. The rules governing RACs are found at 43 CFR subpart 1784 and include the following three membership categories:

Category One—Holders of Federal grazing permits or leases within the area for which the RAC is organized; represent interests associated with transportation or rights-of-way; represent developed outdoor recreation, off-highway vehicle users, or commercial recreation activities; represent the commercial timber industry; or represent energy and mineral development.

Category Two—Representatives of nationally or regionally recognized environmental organizations; dispersed recreational activities; archaeological and historical interests; or nationally or regionally recognized wild horse and burro interest groups.

Category Three—Hold State, county, or local elected office; are employed by a State agency responsible for the management of natural resources, land, or water; represent Indian Tribes within or adjacent to the area for which the RAC is organized; are employed as academicians in natural resource management or the natural sciences; or represent the affected public-at-large.

Individuals may nominate themselves or others. Missouri Basin RAC Nominees must be residents of the States of Montana, North Dakota, or South Dakota. Western Montana RAC Nominees must be residents of the State of Montana. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographic area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making.

The following must accompany all nominations:

—A completed RAC application, which can either be obtained through the nominee's BLM office or online at: *https://www.blm.gov/sites/blm.gov/files/RPMC%20Nomination%20Form.pdf*

—Letters of reference from represented interests or organizations; and

—Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, BLM Montana/Dakotas will issue a press release providing additional information for submitting nominations.

Before including any address, phone number, email address, or other personal identifying information in the application, nominees should be aware this information may be made publicly available at any time. While the nominee can ask to withhold the personal identifying information from public review, the BLM cannot guarantee that it will be able to do so.

(Authority: 43 CFR 1784.4–1)

Theresa M. Hanley,

Acting Montana/Dakotas State Director.

[FR Doc. 2022–00472 Filed 1–11–22; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORW00000.10200000.DF0000. LXSSH1080000.223.HAG 22–0007]

Notice of Public Meetings for the San Juan Islands National Monument Advisory Committee, Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management's (BLM) San Juan Islands National Monument Advisory Committee (MAC) will meet as follows.

DATES: The MAC will meet virtually on Wednesday, February 3, 2022. This meeting will run from 9:00 a.m. to 1:30 p.m. with a public comment period in the afternoon from noon until 1 p.m.

The MAC will meet virtually on Wednesday, May 18, 2022. This meeting will run from 9:00 a.m. to 2:30 p.m. with a public comment period in the afternoon from noon until 1 p.m.

ADDRESSES: Both meetings will be held online through the Zoom meeting application. Participation information will be available on the MACs web page at least 2 weeks in advance of the meetings at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/san-juan-islands-mac.*

The public may send written comments for the MAC to the BLM Spokane District Office, Attn. MAC, 1103 N Fancher, Spokane Valley, WA 99212, or via email to the contact below.

FOR FURTHER INFORMATION CONTACT: Jeff Clark, Spokane District Public Affairs Officer, 1103 N Fancher, Spokane Valley, WA 99212, (509) 536–1297, or *jeffclark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at (800) 877–8339 to contact Mr. Clark during normal business hours. This service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The San Juan Islands MAC is comprised of 12 members representing a wide array of interests, including recreation, Tribal interests, education, environmental organizations, and landowners. The February meeting will begin at 9 a.m. with a welcome of new MAC members. After introductions, the members will spend time reviewing the Proposed Resource Management Plan (RMP) and Final Environmental Impact Statement and clarifying items from the BLM. This discussion/review will continue until a working lunch at noon. At noon, members of the public will have the opportunity to make comments to the MAC during a one-hour public comment period. The review will continue after the public comment period, if necessary. The next topic will be to consider opportunities for the MAC to support implementation of the management plan once the record of decision is signed. The MAC will adjourn no later than 1:30 p.m.

The May meeting will also begin at 9 a.m. with welcomes and introductions. After introductions, the members will: Review the RMP and Record of Decision; discuss whether the MAC will recommend those documents be signed by the Secretary; and other clarifying items from the BLM. This discussion/review will continue until a working lunch at noon. At noon, members of the public will have the opportunity to make comments to the MAC during a one-hour public comment period. The review will continue after the public comment period, if necessary. The next topic will be to consider opportunities for the MAC to support implementation of the approved RMP. The MAC will adjourn no later than 2:30 p.m.

All advisory council meetings are open to the public. Persons wishing to make comments during the public comment period should register in person with the BLM by 11 a.m. on the meeting day. Depending on the number of persons wishing to comment, the length of comments may be limited.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1784.4–2)

Kurt Pindel,

Spokane District Manager.

[FR Doc. 2022–00469 Filed 1–11–22; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–PCE–COR–NTS–NPS0033021; PPWOPCADT0, PPMPSPD1T.Y00000 (211); OMB Control Number 1024–0283]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Application for Designation as National Recreation Trail or National Water Trail

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 14, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, NPS Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Dr., (MS–242) Reston, VA 20192; or by email to *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–0283 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Peter Bonsall, National Trails System Program Specialist, National Recreation Trails Coordinator for the Department of the Interior 12795 W Alameda Parkway, Lakewood, CO 80228; by email at *peter_bonsall@nps.gov,* or by telephone at (303) 969–2620. Individuals who are hearing or speech impaired may call theFederalRelay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501*et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct, or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The NPS is authorized by section 4 of the National Trails System Act (16 U.S.C. 1243) and Secretarial Order No. 3319 to administer the National Recreation Trail (NRT) program, which establishes National Water Trails as a class of National Recreation Trails and directs that such trails collectively be considered in a National Water Trails System.

The NPS uses forms 10–1002: *Application for Designation as National Water Trail* and 10–1003: *Application for Designation as National Recreation Trail* to collect information NPS requires when submitting suitable trails or trail systems and water trails to the Secretary of the Interior for designation. The applications are evaluated for adherence to NRT requirements and criteria. NPS evaluation of an application is based on (1) the sufficiency of information provided on the application form and in supporting documentation, such as photographs, maps, and written landowner consents that accompany the form, and (2) successfully meeting the NRT requirements and criteria. Successful applications are forwarded to the Secretary of the Interior for approval.

Title of Collection: Application for Designation as National Recreation Trail or National Water Trail.

OMB Control Number: 1024–0283.

Form Number: NPS 10–1002: *Application for Designation as National Water Trail* and NPS 10–1003: *Application for Designation as National Recreation Trail.*

Type of Review: Extension of a currently approved collection.

Description of Respondents: Private individuals; businesses; educational institutions; nonprofit organizations; state, tribal, and local governments; and Federal agency land units.

Total Estimated Number of Annual Respondents: 22.

Total Estimated Number of Annual Responses: 23.

Estimated Completion Time per Response: Average 5 hours.

Total Estimated Number of Annual Burden Hours: 156 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Signed:

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2022–00416 Filed 1–11–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWRO–TUSK–33076; PPPWTUSK00, PPMPSPD1Z.YM0000]

Tule Springs Fossil Beds National Monument Advisory Council Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service is hereby giving notice that the Tule Springs Fossil Beds National Monument Advisory Council (Council) will meet as indicated below.

DATES: A teleconference will be held on Wednesday, March 2, 2022, at 5:00 p.m. until 7:00 p.m. (PACIFIC).

ADDRESSES: Information on how to access the meeting will be posted by February 25, 2022, to the Committee's website at *https://www.nps.gov/tusk/index.htm.*

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from Christie Vanover, Public Affairs Officer, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, Nevada 89005, via telephone at (702) 293–8691, or email at *christie_vanover@nps.gov.*

SUPPLEMENTARY INFORMATION: The Council was established pursuant to section 3092(a)(6) of Public Law 113–291 and in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. appendix 1–16). The purpose of the Council is to advise the Secretary of the Interior with respect to the preparation and implementation of the management plan.

Purpose of the Meeting: The Council agenda will include:

1. Minutes Review
2. Superintendent Updates will include:
   General Management Plan—Denver Service Center
3. Resource Management Updates
4. Old Business
5. New Business
6. Public Comments

The meeting is open to the public. Interested persons may make oral or written presentations to the Council during the business meeting or file written statements. Requests to address the Council should be made to the Superintendent prior to the meeting. Members of the public may submit written comments by mailing them to Ashley Pipkin, Acting Superintendent, Tule Springs Fossil Beds National

Monument, 601 Nevada Way, Boulder City, NV 89005, or by email *ashley_pipkin@nps.gov.* All written comments will be provided to members of the Council. Due to time constraints during the meeting, the Council is not able to read written public comments submitted into the record. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2022–00456 Filed 1–11–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NCR–WHHO–NPS0032047; PPNCWHHOP0, PPMVSIE1Z.I00000 (212); OMB Control Number 1024–0277]

Agency Information Collection Activities; National Park Service President's Park National Christmas Tree Music Program Application

AGENCY: National Park Service, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 14, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email at *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–0277 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Katie Wilmes, Chief of Interpretation, President's Park by email at *Katie_Wilmes@nps.gov,* or by telephone at 202–208–1631. Please reference OMB Control Number 1024–0277 in the subject line of your comments. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Authorized by the NPS Organic Act of 1916, 54 U.S.C. 100101 *et seq.,* the NPS has broad authority to regulate the use of the park areas under its jurisdiction. Consistent with the Organic Act, as well as the Constitution's Establishment Clause which mandates government neutrality and allows the placement of holiday secular and religious displays, the National Christmas Tree Music Program's holiday musical entertainment may include both holiday secular and religious music. To ensure that any proposed music selection is consistent with the Establishment Clause, and presented in a prudent and objective manner as a traditional part of the culture and heritage of this annual holiday event, it must be approved in advance by the NPS.

The NPS National Christmas Tree Music Program at President's Park is intended to provide musical entertainment for park visitors during December on the Ellipse, where in celebration of the holiday season, visitors can observe the National Christmas Tree, visit assorted yuletide displays, and attend musical presentations. Each year, park officials accept applications from musical groups who wish to participate in the annual National Christmas Tree Program. The NPS uses Form 10–942, ''National Christmas Tree Music Program Application'' to accept applications from the public for participation in the program. The form collects the following information:

- Contact name, phone number, and email
- Group name and location (city, state)
- Preferred performance dates and times
- Music selections/song list
- Equipment needs
- Number of performers
- Type of group (choir, etc.)
- Acknowledgement of the musical entertainment policy

Park officials use the information collected to select, plan, schedule, and contact performers for the National Christmas Tree Program.

Title of Collection: National Park Service President's Park National Christmas Tree Music Program Application.

OMB Control Number: 1024–0277.

Form Number: NPS Form 10–942, ''National Christmas Tree Music Program Application.''

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Local, national, and international bands, choirs, or dance groups.

Total Estimated Number of Annual Respondents: 75.

Total Estimated Number of Annual Responses: 75.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 19.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2022–00418 Filed 1–11–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NRSS–GRD–NPS0032952; MO# 4311H2; OMB Control Number 1024–0064]

Agency Information Collection Activities; Mining and Mining Claims and Non-Federal Oil and Gas Rights

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 14, 2022.

ADDRESSES: Send written comments on this information collection request (ICR) to Phadrea Ponds, NPS Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, (MS–242) Reston, VA 20192; or by email to *phadrea_ponds@nps.gov.* Please reference OMB Control Number 1024–0064 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Stephen Simon, Policy and Regulatory Specialist, Energy and Minerals Branch, Geologic Resources Division, National Park Service, P.O. Box 25287, Lakewood, Colorado 80225; by email at *Stephen_Simon@nps.gov* or by telephone at (303) 969–2015. Individuals who are hearing or speech impaired may call theFederalRelay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.)* and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Organic Act of 1916 (NPS Organic Act) (54 U.S.C. 100101) authorizes the Secretary of the Interior to develop regulations for units of the national park system (System units) under the Department's jurisdiction. The Mining in the Parks Act (54 U.S.C. 100731 *et seq.*) directs the Secretary of the Interior to regulate all operations in System units in connection with the exercise of mineral rights on patented and unpatented mining claims.

The regulations codified in 36 CFR part 9, subparts A and B, ensure that mining and non-Federal oil and gas activities in System units are conducted in a manner consistent with conserving each System unit for the benefit of present and future generations. The information required by subpart A identifies the claim, claimant, and operator (the claimant and operator are often the same) and details how the operator intends to access and develop the minerals associated with the claim. It also identifies the steps the operator intends to take to minimize any adverse impacts of the mining operations on park resource and values. No information, except claim ownership information, is submitted unless the claimant wishes to conduct mining operations. The information required by subpart B identifies the owner and operator (the owner and operator are often the same) and details how the operator intends to access and develop the oil and gas rights. It also identifies the steps the operator intends to take to minimize any adverse impacts on park resources and values. No information is submitted unless the owner wishes to conduct oil and gas operations. The information collected is used to evaluate proposed operations, ensure that all necessary mitigation measures are employed to protect park resources and values, and ensure compliance with all applicable laws and regulations.

Title of Collection: Mining and Mining Claims and Non-Federal Oil and Gas Rights, 36 CFR part 9, subparts A and B.

OMB Control Number: 1024–0064.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity/requirement	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours
ICs Currently Approved Under 1024–0064			
Mining and Mining Claims	1	176	176
Non-Federal Oil and Gas Rights	20	176	3,520
Previously Exempt Operations (§§ 9.50–9.53)	106	10	1,060
Application for Temporary Access Permit (§§ 9.60–9.63)	5	15	75
Extension of Temporary Access Permit	1	1	1
Accessing Oil and Gas Rights from a Surface Location Outside the Park Boundary—Application for Exemption (§§ 9.70–9.73)	3	80	240
Accessing Oil and Gas Rights from a Surface Location Outside the Park Boundary—Notice of change (§§ 9.70–9.73)	1	2	2
Operations Permit (New Operations)			
Application–(§§ 9.80—9.90)	5	140	700
Operating Standards–Simulation Operations (§ 9.118(b))			
Demonstrate mechanical integrity	5	4	20
Record treating pressures and all annular pressures	5	4	20
Notify Superintendent if mechanical integrity is lost	1	1	1
Report of accident	2	1	2
Operating Standards–Production (§ 9.118(c))			
Document maintenance of mechanical integrity	534	2	1,068
Signage to identify wells	5	4	20
General Terms and Conditions (§§ 9.120–9.122)			
Affidavit that proposed operations are in compliance with all laws and that information submitted to NPS is accurate	111	1	111
Third-Party Monitor Report	60	17	1,020
Notification—Accidents involving Serious Personal Injuries/Death and Fires/Spills	2	1	2
Written Report—Accidents Involving Serious Injuries/Deaths and Fires/Spills	2	16	32
Notification—Discovery of any cultural or scientific resources	1	1	1
Report—Verify Compliance with Permits	534	4	2,136
Reporting for Hydraulic Fracturing	1	2	2
Financial Assurance (§§ 9.140–9.144)	5	1	5
Modification to an Operation (§ 9.150)	1	16	16
Change of Operator (§§ 9.160–9.161)	5	8	40
Well Plugging (§§ 9.170–9.171)	33	14	462
Reconsideration and Appeals (§§ 9.190–9.194)	1	16	16
Public Participation (§ 9.200)	1	4	4
Total	1,451	.....	10,752

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2022–00417 Filed 1–11–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1279]

Notice of a Commission Determination Not To Review an Initial Determination Granting HCY's Motion To Intervene; Certain Flocked Swabs, Products Containing Flocked Swabs, and Methods of Using Same

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 30) of the presiding Administrative Law Judge (''ALJ'') granting non-parties Huanchenyang (Shenzhen) Technology Co., Ltd. and HCY USA LLC's (collectively ''HCY's'') motion to intervene as respondents in this investigation.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On September 2, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on a complaint filed by Copan Italia S.p.A. and Copan Industries, Inc. (''Copan''). 86 FR 49343–44 (Sept. 2, 2021). The complaint alleged a violation of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain flocked swabs, products containing flocked swabs, and methods of using same by reason of infringement of certain claims of U.S. Patent Nos. 9,011,358; 9,173,779; and 10,327,741. The complaint also alleged the existence of a domestic industry. The notice of investigation named Han Chang Medic of Chungnam, Republic of Korea; Wuxi NEST Biotechnology Co., Ltd. of Wuxi, Jiangsu, China; NEST Scientific Inc. of Rahway, New Jersey; NEST Scientific USA of Rahway, New Jersey; Miraclean Technology Co., Ltd. of Shenzhen, Guangdong, China; Vectornate Korea Ltd. of Jangseong, Republic of Korea and Vectornate USA, Inc. of Mahwah, New Jersey (collectively, ''Vectorante''); Innovative Product Brands, Inc. of Highland, California (''IPB''); Thomas Scientific, Inc. of Swedesboro, New Jersey (''Thomas Inc.''); Thomas Scientific, LLC of Owings Mills, Maryland (''Thomas LLC''); Cardinal Health, Inc. of Dublin, Ohio (''Cardinal''); KSL Biomedical, Inc. of Williamsville, New York and KSL Diagnostics, Inc. of Williamsville, New York (collectively, ''KSL''); Jiangsu Changfeng Medical Industry Co., Ltd. of Yangzhou, Jiangsu, China; No Borders Dental Resources, Inc., dba MediDent Supplies of Queen Creek, Arizona; BioTeke Corporation (Wuxi) Co., Ltd. of Wuxi, Jiangsu, China; Fosun Pharma USA Inc. of Princeton, New Jersey; Hunan Runmei Gene Technology Co., Ltd. of Changsha, Hunan, China (''Runmei''); VWR International, LLC of Radnor, Pennsylvania (''VWR''); and Slmp, LLC dba StatLab Medical Products of McKinney, Texas as respondents. *Id.* at 49343–44. The Commission's Office of Unfair Import Investigations (''OUII'') is also named as a party in this investigation. *Id.* at 49344.

Subsequently, the investigation was terminated as to the KSL respondents based on a consent order stipulation and consent order. Order No. 20 (Nov. 15, 2021), *unreviewed by* Notice (Dec. 6, 2021). Also, the investigation was terminated as to the following respondents: Thomas Inc.; Thomas LLC; Cardinal; VWR; Vectornate; and IPB. Orders 21–25 (all issued on November 15, 2021), *unreviewed by* Notice (Dec. 6, 2021). Furthermore, respondent Runmei was found in default. Order No. 27 (Nov. 15, 2021), *unreviewed by* Notice (Dec. 6, 2021).

On November 15, 2021, HCY moved to intervene as respondents in this investigation. On November 26, 2021, Copan filed an opposition to the motion and the Commission Investigative Staff filed a response in support of HCY's motion. On December 1, 2021, HCY filed a reply memorandum in support of the motion. No other responses were received.

On December 7, 2021, the ALJ issued the subject ID granting HCY's motion. The ID noted that Fed. R. Civ. P. 24 ''provides some guidance in determining whether intervention in a particular matter is appropriate.'' ID at 6 (citing *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software,* Inv. No. 337–TA–724, Comm'n Op. at 57 (Dec. 21, 2011) (EDIS Doc. ID 467105)). The ID noted that ''[b]ased on the factors found in Federal Rule 24, a party's motion to intervene is most persuasive where (1) the motion is timely; (2) the movant has an interest relating to the property or transaction which is the subject of the action; (3) the movant is so situated that the disposition of the action may as a practical matter impair or impede the movant's ability to protect that interest; (4) the movant is not adequately represented by existing parties; and (5) the intervention will not unduly delay or prejudice the adjudication of the original parties' rights.'' *Id.* (citing *Electronic Devices,* Comm'n Op. at 57). The ID found that each of the factors identified in *Certain Electronic Devices* weighs in favor of permitting intervention. *Id.* at 7–9. No party petitioned for review of the ID.

The Commission has determined not to review the subject ID. Huanchenyang (Shenzhen) Technology Co., Ltd. and HCY USA LLC are now respondents in this investigation.

The Commission vote for this determination took place on January 6, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: January 6, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–00368 Filed 1–11–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1191]

Certain Audio Players and Controllers, Components Thereof, and Products Containing Same; Notice of a Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and a Cease and Desist Order; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that respondent Google LLC (''Google'') has violated section 337 of the Tariff Act of 1930, as amended, by importing, selling for importation, or selling in the United States after importation certain audio players and controllers, components thereof, and products containing the same that infringe one or more claims of U.S. Patent Nos. 9,195,258; 10,209,953; 9,219,959; 8,588,949; and 10,439,896. The Commission has determined that the appropriate remedies are a limited exclusion order and a cease and desist order against Google. The Commission has also determined to set a bond in the amount of 100 percent of the entered value of the infringing products imported during the period of Presidential review. This investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Richard P. Hadorn, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3179. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: On February 11, 2020, the Commission instituted this investigation based on a complaint filed by Sonos, Inc. (''Sonos'') of Santa Barbara, California. 85 FR 7783 (Feb. 11, 2020). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) (''section 337''), based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain audio players and controllers, components thereof, and products containing the same by reason of infringement of certain claims of U.S. Patent Nos. 9,195,258 (''the '258 patent''); 10,209,953 (''the '953 patent''); 8,588,949 (''the '949 patent''); 9,219,959 (''the '959 patent''); and 10,439,896 (''the '896 patent''). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation named as respondents Google and Alphabet Inc. (''Alphabet''), both of Mountain View, California. *Id.* The Office of Unfair Import Investigations (''OUII'') is also named as a party. *Id.*

On September 21, 2020, the Commission terminated the investigation as to Alphabet based on withdrawal of the allegations in the complaint directed to Alphabet. Order No. 18 (Sept. 1, 2020), *unreviewed by* Comm'n Notice (Sept. 21, 2020). On November 24, 2020, the Commission determined that the importation requirement has been satisfied. Order No. 27 (Oct. 27, 2020), *unreviewed by* Comm'n Notice (Nov. 24, 2020). On February 2, 2021, the Commission determined that the technical prong of the domestic industry requirement has been satisfied as to the '949 patent. Order No. 32 (Jan. 4, 2021), *unreviewed by* Comm'n Notice (Feb. 2, 2021). On February 16, 2021, the Commission determined that the economic prong of the domestic industry requirement has been satisfied as to all asserted patents. Order No. 35 (Jan. 14, 2021), *reviewed and aff'd by* Comm'n Notice (Feb. 16, 2021). On March 12, 2021, the Commission partially terminated the investigation based on withdrawal of the allegations in the complaint as to the following asserted claims: Claims 22 and 23 of the '258 patent; claims 12 and 13 of the '953 patent; claims 5, 9, 29, and 35 of the '959 patent; and claim 3 of the '896 patent. Order No. 58 (Feb. 23, 2021), *unreviewed by* Comm'n Notice (Mar. 12, 2021).

On August 13, 2021, the CALJ issued a combined initial determination (''ID'') on violation and a recommended determination (''RD'') on remedy and bonding. The ID finds violations of section 337 with respect to the following claims of the asserted patents: claims 17, 21, 24, and 26 of the '258 patent; claims 7, 14, and 22–24 of the '953 patent; claim 10 of the '959 patent; claims 1, 2, and 5 of the '949 patent; and claims 1, 5, 6, and 12 of the '896 patent. ID at 180–82. The RD recommends that, should the Commission determine that violations of section 337 occurred, the Commission should: (i) Issue a limited exclusion order against Google; (ii) issue a cease and desist order against Google; and (iii) set a 100 percent bond for any importations of infringing products during the period of Presidential review. RD at 182–88.

On August 27, 2021, Sonos and Google each filed a petition seeking review of certain findings in the ID. On September 7, 2021, the private parties filed responses to each other's petitions, and OUII filed a combined response to both petitions.

On September 13, 2021, the Commission received eight submissions on the public interest from members of the public in response to the Commission's **Federal Register** notice. *See* 86 FR 46715 (Aug. 19, 2021). The Commission did not receive submissions on the public interest from the parties pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)).

On November 19, 2021, the Commission determined to review the ID in part with respect to the ID's analysis of whether the products accused of infringing the '258 and '953 patents are articles that infringe at the time of importation. 86 FR 67492 (Nov. 26, 2021). The Commission also determined to correct two typographical errors on pages 24 and 84 of the ID. *Id.* The Commission did not request briefing on any issue under review. *Id.* The Commission's notice also requested written submissions on remedy, the public interest, and bonding. *Id.*

On December 2, 2021, Sonos, Google, and OUII each filed initial submissions on remedy, the public interest, and bonding. That same day, the Commission also received four additional submissions on the public interest from members of the public. On December 10, 2021, Sonos, Google, and OUII each filed reply submissions on remedy, the public interest, and bonding.

The Commission, having reviewed the record in this investigation, including the final ID, the parties' petitions and responses thereto, has determined that Google has violated section 337 by importing into the United States, selling for importation, or selling in the United States after importation certain audio players and controllers, components thereof, and products containing the same that infringe one or more of claims 17, 21, 24, and 26 of the '258 patent; claims 7, 14, and 22–24 of the '953 patent; claim 10 of the '959 patent; claims 1, 2, and 5 of the '949 patent; and claims 1, 5, 6, and 12 of the '896 patent.

The Commission has determined that the appropriate remedy is: (i) A limited exclusion order prohibiting the importation of certain audio players and controllers, components thereof, and products containing the same that infringe one or more of claims 17, 21, 24, and 26 of the '258 patent; claims 7, 14, and 22–24 of the '953 patent; claim 10 of the '959 patent; claims 1, 2, and 5 of the '949 patent; and claims 1, 5, 6, and 12 of the '896 patent; and (ii) a cease and desist order against Google. The Commission has determined that the public interest factors do not preclude issuance of a remedy. The Commission has also determined to set a bond in the amount of 100 percent of the entered value of the infringing products imported during the period of Presidential review (19 U.S.C. 1337(j)).

The Commission issues its opinion herewith setting forth its determinations on certain issues. This investigation is hereby terminated.

The Commission's orders and opinion were delivered to the President and United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on January 6, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 6, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–00389 Filed 1–11–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1261]

Notice of a Commission Determination To Issue Remedial Orders Against the Defaulting Respondents; Termination of the Investigation; Certain LED Landscape Lighting Devices and Components Thereof

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to issue a limited exclusion order and cease and desist orders against the respondents found to be in default in this investigation, namely, cBright Lighting, Inc. of San Leandro, California (''cBright''), Dauer Manufacturing Corp. of Medley, Florida (''Dauer''), and FUSA Corp. of Medley, Florida (''FUSA''). The Commission has also determined to impose a bond equal to one hundred percent (100%) of the entered value of the infringing products imported during the period of Presidential review. This investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 13, 2021, based on a complaint filed on behalf of Wangs Alliance Corporation, d/b/a WAC Lighting (''WAC''). 86 FR 19282 (Apr. 13, 2021). The complaint alleged a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain LED landscape lighting devices and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 10,571,101 and 10,920,971. *Id.* The complaint further alleged that an industry in the United States exists as required by section 337. *Id.* The following were named as respondents in the investigation: cBright; Dauer; FUSA; Shenzhen Wanjia Lighting Co., Ltd. d/b/a WONKA of Shenzhen, China (''WONKA''); CAST Lighting LLC of Hawthorne, New Jersey (''CAST''); Lumien Enterprise, Inc. d/b/a Lumien Lighting of Acworth, Georgia (''Lumien''); and Jiangsu Sur Lighting Co., Ltd. of Jiangsu Province, China (''Jiangsu''). *Id.* The Office of Unfair Import Investigations is not a party to the investigation.

The Commission previously found cBright, Dauer, and FUSA (collectively, the ''Defaulting Respondents'') in default. Order No. 13 (July 9, 2021) (finding cBright in default), *unreviewed by* Notice (July 29, 2021); Order No. 14 (Aug. 4, 2021) (finding Dauer and FUSA in default), *unreviewed by* Notice (Aug. 18, 2021). The investigation was previously terminated as to all other respondents. Order No. 20 (Sept. 10, 2021) (terminating the investigation as to Lumien and Jiangsu), *unreviewed by* Notice (Oct. 6, 2021); Order No. 22 (Sept. 24, 2021) (terminating the investigation as to CAST), *unreviewed by* Notice (Oct. 14, 2021); Order No. 23 (Sept. 24, 2021) (terminating the investigation as to WONKA), *unreviewed by* Notice (Oct. 26, 2021).

The Commission, in terminating the last active respondent from the investigation, also requested briefing on the issues of remedy, the public interest, and bonding. Notice (Oct. 26, 2021). On November 9, 2021, WAC filed a statement on remedy, public interest, and bonding. Neither the Defaulting Respondents nor any other interested person filed a response to either the Commission's original notice or the statement filed by WAC.

On October 5, 2021, WAC filed a Declaration Seeking Immediate Relief Against Defaulting Respondents.

Upon review of WAC's submission and based upon the request of the complainant, and in the absence of any responses from interested persons, the Commission has determined to issue a limited exclusion order and cease and desist orders against the Defaulting Respondents. The Commission finds that the public interest factors do not preclude issuance of the requested relief. The Commission has further determined to set a bond equal to one hundred percent (100%) of the entered value of the covered products. The Commission also denies as moot WAC's October 5, 2021, Declaration Seeking Immediate Relief Against Defaulting Respondents. This investigation is hereby terminated.

The Commission vote for this determination took place on January 6, 2022.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant(s) complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

By order of the Commission.

Issued: January 6, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–00374 Filed 1–11–22; 8:45 am]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Civil Rules; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Civil Rules; notice of cancellation of open hearing.

SUMMARY: The following virtual public hearing on proposed amendments to the Federal Rules of Civil Procedure has been canceled: Civil Rules Hearing on February 4, 2022. The announcement for this hearing was previously published in the **Federal Register** on August 11, 2021.

DATES: February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: January 6, 2022.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2022–00357 Filed 1–11–22; 8:45 am]

BILLING CODE 2210–55–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Appellate Rules; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Appellate Rules; notice of cancellation of open hearing.

SUMMARY: The following virtual public hearing on proposed amendments to the Federal Rules of Appellate Procedure has been canceled: Appellate Rules Hearing on January 28, 2022. The announcement for this hearing was previously published in the **Federal Register** on August 11, 2021.

DATES: January 28, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: January 6, 2022.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2022–00355 Filed 1–11–22; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities for H–2B Foreign Labor Certification Program; Comment Request

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed revision to the information collection request (ICR) titled ''H–2B Foreign Labor Certification Program,'' and related information collection and retention requirements (OMB Control Number 1205–0509), which covers Forms ETA–9142B, ETA–9142B, Appendices A, B, C, and D, ETA–9142B, Final Determination, ETA–9165, ETA–9155, H–2B Seafood Industry Attestation, and related form instructions. This action seeks to revise the Form ETA–9142B and its instructions, revise the Form ETA–9142B Appendix D, and make a change to the Form ETA–9155 and its instructions to conform to changes made to the Form ETA–9142B. This action seeks to extend without change to the remaining forms in the information collection. This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by March 14, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained for free by contacting Brian Pasternak, Administrator, Office of Foreign Labor Certification, by telephone at 202–693–8200 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *ETA.OFLC.Forms@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by email at *ETA.OFLC.Forms@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Brian Pasternak, Administrator, Office of Foreign Labor Certification, by telephone at 202–693–8200 (this is not a toll-free number) or by email at *ETA.OFLC.Forms@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION:

DOL, in its continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program ensures the public provides all necessary data in the desired format, the reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

This information collection is required by Sections 101(a)(15)(H)(ii)(b) and 214(c) of the Immigration and Nationality Act (INA) (8 U.S.C. 1011(a)(15)(H)(ii)(b) and 1184(c)), as well as 8 CFR 214.2(h)(6), 20 CFR 655, Subpart A, and 29 CFR 503. The H–2B program enables employers to bring nonimmigrant foreign workers to the United States to perform non-agricultural work of a temporary nature. *See* 8 U.S.C. 1101(a)(15)(H)(ii)(b). The Department of Homeland Security (DHS) consults with DOL with respect to the H–2B program, and DOL provides advice on whether U.S. workers capable of performing the temporary services or labor are available. *See* 8 U.S.C. 1184(c)(1), INA Section 214(c)(1) (providing for DHS to consult with ''appropriate agencies of the Government''). Under DHS regulations, an H–2B petition for temporary employment must be accompanied by an approved temporary labor certification from DOL, which serves as DOL's consultative advice to DHS regarding whether a qualified U.S. worker is available to fill the petitioning H–2B employer's job opportunity and whether a foreign worker's employment in the job opportunity will adversely affect the wages or working conditions of similarly employed U.S. workers. *See* 8 CFR 214.2(h)(6)(iii)(A), (iv)(A). DHS and DOL jointly promulgated regulations establishing the processes by which an employer must obtain a prevailing wage and temporary labor certification from DOL, and the rights and obligations of workers and employers. *See* 20 CFR 655, subpart A; 29 CFR part 503; 8 CFR 214.2(h)(6)(iii)–(iv). The information contained in the Form ETA–9142B, *H–2B Application for Temporary Employment Certification,* and corresponding appendices serve as the basis for the Secretary's determination that qualified U.S. workers are not available to perform the services or labor needed by the employer and that the wages and working conditions of similarly employed U.S. workers will not be adversely affected by the employment of H–2B workers.

ETA is seeking comments on proposed revisions to the Form ETA–9142B, *H–2B Application for Temporary Employment Certification,* its instructions, and Form ETA–9142B, *Appendix D.* The proposed revisions to the Form ETA–9142B seek to clarify collection of cap-subject and cap-exempt data which DOL uses to inform its advice to DHS regarding the H–2B numerical cap and seek to streamline the collection of overtime wage information for all worksites for the application. The proposed revisions to the Form ETA–9142B, Appendix D modify the appendix to collect joint employer information, as applicable, in addition to job contractor information.

This ICR includes the collection of information related to the use of employer-provided surveys for determining prevailing wages and the

temporary labor certification process in the H–2B program. The Form ETA–9165, *Employer-Provided Survey Attestations to Accompany H–2B Prevailing Wage Determination Request Based on a Non-OES Survey,* is used to collect information that permits ETA to determine whether an employer-provided survey can be used to establish a prevailing wage in the occupational classification in lieu of a prevailing wage determined using the Bureau of Labor Statistics Occupational Employment Wage Statistics (OEWS) program. ETA seeks approval of extension of this form and its instructions without change.

Additionally, ETA is seeking comments on the Form ETA–9155, *H–2B Registration,* which allows ETA to determine whether the nature and duration of the employer's need for H–2B workers is temporary. Where ETA has not operationalized the registration process through a separate notice in the **Federal Register**, H–2B applications are exempt from the registration requirements under 20 CFR 655.11, and the adjudication of the employer's temporary need will continue to occur based on information collected on the Form ETA–9142B. A change was made to the Form ETA–9155 to conform the registration form to the proposed changes to the Form ETA–9142B.

ETA is also seeking comments on its extension of Appendices A, B, and C to the Form ETA–9142B, and revision to Appendix D of the Form ETA–9142B. *Appendix A* requires an employer to use a standard format to disclose additional place(s) of employment and, if applicable, multiple wage offers for the job opportunity. Employers use *Appendix B* of the Form ETA–9142B to attest that they will comply with all of the terms, conditions, and obligations of the H–2B program. *Appendix C* requires an employer to use a standard format to disclose the identity and location of all foreign labor recruiters. In order to recruit prospective foreign workers for the job opportunities offered by the employer under the Form ETA–9142B, the employer, and its attorney or agent (as applicable), must provide the identity and location of all persons and entities hired by or working for the recruiter or agent and any of the agent(s) or employee(s) of those person and entities. *See* 20 CFR 655.9(b). Collection of this information in a standard format will also permit ETA to more effectively comply with 20 CFR 655.9(c), which requires the maintenance of a publicly available list of foreign labor recruiters and the location(s) in which they are operating. The proposed revisions to *Appendix D* would require joint employers, whether filing as job contractors or not, to disclose the name and contact information of the employer-client or other joint employer.

The ICR contains a one-page Form ETA–9142B, *Final Determination: H–2B Temporary Labor Certification Approval,* which is issued electronically to employers granted temporary labor certification by DOL. In circumstances where the employer or, if applicable, its authorized attorney or agent, is not able to receive the temporary labor certification documents electronically, ETA sends the certification documents printed on standard paper in a manner that ensures overnight delivery. DOL seeks to extend the *Final Determination.*

Finally, ETA is requesting a three-year extension, without change, of the Form ETA–9142B, *Seafood Industry Attestation.* Employers in the seafood industry who wish to stagger the entry of H–2B workers into the United States between 90 and 120 days after the certified start date of need will need to complete the Form ETA–9142B, *Seafood Industry Attestation,* and provide a copy to each H–2B worker to present, upon request by DHS, when seeking entry into the United States.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0509. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection unless OMB, under the PRA, approves it and the collection tool displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0509.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

Agency: DOL-ETA.

Action: Revision.

Title of Collection: H–2B Foreign Labor Certification Program.

OMB Control Number: 1205–0509.

Affected Public: Private Sector.

Form(s): ETA–9142B, ETA–9142B General Instructions, ETA–9142B, Appendices A, B, C, and D, ETA–9165, ETA–9165, Instructions, Seafood Industry Attestation, ETA–9155, ETA–9155, Instructions.

Total Estimated Number of Annual Respondents: 88,193.

Frequency: On occasion.

Total Estimated Annual Responses: 299,551.

Average Time per Response: 3 hours and 45 minutes.

Total Estimated Annual Time Burden: 86,585.91 hours.

Total Estimated Annual Other Costs Burden: $998,310.

Authority: 44 U.S.C. 3507(a)(1)(D).

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–00393 Filed 1–11–22; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Pre-Apprenticeship—Pathways to Success Database Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Pre-Apprenticeship—Pathways to Success.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by March 14, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Natalie Linton by telephone at 202–693–3592 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Linton.Natalie.S@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Apprenticeship, 200 Constitution Avenue NW, Room N–5321, Washington, DC 20210; by email: *Linton.Natalie.S@dol.gov;* or by fax: 202–693–3592.

FOR FURTHER INFORMATION CONTACT: Natalie Linton by telephone at 202–693–3592 (this is not a toll-free number) or by email at *Linton.Natalie.S@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed. The National Apprenticeship Act of 1937, as amended (29 U.S.C. 50), authorizes this information collection.

Through a variety of approaches, pre-apprenticeship programs can be adapted to meet the needs to train different populations, the various employers and other sponsors they serve, and the specific opportunities available in the local labor market. The online database of quality pre-apprenticeship programs provides a valuable tool for job seekers, apprenticeship programs, and American Job Centers' front-line staff. A dedicated database provides a way for job seekers and apprenticeship programs to access pre-apprenticeship programs that meet the requirements outlined in Training and Employment Notice (TEN) 13–12: ''Defining a Quality Pre-Apprenticeship Program and Related Tools and Resources.'' The ''Pre-apprenticeship—Pathways to Success'' database enables ETA to identify pre-apprenticeship programs that meet the ''quality pre-apprenticeship'' definition and the quality framework criteria. Even more importantly, a national database of pre-apprenticeship programs facilitates connections between pre-apprenticeship program participants and apprenticeship programs, resulting in expanded opportunities. This voluntary data is collected using an online form. The public seeking information about pre-apprenticeship programs goes to a map on a website, chooses a state, and views information about the location of pre-apprenticeship programs, including general descriptions of the services and training they provide. ETA is proposing an extension for the authority to conduct the information collection ''Pre-Apprenticeship—Pathways to Success,'' to continue to utilize the database and make updates to the online form. Additionally, OA removed approximately ten (10) questions to streamline the instrument. During the past several years, ETA has worked to expand pre-apprenticeships and apprenticeships with new companies in high demand industries.

The current online form does not contain questions on new types of programs and their employer and educational institution partners. This data is instrumental in helping expand the functionality and usage of the database.

The National Apprenticeship Act of 1937, (subsequently referred to as ''the Act'') Section 50 (29 U.S.C. 50), authorizes and directs the Secretary of Labor ''to formulate and promote the furtherance of labor standards necessary to safeguard the welfare of apprentices, to extend the application of such standards by encouraging the inclusion thereof in contracts of apprenticeship, to bring together employers and labor for formulating programs of apprenticeship, to cooperate with State Apprenticeship Agencies (SAAs) engaged in formulating and promoting standards of apprenticeship, and to cooperate with the Secretary of Education in accordance with Section 17 of Title 20. Section 50a of the Act authorizes the Secretary of Labor to ''publish information relating to existing and proposed labor standards of apprenticeship,'' and to ''appoint national advisory committees . . .'' (29 U.S.C. 50a). The administration of the system is guided by Title 29 Code of Federal Regulations (CFR), part 29, regulations that were updated in 2008 to address the 21st century workforce needs as well as enhance accountability of the recognized SAAs.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0520.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL-ETA.

Type of Review: Revision.

Title of Collection: Pre-Apprenticeship—Pathways to Success.

Form: Pre-Apprenticeship—Contact and Program Information.

OMB Control Number: 1205–0520.

Affected Public: Private sector (businesses or other for-profits and not-for-profit institutions), secondary and post-secondary institutions.

Estimated Number of Respondents: 100.

Frequency: Annually.

Total Estimated Annual Responses: 100.

Estimated Average Time per Response: 8 hours.

Estimated Total Annual Burden Hours: 43 hours.

Total Estimated Annual Other Cost Burden: $0.

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–00394 Filed 1–11–22; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2009–0025]

UL LLC: Grant of Expansion of Recognition and Modification to the NRTL Program's List of Appropriate Test Standards

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the final decision to expand the scope of recognition for UL LLC as a Nationally Recognized Testing Laboratory (NRTL). Additionally, OSHA announces the final decision to add one test standard to the NRTL Program's list of appropriate test standards.

DATES: The expansion of the scope of recognition becomes effective on January 12, 2022.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693–2110 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of UL LLC (UL) as a NRTL. UL's expansion covers the addition of one test standard to the NRTL scope of recognition, which OSHA will add to the NRTL Program's List of Appropriate Test Standards.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within the scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification of the products.

The agency processes applications by a NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides a preliminary finding. In the second notice, the agency provides the final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including UL, which details the NRTL's scope of recognition. These pages are available from the OSHA website at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

UL submitted an application, dated October 4, 2020 (OSHA–2009–0025–0037) to add one additional test standard to UL's NRTL recognition. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

OSHA published the preliminary notice announcing UL's expansion application in the **Federal Register** on August 24, 2021 (86 FR 47333). The agency requested comments by September 8, 2021, but it received no comments in response to this notice. OSHA is now proceeding with this final notice to grant expansion of UL's scope of recognition and modification to the NRTL Program's List of Appropriate Test Standards.

To obtain or review copies of all public documents pertaining to UL's application, go to *http://www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor. Docket No. OSHA–2009–0025 contains all materials in the record concerning UL's recognition. Please note: Due to the COVID–19 pandemic, the Docket Office is closed to the public at this time but can be contacted at (202) 693–2350, TTY (877) 889–5627.

II. Final Decision and Order

OSHA staff examined UL's expansion application, its capability to meet the requirements of the test standard, and other pertinent information. Based on its review of this evidence, OSHA finds that UL meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitations and conditions listed in this notice. OSHA, therefore, is proceeding with this final notice to grant UL's scope of recognition. OSHA limits the expansion of UL's recognition to testing and certification of products for demonstration of conformance to the test standard listed below in Table 1.

TABLE 1—LIST OF APPROPRIATE TEST STANDARD FOR INCLUSION IN UL'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 2580*	Standard for Safety Batteries for Use in Electric Vehicles.

*Represents the standard that OSHA is adding to the NRTL Program's List of Appropriate Test Standards.

In this notice, OSHA also announces the final decision to add one new test standard to the NRTL Program's List of Appropriate Test Standards. Table 2 below lists the standard that is new to the NRTL Program. OSHA has determined that this test standard is an appropriate test standard and will add it to the NRTL Program's List of Appropriate Test Standards.

TABLE 2—STANDARD OSHA IS ADDING TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
UL 2580	Standard for Safety Batteries for Use in Electric Vehicles.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, a NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standard listed above as an American National Standard. However, for convenience, OSHA may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 01–00–004, Chapter 2, Section VIII), only standards determined to be appropriate test standards may be approved for NRTL recognition. Any NRTL recognized for an appropriate test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7, UL must abide by the following conditions of the recognition:

1. UL must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as a NRTL, and provide details of the change(s);
2. UL must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and
3. UL must continue to meet the requirements for recognition, including all previously published conditions on UL's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of UL, subject to the limitations and conditions specified above. OSHA also adds one new test standard to the NRTL Program's List of Appropriate Test Standards.

III. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393, September 18, 2020) and 29 CFR 1910.7.

Signed at Washington, DC, on December 14, 2021.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2022–00395 Filed 1–11–22; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (22–002)]

Aerospace Safety Advisory Panel; Meeting.

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Aeronautics and Space Administration announces a forthcoming meeting of the Aerospace Safety Advisory Panel (ASAP).

DATES: Thursday, January 27, 2022, 1:30 p.m. to 3:00 p.m., Eastern Time.

FOR FURTHER INFORMATION CONTACT: Ms. Lisa M. Hackley, ASAP Administrative Officer, NASA Headquarters, Washington, DC 20546, (202) 358–1947 or *lisa.m.hackley@nasa.gov.*

SUPPLEMENTARY INFORMATION: The Aerospace Safety Advisory Panel (ASAP) will hold its First Quarterly Meeting for 2022. This discussion is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight. The agenda will include:

—Updates on the International Space Station Program
—Updates on the Commercial Crew Program
—Updates on Exploration System Development Program
—Updates on Advanced Exploration Systems Program
—Updates on Human Lunar Exploration Program

This meeting is only available telephonically. Any interested person may call the USA toll free conference call number 888–566–6133; passcode 8343253 and then the # sign. At the beginning of the meeting, members of the public may make a verbal presentation to the Panel on the subject of safety in NASA, not to exceed 5 minutes in length. To do so, members of the public must contact Ms. Lisa M. Hackley at *lisa.m.hackley@nasa.gov* or at (202) 358–1947 at least 48 hours in advance. Any member of the public is permitted to file a written statement with the Panel via electronic submission to Ms. Hackley at the email address previously noted. Verbal presentations and written statements should be limited to the subject of safety in NASA. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2022–00476 Filed 1–11–22; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On December 3, 2021, the National Science Foundation published a notice in the **Federal Register** of a permit modification request received. The permit modification was issued on January 3, 2022, to:

Permit No. 2018–025

Allison Kean, Quark Expeditions Inc.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–00443 Filed 1–11–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by February 11, 2022. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–8030.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2022–028.

1. *Applicant:* Jonathan Hong, COO XM2 Aerial Pty Ltd., 15143 Waterman Dr., Van Nuys CA 91406.

Activity for Which Permit is Requested: Waste Management. The applicant seeks an Antarctic Conservation Act permit for waste management activities associated with the use of Unmanned Aerial Systems (UAS) in Antarctica. The applicant proposes using multiple UAS for commercial filmmaking purposes in areas surrounding the Antarctica Peninsula. UAS are only to be flown by pre-approved pilots with extensive flight experience. The applicant includes various mitigation measures to limit potential impacts to the environment. These measures include the following: Safety measures that minimize the risk of equipment failure, using observers to maintain visual line of sight with the aircraft and to aid in possible retrieval, not flying above any concentrations of wildlife and disinfecting UAVs after flight to prevent possible contamination between operation sites. The applicant seeks a waste permit to cover any accidental release that may result from UAS use.

Location: Antarctic Peninsula Region.

Dates of Permitted Activities: March 1, 2022–February 28, 2023.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–00445 Filed 1–11–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request received and permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of a requested permit modification issued.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–7420; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation (NSF), as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2018–015) to Polar Latitudes Inc. on November 2, 2017. The issued permit allows the applicant to conduct waste management activities associated with coastal camping and operating remotely piloted aircraft systems (RPAS) In the Antarctic Peninsula region.

On October 5, 2021, NSF issued a permit modification authorizing waste management activities associated with planned operations for the 2021–2022 field season. This modification included slight changes in operation. For the 2021–2022 season, Polar Latitudes plans to operate the MS SEAVENTURE, which will carry 149 passengers and 15–20 expedition staff. Polar Latitudes requested that the number of individuals permitted for coastal camping activities be increased from 30 participants to 40 participants and four expedition guides, with increased equipment brought onshore to support a larger group. Now the applicant proposes a modification to his permit to increase the number of individuals permitted for coastal camping activities to be increased from 40 to 50 participants for operator's remaining 2021–2022 season.

The Environmental Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it will have a less than a minor or transitory impact.

DATES: November 2, 2017–March 30, 2022.

The permit modification was issued on December 14, 2021.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–00444 Filed 1–11–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On November 26, 2021, the National Science Foundation published a notice in the **Federal Register** of a permit modification request received. The permit modification was issued on January 3, 2022, to:

Polar Latitudes Inc.
Permit No. 2018–015

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–00442 Filed 1–11–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On November 26, 2021, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on January 03, 2022, to:

Permit No. 2022–025

1. Dr. Kim Bernard

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–00441 Filed 1–11–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0214]

Monthly Notice: Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Monthly notice; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** on November 30, 2021, regarding an application date that was referenced in the License Amendment Request table as ''Application Date October 30, 2020'' to read ''Application Date June 14, 2021.''

DATES: January 12, 2022.

ADDRESSES: You may submit comments by any of the following methods, however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0214. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shirley Rohrer, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5411, email: *Shirley.Rohrer@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** (FR) on November 30, 2021, in FR Doc. 2021–25907, on page 67987, in the table ''License Amendment Request(s),'' for license amendment ''Energy Harbor Nuclear Corp. and Energy Harbor Nuclear Generation LLC; Beaver Valley Power Station, Unit Nos. 1 and 2; Beaver County, PA'' correct ''Application date October 30, 2020'' to read ''Application date June 14, 2021.''

Dated: January 6, 2022.

For the Nuclear Regulatory Commission.

Caroline L. Carusone,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2022–00365 Filed 1–11–22; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Rollover Election (RI 38–117), Rollover Information (RI 38–118), and Special Tax Notice Regarding Rollovers (RI 37–22), 3206–0212

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), Rollover Election (RI 38–117), Rollover Information (RI 38–118), and Special Tax Notice Regarding Rollovers (RI 37–22). This ICR has been revised in the following manner: (1) The display of the OMB control number and (2) updated the edition year.

DATES: Comments are encouraged and will be accepted until March 14, 2022.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—*Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or reached via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0212). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 38–117, Rollover Election, is used to collect information from each payee affected by a change in the tax code so that OPM can make payment in accordance with the wishes of the payee. RI 38–118, Rollover Information, explains the election. RI 37–22, Special Tax Notice Regarding Rollovers, provides more detailed information.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Rollover Election, Rollover Information, and Special Tax Notice Regarding Rollover.

OMB Number: 3206–0212.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 1,500.

Estimated Time per Respondent: 40 minutes.

Total Burden Hours: 1,000.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2022–00450 Filed 1–11–22; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93920; File No. SR–NYSE–2021–78]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 9261 and 9830

January 6, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 27, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes extending the expiration date of the temporary amendments to Rules 9261 and 9830 as set forth in SR–NYSE–2021–76 from December 31, 2021, to March 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE Rules 9261 and 9830. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSE–2020–76 [4] to Rules 9261 (Evidence and Procedure in Hearing) and 9830 (Hearing) from December 31, 2021, to March 31, 2022 to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSE–2020–76 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 9261 and 9830.[5]

Background

In 2013, the NYSE adopted disciplinary rules that are, with certain exceptions, substantially the same as the FINRA Rule 8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[6] The NYSE disciplinary rules were implemented on July 1, 2013.[7]

In adopting disciplinary rules modeled on FINRA's rules, the NYSE adopted the hearing and evidentiary processes set forth in Rule 9261 and in Rule 9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 9800 Series. As adopted, the text of Rule 9261 is identical to the counterpart FINRA rule. Rule 9830 is substantially the same as FINRA's rule, except for conforming and technical amendments.[8]

[4] *See* Securities Exchange Act Release No. 90024 (September 28, 2020), 85 FR 62353 (October 2, 2020) (SR–NYSE–2020–76) (''SR–NYSE–2020–76'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond March 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in NYSE–SR–2020–76. The amended NYSE rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release No. 68678 (January 16, 2013), 78 FR 5213 (January 24, 2013) (SR–NYSE–2013–02) (''2013 Notice''), 69045 (March 5, 2013), 78 FR 15394 (March 11, 2013) (SR–NYSE–2013–02) (''2013 Approval Order''), and 69963 (July 10, 2013), 78 FR 42573 (July 16, 2013) (SR–NYSE–2013–49).

[7] *See* NYSE Information Memorandum 13–8 (May 24, 2013).

[8] *See* 2013 Approval Order, 78 FR at 15394, n.7 & 15400; 2013 Notice, 78 FR at 5228 & 5234.

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[9]

Given that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 15, 2020, the Exchange filed to temporarily amend Rule 9261 and Rule 9830 to permit FINRA to conduct virtual hearings on its behalf.[10] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[11] On December 22, 2020, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to April 30, 2021.[12] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[13] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to August 31, 2021.[14] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[15] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to December 31, 2021, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[16]

While there are signs of improvement, FINRA has determined that much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[17] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[18] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[19] On December 7, 2021, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from December 31, 2021, to March 31, 2022.[20]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE Rules 9261 and 9830 as set forth in SR–NYSE–2020–76 from December 31, 2021, to March 31, 2022.

As set forth in SR–FINRA 2021–031, while there are signs of improvement, much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[21] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[22] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[23] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from December 31, 2021, to March 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE Rules 9261 and 9830 as set forth in SR–NYSE–2020–76 from December 31, 2021, to March 31, 2022. The Exchange agrees with FINRA that, while there are signs of improvement, much uncertainty remains for the coming months. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2021–031, there is a continued need for this temporary relief beyond December 31, 2021. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–

[9] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (the ''August 31 FINRA Filing'').

[10] *See* note 4, *supra.*

[11] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[12] *See* Securities Exchange Act Release No. 90821 (December 30, 2020), 86 FR 644 (January 6, 2021) (SR–NYSE–2020–107).

[13] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[14] *See* Securities Exchange Act Release No. 91629 (April 22, 2021), 86 FR 22505 (April 28, 2021) (SR–NYSE–2020–27).

[15] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[16] *See* Securities Exchange Act Release No. 92907 (September 9, 2021), 86 FR 51421 (September 15, 2021) (SR–NYSE–2021–47).

[17] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–031) (''SR–FINRA–2021–031''). FINRA noted that, for example, President Joe Biden on July 29, 2021, announced several measures to increase the number of people vaccinated against COVID–19 and to slow the spread of the Delta variant, including strengthening safety protocols for federal government employees and contractors. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/factsheet-president-biden-to-announce-new-actions-to-get-more-americansvaccinated-and-slow-the-spread-of-the-delta-variant/.* Thereafter, the Biden Administration announced on November 4, 2021, details of two major vaccination policies to further help fight COVID–19. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/factsheet-biden-administration-announces-details-of-two-major-vaccination-policies/.* Most recently, President Biden announced several new actions to help protect Americans against the Delta and Omicron variants. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/factsheet-president-biden-announces-new-actions-to-protect-americans-against-thedelta-and-omicron-variants-as-we-battle-covid-19-this-winter/. See* SR–FINRA–2021–031, 86 FR at 71695, n. 6.

[18] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recently announced that the first confirmed case of COVID–19 caused by the Omicron variant was detected in the United States. *See https://www.cdc.gov/media/releases/2021/s1201-omicron-variant.html.* The CDC also recommends that fully vaccinated people wear a mask in public indoor settings in areas of substantial or high transmission and noted that fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID–19. *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.* Furthermore, as FINRA also noted, numerous states currently have COVID–19 restrictions in place. Six states (Hawaii, Illinois, Nevada, New Mexico, Oregon, and Washington) require most people to wear masks in indoor public places regardless of vaccination status, and three states (California, Connecticut, and New York) have mask mandates in indoor public places for those individuals who are unvaccinated. Several other states have mask mandates in certain settings, such as healthcare facilities, schools, and correctional facilities. *See* SR–FINRA–2021–031, 86 FR at 71696, n. 7.

[19] *See* SR–FINRA–2021–031, 86 FR at 71695–96.

[20] *See* SR–FINRA–2021–031, 86 FR at 71695.

[21] *See* note 17, *supra.*

[22] *See* note 18, *supra.*

[23] *See* SR–FINRA–2021–031, 86 FR at 71695.

FINRA–2021–031, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2021–031, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[24] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 9261 and 9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[25] in general, and furthers the objectives of Section 6(b)(5),[26] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[27]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2021–031, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in the SR–NYSE–2020–76, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[28] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSE–2020–76, provides only temporary relief. As proposed, the changes would be in place through March 31, 2022. As noted in SR–NYSE–2020–76 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide continued temporary relief given the impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on December 31, 2021.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[29] and Rule 19b–4(f)(6) thereunder.[30] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[31] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[32] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that the proposed rule change to extend the expiration date will continue to prevent

[24] *See* SR–FINRA–2021–031, 86 FR at 71695, n. 13.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78f(b)(7) & 78f(d).

[28] 15 U.S.C. 78f(b)(7) & 78f(d).

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6).

[32] 17 CFR 240.19b–4(f)(6)(iii).

unnecessary impediments to its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets, that would otherwise result if the temporary amendments were to expire on December 31, 2021.[33] Importantly, the Exchange has also stated that extending the relief provided in SR–NYSE–2020–76 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes in a reasonable and fair manner and meet its critical investor protection goals, while also following best practices with respect to the health and safety of hearing participants.[34] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSE–2020–76.[35] As proposed, the changes would be in place through March 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[36] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[37]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[38] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–78 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–78. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–78 and should be submitted on or before February 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00382 Filed 1–11–22; 8:45 am]

BILLING CODE 8011–01–P

[33] *See* supra Item II.

[34] *See* SR–FINRA–2021–031 at 71698 (noting the same with respect to the health and safety of FINRA employees in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2021–031 would become operative immediately upon filing).

[35] *See* supra note 4.

[36] *See* supra note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond March 31, 2022 it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[37] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[38] 15 U.S.C. 78s(b)(2)(B).

[39] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93924; File No. SR–NASDAQ–2021–045]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 2, To Modify Certain Pricing Limitations for Companies Listing in Connection With a Direct Listing Primary Offering

January 6, 2022.

On June 11, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] a proposed rule change to modify certain pricing limitations for companies listing in connection with a direct listing primary offering in which the company will sell shares itself in the opening auction on the first day of trading on the Exchange. The proposed rule change was published for comment in the **Federal Register** on June 30, 2021.[4] On August 12, 2021, pursuant to Section 19(b)(2) of the Act,[5] the Commission designated a longer period within which to either approve or disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On September 24, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 92256 (June 24, 2021), 86 FR 34815 (June 30, 2021). Comments received on the proposal are available on the Commission's website at: *https://www.sec.gov/comments/sr-nasdaq-2021-045/srnasdaq2021045.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *See* Securities Exchange Act Release No. 92649 (August 12, 2021), 86 FR 46295 (August 18, 2021). The Commission designated September 28, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[7] 15 U.S.C. 78s(b)(2)(B).

disapprove the proposed rule change.[8] On December 20, 2021, the Commission extended the time period for approving or disapproving the proposal to February 25, 2022.[9]

On December 22, 2021, the Exchange filed Amendment No. 2 to the proposed rule change, which superseded the proposed rule change as originally filed. Amendment No. 2 to the proposed rule change is described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 2, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify certain pricing limitations for companies listing in connection with a Direct Listing primary offering in which the company will sell shares itself in the opening auction on the first day of trading on Nasdaq. This Amendment No. 2 supersedes the original filing in its entirety.[10]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Summary of Amendment

Nasdaq is filing this amendment to SR–NASDAQ–2021–045 [11] in order to address the issues the Commission raised in the OIP and make other modifications to clarify the proposed rule language.

As a preliminary matter, in this Amendment No. 2 (the ''Amendment'') Nasdaq proposes to clarify how the main provisions of Rules 4120(c)(8)(A) and (c)(9)(A) apply to a Direct Listing with a Capital Raise by restating the provisions of these rule in a clear and direct manner. This change will make the rules easier to understand and apply.

Also in this Amendment, Nasdaq proposes to modify the Initial Proposal to require that a Company offering securities for sale in connection with a Direct Listing with a Capital Raise must register securities by specifying the quantity of shares registered, as permitted by Securities Act Rule 457(a). Nasdaq also proposes to clarify that the price range in the preliminary prospectus included in the effective registration statement must be a bona fide price range in accordance with Item 501(b)(3) of Regulation S–K.

Nasdaq also proposes to revise the certification process described in the Initial Proposal such that two certifications would be required in certain circumstances. In its initial certification to Nasdaq, which would be publicly disclosed and provided to Nasdaq prior to the beginning of the Display Only Period, the Company must confirm that its registration statement contains a sensitivity analysis explaining how the company's plans would change if the actual proceeds from the offering exceed or are less than [sic] the amount assumed in the price range established by the issuer in its effective registration statement.

Further, Nasdaq proposes to add to the operation of the Cross, in certain circumstances, a Post-Pricing Period. Specifically, if the actual price calculated by the Cross is not at or above the price that is 20% below the lowest price and at or below the price that is 20% above the highest price [sic] of the price range established by the issuer in its effective registration statement, Nasdaq will initiate a brief Post-Pricing Period following the calculation of the actual price. In instances where the Post-Pricing Period is triggered, the issuer must confirm to Nasdaq during the Post-Pricing Period that no additional disclosures are required under federal securities laws based on the actual price calculated by the Cross. During the Post-Pricing Period no additional orders for the security may be entered in the Cross and no existing orders in the Cross may be modified. The Post-Pricing Period will end and the security will be released for trading immediately after the issuer provides such confirmation to Nasdaq. If the Company cannot provide the required confirmation, Nasdaq will postpone and reschedule the offering.

In the Amendment, Nasdaq proposes to prohibit market orders (other than by the company) from the opening of a Direct Listing with a Capital Raise. In addition, Nasdaq undertakes to disseminate, free of charge, the Current Reference Price, on a public website, such as *Nasdaq.com*, during the Pre-Launch Period and to indicate whether the Current Reference Price is within the price range established by the issuer in its effective registration statement. Nasdaq also proposes to adopt a new Price Volatility Constraint and disseminate information about whether the Price Volatility Constraint has been satisfied, which will indicate whether the security may be ready to trade. The Price Volatility Constraint requires that the Current Reference Price has not deviated by 10% or more from any Current Reference Price within the previous 10 minutes. The Pre-Launch Period will continue until the Price Volatility Constraint has been satisfied.

Nasdaq also proposes in this Amendment to impose specific requirements on Nasdaq members with respect to a Direct Listing with a Capital Raise. These rules will require members to provide to a customer, before that customer places an order to be executed in the Cross, a notice describing the mechanics of pricing a security subject to a Direct Listing with a Capital Raise in the Cross, including information regarding the dissemination of the Current Reference Price by Nasdaq on a public website such as *Nasdaq.com*.

Nasdaq also proposes to provide that it will distribute, at least one business day prior to the commencement of trading of a security listing in connection with a Direct Listing with a Capital Raise, an information circular to its members that describes any special

[8] *See* Securities Exchange Act Release No. 93119 (September 24, 2021), 86 FR 54262 (September 30, 2021).

[9] *See* Securities Exchange Act Release No. 93830 (December 20, 2021), 86 FR 73071 (December 23, 2021).

[10] On December 21, 2021, Nasdaq submitted Amendment No. 1, which was subsequently withdrawn.

[11] Securities Exchange Act Release No. 92256 (June 24, 2021), 86 FR 34815 (June 30, 2021) (the ''Initial Proposal''). The Commission issued an Order Instituting Proceedings to Determine Whether To Approve or Disapprove the Initial Proposal. *See* Securities Exchange Act Release No. 93119 (September 24, 2021), 86 FR 54262 (September 30, 2021) (the ''OIP'').

characteristics of the offering, and Nasdaq's rules that apply to the initial pricing through the mechanism outlined in Nasdaq Rule 4120(c)(9)(B) and Nasdaq Rule 4753 for the opening auction, including information about the notice they must provide customers and other Nasdaq rules that:

- Require members to use reasonable diligence in regard to the opening and maintenance of every account, to know (and retain) the essential facts concerning every customer and concerning the authority of each person acting on behalf of such customer; and
- require members in recommending transactions for a security subject to a Direct Listing with a Capital Raise to have a reasonable basis to believe that: (i) The recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such members, and (ii) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in such security.

Nasdaq also proposes to make minor technical changes to improve the clarity of this proposal. Nasdaq believes that this amendment addresses the issues raised by the Commission in the OIP. This amendment supersedes and replaces the Initial Proposal in its entirety.

Description of Proposed Rule, as Amended

Nasdaq recently adopted Listing Rule IM–5315–2 to permit a company to list in connection with a primary offering in which the company will sell shares itself in the opening auction on the first day of trading on the Exchange (a ''Direct Listing with a Capital Raise''); [12] created a new order type (the ''CDL Order''), which is used during the Nasdaq Halt Cross (the ''Cross'') for the shares offered by the company in a Direct Listing with a Capital Raise; and established requirements for disseminating information, establishing the opening price and initiating trading through the Cross in a Direct Listing with a Capital Raise.[13] For a Direct Listing with a Capital Raise, Nasdaq rules currently require that the actual price calculated by the Cross be at or above the lowest price and at or below the highest price of the price range established by the issuer in its effective registration statement (the ''Pricing Range Limitation'').

Nasdaq now proposes to modify the Pricing Range Limitation such that a Direct Listing with a Capital Raise can be executed in the Cross at a price that is at or above the price that is 20% below the lowest price and at or below the price that is 20% above the highest price of the price range established by the issuer in its effective registration statement.[14] In addition, Nasdaq proposes to modify the Pricing Range Limitation such that a Direct Listing with a Capital Raise can be executed in the Cross at a price above the price that is 20% above the highest price of such price range, provided that the company's registration statement contains a sensitivity analysis explaining how the company's plans would change if the actual proceeds from the offering exceed the amount assumed in such price range and the company has publicly disclosed and certified to Nasdaq that the company does not expect that such price would materially change the company's previous disclosure in its effective registration statement. Nasdaq also proposes to make related conforming changes.

Listing Rule IM–5315–2 requires that securities listing in connection with a Direct Listing with a Capital Raise must begin trading on Nasdaq following the initial pricing through the Cross, which is described in Rules 4120(c)(9) and 4753. Rule 4120(c)(9) requires that in the case of a Direct Listing with a Capital Raise, for purposes of releasing securities for trading on the first day of listing, Nasdaq, in consultation with the financial advisor to the issuer, will make the determination of whether the security is ready to trade.

Currently, in the case of the Direct Listing with a Capital Raise, a security is not released for trading by Nasdaq unless the actual price calculated by the Cross is at or above the lowest price and at or below the highest price of the price range established by the issuer in its effective registration statement.[15] Specifically, under Rule 4120(c)(9)(B) Nasdaq shall release the security for trading only if: (i) All market orders will be executed in the Cross; and (ii) the actual price calculated by the Cross complies with the Pricing Range Limitation. If there is insufficient buy interest to satisfy the CDL Order and all other market orders, as required by the current rule, or if the actual price calculated by the Cross is outside the price range established by the issuer in its effective registration statement, the Cross would not proceed and such security would not begin trading. Nasdaq shall postpone and reschedule the offering only if either or both such conditions are not met. In such event, because the Cross cannot be conducted, the Exchange would postpone and reschedule the offering and notify market participants via a Trader Update that the Direct Listing with a Capital Raise scheduled for that date has been cancelled and any orders for that security that have been entered on the Exchange would be cancelled back to the entering firms.

Proposed Change to Rule 4120(c)(9)

While many companies are interested in alternatives to the traditional IPOs, based on conversations with companies and their advisors Nasdaq believes that there may be a reluctance to use the existing Direct Listing with a Capital Raise rules because of concerns about the Pricing Range Limitation.

One potential benefit of a Direct Listing with a Capital Raise as an alternative to a traditional IPO is that it could maximize the chances of more efficient price discovery of the initial public sale of securities for issuers and investors. Unlike an IPO where the offering price is informed by underwriter engagement with potential investors to gauge interest in the offering, but ultimately decided through negotiations between the issuer and the underwriters for the offering, in a Direct Listing with a Capital Raise the initial sale price is determined based on market interest and the matching of buy and sell orders in an auction open to all market participants. In that regard, in the Approval Order the Commission stated that:

> The opening auction in a Direct Listing with a Capital Raise provides for a different price discovery method for IPOs which may reduce the spread between the IPO price and subsequent market trades, a potential benefit to existing and potential investors. In this way, the proposed rule change may result in additional investment opportunities while providing companies more options for becoming publicly traded.[16]

[12] A Direct Listing with a Capital Raise includes situations where either: (i) Only the company itself is selling shares in the opening auction on the first day of trading; or (ii) the company is selling shares and selling shareholders may also sell shares in such opening auction.

[13] *See* Securities Exchange Act Release No. 91947 (May 19, 2021), 86 FR 28169 (May 25, 2021) (the ''Approval Order'').

[14] References in this proposal to the price range established by the issuer in its effective registration statement are to the price range disclosed in the prospectus in such registration statement. Separately, as explained in more details below, Nasdaq proposes to prescribe that the 20% threshold will be calculated using the high end of the price range in the prospectus at the time of effectiveness and may be measured from either the high end (in the case of an increase in the price) or low end (in the case of a decrease in the price) of that range [sic].

[15] *See* Rule 4120(c)(9)(B).

[16] *See* Approval Order, 86 FR at 28177.

A successful initial public offering of shares requires sufficient investor interest. If an offering cannot be completed due to lack of investor interest, there is likely to be a substantial amount of negative publicity for the company and the offering may be delayed or cancelled. The Pricing Range Limitation imposed on a Direct Listing with a Capital Raise (but not on a traditional IPO) increases the probability of such a failed offering because the offering cannot proceed without some delay not only for the lack of investor interest, but also if investor interest is greater than the company and its advisors anticipated. In the Approval Order, the Commission noted a frequent academic observation of traditional firm commitment underwritten offerings that the IPO price, established through negotiation between the underwriters and the issuer, is often lower than the price that the issuer could have obtained for the securities, based on a comparison of the IPO price to the closing price on the first day of trading.[17] Nasdaq believes that the price range in a company's effective registration statement for a Direct Listing with a Capital Raise would similarly be determined by the company and its advisors and, therefore, there may be instances of offerings where the price determined by the Nasdaq opening auction will exceed the highest price of the price range in the company's effective registration statement.

As explained above, under the existing rule a security subject to a Direct Listing with a Capital Raise cannot be released for trading by Nasdaq if the actual price calculated by the Cross is above the highest price of the price range established by the issuer in its effective registration statement. In this case, Nasdaq would have to cancel or postpone the offering until the company amends its effective registration statement. At a minimum, such a delay exposes the company to market risk of changing investor sentiment in the event of an adverse market event. In addition, as explained above, the determination of the public offering price of a traditional IPO is not subject to limitations similar to the Pricing Range Limitation for a Direct Listing with a Capital Raise, which, in Nasdaq's view, could make companies reluctant to use this alternative method of going public despite its expected potential benefits.

Accordingly, Nasdaq proposes to modify the Pricing Range Limitation such that in the case of the Direct Listing with a Capital Raise, a security shall not be released for trading by Nasdaq unless the actual price at which the Cross would occur is at or above the price that is 20% below the lowest price of the price range established by the issuer in its effective registration statement and at or below the price that is 20% above the highest price of the price range. In other words, Nasdaq would release the security for trading, provided all other necessary conditions are satisfied, even if the actual price calculated by the Cross is outside the price range established by the issuer in its effective registration statement; provided however that the actual price cannot be more than 20% below the lowest price or more than 20% above the highest price of such range; and the company specified the quantity of shares registered, as permitted by Securities Act Rule 457, as explained below. In addition, there would be no limitation on releasing the security for trading at a price above the price that is 20% above the highest price of the price range established by the issuer in its effective registration statement if the company publicly disclosed and has certified to Nasdaq prior to beginning of the Display Only Period that the company does not expect that such offering price would materially change the company's previous disclosure in its effective registration statement and the company's registration statement contains a sensitivity analysis explaining how the company's plans would change if the actual proceeds from the offering exceed the amount assumed in the price range established by the issuer in its effective registration statement.[18] The goal of the requirement is to have disclosure that allows investors to see how changes in share price ripple through critical elements of the disclosure.[19]

Nasdaq believes that this approach is consistent with SEC Rule 430A and question 227.03 of the SEC Staff's Compliance and Disclosure Interpretations, which generally allow a company to price a public offering 20% outside of the disclosed price range without regard to the materiality of the changes to the disclosure contained in the company's registration statement.[20] Nasdaq believes such guidance also allows deviation above the price range beyond the 20% threshold if such change or deviation does not materially change the previous disclosure. Accordingly, Nasdaq believes that a company listing in connection with a Direct Listing with a Capital Raise can specify the quantity of shares registered, as permitted by Securities Act Rule 457, and, when an auction prices outside of the disclosed price range, use a Rule 424(b) prospectus, rather than a post-effective amendment, when either (i) the 20% threshold noted in Rule 430A is not exceeded, regardless of the materiality or non-materiality of resulting changes to the registration statement disclosure that would be contained in the Rule 424(b) prospectus, or (ii) when there is a deviation above the price range beyond the 20% threshold noted in Rule 430A if such deviation would not materially change the previous disclosure, in each case assuming the number of shares issued is not increased from the number of shares disclosed in the prospectus. For purposes of this rule, the 20% threshold will be calculated based on the maximum offering price set forth in the registration fee table, consistent with the Instruction to paragraph (a) of Securities Act Rule 430 [sic].

Finally, given that, as proposed, there may be a Direct Listing with a Capital Raise that could price outside the price range of the company's effective registration statement and that there may be no upside limit above which the Cross could not proceed, Nasdaq proposes to enhance price discovery transparency by providing readily available, real time pricing information to investors. To that end Nasdaq will disseminate, free of charge, the Current Reference Price on a public website, such as *Nasdaq.com,* during the Pre-Launch Period (as described in the Proposal) and indicate whether the Current Reference Price is within the price range established by the issuer in its effective registration statement. Nasdaq also proposes to adopt a new Price Volatility Constraint and disseminate information about whether the Price Volatility Constraint has been

[17] *See* Approval Order, footnote 91.

[18] The price range in the preliminary prospectus included in the effective registration statement is [sic] a bona fide price range in accordance with Item 501(b)(3) of Regulation S–K.

[19] Sensitivity analysis disclosure may include but is not limited to: Use of proceeds; balance sheet and capitalization; and the company's liquidity position after the offering. An example of this disclosure could be: We will apply the net proceeds from this offering first to repay all borrowings under our credit facility and then, to the extent of any proceeds remaining, to general corporate purposes.

[20] Securities Act Rule 457 permits issuers to register securities either by specifying the quantity of shares registered, pursuant to Rule 457(a), or the proposed maximum aggregate offering amount. Nasdaq proposes to require that companies selling shares through a Direct Listing with a Capital Raise will register securities by specifying the quantity of shares registered and not a maximum offering amount. *See also* Compliance & Disclosure Interpretation of Securities Act Rules #227.03 at *https://www.sec.gov/divisions/corpfin/guidance/securitiesactrules-interps.htm.*

satisfied, which will indicate whether the security may be ready to trade. The Price Volatility Constraint requires that the Current Reference Price has not deviated by 10% or more from any Current Reference Price within the previous 10 minutes. The Pre-Launch Period will continue until the Price Volatility Constraint has been satisfied. This change will provide investors with notice that the Cross nears execution.

Nasdaq also proposes to prohibit market orders (other than by the Company through its CDL Order) from the opening of a Direct Listing with a Capital Raise. This will assure that investors only purchase shares at a price at or better than the price they affirmatively set, after having the opportunity to review the Company's effective registration statement including the sensitivity analysis describing how the Company will use any additional proceeds raised.

In addition, to protect investors and assure that they are informed about the attributes of a Direct Listing with a Capital Raise, Nasdaq proposes to impose specific requirements on Nasdaq members with respect to a Direct Listing with a Capital Raise. These rules will require members to provide to a customer, before that customer places an order to be executed in the Cross, a notice describing the mechanics of pricing a security subject to a Direct Listing with a Capital Raise in the Cross, including information regarding the location of the public website where Nasdaq will disseminate the Current Reference Price.

To assure that members have the necessary information to be provided to their customers, Nasdaq proposes to distribute, at least one business day prior to the commencement of trading of a security listing in connection with a Direct Listing with a Capital Raise, an information circular to its members that describes any special characteristics of the offering, and Nasdaq's rules that apply to the initial pricing through the mechanism outlined in Nasdaq Rule 4120(c)(9)(B) and Nasdaq Rule 4753 for the opening auction, including information about the notice they must provide customers and other Nasdaq rules that:

- Require members to use reasonable diligence in regard to the opening and maintenance of every account, to know (and retain) the essential facts concerning every customer and concerning the authority of each person acting on behalf of such customer; and
- require members in recommending transactions for a security subject to a Direct Listing with a Capital Raise to have a reasonable basis to believe that: (i) The recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such members, and (ii) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in such security.

These member requirements are intended to remind members of their obligations to ''know their customers,'' increase transparency of the pricing mechanisms of a Direct Listing with a Capital Raise, and help assure that investors have sufficient price discovery information.

In each instance of a Direct Listing with a Capital Raise, Nasdaq's information circular [21] will inform the market participants that the auction could price up to 20% below the lowest price of the price range in the company's effective registration statement and specify what that price is. Nasdaq will also indicate in such circular whether or not there is an upside limit above which the Cross could not proceed, based on the company's certification, as described above. Nasdaq will also remind the market participants that Nasdaq prohibits market orders (other than by the Company) from the opening of a Direct Listing with a Capital Raise.

To assure that the issuer has the ability, prior to the completion of the offering, to provide any necessary additional disclosures that are dependent on the price of the offering, Nasdaq proposes to introduce to the operation of the Cross a brief Post-Pricing Period, in circumstances where the actual price calculated by the Cross is above the price that is 20% above the highest price of the price range established by the issuer in its effective registration statement. Specifically, in such circumstances, Nasdaq will initiate a Post-Pricing Period following the calculation of the actual price. During the Post-Pricing Period the issuer must confirm to Nasdaq that no additional disclosures are required under federal securities laws based on the actual price calculated by the Cross. During the Post-Pricing Period no additional orders for the security may be entered in the Cross and no existing orders in the Cross may be modified. The security shall be released for trading immediately following the Post-Pricing Period. If the Company cannot provide the required confirmation, then Nasdaq will postpone and reschedule the offering.

[21] The Information circular is an industry wide free service provided by Nasdaq.

Proposed Conforming Changes to Listing Rule IM–5315–2

Listing Rule IM–5315–2 allows a company that has not previously had its common equity securities registered under the Act to list its common equity securities on the Nasdaq Global Select Market at the time of effectiveness of a registration statement pursuant to which the company itself will sell shares in the opening auction on the first day of trading on the Exchange.

Listing Rule IM–5315–2 provides that in determining whether a company listing in connection with a Direct Listing with a Capital Raise satisfies the Market Value of Unrestricted Publicly Held Shares [22] for initial listing on the Nasdaq Global Select Market, the Exchange will deem such company to have met the applicable requirement if the amount of the company's Unrestricted Publicly Held Shares before the offering along with the market value of the shares to be sold by the company in the Exchange's opening auction in the Direct Listing with a Capital Raise is at least $110 million (or $100 million, if the company has stockholders' equity of at least $110 million).

Listing Rule IM–5315–2 further provides that, for this purpose, the Market Value of Unrestricted Publicly Held Shares will be calculated using a price per share equal to the lowest price of the price range disclosed by the issuer in its effective registration statement.

Because Nasdaq proposes to allow the opening auction to price up to 20% below the lowest price of the price range established by the issuer in its effective registration statement, Nasdaq proposes to make a conforming change to Listing Rule IM–5315–2 to provide that the price used to determine such company's compliance with the Market Value of Unrestricted Publicly Held Shares is the price per share equal to the price that is 20% below the lowest price of the price range disclosed by the issuer in its effective registration statement as this is the minimum price at which the company could qualify to be listed. Nasdaq will determine that the company has met the applicable bid price and market capitalization requirements based on the same per share price.

Any company listing in connection with a Direct Listing with a Capital Raise would continue to be subject to, and required to meet, all other applicable initial listing requirements, including the requirements to have the

[22] *See* Listing Rules 5005(a)(23) and 5005(a)(45).

applicable number of shareholders and at least 1,250,000 Unrestricted Publicly Held Shares outstanding at the time of initial listing, and the requirement to have a price per share of at least $4.00 at the time of initial listing.[23]

Proposed Conforming Changes to Rules 4753(a)(3)(A) and 4753(b)(2)

Nasdaq proposes to amend Rules 4753(a)(3)(A) and 4753(b)(2) to conform the requirements for disseminating information and establishing the opening price through the Cross in a Direct Listing with a Capital Raise to the proposed amendment to allow the opening auction to price as much as 20% below the lowest price of the price range established by the issuer in its effective registration statement.

Specifically, Nasdaq proposes changes to Rules 4753(a)(3)(A) and 4753(b)(2) to make adjustments to the calculation of the Current Reference Price, which is disseminated in the Nasdaq Order Imbalance Indicator, in the case of a Direct Listing with a Capital Raise and for how the price at which the Cross will execute. These rules currently provide that where there are multiple prices that would satisfy the conditions for determining a price, the fourth tie-breaker for a Direct Listing with a Capital Raise is the price that is closest to the lowest price of the price range disclosed by the issuer in its effective registration statement.[24]

To conform these rules to the modification of the Pricing Range Limitation change, as described above, Nasdaq proposes to modify the fourth tie-breaker for a Direct Listing with a Capital Raise, to use the price closest to the price that is 20% below the lowest price of the price range disclosed by the issuer in its effective registration statement.[25]

Lastly, Nasdaq proposes to clarify several provisions of the existing rules without changing them. Specifically, Nasdaq proposes to clarify the mechanics of the Cross by specifying that Nasdaq will initiate a 10-minute Display Only Period only after the CDL Order had been entered. This clarification simply states what is already implied by the rule because the Cross and the offering may not proceed without the company's order to sell the securities in a Direct Listing with a Capital Raise. Similarly, Nasdaq proposes to clarify without changing the existing rule that Nasdaq shall select price bands for purposes of applying the price validation test in the Cross in connection with a Direct Listing with a Capital Raise. Under the price validation test, the System compares the Expected Price with the actual price calculated by the Cross to ascertain that the difference, if any, is within the price bands. Nasdaq shall select an upper price band and a lower price band. The default for an upper and a lower price band is set at zero. If a security does not pass the price validation test, Nasdaq may, but is not required to, select different price bands before recommencing the process to release the security for trading.[26] Nasdaq also proposes to clarify that the ''actual price,'' as the term is used in the rule, is the Current Reference Price at the time the system applies the price bands test.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[27] in general, and furthers the objectives of Section 6(b)(5) of the Act,[28] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Nasdaq believes that the proposed amendment to modify the Pricing Range Limitation is consistent with the protection of investors because this approach is similar to the pricing of an IPO where an issuer is permitted to price outside of the price range disclosed by the issuer in its effective registration statement in accordance with the SEC's Staff guidance, as described above.[29] Specifically, Nasdaq believes that a company listing in connection with a Direct Listing with a Capital Raise can specify the quantity of shares registered, as permitted by Securities Act Rule 457, and, when an auction prices outside of the disclosed price range, use a Rule 424(b) prospectus, rather than a post-effective amendment, when either (i) the 20% threshold noted in Rule 430A is not exceeded, regardless of the materiality or non-materiality of resulting changes to the registration statement disclosure that would be contained in the Rule 424(b) prospectus, or (ii) when there is a deviation above the price range beyond the 20% threshold noted in Rule 430A if such deviation would not materially change the previous disclosure, in each case assuming the number of shares issued is not increased from the number of shares disclosed in the prospectus. As a result, Nasdaq will allow the Cross to take place as low as 20% below the lowest price of the price range disclosed by the issuer in its effective registration statement, but no lower, and so this is the minimum price at which the company could be listed. In addition, to better inform investors and market participants, Nasdaq will issue an industry wide circular to inform the participants that the auction could price up to 20% below the lowest price of the price range in the company's effective registration statement and specify what that price is. Nasdaq will also indicate in such circular whether or not there is an upside limit above which the Cross could not proceed, based on the company's certification, as described above. Nasdaq will also remind the market participants that Nasdaq prohibits market orders (other than by the Company) from the opening of a Direct Listing with a Capital Raise.

To assure that the issuer has the ability, prior to the completion of the offering, to provide any necessary additional disclosures that are dependent on the price of the offering, Nasdaq proposes to introduce to the operation of the Cross a brief Post-Pricing Period, in circumstances where the actual price calculated by the Cross is above the price that is 20% above the highest price of the price range established by the issuer in its effective registration statement. Specifically, in such circumstances, Nasdaq will initiate a Post-Pricing Period following the calculation of the actual price. During the Post-Pricing Period the issuer must

[23] *See* Listing Rules 5315(f)(1), (e)(1) and (2), respectively. Rule 5315(f)(1) requires a security to have: (A) At least 550 total holders and an average monthly trading volume over the prior 12 months of at least 1,100,000 shares per month; or (B) at least 2,200 total holders; or (C) a minimum of 450 round lot holders and at least 50% of such round lot holders must each hold unrestricted securities with a market value of at least $2,500.

[24] To illustrate: The bottom of the range is $10. More than one price exists within the range under the previous set of tie-breakers such that both $10.15 and $10.25, satisfy all other requirements. The operation of the fourth tie-breaker will result in the auction price of $10.15 because it is the price that is closest to $10.

[25] Note that using the price that is 20% below the lowest price of the price range disclosed by the issuer in its effective registration statement as a tie-breaker (rather than the price representing the bottom of the range) does not change the outcome in the example in footnote 24 above because $10.15 is the price that is closest to either.

[26] This function is provided by the underwriter in an IPO and by a Financial Advisor in a Direct Listing. The Commission previously approved Nasdaq performing this function. *See* Approval Order.

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(5).

[29] In a recent speech, SEC Chair Gary Gensler emphasized that an overarching principle of regulation is that like activities ought to be treated alike. *See https://www.sec.gov/news/speech/gensler-healthy-markets-association-conference-120921.*

confirm to Nasdaq that no additional disclosures are required under federal securities laws based on the actual price calculated by the Cross. During the Post-Pricing Period no additional orders for the security may be entered in the Cross and no existing orders in the Cross may be modified. The security shall be released for trading immediately following the Post-Pricing Period. If the Company cannot provide the required confirmation, then Nasdaq will postpone and reschedule the offering. Nasdaq believes that this modification is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market because it will help assure that a company listing in connection with a Direct Listing with a Capital Raise complies with the disclosure requirements under federal securities laws.

Nasdaq believes that the proposal to allow a Direct Listing with a Capital Raise to price above any price above the price range of the company's effective registration statement is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market investors because this approach is similar to that of pricing a traditional IPO. In addition, to protect investors Nasdaq proposes to enhance price discovery transparency by providing readily available, real time pricing information to investors. To that end Nasdaq will disseminate, free of charge, the Current Reference Price on a public website (such as *Nasdaq.com*) during the Pre-Launch Period and indicate whether the Current Reference Price is within the price range established by the issuer in its effective registration statement. Nasdaq also proposes to adopt a new Price Volatility Constraint and disseminate information about whether the Price Volatility Constraint has been satisfied, which will indicate whether the security may be ready to trade. The Price Volatility Constraint requires that the Current Reference Price has not deviated by 10% or more from any Current Reference Price within the previous 10 minutes. The Pre-Launch Period will continue until the Price Volatility Constraint has been satisfied. This change will provide investors with notice that the Cross nears execution.

Nasdaq believes that the provision prohibiting market orders (other than by the Company) from the opening of a Direct Listing with a Capital Raise is designed to protect investors because this provision will assure that investors only purchase shares at a price that is at, or better than, the price they affirmatively set, after having the opportunity to review the Company's effective registration statement including the sensitivity analysis describing how the Company will use any additional proceeds raised.

In addition, to protect investors and assure that they are informed about the attributes of a Direct Listing with a Capital Raise, Nasdaq proposes to impose specific requirements on Nasdaq members with respect to a Direct Listing with a Capital Raise. These rules will require members to provide to a customer, before that customer places an order to be executed in the Cross, a notice describing the mechanics of pricing a security subject to a Direct Listing with a Capital Raise in the Cross, including information regarding the dissemination of the Current Reference Price on a public website such as *Nasdaq.com.*

To assure that members have the necessary information to be provided to their customers, Nasdaq proposes to distribute, at least one business day prior to the commencement of trading of a security listing in connection with a Direct Listing with a Capital Raise, an information circular to its members that describes any special characteristics of the offering, and Nasdaq's rules that apply to the initial pricing through the mechanism outlined in Nasdaq Rule 4120(c)(9)(B) and Nasdaq Rule 4753 for the opening auction, including information about the notice they must provide customers and other Nasdaq rules that:

- Require members to use reasonable diligence in regard to the opening and maintenance of every account, to know (and retain) the essential facts concerning every customer and concerning the authority of each person acting on behalf of such customer; and
- require members in recommending transactions for a security subject to a Direct Listing with a Capital Raise to have a reasonable basis to believe that: (i) The recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such members, and (ii) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in such security.

These member requirements are consistent with the protection of investors because they are designed to remind members of its obligations to ''know their customers,'' increase transparency of the pricing mechanisms of a Direct Listing with a Capital Raise, and help assure that investors have sufficient price discovery information.

Nasdaq believes that the Commission Staff has already concluded that pricing up to 20% below the lowest price and at a price above the highest price of the price range in the company's effective registration statement is appropriate for a company conducting an initial public offering notwithstanding it being outside of the range stated in an effective registration statement, and investors have become familiar with this approach at least since the Commission Staff last revised Compliance and Disclosure Interpretation 227.03 in January 2009.[30] Allowing Direct Listings with a Capital Raise to similarly price up to 20% below the lowest price and at a price above the highest price of the price range in the company's effective registration statement would be consistent with Chair Gensler's recent call to treat ''like cases alike.'' [31]

Nasdaq believes that the proposed amendments to Listing Rule IM–5315–2 and Rules 4753(a)(3)(A) and 4753(b)(2) to conform these rules to the modification of the Pricing Range Limitation is consistent with the protection of investors. These amendments would simply substitute Nasdaq's reliance on the price equal to the lowest price of the price range disclosed by the issuer in its effective registration statement to the price that is 20% below such lowest price. In the case of Listing Rule IM–5315–2, a company listing in connection with a Direct Listing with a Capital Raise would still need to meet all applicable initial listing requirements based on the price that is 20% below the lowest price of the price range disclosed by the issuer in its effective registration statement. In the case of the Rules 4753(a)(3)(A) and 4753(b)(2) such price, which is the minimum price at which the Cross will occur, will serve as the fourth tie-breaker where there are multiple prices that would satisfy the conditions for determining the auction price, as described above. Nasdaq believes that this proposal to resolve a potential tie among the prices that satisfy all other requirements in the Cross, by choosing the price that is closest to the price that is 20% below the range, is consistent with Section 6(b)(5) of the Act because it is designed to protect investors by providing them with the most advantageous offering price among possible alternative prices.

[30] *https://www.sec.gov/divisions/corpfin/guidance/securitiesactrules-interps.htm.*

[31] *See https://www.sec.gov/news/speech/gensler-healthy-markets-association-conference-120921.*

Nasdaq also believes that the proposal, by eliminating an impediment to companies using a Direct Listing with a Capital Raise, will help removing potential impediments to free and open markets consistent with Section 6(b)(5) of the Exchange Act while also supporting capital formation.

Finally, Nasdaq believes that the proposal to clarify several provisions of the existing rules without changing them is designed to remove impediments to and perfect the mechanism of a free and open market because such changes make the rules easier to understand and apply without changing their substance.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed amendments would not impose any burden on competition, but would rather increase competition. Nasdaq believes that allowing listing venues to improve their rules enhances competition among exchanges. Nasdaq also believes that this proposed change will give issuers interested in this pathway to access the capital markets additional flexibility in becoming a public company, and in that way promote competition among service providers, such as underwriters and other advisors, to such companies.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 2, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2021–045 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–045. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2021–045, and should be submitted on or before February 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00383 Filed 1–11–22; 8:45 am]

BILLING CODE 8011–01–P

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93919; File No. SR–NYSENAT–2021–25]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 10.9261 and 10.9830

January 6, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 27, 2021, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes extending the expiration date of the temporary amendments to Rules 10.9261 and 10.9830 as set forth in SR–NYSENAT–2020–31 from December 31, 2021, to March 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE National Rules 10.9261 and 10.9830. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSENAT–2020–31[4] to Rules 10.9261 (Evidence and Procedure in Hearing) and 10.9830 (Hearing) from December 31, 2021, to March 31, 2022 to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSENAT–2020–31 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 10.9261 and 10.9830.[5]

Background

In 2018, NYSE National adopted disciplinary rules that are, with certain exceptions, substantially the same as the disciplinary rules of its affiliate NYSE American LLC, which are in turn substantially similar to the FINRA Rule 8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[6]

In adopting disciplinary rules modeled on FINRA's rules, NYSE National adopted the hearing and evidentiary processes set forth in Rule 10.9261 and in Rule 10.9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 10.9800 Series. As adopted, the text of Rule 10.9261 and Rule 10.9830 are substantially the same as the FINRA rules with certain modifications.[7]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[8]

Given that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 29, 2020, the Exchange filed to temporarily amend Rule 10.9261 and Rule 10.9830 to permit FINRA to conduct virtual hearings on its behalf.[9] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[10] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to April 30, 2021.[11] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[12] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to August 31, 2021.[13] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[14] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to December 31, 2021, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[15]

While there are signs of improvement, FINRA has determined that much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[16] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[17] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[18] On December 7, 2021,

[4] *See* Securities Exchange Act Release No. 90137 (October 8, 2020), 85 FR 65087 (October 14, 2020) (SR–NYSENAT–2020–31) (''SR–NYSENAT–2020–31'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond March 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in SR–NYSENAT–2020–31. The amended NYSE National rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release No. 83289 (May 17, 2018), 83 FR 23968, 23976 (May 23, 2018) (SR–NYSENAT–2018–02) (''2018 Approval Order'').

[7] *See id.*

[8] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''SR–FINRA–2020–027'').

[9] *See* note 4, *supra.*

[10] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[11] *See* Securities Exchange Act Release No. 90822 (December 30, 2020), 86 FR 627 (January 6, 2021) (SR–NYSENAT–2020–39).

[12] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[13] *See* Securities Exchange Act Release No. 91634 (April 22, 2021), 86 FR 22477 (April 28, 2021) (SR–NYSENAT–2021–11).

[14] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[15] *See* Securities Exchange Act Release No. 92907 (September 9, 2021), 86 FR 51424 (September 15, 2021) (SR–NYSENAT–2021–16).

[16] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–031) (''SR–FINRA–2021–031''). FINRA noted that, for example, President Joe Biden on July 29, 2021, announced several measures to increase the number of people vaccinated against COVID–19 and to slow the spread of the Delta variant, including strengthening safety protocols for federal government employees and contractors. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/factsheet-president-biden-to-announce-new-actions-to-get-more-americansvaccinated-and-slow-the-spread-of-the-delta-variant/.* Thereafter, the Biden Administration announced on November 4, 2021, details of two major vaccination policies to further help fight COVID–19. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/factsheet-biden-administration-announces-details-of-two-major-vaccination-policies/.* Most recently, President Biden announced several new actions to help protect Americans against the Delta and Omicron variants. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/factsheet-president-biden-announces-new-actions-to-protect-americans-against-thedelta-and-omicron-variants-as-we-battle-covid-19-this-winter/. See* SR–FINRA–2021–031, 86 FR at 71695, n. 6.

[17] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recently announced that the first confirmed case of COVID–19 caused by the Omicron variant was detected in the United States. *See https://www.cdc.gov/media/releases/2021/s1201-omicron-variant.html.* The CDC also recommends that fully vaccinated people wear a mask in public indoor settings in areas of substantial or high transmission and noted that fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID–19. *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.* Furthermore, as FINRA also noted, numerous states currently have COVID–19 restrictions in place. Six states (Hawaii, Illinois, Nevada, New Mexico, Oregon, and Washington) require most people to wear masks in indoor public places regardless of vaccination status, and three states (California, Connecticut, and New York) have mask mandates in indoor public places for those individuals who are unvaccinated. Several other states have mask mandates in certain settings, such as healthcare facilities, schools, and correctional facilities. *See* SR–FINRA–2021–031, 86 FR at 71696, n. 7.

[18] *See* SR–FINRA–2021–031, 86 FR at 71695–96.

FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from December 31, 2021, to March 31, 2022.[19]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE National Rules 10.9261 and 10.9830 as set forth in SR–NYSENAT–2020–31 from December 31, 2021, to March 31, 2022.

As set forth in SR–FINRA 2021–031, while there are signs of improvement, much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[20] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[21] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[22] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from December 31, 2021, to March 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE National Rules 10.9261 and 10.9830 as set forth in SR–NYSENAT–2020–31 from December 31, 2021, to March 31, 2022. The Exchange agrees with FINRA that, while there are signs of improvement, much uncertainty remains for the coming months. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2021–031, there is a continued need for this temporary relief beyond December 31, 2021. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2021–031, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2021–031, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[23] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 9261 and 9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Section 6(b)(5),[25] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[26]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2021–031, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in SR–NYSENAT–2020–31, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[27] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSENAT–2020–31, provides only temporary relief. As proposed, the changes would be in place through March 31, 2022. As noted in SR–NYSENAT–2020–31 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

[19] *See* SR–FINRA–2021–031, 86 FR at 71695.

[20] *See* note 17, *supra.*

[21] *See* note 16, *supra.*

[22] *See* SR–FINRA–2021–031, 86 FR at 71695.

[23] *See* SR–FINRA–2021–031, 86 FR at 71695, n. 13.

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] 15 U.S.C. 78f(b)(7) & 78f(d).

[27] 15 U.S.C. 78f(b)(7) & 78f(d).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide continued temporary relief given the impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on December 31, 2021.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [28] and Rule 19b–4(f)(6) thereunder.[29] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [30] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[31] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that the proposed rule change to extend the expiration date will continue to prevent unnecessary impediments to its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets, that would otherwise result if the temporary amendments were to expire on December 31, 2021.[32] Importantly, the Exchange has also stated that extending the relief provided in SR–NYSENAT–2020–31 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes in a reasonable and fair manner and meet its critical investor protection goals, while also following best practices with respect to the health and safety of hearing participants.[33] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSENAT–2020–31.[34] As proposed, the changes would be in place through March 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[35] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[36]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [37] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSENAT–2021–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2021–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2021–25 and should be submitted on or before February 2, 2022.

[28] 15 U.S.C. 78s(b)(3)(A)(iii).

[29] 17 CFR 240.19b–4(f)(6).

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6)(iii).

[32] *See* supra Item II.

[33] *See* SR–FINRA–2021–031 at 71698 (noting the same with respect to FINRA employees in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2021–031 would become operative immediately upon filing).

[34] *See* supra note 4.

[35] *See* supra note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond March 31, 2022 it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[36] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[37] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00381 Filed 1–11–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–11021; 34–93925; IA–5938; IC–34466]

Adjustments to Civil Monetary Penalty Amounts

AGENCY: Securities and Exchange Commission.

ACTION: Notice.

SUMMARY: The Securities and Exchange Commission (the ''Commission'') is publishing this notice (the ''Notice'') pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the ''2015 Act''). This Act requires all agencies to annually adjust for inflation the civil monetary penalties that can be imposed under the statutes administered by the agency and publish the adjusted amounts in the **Federal Register**. This Notice sets forth the annual inflation adjustment of the maximum amount of civil monetary penalties (''CMPs'') administered by the Commission under the Securities Act of 1933, the Securities Exchange Act of 1934 (the ''Exchange Act''), the Investment Company Act of 1940, the Investment Advisers Act of 1940, and certain penalties under the Sarbanes-Oxley Act of 2002. These amounts are effective beginning on January 15, 2022, and will apply to all penalties imposed after that date for violations of the aforementioned statutes that occurred after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ng, Senior Special Counsel, Office of the General Counsel, at (202) 551–7957, or Hannah W. Riedel, Senior Counsel, Office of the General Counsel, at (202) 551–7918.

SUPPLEMENTARY INFORMATION:

I. Background

This Notice is being published pursuant to the 2015 Act,[1] which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the ''Inflation Adjustment Act'').[2] The Inflation Adjustment Act previously had been amended by the Debt Collection Improvement Act of 1996 (the ''DCIA'')[3] to require that each federal agency adopt regulations at least once every four years that adjust for inflation the CMPs that can be imposed under the statutes administered by the agency. Pursuant to this requirement, the Commission previously adopted regulations in 1996, 2001, 2005, 2009, and 2013 to adjust the maximum amount of the CMPs that could be imposed under the statutes the Commission administers.[4]

The 2015 Act replaces the inflation adjustment formula prescribed in the DCIA with a new formula for calculating the inflation-adjusted amount of CMPs. The 2015 Act requires that agencies use this new formula to re-calculate the inflation-adjusted amounts of the penalties they administer on an annual basis and publish these new amounts in the **Federal Register** by January 15 of each year.[5] The Commission previously published the first annual adjustment required by the 2015 Act on January 6, 2017 (the ''2017 Adjustment'').[6] As part of the 2017 Adjustment, the Commission promulgated 17 CFR 201.1001(a) and Table I to Subsection 1001, which lists the penalty amounts for all violations that occurred on or before November 2, 2015. For violations occurring after November 2, 2015, Subsection 1001(b) provides that the applicable penalty amounts will be adjusted annually based on the formula set forth in the 2015 Act. Subsection 1001(b) further provides that these adjusted amounts will be published in the **Federal Register** and on the Commission's website. The Commission published the two most recent annual adjustments on January 8, 2020 (''2020 Adjustment'')[7] and January 8, 2021 (''2021 Adjustment'').[8]

A CMP is defined in relevant part as any penalty, fine, or other sanction that: (1) Is for a specific amount, or has a maximum amount, as provided by federal law; and (2) is assessed or enforced by an agency in an administrative proceeding or by a federal court pursuant to federal law.[9] This definition applies to the monetary penalty provisions contained in four statutes administered by the Commission: The Securities Act, the Exchange Act, the Investment Company Act, and the Investment Advisers Act. In addition, the Sarbanes-Oxley Act provides the Public Company Accounting Oversight Board (the ''PCAOB'') authority to levy civil monetary penalties in its disciplinary proceedings pursuant to 15 U.S.C. 7215(c)(4)(D).[10] The definition of a CMP in the Inflation Adjustment Act encompasses such civil monetary penalties.[11]

II. Adjusting the Commission's Penalty Amounts for Inflation

This Notice sets forth the annual inflation adjustment required by the 2015 Act for all CMPs under the Securities Act, the Exchange Act, the Investment Company Act, and the Investment Advisers Act, and certain civil monetary penalties under the Sarbanes-Oxley Act.

[38] 17 CFR 200.30–3(a)(12).

[1] Public Law 114–74 Sec. 701, 129 Stat. 599–601 (Nov. 2, 2015), codified at 28 U.S.C. 2461 note.

[2] Public Law 101–410, 104 Stat. 890–892 (1990), codified at 28 U.S.C. 2461 note.

[3] Public Law 104–134, Title III, § 31001(s)(1), 110 Stat. 1321–373 (1996), codified at 28 U.S.C. 2461 note.

[4] *See* Release Nos. 33–7361, 34–37912, IA–1596, IC–22310, dated November 1, 1996 (effective December 9, 1996), previously found at 17 CFR 201.1001 and Table I to Subpart E of Part 201; Release Nos. 33–7946, 34–43897, IA–1921, IC–24846, dated January 31, 2001 (effective February 2, 2001), previously found at 17 CFR 201.1002 and Table II to Subpart E of Part 201; Release Nos. 33–8530, 34–51136, IA–2348, IC–26748, dated February 9, 2005 (effective February 14, 2005), previously found at 17 CFR 201.1003 and Table III to Subpart E of Part 201; Release Nos. 33–9009, 34–59449, IA–2845, IC–28635, dated February 25, 2009 (effective March 3, 2009), previously found at 17 CFR 201.1004 and Table IV to Subpart E of Part 201; and Release Nos. 33–9387, 34–68994, IA–3557, IC–30408, dated February 27, 2013 (effective March 5, 2013), previously found at 17 CFR 201.1005 and Table V to Subpart E of Part 201. The penalty amounts contained in these releases have now been consolidated into Table I to 17 CFR 201.1001.

[5] 28 U.S.C. 2461 note Sec. 4.

[6] Release Nos. 33–10276; 34–79749; IA–4599; IC–32414 (effective Jan. 18, 2017).

[7] Release Nos. 33–10740; 34–87905; IA–5428; IC–33740 (effective Jan. 15, 2020).

[8] Release Nos. 33–10918; 34–90874; IA–5664; IC–34166 (effective Jan. 15, 2021).

[9] 28 U.S.C. 2461 note Sec. 3(2).

[10] 15 U.S.C. 7215(c)(4)(D).

[11] The Commission may by order affirm, modify, remand, or set aside sanctions, including civil monetary penalties, imposed by the PCAOB. *See* Section 107(c) of the Sarbanes-Oxley Act of 2002, 15 U.S.C. 7217. The Commission may enforce such orders in federal district court pursuant to Section 21(e) of the Exchange Act. As a result, penalties assessed by the PCAOB in its disciplinary proceedings are penalties ''enforced'' by the Commission for purposes of the Inflation Adjustment Act. *See Adjustments to Civil Monetary Penalty Amounts,* Release No. 33–8530 (Feb. 4, 2005) [70 FR 7606 (Feb. 14, 2005)].

Pursuant to the 2015 Act, the penalty amounts in the 2021 Adjustment are adjusted for inflation by increasing them by the percentage change between the Consumer Price Index for all Urban Consumers (''CPI–U'') for October 2020 and the October 2021 CPI–U.[12] OMB has provided its calculation of this multiplier (the ''CPI–U Multiplier'') to agencies.[13] The new penalty amounts are determined by multiplying the amounts in the 2021 Adjustment by the CPI–U Multiplier and then rounding to the nearest dollar.

For example, the CMP for certain insider trading violations by controlling persons under Exchange Act Section 21A(a)(3) [14] was readjusted for inflation as part of the 2021 Adjustment to $2,166,279. To determine the new CMP under this provision, the Commission multiplies this amount by the CPI–U Multiplier of 1.06222, and rounds to the nearest dollar. Thus, the new CMP for Exchange Act Section 21A(a)(3) is $2,301,065.

Below is the Commission's calculation of the new penalty amounts for the penalties it administers:

U.S. code citation	Civil monetary penalty description	2021 Adjustment penalty amounts	CPI–U multiplier	2022 Adjusted penalty amounts
15 U.S.C. 77h–1(g) (Securities Act Sec. 8A(g)).	For natural person	$8,928	1.06222	$9,484
	For any other person	89,291	1.06222	94,847
	For natural person/fraud	89,291	1.06222	94,847
	For any other person/fraud	446,455	1.06222	474,233
	For natural person/fraud/substantial losses or risk of losses to others or gains to self.	178,582	1.06222	189,693
	For any other person/fraud/substantial losses or risk of losses to others or gain to self.	863,145	1.06222	916,850
15 U.S.C. 77t(d) (Securities Act Sec. 20(d)).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others.	195,047	1.06222	207,183
	For any other person/fraud/substantial losses or risk of losses to others.	975,230	1.06222	1,035,909
15 U.S.C. 78u(d)(3) (Exchange Act Sec. 21(d)(3)).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others or gains to self.	195,047	1.06222	207,183
	For any other person/fraud/substantial losses or risk of losses to others or gain to self.	975,230	1.06222	1,035,909
15 U.S.C. 78u–1(a)(3) (Exchange Act Sec. 21A(a)(3)).	Insider Trading—controlling person	2,166,279	1.06222	2,301,065
15 U.S.C. 78u–2 (Exchange Act Sec. 21B).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others.	195,047	1.06222	207,183
	For any other person/fraud/substantial losses or risk of losses to others.	975,230	1.06222	1,035,909
15 U.S.C. 78ff(b) (Exchange Act Sec. 32(b)).	Exchange Act/failure to file information documents, reports.	576	1.06222	612
15 U.S.C. 78ff(c)(1)(B) (Exchange Act Sec. 32(c)(1)(B)).	Foreign Corrupt Practices—any issuer	21,663	1.06222	23,011
15 U.S.C. 78ff(c)(2)(B) (Exchange Act Sec. 32(c)(2)(B)).	Foreign Corrupt Practices—any agent or stockholder acting on behalf of issuer.	21,663	1.06222	23,011
15 U.S.C. 80a–9(d) (Investment Company Act Sec. 9(d)).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others or gains to self.	195,047	1.06222	207,183
	For any other person/fraud/substantial losses or risk of losses to others or gain to self.	975,230	1.06222	1,035,909
15 U.S.C. 80a–41(e) (Investment Company Act Sec. 42(e)).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others.	195,047	1.06222	207,183

[12] 28 U.S.C. 2461 note Sec. 5.

[13] Office of Management and Budget, *Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (December 15, 2021), available at *https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-07.pdf*. This multiplier represents the percentage increase between the October 2020 CPI–U and the October 2021 CPI–U, plus 1.

[14] 15 U.S.C. 78u–1(a)(3).

U.S. code citation	Civil monetary penalty description	2021 Adjustment penalty amounts	CPI–U multiplier	2022 Adjusted penalty amounts
	For any other person/fraud/substantial losses or risk of losses to others.	975,230	1.06222	1,035,909
15 U.S.C. 80b–3(i) (Investment Advisers Act Sec. 203(i)).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others or gains to self.	195,047	1.06222	207,183
	For any other person/fraud/substantial losses or risk of losses to others or gain to self.	975,230	1.06222	1,035,909
15 U.S.C. 80b–9(e) (Investment Advisers Act Sec. 209(e)).	For natural person	9,753	1.06222	10,360
	For any other person	97,523	1.06222	103,591
	For natural person/fraud	97,523	1.06222	103,591
	For any other person/fraud	487,616	1.06222	517,955
	For natural person/fraud/substantial losses or risk of losses to others.	195,047	1.06222	207,183
	For any other person/fraud/substantial losses or risk of losses to others.	975,230	1.06222	1,035,909
15 U.S.C. 7215(c)(4)(D)(i) (Sarbanes-Oxley Act Sec. 105(c)(4)(D)(i)).	For natural person	143,621	1.06222	152,557
	For any other person	2,872,441	1.06222	3,051,164
15 U.S.C. 7215(c)(4)(D)(ii) (Sarbanes-Oxley Act Sec. 105(c)(4)(D)(ii)).	For natural person	1,077,165	1.06222	1,144,186
	For any other person	21,543,299	1.06222	22,883,723

Pursuant to the 2015 Act and 17 CFR 201.1001, the adjusted penalty amounts in this Notice (and all penalty adjustments performed pursuant to the 2015 Act) apply to penalties imposed after the date the adjustment is effective for violations that occurred after November 2, 2015, the 2015 Act's enactment date. These penalty amounts supersede the amounts in the 2021 Adjustment.[15] For violations that occurred on or before November 2, 2015, the penalty amounts in Table I to 17 CFR 201.1001 continue to apply.[16]

By the Commission.

Dated: January 6, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–00384 Filed 1–11–22; 8:45 am]

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[15] The penalty amounts in this Notice are being published in the **Federal Register** and will not be added to the Code of Federal Regulations in accordance with the 2015 Act and 17 CFR 201.1001(b). *See* 28 U.S.C. 2461 note Sec. 4(a)(2); 17 CFR 201.1001(b). In addition to being published in the **Federal Register**, the penalty amounts in this Notice will be made available on the Commission's website at *https://www.sec.gov/enforce/civil-penalties-inflation-adjustments.htm,* as detailed in 17 CFR 201.1001(b). This website also lists the penalty amounts for violations that occurred on or before November 2, 2015.

[16] 17 CFR 201.1001(a).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93918; File No. SR–NYSEARCA–2021–107]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 10.9261 and 10.9830

January 6, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 27, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes extending the expiration date of the temporary amendments to Rules 10.9261 and 10.9830 as set forth in SR–NYSEArca–2020–85 from December 31, 2021, to March 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE Arca Rules 10.9261 and 10.9830. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSEArca–2020–85 [4] to Rules 10.9261 (Evidence and Procedure in Hearing)

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 90088 (October 5, 2020), 85 FR 64186 (October 9, 2020) (SR–NYSEArca–2020–85) (''SR–NYSEArca–2020–85'').

and 10.9830 (Hearing) from December 31, 2021, to March 31, 2022, to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSEArca–2020–85 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 10.9261 and 10.9830.[5]

Background

In 2019, NYSE Arca adopted disciplinary rules based on the text of the Rule 8000 and Rule 9000 Series of its affiliate NYSE American LLC (''NYSE American''), with certain changes. The NYSE American disciplinary rules are, in turn, substantially the same as the Rule 8000 Series and Rule 9000 Series of FINRA and the New York Stock Exchange LLC.[6] The NYSE Arca disciplinary rules were implemented on May 27, 2019.[7]

In adopting disciplinary rules modeled on FINRA's rules, NYSE Arca adopted the hearing and evidentiary processes set forth in Rule 10.9261 and in Rule 10.9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 10.9800 Series. As adopted, the text of Rule 10.9261 and Rule 10.9830 are substantially the same as the FINRA rules with certain modifications.[8]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[9]

Given that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 23, 2020, the Exchange filed to temporarily amend Rule 10.9261 and Rule 10.9830 to permit FINRA to conduct virtual hearings on its behalf.[10] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[11] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to April 30, 2021.[12] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[13] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to August 31, 2021.[14] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[15] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to December 31, 2021, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[16]

While there are signs of improvement, FINRA has determined that much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[17] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[18] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[19] On December 7, 2021, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from December 31, 2021, to March 31, 2022.[20]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond March 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in SR–NYSEArca–2020–85. The amended NYSE Arca rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release No. 85639 (April 12, 2019), 84 FR 16346 (April 18, 2019) (SR–NYSEArca–2019–15) (''2019 Notice'').

[7] *See* NYSE Arca Equities RB–19–060 & NYSE Arca Options RB–19–02 (April 26, 2019).

[8] *See* 2019 Notice, 84 FR at 16365 & 16373–4.

[9] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''SR–FINRA–2020–027'').

[10] *See* note 4, *supra.*

[11] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[12] *See* Securities Exchange Act Release No. 90820 (December 30, 2020), 86 FR 647 (January 6, 2021) (SR–NYSEArca–2020–116).

[13] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[14] *See* Securities Exchange Act Release No. 91633 (April 22, 2021), 86 FR 22474 (April 28, 2021) (SR–NYSEArca–2021–27).

[15] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[16] *See* Securities Exchange Act Release No. 92909 (September 9, 2021), 86 FR 51415 (September 15, 2021) (SR–NYSEArca–2021–76).

[17] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–031) (''SR–FINRA–2021–031''). FINRA noted that, for example, President Joe Biden on July 29, 2021, announced several measures to increase the number of people vaccinated against COVID–19 and to slow the spread of the Delta variant, including strengthening safety protocols for federal government employees and contractors. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/factsheet-president-biden-to-announce-new-actions-to-get-more-americansvaccinated-and-slow-the-spread-of-the-delta-variant/.* Thereafter, the Biden Administration announced on November 4, 2021, details of two major vaccination policies to further help fight COVID–19. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/factsheet-biden-administration-announces-details-of-two-major-vaccination-policies/.* Most recently, President Biden announced several new actions to help protect Americans against the Delta and Omicron variants. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/factsheet-president-biden-announces-new-actions-to-protect-americans-against-thedelta-and-omicron-variants-as-we-battle-covid-19-this-winter/. See* SR–FINRA–2021–031, 86 FR at 71695, n. 6.

[18] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recently announced that the first confirmed case of COVID–19 caused by the Omicron variant was detected in the United States. *See https://www.cdc.gov/media/releases/2021/s1201-omicron-variant.html.* The CDC also recommends that fully vaccinated people wear a mask in public indoor settings in areas of substantial or high transmission and noted that fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID–19. *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.* Furthermore, as FINRA also noted, numerous states currently have COVID–19 restrictions in place. Six states (Hawaii, Illinois, Nevada, New Mexico, Oregon, and Washington) require most people to wear masks in indoor public places regardless of vaccination status, and three states (California, Connecticut, and New York) have mask mandates in indoor public places for those individuals who are unvaccinated. Several other states have mask mandates in certain settings, such as healthcare facilities, schools, and correctional facilities. *See* SR–FINRA–2021–031, 86 FR at 71696, n. 7.

[19] *See* SR–FINRA–2021–031, 86 FR at 71695–96.

[20] *See* SR–FINRA–2021–031, 86 FR at 71695.

Arca Rules 10.9261 and 10.9830 as set forth in SR–NYSEArca–2020–85 from December 31, 2021, to March 31, 2022.

As set forth in SR–FINRA–2021–031, while there are signs of improvement, much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[21] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[22] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[23] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from December 31, 2021, to March 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE Arca Rules 10.9261 and 10.9830 as set forth in SR–NYSEArca–2020–85 from December 31, 2021, to March 31, 2022. The Exchange agrees with FINRA that, while there are signs of improvement, much uncertainty remains for the coming months. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2021–031, there is a continued need for this temporary relief beyond December 31, 2021. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2021–031, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2021–031, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[24] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 10.9261 and 10.9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[25] in general, and furthers the objectives of Section 6(b)(5),[26] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[27]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2021–031, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in the SR–NYSEArca–2020–85, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[28] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like, like SR–NYSEArca–2020–85, provides only temporary relief. As proposed, the changes would be in place through March 31, 2022. As noted in SR–NYSEArca–2020–85 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide continued temporary relief given the impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory

[21] *See* note 17, *supra*.

[22] *See* note 18, *supra*.

[23] *See* SR–FINRA–2021–031, 86 FR at 71695.

[24] *See* SR–FINRA–2021–031, 86 FR at 71695, n. 13.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78f(b)(7) & 78f(d).

[28] 15 U.S.C. 78f(b)(7) & 78f(d).

processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on December 31, 2021.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [29] and Rule 19b–4(f)(6) thereunder.[30] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [31] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[32] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that the proposed rule change to extend the expiration date will continue to prevent unnecessary impediments to its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on December 31, 2021.[33] Importantly, the Exchange has also stated that extending the relief provided in SR–NYSEArca–2020–85 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes in a reasonable and fair manner and meet its critical investor protection goals, while also following best practices with respect to the health and safety of hearing participants.[34] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSEArca–2020–85.[35] As proposed, the changes would be in place through March 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[36] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[37]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [38] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2021–107 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2021–107. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2021–107 and should be submitted on or before February 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00380 Filed 1–11–22; 8:45 am]

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[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6).

[32] 17 CFR 240.19b–4(f)(6)(iii).

[33] *See* supra Item II.

[34] *See* SR–FINRA–2021–031 at 71698 (noting the same with respect to FINRA employees in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2021–031 would become operative immediately upon filing).

[35] *See* supra note 4.

[36] *See* supra note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond March 31, 2022 it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[37] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[38] 15 U.S.C. 78s(b)(2)(B).

[39] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93915; File No. SR–OCC–2021–803]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Advance Notice Concerning The Options Clearing Corporation's Cash and Investment Management

January 6, 2022.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) [2] under the Securities Exchange Act of 1934 (''Exchange Act''),[3] notice is hereby given that on December 23, 2021, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') an advance notice as described in Items I, II and III below, which Items have been prepared by OCC. The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice is submitted in connection with proposed changes to: (1) Formalize OCC's policy for safeguarding cash and related investments; (2) amend OCC's Rules governing use of the Clearing Fund in the event of the failure of a bank to meet a settlement obligation with OCC to ensure such access extends to the failure of an investment counterparty with whom OCC has invested cash deposited by Clearing Members in respect of margin or Clearing Fund requirements under the conditions identified in OCC Rule 1006(c) and (f), regardless of whether the investment counterparty is a bank; and (3) implement changes to OCC's revolving credit facility to reflect the proposed changes to OCC's Rules. The proposed changes are described in detail in Item II below. The Cash and Investment Management Policy is included in confidential Exhibit 5a of File Number SR–OCC–2021–803. Proposed amendments to OCC's Rules are included in Exhibit 5b of File Number SR–OCC–2021–803. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[4]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A) and (B) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the advance notice and none have been received. OCC will notify the Commission of any written comments received by OCC.

(B) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing, and Settlement Supervision Act

OCC is proposing to enhance its cash and investment management practices by: (1) Formalizing OCC's policy for safeguarding cash and related investments; (2) amending OCC's Rules to ensure access to the Clearing Fund if a non-bank investment counterparty fails to return Clearing Member cash deposited in respect of margin or Clearing Fund requirements under the conditions identified in OCC Rule 1006(c) and (f); and (3) implementing changes to OCC's revolving credit facility to reflect the changes to OCC's Rules.

Background

OCC's By-Laws and Rules govern the management and investment of OCC's own funds and cash deposited by Clearing Members. With respect to OCC's own funds (other than Clearing Fund deposits), Article IX, Section 1 of OCC's By-Laws provides that funds in excess of the amount needed as working capital may be invested by the Board in Government securities or such other securities or financial instruments as the Board or a Board-level committee may from time to time approve.[5] With respect to cash deposited by Clearing Members, OCC Rules 604(a) and 1002(c) provide that cash deposited in respect of a Clearing Member's margin requirements or Clearing Fund contributions may from time to time be partially or wholly invested by OCC for its account in Government securities.[6] OCC does not propose to amend these By-Laws or Rules.

OCC's investments historically have been limited to overnight transactions under deliver-versus-payment (''DVP'') reverse repurchase agreements. As collateral, the investment counterparty deliveries Government securities equal to 102% of the cash invested at the time the investment is made. Such investments reduce OCC's investment risks by permitting quick liquidation with little adverse price effect and controlling the movement of OCC's assets via a custodian bank. To minimize counterparty risk, OCC restricts its potential counterparties to financial institutions that meet certain standards of size, capital adequacy, product offering and operational capacity.

In the event of a failure or disruption of an investment counterparty that is a bank, OCC's Rules provide OCC with authority to access the Clearing Fund to address liquidity shortfalls, including shortfalls arising from the investment of Clearing Member cash in Government securities. Specifically, OCC Rule 1006(f) authorizes OCC to take possession of cash or securities deposited by Clearing Members in respect of the Clearing Fund when OCC reasonably believes it necessary to meet its liquidity needs for same-day settlement as a result of the failure of any bank to achieve daily settlement with OCC.[7] In the extremely unlikely event that a bank investment counterparty failed to return the cash versus return of the Government securities to unwind a transaction under a reverse repurchase agreement—*e.g.,* because of a systems disruption, operational outage, or otherwise—OCC could exercise authority under Rule 1006(f) to borrow from the Clearing Fund to the extent required for OCC to meet its settlement obligations with Clearing Members.[8]

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

[4] OCC's By-Laws and Rules can be found on OCC's website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

[5] *See* By-Law Art. IX, Sec. 1.

[6] *See* OCC Rule 604(a); Rule 1006(c).

[7] *See* OCC Rule 1006(f). As discussed, *infra,* the proposed changes would amend this clause to apply when OCC reasonably believes it necessary to meet its liquidity needs for ''daily settlement'' as a result of the failure of any bank ''to perform any obligation to the Corporation when due.''

[8] OCC amended its Rules in 2018 to extend access to the Clearing Fund in the extraordinary event that OCC faces a liquidity need in order to complete same-day settlement for reasons other than a bank or clearing organization's bankruptcy, insolvency, receivership, suspension of operations, or any similar event. *See* Securities Exchange Act

In the unlikely event that any part of the borrowing under Rule 1006(f) is outstanding after 30 calendar days, or if OCC determines that some or all of the amount borrowed constituted an actual loss, OCC would charge the loss to the Clearing Fund.[9] In the unlikely event that OCC incurred an investment loss resulting from a bank's failure to return the invested cash because of bankruptcy, insolvency, receivership, suspension of operations or other similar event, OCC may, at its discretion, charge the loss to the Clearing Fund.[10] OCC may also, at its discretion, apply skin-in-the-game to a loss resulting from a borrowing or bank failure in the form of liquid net assets funded by equity [11] in excess of 110% of OCC's Target Capital Requirement.[12]

Description of Proposed Change

Cash and Investment Management Policy

OCC proposes to file its Cash and Investment Management Policy (or ''Policy'') as a proposed rule of the clearing agency within the meaning of Section 19(b)(1) of the Exchange Act [13] and SEC Rule 19b–4.[14] The Policy would include statements of purpose, applicability and scope, safeguarding standards for maintaining cash and related investments to minimize credit and liquidity risk, and guidelines for investing OCC Cash and Clearing Member Cash, as defined below.

Purpose, Applicability and Scope

The Policy would include statements of the Policy's purpose, applicability, and scope. The purpose of the Policy would be to (1) outline the safeguarding standards for cash and related investments managed by OCC to minimize credit and liquidity risk, and (2) provide guidelines for investments permitted by OCC's By-Laws and Rules. The Policy principally would apply to OCC's Treasury department (''Treasury''), which has responsibility for managing cash on behalf of OCC. The Policy's scope would include the safeguarding standards and investment activities specific to OCC's own cash (''OCC Cash'') and cash from OCC's Clearing Members (''Clearing Member Cash'').

The Policy would define OCC Cash to include working capital related to future operating costs, inclusive of financial resource held to meet liquidity and resiliency requirements,[15] proceeds from lines of credit, if any, maintained to support OCC's working capital,[16] the Minimum Corporate Contribution,[17] and investments made with OCC Cash. The Policy would not apply to cash held in respect of OCC's pension plan, post-retirement welfare plan, or other deferred compensation plans. The Policy would define Clearing Member Cash to include Clearing Fund cash deposits, cash deposited by Clearing Members in respect of margin requirements, cash held in liquidating settlement accounts for suspended Clearing Members,[18] proceeds from OCC's syndicated credit facility and liquidity facilities,[19] and investments made with Clearing Member Cash.[20] The Policy would not apply to non-cash collateral deposited by Clearing Members to satisfy margin or Clearing Fund requirements.

Safeguarding Standards

The Policy would address the safeguarding standards for managing OCC Cash and Clearing Member Cash, which OCC would either hold in a demand deposit or Federal Reserve Bank accounts or invest in accordance with OCC's By-Laws and investment strategy, as discussed below.

OCC Cash

Unless invested, OCC Cash would be held in demand deposit accounts or at a Federal Reserve Bank. Demand deposit accounts would be limited to commercial financial institutions that meet initial and ongoing standards for depository banks outlined in OCC's procedures concerning its banking relationships.

Treasury would be responsible for maintaining appropriate levels of liquidity in OCC's operating accounts to meet general business obligations and regulatory requirements. To fulfill this responsibility, the Policy would provide that OCC may maintain bank lines of credit for working capital purposes. The source of such credit line would need to meet the standards for credit facility banks outlined in OCC's procedures concerning its banking relationships.

Clearing Member Cash

The Policy would provide that unless invested, Clearing Member Cash would be held in a demand deposit account or in accounts at a Federal Reserve Bank. With respect to commercial banks, Clearing Member Cash would only be held in financial institutions that meet the initial and ongoing standards for depository banks as provided in OCC's procedures concerning banking relationships. The Policy would provide that Clearing Member Cash collected at OCC's settlement banks may be transferred to other depository banks, including to and from OCC's bank accounts for settlement, investment, and cash management purposes. Upon the suspension of a Clearing Member, OCC would promptly move all margin and Clearing Fund cash related to the Clearing Member into a liquidating settlement account for use in meeting the obligations of the Clearing Member, as provided under OCC's Rules.[21] Treasury would be responsible for ensuring accounts are appropriately funded to meet financial obligations. Interest earned on Clearing Fund cash deposits held at a Federal Reserve Bank would accrue to the benefit of Clearing Members, less a cash management fee.

The Policy would also provide that OCC would employ a bank account structure that segregates customer funds per applicable regulatory requirements [22] and OCC's By-Laws and Rules.[23] Futures customer segregated cash would be held in segregated fund accounts pursuant to applicable Commodity and Futures Trading Commission (''CFTC'') regulations,

(''Exchange Act'') Release No. 82309 (Dec. 13, 2017), 82 FR 60262 (Dec. 19, 2017) (File No. SR–OCC–2017–017).

[9] *See* OCC Rule 1006(c)(ii).

[10] *See* OCC Rule 1006(c)(i).

[11] OCC's Capital Management Policy defines ''liquid net assets funded by equity'' to be the level of cash or cash equivalents, no greater than OCC's shareholders' equity, less any approved adjustments (*e.g.,* agency-related liabilities such as Section 31 fees held by OCC and the Minimum Corporate Contribution). *See* Exchange Act Release No. 91199 (Feb. 24, 2021), 86 FR 12237, 12241 (Mar. 2, 2021) (File No. SR–OCC–2021–003).

[12] *See* OCC Rule 1006(e)(ii).

[13] 15 U.S.C. 78s(b)(1).

[14] 17 CFR 240.19b–4.

[15] *See* Exchange Act Release No. 88029 (Jan. 24, 2020), 85 FR 5500, 5501–02 (Jan. 30, 2020) (File No. SR–OCC–2019–007) (discussing the determination of Target Capital Requirement under OCC's Capital Management Policy).

[16] Working capital lines of credit, if any, are separate from the syndicated credit facility and liquidity facilities that OCC maintains to cover default losses or liquidity shortfalls. *See* Exchange Act Release No. 88971 (May 28, 2020), 85 FR 34257 (June 3, 2020) (File No. SR–OCC–2020–804) (discussing OCC's revolving credit facility); Exchange Act Release No. 89039 (June 10, 2020), 85 FR 36444 (June 16, 2020) (File No. SR–OCC–2020–803) (discussing OCC's non-bank liquidity facility).

[17] *See* Exchange Act Release No. 92038 (May 27, 2021), 86 FR 29861 (Jun. 3, 2021) (File No. SR–OCC–2021–003) (establishing a persistent minimum level of OCC's own capital that it would contribute to default losses or liquidity shortfalls prior to allocating a default loss to the Clearing Fund contributions of non-defaulting Clearing Members).

[18] *See* OCC Rule 1104.

[19] *See supra* note 16 (citing SEC notices of no-objection to advance notices concerning OCC's credit and liquidity facilities).

[20] *See supra* note 6 and accompanying text.

[21] *See* OCC Rule 1104.

[22] *See* 17 CFR 39.15 (requiring a derivatives clearing organization to comply with the segregation requirements section 4d of the Commodity Exchange Act).

[23] *See* OCC By-Laws Art. VI, Sec. 3(f) (providing for maintenance of segregated futures accounts).

including that OCC ensures that it receives proper written acknowledgment from the depository for each new segregated funds account that the account has been established to hold segregated cash generated from futures customers.[24] The Policy would further provide that if OCC sustains an investment loss with respect to invested margin cash OCC will not pass on the loss to a futures customer segregated account.

Investment Guidelines

The Policy would also provide guidelines for investments permitted by OCC's By-Laws and Rules and approved by the Board or Compensation and Performance Committee (''CPC''), including OCC's investment strategy, investment governance principles, and guidelines for the investment of OCC Cash and Clearing Member Cash.

Investment Strategy

The Policy would provide that OCC's investment strategy is to preserve principal and maintain adequate liquidity. After principal and liquidity requirements are satisfied, only then would Management seek to optimize investment returns. OCC would disclose its investment strategy through its public website on a periodic basis via its qualitative disclosures to the Principles for Financial Market Infrastructure Disclosures.[25]

Investment Governance Principles

The Policy would provide that OCC may invest OCC Cash and Clearing Member Cash in permitted investments per applicable regulatory requirements, OCC's By-Laws and Rules, the investment strategy and the following governance principles. Current investment practices would be outlined in procedures maintained by OCC. Investment counterparties would need to be financial institutions or financial market utilities that meet initial and on-going standards outlined in OCC's procedures concerning its banking relationships, which consider the financial institution's size, capital adequacy, product offering and operational capabilities. Any interest or gain received on the investments would belong to OCC except as may otherwise be provided in OCC's By-Laws, Rules or Board-approved policies.[26] OCC would not commingle investments of OCC Cash with investments of Clearing Member Cash.

Investment of OCC Cash

The Policy would provide that OCC Cash may be invested in instruments that pose minimal credit and liquidity risk pursuant to applicable regulatory requirements, OCC's By-Laws, the investment strategy, and Board or CPC approved investments. Approved investments other than in Government securities would continue to be subject to Board or CPC approval, as required under Section 1 of Article IX of OCC's By-Laws.[27] In addition, investment of working capital in excess of 110% of OCC's Target Capital Requirement would not be limited to overnight transactions.[28]

Investment of Clearing Member Cash

The Policy would further provide that Clearing Member Cash may be invested in Government securities by OCC in transactions that provide next-day liquidity in accordance with applicable regulatory requirements, OCC's Rules, and the investment strategy, subject to the following guiding principles. First, the Policy would provide that notwithstanding the authority to invest Clearing Fund cash under OCC Rule 1002(c), it is OCC's policy not to invest Clearing Fund cash, which is instead maintained in accounts at a Federal Reserve Bank or a commercial bank. This policy would be subject to an exception approved by the Chief Executive Officer or Chief Operating Officer in emergency situations (such as a disruption at a Federal Reserve Bank) when necessary or advisable for the protection of the Corporation or otherwise in the public interest to continue to facilitate the prompt and accurate clearance and settlement of confirmed trades or other transactions and to provide OCC's services in a safe and sound manner. Second, the Policy would provide that margin cash would only be invested in instruments that provide liquidity to OCC by the following business day. Third, the Policy would provide that OCC will implement procedures to ensure that end-of-day margin cash balances remain above the aggregate level of any Required Cash Deposits, as that term is defined in OCC's Liquidity Risk Management Framework.[29] The policy with respect to investing Required Cash Deposits would be subject to the same exception as for investment of Clearing Fund cash. Fourth, any change regarding whether to investment futures customer segregated funds would be approved by OCC's Chief Financial Officer in consultation with OCC's Legal and Compliance departments.[30]

The Policy would also describe how OCC maintains liquidity facilities for immediate access to liquidity in the event of a suspension of a Clearing Member or a failure of a bank, securities or commodity clearing organization, or investment counterparty (with respect to the investment of Clearing Member Cash) to meet an obligation owing to OCC, or in anticipation thereof, pursuant to OCC Rules 1006(c) and (f), proposed amendments to which are discussed below. The liquidity providers for these facilities would be approved and monitored according to OCC's Third-Party Risk Management Framework and Liquidity Risk Management Framework.[31]

Amendments to OCC Rule 1006

OCC proposes to amend OCC Rule 1006, which governs its ability to access the Clearing Fund in the event of the failure (or anticipated failure) of bank to meet a settlement obligation with OCC, to extend such access to the failure of a non-bank investment counterparty to meet settlement obligations with OCC

[24] *See* 17 CFR 1.20(g)(4).

[25] *See* Disclosure Framework, *available at https://www.theocc.com/Risk-Management/PFMI-Disclosures.*

[26] As discussed, interest earned on Clearing Fund cash deposits held at a Federal Reserve Bank would accrue to the benefit of Clearing Members, less a cash management fee.

[27] In addition to investments in Government securities through overnight DVP transactions, the Board has approved investments of OCC's own cash in U.S. government money market mutual funds.

[28] With respect to OCC's liquid net assets funded by equity in excess of 110% of the Target Capital Requirement, the Board has initially approved investment of such funds in Government securities through DVP transactions for terms no more than 30 days.

[29] The Liquidity Risk Management Framework defines ''Required Cash Deposits'' (sometimes referred to as minimum cash requirements or ''MCR'') as deposits of cash under OCC's Contingency Funding Plan that supplement OCC's Base Liquidity Resources (*i.e.,* the amount of committed liquidity resources maintained at all times by OCC to meet its minimum Cover 1 liquidity resource requirements under the applicable regulations). Under that framework, OCC may require a Clearing Member Group to post such additional cash collateral to supplement OCC's Available Liquidity Resources (*i.e.,* Base Liquidity Resources plus allowed Clearing Fund cash deposits in excess of the minimum required amount) when stressed liquidity demands for that Clearing Member Group are above established thresholds or until the settlement demand is met. *See* Exchange Act Release No. 89014 (June 4, 2020), 85 FR 35446, 35449 (June 10, 2020) (File No. SR–OCC–2020–003).

[30] Like Clearing Fund cash, OCC does not currently invest futures customer segregated funds. If OCC determined to invest such funds, such investments would be subject to CFTC regulations regarding a derivatives clearing organization's investment of futures customer funds. *See* 17 CFR 1.25.

[31] *See* Exchange Act Release No. 90797 (Dec. 23, 2020), 85 FR 86592 (Dec. 30, 2020) (File No. SR–OCC–2020–014) (approving OCC's framework for identifying, measuring, monitoring, and managing OCC's exposures to its counterparties); Exchange Act Release No. 89014, 85 FR 35446 (approving OCC's approach to managing liquidity risk).

under the conditions identified in OCC Rule 1006(c) and (f). In addition, OCC proposes to restate OCC Rule 1006(f) for clarity.

To ensure that OCC may access the Clearing Fund in the event of a failure or disruption of a non-bank counterparty with whom OCC has invested Clearing Member Cash, OCC would amend OCC Rule 1006(f) to include ''investment counterparty'' to the list of counterparties—currently, any bank or securities or commodities clearing organization—whose failure or disruption may result in a borrowing under Rule 1006(f). Similarly, OCC would also amend OCC Rule 1006(a) and (c) to add the same phrase to the list of counterparties whose failure resulting from bankruptcy, insolvency, receivership, suspension of operations, or any similar event may result in allocation of losses to the Clearing Fund. Rule 1006(c) and (f) would be further amended to provide that failure of an investment counterparty under those paragraphs would be limited to a failure with respect to Clearing Member Cash (*i.e.,* cash invested under Rule 604(a) or Rule 1002(c)).[32] Any investment loss resulting from investment of OCC Cash would be treated as an operational loss that would be addressed under OCC's Capital Management Policy, rather than a loss that would be allocated to the Clearing Fund.[33]

OCC would also amend the condition that triggers borrowing authority under Rule 1006(f)—currently clause (iii) of the first sentence of Rule 1006(f)—which would be renumbered as Rule 1006(f)(1)(C). That condition would be amended to apply when the Corporation reasonably believes it necessary to borrow to meet its liquidity needs for ''daily settlement'' rather than ''same-day settlement,'' as in the current text. OCC may reasonably believe that a disruption at a bank, securities or commodities clearing organization, or investment counterparty could last multiple days, resulting in liquidity needs for daily settlement over more than one day. This amendment would ensure that OCC has authority to initiate a borrowing for the amount OCC believes necessary to meet its liquidity needs over the timeframe OCC believes the disruption will affect OCC's ability to meet daily settlement requirements with Clearing Members, rather than only that amount that OCC believes it needs on a day-by-day basis.

OCC would further amend the condition in Rule 1006(f)(1)(C) to apply when OCC reasonably believes such a liquidity need will arise because of one of the identified counterparty's failure ''to perform any obligation to the Corporation when due,'' rather than such a counterparty's failure ''to achieve daily settlement.'' This change aligns with the condition for allocation of losses under Rule 1006(c) and eliminates any ambiguity that might arise concerning the settlement obligations to which the current Rule refers. As under the current Rule, use of funds obtained through such a borrowing would continue to be limited to the purposes described in Rule 1006(f)(1)(C), as amended, *i.e.,* to meet OCC's liquidity needs for daily settlement with Clearing Members.

In addition to the substantive changes discussed above, OCC would also restate Rule 1006(f) for clarity. The current paragraph would be divided into four subparagraphs with courtesy headings: (1) Conditions; (2) Uses; (3) Term; Clearing Fund Charge; and (4) Substitution Requests. The conditions in Rule 1006(f)(1) would begin with the first sentence of current Rule 1006(f), less the conjoined clause beginning with ''and use such assets,'' the substance of which would be moved to paragraph (f)(2). The remaining clause before the conjunction would be amended to describe OCC's investment of Clearing Fund cash contributions in the active voice. The three conditions for a borrowing identified in Rule 1006(f), currently numbered (i) through (iii), would then follow after the conjunction as items (A) through (C). Item (A) would be further amended to remove legalese and state the condition more plainly. Item (C) would be amended substantively as discussed above.

The prescribed uses for the borrowed funds described in several places throughout current Rule 1006(f) would be aggregated in Rule 1006(f)(2). As currently found in the conjoined clause in the first sentence of current Rule 1006(f), Rule 1006(f)(2)(A) would provide that OCC may use funds it takes possession of under Rule 1006(f) to (i) meet obligations, losses or liquidity needs; or (ii) borrow or otherwise obtain funds through any means determined to be reasonable at the discretion of the Chairman, Chief Executive Officer or the Chief Operating Officer (including, without limitation, pledging such assets as security for loans and/or using such assets to effect repurchase, securities lending or other transactions). Proposed Rule 1006(f)(ii) would also be restated to remove a gendered pronoun. Rule 1006(f)(2)(B) would describe the limitations on use of funds borrowed under the renumbered conditions in Rule 1006(f)(1)(A) and (C).

Rule 1006(f)(3) would contain the term for a borrowing, as well as the conditions that would trigger a loss chargeable to the Clearing Fund. The 30-day period before which OCC would be obligated to charge a borrowed amount as a loss to the Clearing Fund would be located at Rule 1006(f)(3)(A), with certain non-substantive edits to the text. The conditions that would trigger the loss allocation to the Clearing Fund would be located at Rule 1006(f)(3)(B) and would be restated to move the lengthy conditions after the main clause, among other non-substantive revisions.

Finally, Rule 1006(f)(4) would relocate OCC's authority to refuse Clearing Member substitution requests regarding securities contributed to the Clearing Fund that the Corporation has taken possession of under Rule 1006(f). In addition to relocating that provision to the end of Rule 1006(f), the proposed changes would restate that provision to reflect the reorganization of Rule 1006(f).

Revolving Credit Facility Agreement Modifications

Approval of the Rule 1006 amendments discussed above will put into effect modifications to OCC's revolving credit facility that conform with the extended borrowing authority under the Rule amendments. OCC's existing credit facility was implemented as of June 21, 2021. In anticipation of the changes in this filing, OCC modified the permitted uses set forth in the 2021 credit agreement to align with the proposed changes to OCC Rule 1006, provided those proposed changes receive regulatory approval. A summary of the terms and conditions for the 2021 credit agreement reflecting the modification is provided in confidential Exhibit 3 to File No. SR–OCC–2021–803. Upon approval of those proposed changes, the modified credit agreement provisions will become effective, and OCC will be able to draw on the revolving credit facility to address non-bank investment counterparty failures with respect to Clearing Member Cash.

Anticipated Effect on and Management of Risk

As a rule of the clearing agency within the meaning of Section 19(b)(1)[34] of the Exchange Act and Rule

[32] The same limitation would apply to Rule 1006(a), which incorporates the reasons specified in Rule 1006(c) by reference.

[33] *See* Exchange Act Release No. 88029, 85 FR at 5502–03 (discussing OCC's plan for replenishing its capital in the event that shareholders' equity falls below certain thresholds).

[34] 15 U.S.C. 78s(b)(1).

19b–4,[35] OCC's Cash and Investment Management Policy would promote the reduction of risks to OCC, its Clearing Members, and the markets OCC serves by outlining the safeguarding standards for cash and related investments managed by OCC to minimize credit and liquidity risk. In addition, the changes to OCC's Rule 1006 help OCC minimize losses and address liquidity shortfalls by allowing OCC to access the Clearing Fund in the event of a failure or disruption at a non-bank investment counterparty. Similarly, implementing the related modifications to OCC's revolving credit facility would allow OCC to obtain funds on extremely short notice to ensure clearance and settlement of transactions in options and other contracts without interruption. By drawing on the facility, OCC would also be able to avoid liquidating Clearing Fund contributions in what would likely be volatile market conditions, which would preserve funds available to cover any losses resulting from the failure or disruption at a non-bank investment counterparty.

Consistency With the Payment, Clearing and Settlement Supervision Act

The stated purpose of the Clearing Supervision Act is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[36] Section 805(a)(2) of the Clearing Supervision Act[37] also authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like OCC, for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act[38] states that the objectives and principles for risk management standards prescribed under Section 805(a) shall be to:

- Promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and the Exchange Act in furtherance of these objectives and principles.[39] Rule 17Ad–22 requires registered clearing agencies, like OCC, to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[40] Therefore, the Commission has stated[41] that it believes it is appropriate to review changes proposed in advance notices against Rule 17Ad–22 and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act.[42]

OCC believes that the proposed changes are consistent with Section 805(b)(1) of the Clearing Supervision Act[43] because the Cash and Investment Management Policy would promote the reduction of risks to OCC, its Clearing Members, and the markets OCC serves by outlining the safeguarding standards for cash and related investments managed by OCC to minimize credit and liquidity risk. Additionally, the proposed changes to Rule 1006 and corresponding modifications to the revolving credit facility would help OCC minimize losses and address liquidity shortfalls by allowing OCC to access the Clearing Fund and initiate a borrowing through the credit facility in the event of a failure or disruption at a non-bank investment counterparty. Allowing OCC to access liquid resources in the event of a disruption at a non-bank investment counterparty would help prevent disruption of OCC's ability to meet its settlement obligations with Clearing Members. Accordingly, OCC believes that the proposed changes: (i) Are designed to promote robust risk management; (ii) are consistent with promoting safety and soundness; and (iii) are consistent with reducing systemic risks and promoting the stability of the broader financial system.

OCC also believes the proposed changes are consistent with Rule 17Ad–22(e)(7)(viii),[44] Rule 17Ad–22(e)(13),[45] and Rule 17Ad–22(e)(16)[46] under the Exchange Act. 17Ad–22(e)(16) under the Exchange Act requires, in part, that OCC establish, implement, maintain and enforce written policies and procedures reasonably designed to safeguard OCC's own and its participants' assets, minimize the risk of loss and delay in access to these assets, and invest such assets in instruments with minimal credit, market, and liquidity risks.[47] As discussed above, the Policy outlines safeguarding standards for cash and related investments intended to minimize credit and liquidity risks. In addition, the Policy sets forth OCC's conservative investment strategy, according to which OCC's primary objective is to preserve principal and maintain adequate liquidity. The Policy also requires cash and related investments to be maintained with counterparties that have been initially approved and routinely monitored in accordance with OCC's Third Party Risk Management Policy and procedures governing banking relationships. Accordingly, OCC believes that the Policy is consistent with Rule 17Ad–22(e)(16).

Additionally, Rule 17Ad–22(e)(7)(viii) requires that OCC address foreseeable liquidity shortfalls that would not be covered by OCC's liquid resources and seek to avoid unwinding, revoking, or delaying the settlement of payment obligations.[48] As stated above, OCC believes that it could be foreseeable, though extremely unlikely, that an investment counterparty that is not a bank may fail to return Clearing Member Cash as the result of the investment counterparty's disruption or failure. An alternative available to OCC for addressing uncovered liquidity shortfalls would be to exercise authority under Rule 505 to extend the settlement window to the close of Fedwire.[49] The proposed changes would improve OCC's ability to address such situations by expanding OCC's borrowing authority to enable OCC to borrow against the Clearing Fund to address a failure or disruption at a non-bank investment counterparty rather than disrupting OCC's ordinary settlement cycle. Accordingly, OCC believes that proposed changes to OCC Rules are consistent with Rule 17Ad–22(e)(7)(viii).

Finally, Rule 17Ad–22(e)(13) requires, in part, that OCC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure OCC has the authority to take timely action to contain losses and liquidity demands and continue to meet its obligations.[50] As described above, this proposal would amend OCC's Rules

[35] 17 CFR 240.19b–4.

[36] 12 U.S.C. 5461(b).

[37] 12 U.S.C. 5464(a)(2).

[38] 12 U.S.C. 5464(b).

[39] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies'').

[40] 17 CFR 240.17Ad–22.

[41] *See, e.g.,* Exchange Act Release No. 89039, 85 FR at 36446.

[42] 12 U.S.C. 5464(b).

[43] 12 U.S.C. 5464(b)(1).

[44] 17 CFR 240.17Ad–22(e)(7)(viii).

[45] 17 CFR 240.17Ad–22(e)(13).

[46] 17 CFR 240.17Ad–22(e)(16).

[47] 17 CFR 240.17Ad–22(e)(16).

[48] 17 CFR 240.17Ad–22(e)(7)(viii).

[49] *See* OCC Rule 505 (Extension of Settlements).

[50] 17 CFR 240.17Ad–22(e)(13).

concerning loss allocation in the extremely unlikely event that the failure or disruption of a non-bank investment counterparty results in a loss to OCC arising from the investment of Clearing Member Cash. The expansion of existing authority to allocate such losses attributable to a non-bank investment counterparty helps establish a more transparent and clear loss allocation process and ensure OCC's authority to take action to contain losses and continue to meet its clearance and settlement obligations. Accordingly, OCC believes the proposed changes to OCC's Rules are consistent with Rule 17Ad–22(e)(13).

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date the proposed change was filed with the Commission or (ii) the date any additional information requested by the Commission is received. OCC shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

OCC shall post notice on its website of proposed changes that are implemented. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the advance notice is consistent with the Clearing Supervision Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2021–803 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–OCC–2021–803. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the self-regulatory organization.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2021–803 and should be submitted on or before February 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[51]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00377 Filed 1–11–22; 8:45 am]

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[51] 17 CFR 200.30–3(a)(91).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93916; File No. SR–OCC–2021–014]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change Concerning the Options Clearing Corporation's Cash and Investment Management

January 6, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 23, 2021, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change would (1) formalize OCC's policy for safeguarding cash and related investments and (2) amend OCC's Rules governing use of the Clearing Fund in the event of the failure of a bank to meet a settlement obligation with OCC to ensure such access extends to the failure of an investment counterparty with whom OCC has invested cash deposited by Clearing Members in respect of margin or Clearing Fund requirements under the conditions identified in OCC Rule 1006(c) and (f), regardless of whether the investment counterparty is a bank. The Cash and Investment Management Policy is included in confidential Exhibit 5a of File Number SR–OCC–2021–014. Proposed amendments to OCC's Rules are included in Exhibit 5b of File Number SR–OCC–2021–014. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] OCC's By-Laws and Rules can be found on OCC's website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

OCC is proposing to enhance its cash and investment management practices by: (1) Formalizing OCC's policy for safeguarding cash and related investments, and (2) amending OCC's Rules to ensure access to the Clearing Fund if a non-bank investment counterparty fails to return Clearing Member cash deposited in respect of margin or Clearing Fund requirements under the conditions identified in OCC Rule 1006(c) and (f).

Background

OCC's By-Laws and Rules govern the management and investment of OCC's own funds and cash deposited by Clearing Members. With respect to OCC's own funds (other than Clearing Fund deposits), Article IX, Section 1 of OCC's By-Laws provides that funds in excess of the amount needed as working capital may be invested by the Board in Government securities or such other securities or financial instruments as the Board or a Board-level committee may from time to time approve.[4] With respect to cash deposited by Clearing Members, OCC Rules 604(a) and 1002(c) provide that cash deposited in respect of a Clearing Member's margin requirements or Clearing Fund contributions may from time to time be partially or wholly invested by OCC for its account in Government securities.[5] OCC does not propose to amend these By-Laws or Rules by this proposed rule change.

OCC's investments historically have been limited to overnight transactions under deliver-versus-payment (''DVP'') reverse repurchase agreements. As collateral, the investment counterparty deliveries Government securities equal to 102% of the cash invested at the time the investment is made. Such investments reduce OCC's investment risks by permitting quick liquidation with little adverse price effect and controlling the movement of OCC's assets via a custodian bank. To minimize counterparty risk, OCC restricts its potential counterparties to financial institutions that meet certain standards of size, capital adequacy, product offering and operational capacity.

In the event of a failure or disruption of an investment counterparty that is a bank, OCC's Rules provide OCC with authority to access the Clearing Fund to address liquidity shortfalls, including shortfalls arising from the investment of Clearing Member cash in Government securities. Specifically, OCC Rule 1006(f) authorizes OCC to take possession of cash or securities deposited by Clearing Members in respect of the Clearing Fund when OCC reasonably believes it necessary to meet its liquidity needs for same-day settlement as a result of the failure of any bank to achieve daily settlement with OCC.[6] In the extremely unlikely event that a bank investment counterparty failed to return the cash versus return of the Government securities to unwind a transaction under a reverse repurchase agreement—*e.g.,* because of a systems disruption, operational outage, or otherwise—OCC could exercise authority under Rule 1006(f) to borrow from the Clearing Fund to the extent required for OCC to meet its settlement obligations with Clearing Members.[7]

In the unlikely event that any part of the borrowing under Rule 1006(f) is outstanding after 30 calendar days, or if OCC determines that some or all of the amount borrowed constituted an actual loss, OCC would charge the loss to the Clearing Fund.[8] In the unlikely event that OCC incurred an investment loss resulting from a bank's failure to return the invested cash because of bankruptcy, insolvency, receivership, suspension of operations or other similar event, OCC may, at its discretion, charge the loss to the Clearing Fund.[9] OCC may also, at its discretion, apply skin-in-the-game to a loss resulting from a borrowing or bank failure in the form of liquid net assets funded by equity[10] in excess of 110% of OCC's Target Capital Requirement.[11]

Proposed Changes

Cash and Investment Management Policy

OCC proposes to file its Cash and Investment Management Policy (or ''Policy'') as a proposed rule of the clearing agency within the meaning of Section 19(b)(1) of the Exchange Act[12] and SEC Rule 19b–4.[13] The Policy would include statements of purpose, applicability and scope, safeguarding standards for maintaining cash and related investments to minimize credit and liquidity risk, and guidelines for investing OCC Cash and Clearing Member Cash, as defined below.

Purpose, Applicability and Scope

The Policy would include statements of the Policy's purpose, applicability, and scope. The purpose of the Policy would be to (1) outline the safeguarding standards for cash and related investments managed by OCC to minimize credit and liquidity risk, and (2) provide guidelines for investments permitted by OCC's By-Laws and Rules. The Policy principally would apply to OCC's Treasury department (''Treasury''), which has responsibility for managing cash on behalf of OCC. The Policy's scope would include the safeguarding standards and investment activities specific to OCC's own cash (''OCC Cash'') and cash from OCC's Clearing Members (''Clearing Member Cash'').

The Policy would define OCC Cash to include working capital related to future operating costs, inclusive of financial resource held to meet liquidity and resiliency requirements,[14] proceeds from lines of credit, if any, maintained to support OCC's working capital,[15] the

[4] *See* By-Law Art. IX, Sec. 1.

[5] *See* OCC Rule 604(a); Rule 1006(c).

[6] *See* OCC Rule 1006(f). As discussed, *infra,* this proposed rule change would amend this clause to apply when OCC reasonably believes it necessary to meet its liquidity needs for ''daily settlement'' as a result of the failure of any bank ''to perform any obligation to the Corporation when due.''

[7] OCC amended its Rules in 2018 to extend access to the Clearing Fund in the extraordinary event that OCC faces a liquidity need in order to complete same-day settlement for reasons other than a bank or clearing organization's bankruptcy, insolvency, receivership, suspension of operations, or any similar event. *See* Securities Exchange Act (''Exchange Act'') Release No. 82309 (Dec. 13, 2017), 82 FR 60262 (Dec. 19, 2017) (File No. SR–OCC–2017–017).

[8] *See* OCC Rule 1006(c)(ii).

[9] *See* OCC Rule 1006(c)(i).

[10] OCC's Capital Management Policy defines ''liquid net assets funded by equity'' to be the level of cash or cash equivalents, no greater than OCC's shareholders' equity, less any approved adjustments (*e.g.,* agency-related liabilities such as Section 31 fees held by OCC and the Minimum Corporate Contribution). *See* Exchange Act Release No. 91199 (Feb. 24, 2021), 86 FR 12237, 12241 (Mar. 2, 2021) (File No. SR–OCC–2021–003).

[11] *See* OCC Rule 1006(e)(ii).

[12] 15 U.S.C. 78s(b)(1).

[13] 17 CFR 240.19b–4.

[14] *See* Exchange Act Release No. 88029 (Jan. 24, 2020), 85 FR 5500, 5501–02 (Jan. 30, 2020) (File No. SR–OCC–2019–007) (discussing the determination of Target Capital Requirement under OCC's Capital Management Policy).

[15] Working capital lines of credit, if any, are separate from the syndicated credit facility and liquidity facilities that OCC maintains to cover default losses or liquidity shortfalls. *See* Exchange Act Release No. 88971 (May 28, 2020), 85 FR 34257 (June 3, 2020) (File No. SR–OCC–2020–804) (discussing OCC's revolving credit facility); Exchange Act Release No. 89039 (June 10, 2020), 85

Minimum Corporate Contribution,[16] and investments made with OCC Cash. The Policy would not apply to cash held in respect of OCC's pension plan, post-retirement welfare plan, or other deferred compensation plans. The Policy would define Clearing Member Cash to include Clearing Fund cash deposits; cash deposited by Clearing Members in respect of margin requirements; cash held in liquidating settlement accounts for suspended Clearing Members,[17] proceeds from OCC's syndicated credit facility and liquidity facilities,[18] and investments made with Clearing Member Cash.[19] The Policy would not apply to non-cash collateral deposited by Clearing Members to satisfy margin or Clearing Fund requirements.

Safeguarding Standards

The Policy would address the safeguarding standards for managing OCC Cash and Clearing Member Cash, which OCC would either hold in a demand deposit or Federal Reserve Bank accounts or invest in accordance with OCC's By-Laws and investment strategy, as discussed below.

OCC Cash

Unless invested, OCC Cash would be held in demand deposit accounts or at a Federal Reserve Bank. Demand deposit accounts would be limited to commercial financial institutions that meet initial and ongoing standards for depository banks outlined in OCC's procedures concerning its banking relationships.

Treasury would be responsible for maintaining appropriate levels of liquidity in OCC's operating accounts to meet general business obligations and regulatory requirements. To fulfill this responsibility, the Policy would provide that OCC may maintain bank lines of credit for working capital purposes. The source of such credit line would need to meet the standards for credit facility banks outlined in OCC's procedures concerning its banking relationships.

Clearing Member Cash

The Policy would provide that unless invested, Clearing Member Cash would be held in a demand deposit account or in accounts at a Federal Reserve Bank. With respect to commercial banks, Clearing Member Cash would only be held in financial institutions that meet the initial and ongoing standards for depository banks as provided in in OCC's procedures concerning banking relationships. The Policy would provide that Clearing Member Cash collected at OCC's settlement banks may be transferred to other depository banks, including to and from OCC's bank accounts for settlement, investment, and cash management purposes. Upon the suspension of a Clearing Member, OCC would promptly move all margin and Clearing Fund cash related to the Clearing Member into a liquidating settlement account for use in meeting the obligations of the Clearing Member, as provided under OCC's Rules.[20] Treasury would be responsible for ensuring accounts are appropriately funded to meet financial obligations. Interest earned on Clearing Fund cash deposits held at a Federal Reserve Bank would accrue to the benefit of Clearing Members, less a cash management fee.

The Policy would also provide that OCC would employ a bank account structure that segregates customer funds per applicable regulatory requirements[21] and OCC's By-Laws and Rules.[22] Futures customer segregated cash would be held in segregated fund accounts pursuant to applicable Commodity and Futures Trading Commission (''CFTC'') regulations, including that OCC ensures that it receives proper written acknowledgment from the depository for each new segregated funds account that the account has been established to hold segregated cash generated from futures customers.[23] The Policy would further provide that if OCC sustains an investment loss with respect to invested margin cash OCC will not pass on the loss to a futures customer segregated account.

Investment Guidelines

The Policy would also provide guidelines for investments permitted by OCC's By-Laws and Rules and approved by the Board or Compensation and Performance Committee (''CPC''), including OCC's investment strategy, investment governance principles, and guidelines for the investment of OCC Cash and Clearing Member Cash.

Investment Strategy

The Policy would provide that OCC's investment strategy is to preserve principal and maintain adequate liquidity. After principal and liquidity requirements are satisfied, only then would Management seek to optimize investment returns. OCC would disclose its investment strategy through its public website on a periodic basis via its qualitative disclosures to the Principles for Financial Market Infrastructure Disclosures.[24]

Investment Governance Principles

The Policy would provide that OCC may invest OCC Cash and Clearing Member Cash in permitted investments per applicable regulatory requirements, OCC's By-Laws and Rules, the investment strategy and the following governance principles. Current investment practices would be outlined in procedures maintained by OCC. Investment counterparties would need to be financial institutions or financial market utilities that meet initial and on-going standards outlined in OCC's procedures concerning its banking relationships, which consider the financial institution's size, capital adequacy, product offering and operational capabilities. Any interest or gain received on the investments would belong to OCC except as may otherwise be provided in OCC's By-Laws, Rules or Board-approved policies.[25] OCC would not commingle investments of OCC Cash with investments of Clearing Member Cash.

Investment of OCC Cash

The Policy would provide that OCC Cash may be invested in instruments that pose minimal credit and liquidity risk pursuant to applicable regulatory requirements, OCC's By-Laws, the investment strategy, and Board or CPC approved investments. Approved investments other than in Government securities would continue to be subject to Board or CPC approval, as required under Section 1 of Article IX of OCC's By-Laws.[26] In addition, investment of

FR 36444 (June 16, 2020) (File No. SR–OCC–2020–803) (discussing OCC's non-bank liquidity facility).

[16] *See* Exchange Act Release No. 92038 (May 27, 2021), 86 FR 29861 (Jun. 3, 2021) (File No. SR–OCC–2021–003) (establishing a persistent minimum level of OCC's own capital that it would contribute to default losses or liquidity shortfalls prior to allocating a default loss to the Clearing Fund contributions of non-defaulting Clearing Members).

[17] *See* OCC Rule 1104.

[18] *See supra* note 17 (citing SEC notices of no-objection to advance notices concerning OCC's credit and liquidity facilities).

[19] *See supra* note 7 and accompanying text.

[20] *See* OCC Rule 1104.

[21] *See* 17 CFR 39.15 (requiring a derivatives clearing organization to comply with the segregation requirements section 4d of the Commodity Exchange Act).

[22] *See* OCC By-Laws Art. VI, Sec. 3(f) (providing for maintenance of segregated futures accounts).

[23] *See* 17 CFR 1.20(g)(4).

[24] *See* Disclosure Framework, *available at https://www.theocc.com/Risk-Management/PFMI-Disclosures.*

[25] As discussed, interest earned on Clearing Fund cash deposits held at a Federal Reserve Bank would accrue to the benefit of Clearing Members, less a cash management fee.

[26] In addition to investments in Government securities through overnight DVP transactions, the

Continued

working capital in excess of 110% of OCC's Target Capital Requirement would not be limited to overnight transactions.[27]

Investment of Clearing Member Cash

The Policy would further provide that Clearing Member Cash may be invested in Government securities by OCC in transactions that provide next-day liquidity in accordance with applicable regulatory requirements, OCC's Rules, and the investment strategy, subject to the following guiding principles. First, the Policy would provide that notwithstanding the authority to invest Clearing Fund cash under OCC Rule 1002(c), it is OCC's policy not to invest Clearing Fund cash, which is instead maintained in accounts at a Federal Reserve Bank or a commercial bank. This policy would be subject to an exception approved by the Chief Executive Officer or Chief Operating Officer in emergency situations (such as a disruption at a Federal Reserve Bank) when necessary or advisable for the protection of the Corporation or otherwise in the public interest to continue to facilitate the prompt and accurate clearance and settlement of confirmed trades or other transactions and to provide OCC's services in a safe and sound manner. Second, the Policy would provide that margin cash would only be invested in instruments that provide liquidity to OCC by the following business day. Third, the Policy would provide that OCC will implement procedures to ensure that end-of-day margin cash balances remain above the aggregate level of any Required Cash Deposits, as that term is defined in OCC's Liquidity Risk Management Framework.[28] The policy with respect to investing Required Cash Deposits would be subject to the same exception as for investment of Clearing Fund cash. Fourth, any change regarding whether to investment futures customer segregated funds would be approved by OCC's Chief Financial Officer in consultation with OCC's Legal and Compliance departments.[29]

The Policy would also describe how OCC maintains liquidity facilities for immediate access to liquidity in the event of a suspension of a Clearing Member or a failure of a bank, securities or commodity clearing organization, or investment counterparty (with respect to the investment of Clearing Member Cash) to meet an obligation owing to OCC, or in anticipation thereof, pursuant to OCC Rules 1006(c) and (f), proposed amendments to which are discussed below. The liquidity providers for these facilities would be approved and monitored according to the OCC's Third-Party Risk Management Framework and Liquidity Risk Management Framework.[30]

Amendments to OCC Rule 1006

OCC proposes to amend OCC Rule 1006, which governs its ability to access the Clearing Fund in the event of the failure (or anticipated failure) of bank to meet a settlement obligation with OCC, to extend such access to the failure of a non-bank investment counterparty to meet settlement obligations with OCC under the conditions identified in OCC Rule 1006(c) and (f). In addition, OCC proposes to restate OCC Rule 1006(f) for clarity.

To ensure that OCC may access the Clearing Fund in the event of a failure or disruption of a non-bank counterparty with whom OCC has invested Clearing Member Cash, OCC would amend OCC Rule 1006(f) to include ''investment counterparty'' to the list of counterparties—currently, any bank or securities or commodities clearing organization—whose failure or disruption may result in a borrowing under Rule 1006(f). Similarly, OCC would also amend OCC Rule 1006(a) and (c) to add the same phrase to the list of counterparties whose failure resulting from bankruptcy, insolvency, receivership, suspension of operations, or any similar event may result in allocation of losses to the Clearing Fund. Rule 1006(c) and (f) would be further amended to provide that failure of an investment counterparty under those paragraphs would be limited to a failure with respect to Clearing Member Cash (*i.e.,* cash invested under Rule 604(a) or Rule 1002(c)).[31] Any investment loss resulting from investment of OCC Cash would be treated as an operational loss that would be addressed under OCC's Capital Management Policy, rather than a loss that would be allocated to the Clearing Fund.[32]

OCC would also amend the condition that triggers borrowing authority under Rule 1006(f)—currently clause (iii) of the first sentence of Rule 1006(f)—which would be renumbered as Rule 1006(f)(1)(C). That condition would be amended to apply when the Corporation reasonably believes it necessary to borrow to meet its liquidity needs for ''daily settlement'' rather than ''same-day settlement,'' as in the current text. OCC may reasonably believe that a disruption at a bank, securities or commodities clearing organization, or investment counterparty could last multiple days, resulting in liquidity needs for daily settlement over more than one day. This amendment would ensure that OCC has authority to initiate a borrowing for the amount OCC believes necessary to meet its liquidity needs over the timeframe OCC believes the disruption will affect OCC's ability to meet daily settlement requirements with Clearing Members, rather than only that amount that OCC believes it needs on a day-by-day basis.

OCC would further amend the condition in Rule 1006(f)(1)(C) to apply when OCC reasonably believes such a liquidity need will arise because of one of the identified counterparty's failure ''to perform any obligation to the Corporation when due,'' rather than such a counterparty's failure ''to achieve daily settlement.'' This change aligns with the condition for allocation of losses under Rule 1006(c) and eliminates any ambiguity that might arise concerning the settlement obligations to which the current Rule refers. As under the current Rule, use of funds obtained through such a

Board has approved investments of OCC's own cash in U.S. government money market mutual funds.

[27] With respect to OCC's liquid net assets funded by equity in excess of 110% of the Target Capital Requirement, the Board has initially approved investment of such funds in Government securities through DVP transactions for terms no more than 30 days.

[28] The Liquidity Risk Management Framework defines ''Required Cash Deposits'' (sometimes referred to as minimum cash requirements or ''MCR'') as deposits of cash under OCC's Contingency Funding Plan that supplement OCC's Base Liquidity Resources (*i.e.,* the amount of committed liquidity resources maintained at all times by OCC to meet its minimum Cover 1 liquidity resource requirements under the applicable regulations). Under that framework, OCC may require a Clearing Member Group to post such additional cash collateral to supplement OCC's Available Liquidity Resources (*i.e.,* Base Liquidity Resources plus allowed Clearing Fund cash deposits in excess of the minimum required amount) when stressed liquidity demands for that Clearing Member Group are above established thresholds or until the settlement demand is met. *See* Exchange Act Release No. 89014 (June 4, 2020), 85 FR 35446, 35449 (June 10, 2020) (File No. SR–OCC–2020–003).

[29] Like Clearing Fund cash, OCC does not currently invest futures customer segregated funds. If OCC determined to invest such funds, such investments would be subject to CFTC regulations regarding a derivatives clearing organization's investment of futures customer funds. *See* 17 CFR 1.25.

[30] *See* Exchange Act Release No. 90797 (Dec. 23, 2020), 85 FR 86592 (Dec. 30, 2020) (File No. SR–OCC–2020–014) (approving OCC's framework for identifying, measuring, monitoring, and managing OCC's exposures to its counterparties); Exchange Act Release No. 89014, 85 FR 35446 (approving OCC's approach to managing liquidity risk).

[31] The same limitation would apply to Rule 1006(a), which incorporates the reasons specified in Rule 1006(c) by reference.

[32] *See* Exchange Act Release No. 88029, 85 FR at 5502–03 (discussing OCC's plan for replenishing its capital in the event that shareholders' equity falls below certain thresholds).

borrowing would continue to be limited to the purposes described in Rule 1006(f)(1)(C), as amended, *i.e.,* to meet OCC's liquidity needs for daily settlement with Clearing Members.

In addition to the substantive changes discussed above, OCC would also restate Rule 1006(f) for clarity. The current paragraph would be divided into four subparagraphs with courtesy headings: (1) *Conditions;* (2) *Uses;* (3) *Term; Clearing Fund Charge;* and (4) *Substitution Requests.* The conditions in Rule 1006(f)(1) would begin with the first sentence of current Rule 1006(f), less the conjoined clause beginning with ''and use such assets,'' the substance of which would be moved to paragraph (f)(2). The remaining clause before the conjunction would be amended to describe OCC's investment of Clearing Fund cash contributions in the active voice. The three conditions for a borrowing identified in Rule 1006(f), currently numbered (i) through (iii), would then follow after the conjunction as items (A) through (C). Item (A) would be further amended to remove legalese and state the condition more plainly. Item (C) would be amended substantively as discussed above.

The prescribed uses for the borrowed funds described in several places throughout current Rule 1006(f) would be aggregated in Rule 1006(f)(2). As currently found in the conjoined clause in the first sentence of current Rule 1006(f), Rule 1006(f)(2)(A) would provide that OCC may use funds it takes possession of under Rule 1006(f) to (i) meet obligations, losses or liquidity needs; or (ii) borrow or otherwise obtain funds through any means determined to be reasonable at the discretion of the Chairman, Chief Executive Officer or the Chief Operating Officer (including, without limitation, pledging such assets as security for loans and/or using such assets to effect repurchase, securities lending or other transactions). Proposed Rule 1006(f)(ii) would also be restated to remove a gendered pronoun. Rule 1006(f)(2)(B) would describe the limitations on use of funds borrowed under the renumbered conditions in Rule 1006(f)(1)(A) and (C).

Rule 1006(f)(3) would contain the term for a borrowing, as well as the conditions that would trigger a loss chargeable to the Clearing Fund. The 30-day period before which OCC would be obligated to charge a borrowed amount as a loss to the Clearing Fund would be located at Rule 1006(f)(3)(A), with certain non-substantive edits to the text. The conditions that would trigger the loss allocation to the Clearing Fund would be located at Rule 1006(f)(3)(B) and would be restated to move the lengthy conditions after the main clause, among other non-substantive revisions.

Finally, Rule 1006(f)(4) would relocate OCC's authority to refuse Clearing Member substitution requests regarding securities contributed to the Clearing Fund that the Corporation has taken possession of under Rule 1006(f). In addition to relocating that provision to the end of Rule 1006(f), this proposed rule change would restate that provision to reflect the reorganization of Rule 1006(f).

(2) Statutory Basis

Section 17A(b)(3)(F) of the Exchange Ac,[33] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible, to perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions, and, in general, to protect investors and the public interest. For the reasons discussed below, OCC believes the proposed rule change is consistent with Section 17A(b)(3)(F) [34] of the Exchange Act and Rule 17Ad–22(e)(7)(viii),[35] Rule 17Ad–22(e)(13),[36] and Rule 17Ad–22(e)(16) [37] thereunder.

Consistency With Section 17A(b)(3)(F) of the Exchange Act

The Cash and Investment Management Policy is designed to safeguard cash and related investments within OCC's custody or control. The Policy applies to, among other things, cash deposited by Clearing Members in respect of margin and Clearing Fund requirements, any Government securities in which OCC invests such cash, and the Minimum Corporate Contribution, each of which are liquid resources available to facilitate settlement and to cover potential losses in the event of a Clearing Member default. The Policy also extends to OCC's own cash, including cash OCC maintains to cover potential general business losses so that OCC can continue operations and services as a going concern if those losses materialize, in accordance with OCC's Capital Management Policy. By providing safeguarding standards for managing such cash and related investments, the Policy would help ensure those resources will be available to facilitate settlement, cover potential default losses, or cover potential general business losses, as applicable. Therefore, OCC believes the Policy is designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible, and, in general, to protect investors and the public interest, consistent with Section 17A(b)(3)(F) of the Exchange Act.[38]

The proposed rule change is also designed to ensure that OCC can continue to promptly settle the securities and derivatives transactions it clears by enhancing the existing tools OCC has to address potential liquidity shortfalls. Specifically, the proposed rule change would expand the existing borrowing authority in OCC's By-Laws to authorize borrowing in the extraordinary event that OCC faces a liquidity need in order to complete daily settlement with its Clearing Members resulting from the failure or disruption of an investment counterparty with whom OCC has invested Clearing Member Cash that is not a bank.

It is conceivable, though extremely unlikely, that an investment counterparty may fail to return Clearing Member Cash that OCC has invested in Government securities with the counterparty in a DVP transaction as a result of a disruption or failure at that investment counterparty. The proposed rule change would enable OCC to borrow against the Clearing Fund in this scenario in order to avoid disrupting OCC's ordinary settlement cycle. In the extremely unlikely event that OCC incurs a loss resulting from the investment of Clearing Member Cash, OCC would retain authority to allocate such loss to the Clearing Fund, at OCC's discretion. Accordingly, OCC believes the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, in accordance with the requirements of Section 17A(b)(3)(F) of the Exchange Act.[39]

Consistency With Rule 17Ad–22(e)(16)

Rule 17Ad–22(e)(16) under the Exchange Act requires, in part, that OCC establish, implement, maintain and enforce written policies and procedures reasonably designed to safeguard OCC's

[33] 15 U.S.C. 78q–1(b)(3)(F).

[34] 15 U.S.C. 78q–1(b)(3)(F).

[35] 17 CFR 240.17Ad–22(e)(7)(viii).

[36] 17 CFR 240.17Ad–22(e)(13).

[37] 17 CFR 240.17Ad–22(e)(16).

[38] 15 U.S.C. 78q–1(b)(3)(F).

[39] *Id.*

own and its participants' assets, minimize the risk of loss and delay in access to these assets, and invest such assets in instruments with minimal credit, market, and liquidity risks.[40] As discussed above, the Policy outlines safeguarding standards for cash and related investments intended to minimize credit and liquidity risks. In addition, the Policy sets forth OCC's conservative investment strategy, according to which OCC's primary objective is to preserve principal and maintain adequate liquidity. The Policy also requires cash and related investments to be maintained with counterparties that have been initially approved and routinely monitored in accordance with OCC's Third Party Risk Management Policy and procedures governing banking relationships. Accordingly, OCC believes that the Policy is consistent with Rule 17Ad–22(e)(16).

Consistency With Rule 17Ad–22(e)(7)(viii)

Additionally, Rule 17Ad–22(e)(7)(viii) requires that OCC address foreseeable liquidity shortfalls that would not be covered by OCC's liquid resources and seek to avoid unwinding, revoking, or delaying the settlement of payment obligations.[41] As stated above, OCC believes that it could be foreseeable, though extremely unlikely, that an investment counterparty that is not a bank may fail to return Clearing Member Cash as the result of the investment counterparty's disruption or failure. An alternative available to OCC for addressing uncovered liquidity shortfalls would be to exercise authority under Rule 505 to extend the settlement window to the close of Fedwire.[42] The proposed rule change would improve OCC's ability to address such situations by expanding OCC's borrowing authority to enable OCC to borrow against the Clearing Fund to address a failure or disruption at a non-bank investment counterparty rather than disrupting its ordinary settlement cycle. Accordingly, OCC believes that proposed changes to OCC Rules are consistent with Rule 17Ad–22(e)(7)(viii).

Consistency With Rule 17Ad–22(e)(13)

Finally, Rule 17Ad–22(e)(13) requires, in part, that OCC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure OCC has the authority to take timely action to contain losses and liquidity demands and continue to meet its obligations.[43] As described above, this proposal would amend OCC's Rules concerning loss allocation in the extremely unlikely event that the failure or disruption of a non-bank investment counterparty results in a loss to OCC arising from the investment of Clearing Member Cash. The expansion of existing authority to allocate such losses attributable to a non-bank investment counterparty helps establish a more transparent and clear loss allocation process that ensures OCC's authority to take action to contain losses and continue to meet its clearance and settlement obligations. Accordingly, OCC believes the proposed changes to OCC's Rules are consistent with Rule 17Ad–22(e)(13).

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Exchange Act[44] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. OCC does not believe the proposed rule change would have any impact or impose any burden on competition. The primary purpose of the proposed rule change is to formalize OCC's Cash and Investment Management Policy and enhance OCC's access to the Clearing Fund by expanding the existing authority concerning bank failures to also apply in the case of failures by other investment counterparties. The proposed rule change would not affect Clearing Members' access to OCC's services or disadvantage or favor any particular user in relationship to another user. As such, OCC believes that the proposed changes would not have any impact or impose any burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

OCC shall post notice on its website of proposed changes that are implemented. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2021–014 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2021–014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at

[40] 17 CFR 240.17Ad–22(e)(16).

[41] 17 CFR 240.17Ad–22(e)(7)(viii).

[42] *See* OCC Rule 505 (Extension of Settlements).

[43] 17 CFR 240.17Ad–22(e)(13).

[44] 15 U.S.C. 78q–1(b)(3)(I).

https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2021–014 and should be submitted on or before February 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

J. Matthew DeLesDernier,

Assistant Secretary.

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[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93917; File No. SR–NYSEAMER–2021–49]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 9261 and 9830

January 6, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 27, 2021, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes extending the expiration date of the temporary amendments to Rules 9261 and 9830 as set forth in SR–NYSEAMER–2020–69 from December 31, 2021 to March 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE American Rules 9261 and 9830. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSEAMER–2020–69[4] to Rules 9261 (Evidence and Procedure in Hearing) and 9830 (Hearing) from December 31, 2021 to March 31, 2022, to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSEAMER–2020–69 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 9261 and 9830.[5]

Background

In 2016, NYSE American (then known as NYSE MKT LLC) adopted disciplinary rules that are, with certain exceptions, substantially the same as the Rule 8000 Series and Rule 9000 Series of FINRA and its affiliate the New York Stock Exchange LLC (''NYSE''), and which set forth rules for conducting investigations and enforcement actions.[6] The NYSE American disciplinary rules were implemented on April 15, 2016.[7]

In adopting disciplinary rules modeled on FINRA's rules, NYSE American adopted the hearing and evidentiary processes set forth in Rule 9261 and in Rule 9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 9800 Series. As adopted, the text of Rule 9261 and Rule 9830 are substantially the same as the FINRA rules with certain modifications.[8]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[9]

Given that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 15, 2020, the Exchange filed to temporarily amend Rule 9261 and Rule 9830 to permit FINRA to conduct virtual hearings on its behalf.[10] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[11] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 9261 and Rule 9830 to April 30, 2021.[12] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 90085 (October 2, 2020), 85 FR 63603 (October 8, 2020) (SR–NYSEAMER–2020–69) (''SR–NYSEAMER–2020–69'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond March 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in SR–NYSEAMER–2020–69. The amended NYSE American rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release Nos. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR–NYSEMKT–2016–30) (''2016 Notice'').

[7] *See* NYSE MKT Information Memorandum 16–02 (March 14, 2016).

[8] *See* 2016 Notice, 81 FR at 11327 & 11332.

[9] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''SR–FINRA–2020–027'').

[10] *See* note 4, *supra.*

[11] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[12] *See* Securities Exchange Act Release No. 90823 (December 30, 2020), 86 FR 650 (January 6, 2021) (SR–NYSEAMER–2020–88).

temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[13] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to August 31, 2021.[14] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[15] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to December 31, 2021, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[16]

While there are signs of improvement, FINRA has determined that much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[17] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[18] FINRA believes that there is a continued need for temporary relief beyond December 31, 2021.[19] On December 7, 2021, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from December 31, 2021, to March 31, 2022.[20]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE American Rules 9261 and 9830 as set forth in SR–NYSEAMER–2020–69 from December 31, 2021, to March 31, 2022.

As set forth in SR–FINRA–2021–031, while there are signs of improvement, much uncertainty remains for the coming months. The presence of the Delta variant, dissimilar vaccination rates throughout the United States, and the uptick in transmissions in many locations indicate that COVID–19 remains an active and real public health concern.[21] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[22] FINRA believes that there is a continued need for temporary relief beyond March 31, 2022.[23] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from December 31, 2021, to March 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE American Rules 9261 and 9830 as set forth in SR–NYSEAMER–2020–69 from December 31, 2021, to March 31, 2022. The Exchange agrees with FINRA that, while there are signs of improvement, much uncertainty remains for the coming months. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2021–031, there is a continued need for this temporary relief beyond December 31, 2021. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2021–031, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2021–031, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[24] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 9261 and 9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[25] in general, and furthers the objectives of Section 6(b)(5),[26] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the

[13] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[14] *See* Securities Exchange Act Release No. 91631 (April 22, 2021), 86 FR 22471 (April 28, 2021) (SR–NYSEAMER–2021–23).

[15] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[16] *See* Securities Exchange Act Release No. 92910 (September 9, 2021), 86 FR 51418 (September 15, 2021) (SR–NYSEAMER–2021–37).

[17] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–031) (''SR–FINRA–2021–031''). FINRA noted that, for example, President Joe Biden on July 29, 2021, announced several measures to increase the number of people vaccinated against COVID–19 and to slow the spread of the Delta variant, including strengthening safety protocols for federal government employees and contractors. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/factsheet-president-biden-to-announce-new-actions-to-get-more-americansvaccinated-and-slow-the-spread-of-the-delta-variant/*. Thereafter, the Biden Administration announced on November 4, 2021, details of two major vaccination policies to further help fight COVID–19. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/factsheet-biden-administration-announces-details-of-two-major-vaccination-policies/*. Most recently, President Biden announced several new actions to help protect Americans against the Delta and Omicron variants. *See https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/factsheet-president-biden-announces-new-actions-to-protect-americans-against-thedelta-and-omicron-variants-as-we-battle-covid-19-this-winter/*. *See* SR–FINRA–2021–031, 86 FR at 71695, n. 6.

[18] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recently announced that the first confirmed case of COVID–19 caused by the Omicron variant was detected in the United States. *See https://www.cdc.gov/media/releases/2021/s1201-omicron-variant.html*. The CDC also recommends that fully vaccinated people wear a mask in public indoor settings in areas of substantial or high transmission and noted that fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID–19. *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html*. Furthermore, as FINRA also noted, numerous states currently have COVID–19 restrictions in place. Six states (Hawaii, Illinois, Nevada, New Mexico, Oregon, and Washington) require most people to wear masks in indoor public places regardless of vaccination status, and three states (California, Connecticut, and New York) have mask mandates in indoor public places for those individuals who are unvaccinated. Several other states have mask mandates in certain settings, such as healthcare facilities, schools, and correctional facilities. *See* SR–FINRA–2021–031, 86 FR at 71696, n. 7.

[19] *See* SR–FINRA–2021–031, 86 FR at 71695–96.

[20] *See* SR–FINRA–2021–031, 86 FR at 71695.

[21] *See* note 17, *supra*.

[22] *See* note 18, *supra*.

[23] *See* SR–FINRA–2021–031, 86 FR at 71695.

[24] *See* SR–FINRA–2021–031, 86 FR at 71695, n. 13.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[27]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2021–031, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in the SR–NYSEAMER–2020–69, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[28] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSEAMER–2020–69, provides only temporary relief. As proposed, the changes would be in place through March 31, 2022. As noted in SR–NYSEAMER–2020–69 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide continued temporary relief given the impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on December 31, 2021.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[29] and Rule 19b–4(f)(6) thereunder.[30] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[31] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[32] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that the proposed rule change to extend the expiration date will continue to prevent unnecessary impediments to its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets, that would otherwise result if the temporary amendments were to expire on December 31, 2021.[33] Importantly, the Exchange has also stated that extending the relief provided in SR–NYSEAMER–2020–69 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes in a reasonable and fair manner and meet its critical investor protection goals, while also following best practices with respect to the health and safety of hearing participants.[34] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSEAMER–2020–69.[35] As proposed, the changes would be in place through March 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[36] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent

[27] 15 U.S.C. 78f(b)(7) & 78f(d).

[28] 15 U.S.C. 78f(b)(7) & 78f(d).

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6).

[32] 17 CFR 240.19b–4(f)(6)(iii).

[33] *See* supra Item II.

[34] *See* SR–FINRA–2021–031 at 71698 (noting the same with respect to the health and safety of FINRA employees in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2021–031 would become operative immediately upon filing).

[35] *See* supra note 4.

[36] *See* supra note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond March 31, 2022 it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[37]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[38] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2021–49 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2021–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2021–49 and should be submitted on or before February 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

J. Matthew DeLesDernier,

Assistant Secretary.

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[37] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[38] 15 U.S.C. 78s(b)(2)(B).

[39] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2120–0671]

Agency Information Collection Activities: Request for Renewal of a Previously Approved Information Collection(s): Safety Management Systems for Part 121 Certificate Holders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to reinstate with change an information collection used to support the analysis of safety data as part of the Safety Management System requirement for part 121 certificate holders. The information collected will be used to identify hazards and show ongoing compliance with part 5, Safety Management Systems.

DATES: Written comments should be submitted by February 11, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sean Denniston, Safety Management Program Office (AFS–910), by email at: *sean.denniston@faa.gov* or by phone: 571–758–7362.

SUPPLEMENTARY INFORMATION: *Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0763.

Title: Agency Information Collection Activities: Request for Renewal of a Previously Approved Information Collection(s); Safety Management Systems for Part 121 Certificate Holders.

Form Numbers: None.

Type of Review: Renewal of an Information Collection with changes.

Background: The information collected involves the collection and analysis of safety data as part of a Safety Management System (SMS), as required for part 121 by 14 CFR part 5, Safety Management Systems. The information to be collected will continue to be used to show compliance with part 5.

The existing information collection included the submission of SMS Implementation Plans to the FAA by March 9, 2018. That portion of the information collection has been completed and only new applicants for a part 121 certificate will be required to submit SMS Implementation Plans in the future. While the burden for existing part 121 certificate holders is significantly reduced, it is anticipated there will be some ongoing recordkeeping requirements for part 5 compliance.

A 60-Day **Federal Register** Notice and request for comments was published on June 20, 2018 (83 FR 28758) and a 30-Day **Federal Register** Notice and request for comments was published on September 17, 2018 (83 FR 46990). The FAA did not receive any comments on either notice. Since the 60-Day and 30-Day notices, there are changes to the original request and an additional 60-Day **Federal Register** Notice was

published on December 9, 2020 (85 FR 79256). The current number of certificate holders in 2020 is 68 compared to 90 in 2015. The 68 part 121 certificate holders implemented a Safety Management System by the March 9, 2018 part 5 deadline. The burden analysis has been revised reflecting part 121 SMS implementation, revised industry numbers, and analysis of post-implementation recordkeeping.

Respondents: All 68 existing part 121 certificate holders.

Frequency: Implementation Plan collection: 1 future applicant for part 121 certificate (anticipating no more than one new applicant a year). Recordkeeping requirement: Annual recordkeeping requirements for all 68 existing part 121 certificates.

Air carrier groups	Number of air carriers
Large (50+ aircraft)	25
Medium (10–49 aircraft)	19
Small (<9 aircraft)	24
Number of Operators	68

Respondents:

Summary (annual number)	Reporting	Recordkeeping	Disclosure
Large Air Carrier			
Number of Respondents		25	N/A
Number of Responses per Respondents		1	N/A
Time per Response		2,000	N/A
Total Number of Responses		25	N/A
Total burden (hours)		50,000	N/A
Medium Air Carrier			
Number of Respondents		19	N/A
Number of Responses per Respondents		1	N/A
Time per Response		4,000	N/A
Total Number of Responses		19	N/A
Total burden (hours)		76,000	N/A
Small Air Carrier			
Number of Respondents		24	N/A
Number of Responses per Respondents		1	N/A
Time per Response		1,000	N/A
Total Number of Responses		24	N/A
Total burden (hours)		24,000	N/A

Estimated annual collection activity for one new medium part 121 air carrier.

Summary (annual number)	Gap analysis	Implementation plan	SMS
Number of Respondents		1	
Number of Responses per Respondents		1	
Time per Response		2,732	
Total number of responses		1	
Total burden (hours)		2,732	

Estimated Average Burden per Response: 2,732 Hours.

Estimated Total Annual Burden: Large Air Carriers 50,000, Medium Air Carriers 76,000, Small Air Carriers 24,000, total annual burden 150,000 hours.

Robert C. Carty,

Acting Executive Director, Flight Standards Service, AFX–1.

[FR Doc. 2022–00471 Filed 1–11–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0094]

Agency Information Collection Activities; Notice and Request for Comments; Exemption for the Make Inoperative Prohibition To Accommodate People With Disabilities

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for reinstatement of a previously approved collection of information.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for reinstatement of a previously approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes a collection of information for which NHTSA intends

to seek OMB approval on the information collections related to aftermarket modification of vehicles to accommodate people with disabilities.

DATES: Comments must be submitted on or before March 14, 2022.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2021–0094 through any of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Gunyoung Lee, Office of Rulemaking (NRM230), 202–366–6005, Room W43–463, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) How to enhance the quality, utility, and clarity of the information to be collected; and (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Exemption for the Make Inoperative Prohibition to Accommodate People With Disabilities.

OMB Control Number: 2127–0635.

Form Number: This collection of information uses no standard form.

Type of Request: Reinstatement of a previously approved collection of information.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information:

The National Traffic and Motor Vehicle Safety Act (49 U.S.C. Chapter 301) authorizes NHTSA to issue Federal motor vehicle safety standards (FMVSS) applicable to new motor vehicle and new items of motor vehicle equipment. In addition to regulating the manufacture and sale of new motor vehicles and items of motor vehicle equipment, the act also prohibits certain regulated entities from knowingly making inoperative a part of a device or element of design installed on or in a motor vehicle or motor vehicle in compliance with an applicable FMVSS (49 U.S.C. 30122). The statute authorizes the Secretary of Transportation (NHTSA) to prescribe regulations to exempt a regulated entity from the make inoperative provision if such an exemption is consistent with motor vehicle safety (49 U.S.C. 30122(c)(1)).

On February 27, 2001, NHTSA published a final rule (66 FR 12638) to facilitate the modification of motor vehicles so that persons with disabilities can drive or ride in them as passengers. In that final rule, the agency issued a limited exemption from a statutory provision that prohibits specified types of commercial entities from either removing safety equipment or features installed on motor vehicles pursuant to the Federal motor vehicle safety standards or altering the equipment or features to adversely affect their performance. The exemption is limited in that it allows repair businesses to modify only certain types of FMVSS-required safety equipment and features, under specified circumstances. The regulation is found at 49 CFR part 595 subpart C, ''Vehicle Modifications to Accommodate People with Disabilities.'' The regulation includes three collections of information: (1) A requirement for modifiers to submit identification information to NHTSA; (2) a requirement for modifiers to provide a document to the owner of the modified vehicle stating the exemptions used for that vehicle and any reduction in load carrying capacity of the vehicle of more than 100 kg (220 lbs); and (3) a requirement for modifiers to retain a copy of the information provide to the owner of the modified vehicle for five years.

Description of the Need for the Information and Proposed Use of the Information

Commercial entities that modify vehicles after the first retail sale and wish to use the exemptions offered under this rule are required to provide NHTSA with their identification information. The registration involves a one-time submission using NHTSA's online Manufacturer Portal [1] containing only the name, address, and telephone number of the modifier and a prescribed statement that they will modify vehicles for persons with disabilities and intend to avail themselves of the exemptions. Any changes in the identification information must be conveyed to the agency within 30 days. This information will be used by the agency to track entities involved in vehicle modification for persons with disabilities and is available to the public on NHTSA's website.

Modifiers must also provide each customer whose vehicle modification involves the use of the make inoperative

[1] NHTSA's Manufacturer's Portal is found at *https://vpic.nhtsa.dot.gov/mfrportal/.*

exemptions with a list of the exemptions used in the process of modifying that vehicle.[2] The simplest form of this document is an annotated invoice. No specific or special forms are required. A copy of this document must also be retained by the modifier for five years. This document will be used by the consumer to understand the modifications made to his/her vehicle and their effect on vehicle safety. It may be requested by NHTSA in the event of an inquiry about the safety of the modified vehicles.

Affected Public: Motor vehicle repair business.

Estimated Number of Respondents: 765.

For this estimate, NHTSA assumed that there are 900 businesses making vehicle modifications for people with disabilities, and 85 percent of these (*i.e.,* 765 businesses) will elect to use the exemptions available under the rule.

Frequency: On occasion (*e.g.,* a customer demands a vehicle modification to accommodate people with disabilities, or a company decides to become an adaptive vehicle modification business or changes its identification information).

Estimated Total Annual Burden Hours: 1,432.

This ICR is for three information collections. We estimate the total burden hours for this ICR to be 1,432. The burden hours for the three information collections were calculated as follows:

Information Collection 1: Requirement To Submit Identification Information to NHTSA To Use the Exemptions

NHTSA estimates that compiling and submitting the identification information will take approximately 10 minutes. NHTSA estimates that there are approximately 900 businesses making vehicle modifications for persons with disabilities in the United States and that 85 percent of these, or 765 businesses, will elect to use the exemptions available under the rule. After the initial registration (which occurred in 2001), NHTSA estimates that 90 businesses will either need to change their information or become new registrants who elect to use the exemptions each year. Therefore, NHTSA estimates the total burden hours associated with submitting new or updated identification information is 15 hours (90 business × 10 minutes).

To calculate the labor cost associated with submitting modifier identification information, NHTSA looked at wage estimates for the type of personnel involved with compiling and submitting the information. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for ''General Office Clerks'' (BLS Occupation code 43–9061) is $16.98.[3] The Bureau of Labor Statistics estimates that private industry workers' wages represent 70.4% of total labor compensation costs.[4] Therefore, NHTSA estimates the hourly labor costs to be $24.12for ''General Office Clerks'' (BLS Occupation code 43–9061). NHTSA estimates the total labor cost associated with the 15 burden hours (for submitting modifier identification by ''office clerks'') to be approximately $362. (15 × $24.12 = $361.80.)

Information Collection 2: Requirement To Provide a Document to the Owner of the Modified Vehicle

The second information collection in part 595 is the requirement to provide a disclosure to the vehicle owner. This disclosure is made with each vehicle modified using exemptions under part 595. In the final rule, we anticipated that the least costly way for a repair business to comply with this portion of the new rule would be to annotate the vehicle modification invoice as to the exemption, if any, involved with each item on the invoice. The cost of preparing the invoice is not a portion of our burden calculation, as that preparation would be done in the normal course of business. Additionally, NHTSA's burden estimate does not include an estimate for the time to gather the information required for the disclosure as it is assumed that this information would be gathered in the normal course of vehicle modification. Instead, NHTSA estimates that the only extra burden would be incurred for calculation of the reduction in loading-carrying capacity and annotating the information on the invoice. NHTSA estimates the time needed to annotate the invoice is 20 minutes. NHTSA estimates that there are approximately 4,250 vehicles modified under exemptions provided by 49 CFR 595.7 each year. Therefore, NHTSA estimates the total burden associated with providing disclosures to vehicle owners is 1,417 hours (20 minutes × 4,250 vehicles = 1,416.67 hours).

To calculate the labor cost associated with the 1,417 burden hours for the disclosure document requirement, NHTSA looked at the average hourly wage for ''Mechanical Engineering Technicians'' (BLS Occupation code 17–3027). With the BLS's average hourly wage of $28.00 (which represents 70.4% of total compensation according to the Bureau of Labor Statistics), NHTSA estimates the hourly labor costs to be $39.78 for ''Mechanical Engineering Technicians (BLS Occupation code 17–3027). Therefore, NHTSA estimates the total labor cost associated with the 1,417 burden hours (for providing disclosure documents to vehicle owners by ''engineering technicians'') to be $56,368 (1,417 × $39.78 = $56,368.28).

Information Collection 3: Retaining a Copy of the Document Provided to Vehicle Owners

NHTSA estimates that there are no additional burden hours associated with the requirement to retain a copy of the disclosures provided to vehicle owners. Accordingly, there are also no labor costs associated with this requirement.

Table 1 provides a summary of the estimated burden hours and labor costs associated with this collection of information request.

TABLE 1—BURDEN ESTIMATES

	Annual submissions or responses	Estimated burden per submission	Average hourly labor cost	Labor cost per submission	Total burden hours	Total labor costs
Modifier identification	90	10 minutes	$24.12	$4.02	15	$362
Disclosure document (to vehicle owners)	4,250	20 minutes	39.78	13.26	1,417	56,368
Retention of a copy of document provided to vehicle owner.	4,250	0 minutes	N/A	$0.00	0	0.00

[2] 49 CFR 595.7(b) and (e).

[3] *See* May 2020 National Occupational Employment and Wage Estimates, United States, available at *https://www.bls.gov/oes/current/oes_nat.htm.*

[4] *See* Table 1. Employer Costs for Employee Compensation by ownership (Mar. 2021), available at *https://www.bls.gov/news.release/ecec.t01.htm.*

TABLE 1—BURDEN ESTIMATES—Continued

	Annual submissions or responses	Estimated burden per submission	Average hourly labor cost	Labor cost per submission	Total burden hours	Total labor costs
Annual total burden hours & labor costs.	.....		.....	.....	1,432	56,730

Estimated Total Annual Burden Cost:

NHTSA estimates that there are no additional costs associated with this information collection request. There will be no additional material cost associated with complying with this requirement because no additional materials need to be used except those used to prepare the invoice in the normal course of business. We are assuming that it is normal and customary in the course of vehicle modification business to prepare an invoice, to provide a copy of the invoice to the vehicle owner, and to keep a copy of the invoice for five years after the vehicle is delivered to the owner in finished form.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–00371 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0031]

Agency Information Collection Activities; Notice and Request for Comment; Motorcycle Helmets (Labeling)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a reinstatement of a previously approved collection of information.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) summarized below is being submitted to the Office of Management and Budget (OMB) for review and approval. The ICR for motorcycle helmet labeling describes the nature of the information collection and its expected burden. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on May 12, 2021.

DATES: Comments must be submitted on or before February 11, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Ms. Cristina Echemendia, U.S. Department of Transportation, NHTSA, 1200 New Jersey Avenue SE, West Building Room W43–447, NRM–130, Washington, DC 20590. Ms. Cristina Echemendia's telephone number is 202–366–6345 and fax number is 202–366–7002. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public, and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with those requirements, this notice announces that the following information collection request is being submitted to OMB.

Title: Motorcycle Helmets (Labeling).

OMB Control Number: 2127–0518.

Form Number: N/A.

Type of Request: Reinstatement of previously approved collection of information.

Type of Review Requested: Regular.

Length of Approval Requested: Three years.

Summary of the Collection of Information

The National Traffic and Motor Vehicle Safety Act, at 49 U.S.C. 30111, authorizes the Secretary of Transportation (NHTSA by delegation) to issue Federal Motor Vehicle Safety Standards (FMVSS) that set performance standards for motor vehicles and items of motor vehicle equipment. Vehicle and equipment manufacturers must certify that their vehicles and equipment comply with the safety standards. Moreover, under 49 U.S.C. 30117, the Secretary (NHTSA by delegation) is also authorized to require manufacturers to provide information to first purchasers of motor vehicles or motor vehicle equipment when the vehicle equipment is purchased, in the form of printed matter placed in the vehicle or attached to the motor vehicle or motor vehicle equipment.

Using this authority, NHTSA issued the initial FMVSS No. 218 in 1974. Motorcycle helmets are devices used to protect motorcyclists from head injury in motor vehicle crashes. Manufacturers must label every helmet produced to indicate that the helmet is in compliance with the requirements of the standard. The certification label consists of the symbol ''DOT,'' the term ''FMVSS No. 218,'' the word ''CERTIFIED,'' the

precise model designation, and the manufacturer's name and/or brand on the outer shell of the helmet towards the posterior bottom edge. Manufacturers are also required to label every helmet to provide helmet owners with important safety information including manufacturer's name, discrete size, month and year of manufacture, and specific instructions to the purchaser. FMVSS No. 218 S5.6 requires that each helmet shall be labeled permanently and legibly in a manner such that the label(s) can be read easily without removing padding or any other permanent part.

Description of the Need for the Information and Proposed Use of the Information

The labeling requirement in the standard supports the Department of Transportation's strategic goal in safety. NHTSA uses this information for enforcement purposes to ensure that manufacturers certify compliance with the Standard. State and local law enforcement use this information to enforce helmet-use laws, and consumers use the information to make decisions when purchasing motorcycle helmets.

60-Day Notice

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on May 12, 2021(86 FR 26136). The closing date for comments was July 12, 2021. The agency received no comments.

Affected Public: Motorcycle helmet manufacturers.

Estimated Number of Respondents: 45.

Frequency: On occasion.

Number of Responses: 3,250,000.

Estimated Total Annual Burden Hours: 9,100.

Estimated Total Annual Burden Cost: $1,137,500.

The 45 respondents (helmet manufacturers) produce a total of 3,250,000 annual responses (3,250,000 motorcycle helmets are manufactured annually). A manufacturer spends approximately 10 seconds per response for labeling. The estimated total annual burden hours for helmet manufacturers to label motorcycle helmets as required in FMVSS No. 218 is 9,100 burden hours (3,250,000 × 10 seconds, rounded).

Estimated Total Annual Burden Cost: $1,137,500.

NHTSA estimates that the printing and material cost per helmet is $0.35. Therefore, the estimated total annual burden cost is $1,137,500 (3,250,000 helmets produced per year × $0.35). The total estimated annual burden costs are detailed in the table below:

Number of respondents (helmet manufacturers)	Number of helmets produced annually per respondent	Printing and material cost per helmet	Annual printing and material cost per manufacturer	Total number of helmets produced annually	Estimated total annual printing and material costs
45	72,000 (Rounded)	$0.35	$25,200.00 (Rounded)	3,250,000	$1,137,500

Public Comments Invited: You are asked to comment on any aspects of this information collection, including: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended; Delegation of Authority at 49 CFR 1.95, and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–00370 Filed 1–11–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA–2020–0069]

Agency Information Collection Activities; Notice and Request for Comment; Consolidated Labeling Requirements and Procedures for Selecting Lines To Be Covered by the Theft Prevention Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for reinstatement of a previously approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a reinstatement of a previously approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. On February 23, 2018, NHTSA published a notice in the **Federal Register** soliciting public comments with a 60-day comment period. NHTSA received 1 public comment that was not relevant to the information collection request. Given the extended time period since the initial publication of that notice, NHTSA is publishing this new 60-day notice.

DATES: Written comments must be submitted by March 14, 2022.

ADDRESSES: You may submit comments, identified by the Docket No. NHTSA–2020–0069, through one of the following methods:

- *Electronic Submissions:* Go to the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590.
- *Hand Delivery/Courier:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. To be sure someone is there to help you, please call 202–366–9322 before coming.

Instructions: Each submission must include the agency name and docket number for this notice of proposed collection of information. Note all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* at any time or to Room W12–140 on the ground level of the DOT Building, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. To be sure someone is there to help you, please call 202–366–9322 before coming.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Ms. Carlita Ballard, International Policy, Fuel Economy and Consumer Programs (NRM–310), 202–366–5222, National Highway Traffic Safety Administration, W43–439, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: This document describes a collection of information for which NHTSA intends to seek OMB approval titled, Consolidated Labeling Requirements for 49 CFR part 541 and Procedures for Selecting Lines to be Covered by the Theft Prevention Standard for 49 CFR part 542.

Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, *e.g.* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information for which the agency is seeking approval from OMB.

Title: Consolidated Labeling Requirements for 49 CFR part 541 and Procedures for Selecting Lines to be Covered by the Theft Prevention Standard for 49 CFR part 542.

OMB Control Number: 2127–0539.

Form Number(s): N/A.

Type of Request: Reinstatement of a previously approved information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information:

NHTSA is seeking approval from OMB for four information collections in the Federal Motor Vehicle Theft Prevention Standard. In 1984, Congress enacted the Motor Vehicle Theft Law Enforcement Act (The Theft Act) directing NHTSA to issue a theft prevention standard requiring vehicle manufacturers to mark the major parts of high-theft lines of passenger motor vehicles. (Pub. L. 98–547.) In 1992, Congress enacted the Anti Car Theft Act (Pub. L. 102–519, codified at 49 U.S.C. Chapter 331), which expanded the parts-marking requirement to include multipurpose passenger vehicles and certain light duty trucks. In a final rule published on April 6, 2004 (69 FR 17960), the Federal Motor Vehicle Theft Prevention Standard was extended to include all passenger cars and, multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 6,000 pounds or less, all light-duty trucks (LDTs) determined to be high-theft (with a gross vehicle weight rating of 6,000 pounds or less) and all low-theft LDTs with major parts that are interchangeable with a majority of the covered major parts of those passenger motor vehicle lines subject to the theft prevention standard. The four information collections are: (1) The requirement to mark major parts of covered motor vehicles; (2) the requirement to submit to NHTSA target areas showing where the parts will be marked; (3) the requirement for manufacturers of new LDT lines to submit information to NHTSA to allow the agency to determine whether the LDT line will be required to comply with the parts-marking requirements because it is likely to be a high theft line; and (4) the requirement for manufacturers of new LDT lines to submit information to NHTSA to allow the agency to determine the LDT will be required to comply with the parts-marking requirements because it contains major parts that are interchangeable with the majority of the covered major parts of passenger motor vehicles covered by the standard. Each of the information collections are describe in more detail below.

49 CFR Part 541—Federal Motor Vehicle Theft Prevention Standard: The Theft Act requires specified parts of high-theft vehicles to be marked with vehicle identification numbers (parts-marking). Part 541 specifies performance requirements for identifying numbers or symbols to be placed on major parts of certain passenger motor vehicles to reduce the incidence of motor vehicle thefts through tracing and recovery of parts from stolen vehicles. All passenger cars and multipurpose passenger vehicles with a gross vehicle weight rating of 6,000 pounds or less, and light duty trucks with major parts that are interchangeable with the majority of the covered major parts of passenger motor vehicles covered by the standard are required to be parts-marked. Each major component part must be either labeled or affixed with the VIN and its replacement component part must be marked with the ''DOT'' symbol, the letter ''R'' and the manufacturers' logo. For each vehicle line, manufacturers must inform NHTSA of the location of the VIN marking on each part (target area) and the location of the VIN marking for the replacement part. This information is publicly available to aid law enforcement personnel in tracing stolen vehicles and their parts.

49 CFR Part 542—Procedures for Selecting Light Duty Truck Lines to be Covered by the Theft Prevention Standard: Manufacturers of light duty trucks must identify new model

introductions that are likely to be high-theft vehicle lines as defined in 49 U.S.C. 33104. The specific vehicle lines are to be selected by agreement between the manufacturer and the agency. NHTSA's procedures for selecting high-theft vehicle lines are contained in 49 CFR part 542. Manufacturers use the criteria in Appendix C of Part 541 to evaluate new lines and determine whether the new line is likely to be high theft. Next, the manufacturers submit their evaluations and conclusions, together with the underlying factual information, to NHTSA at least 15 months before introduction of the vehicle line into U.S. commerce.

Description of the Need for the Information and Proposed Use of the Information

49 CFR part 541: The identification of major parts of high theft motor vehicle lines is designed to decrease automobile theft by making it more difficult for criminals to ''chop'' vehicles into component parts and then fence such parts. The information would aid law enforcement officials at all levels of Government in the investigation of ''chop shops'' by creating evidence for prosecution of the operators for possession of stolen motor vehicle parts. Officials have great difficulty in establishing that particular parts in the possession of a ''chop shop'' are in fact stolen when the parts are not marked. Operators of both ''chop shops'' and auto body repair shops would avoid possession of parts bearing identification that links the parts to a stolen vehicle. Also, stolen parts, when recovered, could not easily be traced back to the proper owner and returned to the owner or insurer if the parts were not marked. Congress intended for major parts identification to decrease the market for stolen parts and, therefore, decrease the incentive for motor vehicle theft.

49 CFR part 542: Manufacturers of light duty trucks must identify new model introductions that are likely to be high-theft vehicle lines as defined in 49 U.S.C. 33104. Because the specific vehicle lines are to be selected by agreement between the manufacturer and NHTSA, the agency could not perform its statutory requirement without the information provided by the manufacturers.

Affected Public: Vehicle manufacturers.

This information collections affects manufacturers of passenger cars, MPVs, and trucks that are subject to the requirements in Part 541. It also affects the manufacturers of LDTs that must submit information to NHTSA to allow the agency to determine whether new LDTs must comply with the parts-marking requirements.

Estimated Number of Respondents: 21.

Based on current information, the agency estimates that there are, on average, 21 unique respondents to the four information collections in parts 541 and 542. Further, NHTSA estimates that there are approximately 21 manufacturers that are required to comply with the parts marking requirements of part 541 each year and submit information on target areas to NHTSA. For the information collections contained in part 542, NHTSA estimates that there are currently 7 manufacturers of LDTs that could be subject to the parts-marking requirements. However, these manufacturers are not required to submit information every year. Instead, these manufacturers would only need to submit information under part 542 before they introduce a new LDT line. Because NHTSA estimates that it will only receive one submission under section 542.1 and one submission under section 542.2 in each of the next three years, NHTSA estimates there will only be one respondent to these information collections annually.

Frequency: On Occasion.

Manufacturers comply with the parts-marking requirements when they manufacture new vehicles. Manufacturers submit new target area information when they introduce new vehicle lines or make changes to existing vehicle lines that require changes to where parts are marked. Manufacturers only submit information under part 542 when they introduce new LDT lines.

Number of Responses: For the four information collections in part 541 and part 542, NHTSA estimates the annual number of responses as follows: (1) 4.5 million for the parts-marking requirement; (2) 23 for submissions of target area information; (3) 1 for reporting on whether a LDT line is likely to be high-theft; and (4) 1 for reporting on whether a LDT line shares interchangeable parts with a high theft line subject to the parts-marking requirements.

Estimated Total Annual Burden Hours: 150,550.

49 CFR part 541. Current information indicates there has been a gradual increase in new vehicle manufacturer mergers, granting of parts-marking exemptions (49 CFR part 543) and vehicle design stability which have resulted in decreased production of vehicles requiring parts-marking. The agency estimates that, based on the most currently available data, there has been a decrease in the production of vehicles requiring parts-marking from 8 million vehicles to approximately 4.5 million for all manufacturers. To calculate the burden associated with the parts marking requirement, NHTSA assumes that manufacturers will use the least burdensome method for complying with the requirement, based on historical practice and the agency's current understanding of how manufacturers fit labeling into the vehicle assembly line. For the antitheft requirement, the cost of labeling the major parts (*i.e.,* a paper label with the VIN is placed on each major part) is less than the cost of stamping the VIN on each major part with a stamping machine.

To meet the Theft Prevention Standard, the agency estimates that the time to number and affix the average of 14 labels to each vehicle is approximately 2 minutes. If 4.5 million vehicles are covered, the hourly burden for labeling 4.5 million motor vehicles would be 150,000 hours (4.5 million cars × 2 minutes per car ÷ 60 minutes in an hour).

The agency estimates that the time to stamp both the engine and transmission will take approximately 1 minute. If 4.5 million vehicles are covered, the total burden for stamping is estimated to total 75,000 hours (4.5 million cars × 1 minute per car ÷ 60 minutes in an hour). Please note that in this analysis each vehicle would either have its major parts labeled or stamped, *but not both.* We will use the highest hour number in the hour burden estimate.

Each manufacturer of vehicles that are required to be parts-marked must submit reports of the target area locations for the labels or stamping. The target area designated for a part on a vehicle line shall be maintained for the duration of the production of the vehicle line, unless a restyling of the part makes it no longer practicable to mark within the original target area. If there is such a restyling, the vehicle manufacturer shall inform NHTSA of that fact and provide a new target area submission.

NHTSA estimates that approximately 70 target area responses will be submitted to the agency in the next three years, or approximately 23 submissions each year. This estimate is based on the number of the submissions over the three-year period for MYs 2014–2016. Specifically, 18, 29 and 23 target areas were submitted for MYs 2014, 2015 and 2016, respectively. Due to the decreased production of vehicles requiring parts-marking, the agency estimates on an average, there will be a total of 23 target areas submitted by approximately 21 manufacturers. The

average time to prepare and submit the target areas will be 20 hours for each submission. The burden hour for submissions will be 460 hours (23 submissions × 20 hours).

NHTSA estimates the labor cost associated with this collection of information by (1) applying the appropriate average hourly labor rate published by the Bureau of Labor Statistics (BLS), (2) dividing by 0.704 [1] (70.4%), for private industry workers to obtain the total cost of compensation, and (3) multiplying by the estimated burden hours for each respondent type. NHTSA estimates the labor costs associated with preparing and affixing labels to 14 major parts under § 541.5(a) using the average wage for manufacturers and assemblers in the motor vehicle manufacturing industry (Standard Occupational Classification #51–2000), which BLS estimates to be $23.18 [2] per hour. Using this estimate, NHTSA estimates the total compensation costs per hour to be $32.93 per hour ($23.18 per hour ÷ 0.704). The labor cost per vehicle is estimated to be $1.10 ($32.93 × 2 minutes/60), and the total labor cost for preparing and affixing labels to the estimated 4.5 million vehicles each year is estimated to be $4,950,000 ($1.10 × 4.5 million vehicles).

NHTSA estimates the labor costs associated with developing and submitting reports of the target area locations for labels or stamping under § 541.5(e) using the average wage for compliance officers in the motor vehicle manufacturing industry (Standard Occupational Classification #13–1041), which BLS estimates to be $42.30 [3] per hour. Using this estimate, NHTSA estimates the total compensation costs per hour to be $60.09 per hour ($42.30 per hour ÷ 0.704). The labor cost to prepare each report submitted under § 541.5(e) is estimated to be $1,201.80 ($60.09 × 20 hours per submission), and the total labor cost for the estimated 23 target area reports that will be submitted each year is estimated to be $27,641 ($1,201.80 × 23 reports, rounded).

We estimate that Part 541 will impose an annual reporting burden of 150,460 burden-hours, and the total estimated labor costs associated with these burden hours endured by the responding manufacturers are $4,977,641 ($4,950,000 + $27,641).

49 CFR part 542. Currently there are seven manufacturers who produce LDTs that could be subject to the parts-marking requirements. While NHTSA estimates that all seven are still active in the U.S. market, only manufacturers that introduce new LDT lines would be required to report to NHTSA under 49 CFR 542.1 and 49 CFR 542.2. On average, NHTSA estimates that approximately that one LDT line will be introduced each year for which the manufacturer will need to submit information under § 542.1 and one LDT line will be introduced for which the manufacturer will need to submit information under § 541.2.

Section 542.1 specifies procedures for motor vehicle manufacturers and the agency to follow in the determination of new LDT lines that are likely to have a theft rate above or below the median theft rate of 3.5826. This section also provides the manufacturers with notice of their rights and responsibilities during the selection and appeals process. On average, NHTSA estimates that there will be approximately one manufacturer submittal a year. NHTSA further estimates that the burden for each § 542.1 submittal is approximately 45 hours. Therefore, the total annual burden for § 542.1 submittals is estimated to be 45 hours.

Section 542.2 specifies procedures for motor vehicle manufacturers and NHTSA to follow in the determination of new LTD lines that will likely have a low theft rate and have major parts interchangeable with a majority of the major parts of a passenger motor vehicle line subject to the parts-marking requirements. This section also provides the manufacturers with notice of their rights and responsibilities during the selection and appeal process. On average, NHTSA estimates that there will be approximately one manufacturer submittal a year. NHTSA further estimates that the burden for each § 542.2 submittal is approximately 45 hours. Therefore, the total annual burden for § 542.2 submittals is estimated to be 45 hours.

NHTSA estimates the labor cost associated with this collection of information by (1) applying the appropriate average hourly labor rate published by the Bureau of Labor Statistics (BLS), (2) dividing by 0.704 [4] (70.4%), for private industry workers to obtain the total cost of compensation, and (3) multiplying by the estimated burden hours for each respondent type.

Table 1 below provides a summary of the estimated burden hours and Table 2 provides a summary of the labor costs associated with the burden hours.

TABLE 1—TOTAL ESTIMATED BURDEN HOURS FOR PARTS 541 AND 542

IC No.	ICR title	Type of IC	Estimated number of respondents	Estimated number of responses	Estimated time per response	Total burden hours
1	541: Parts-Marking on 14 major parts (49 CFR 541.5(a)).	Third-Party Disclosure	21	4.5 million	2 minutes	150,000
2	541: Reporting of Target Areas to NHTSA	Reporting	21	23	20 hours	460
3	542: Submissions for Determination of whether LDT Line is High Theft.	Reporting	1	1	45 hours	45
4	542: Submission for Determination of whether LDT line Shares Interchangeable Parts with High Theft Line.	Reporting	1	1	45 hours	45
Total						150,550

[1] *See* Table 1. Employer Costs for Employee Compensation by ownership (Mar. 2021), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed August 31, 2021).

[2] May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 336100—Motor Vehicle Manufacturing, *Assemblers and Fabricators, Occupation Code 51–2000, https://www.bls.gov/oes/current/oes_nat.htm* (accessed August 31, 2021).

[3] May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 336100—Motor Vehicle Manufacturing, *Compliance Officer, Occupation Code 13–1041, https://www.bls.gov/oes/current/oes_nat.htm* (accessed August 31, 2021).

[4] *See* Table 1. Employer Costs for Employee Compensation by ownership (Mar. 2021), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed August 31, 2021).

TABLE 2—ESTIMATED LABOR COSTS FOR BURDEN HOURS

ICR No.	ICR title	Labor cost per hour	Time per response	Labor cost per response	Total burden hours	Total labor cost
1	541: Parts-Marking on 14 major parts (49 CFR 541.5(a)	$32.93	2 minutes	$1.10	150,000	$4,950,000
2	541: Reporting of Target Areas to NHTSA	60.09	20 hours	1,201.80	460	27,641.40 27,641
3	542: Submissions for Determination of whether LDT Line is High Theft.	60.09	45 hours	2,704.05	45	2,704.05 2,704
4	542: Submission for Determination of whether LDT line Shares Interchangeable Parts with High Theft Line.	60.09	45 hours	2,704.05	45	2,704.05 2,704
Total					150,550	4,983,049

Estimated Total Annual Cost Burden: $24,003,000.

49 CFR part 541: NHTSA assumes that most manufacturers will use the less expensive method of labeling the major parts on vehicles, and not stamp the VINs onto major parts, based on historical practice and the agency's current understanding of how manufacturers fit labeling into the vehicle assembly line. The cost of this collection of information will comprise of printing costs for the labels affixed to the vehicle parts. NHTSA estimates that the average cost to print each label is $0.381. There are an average 14 parts per vehicle to label; therefore, the printing cost per vehicle is $5.33. At present, the agency estimates that 4.5 million motor vehicles annually must have their major parts marked. The total annual costs are estimated to be $24,003,000 for label identifiers ($5.33 × 4.5 million vehicles).

Number of parts labeled per vehicle	Printing cost per label	Total printing cost per vehicle	Number of vehicles per year	Total estimated printing cost
14	$0.381	$5.33	4.5 million	$24,003,000

Target area submissions require no additional costs to the respondents above and beyond the labor costs.

49 CFR parts 542: NHTSA estimates that meeting Part 542 involves no additional costs to the respondents above and beyond the labor costs.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information collection; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–00372 Filed 1–11–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Modifications to Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before January 27, 2022.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on January 7, 2022.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
9221–M	Applied Pressure Vessels, Inc	173.302a(a)	To modify the special permit to authorize an additional cylinder. (modes 1, 2, 3, 4).
10945–M	Structural Composites Industries LLC.	173.302a(a), 173.304a(a), 175.3, 180.205.	To modify the special permit to authorize additional hazardous materials. (modes 1, 2, 3, 4, 5).
16410–M	Snap-On Incorporated		To modify the special permit to authorize lithium ion or metal cells or batteries conforming to 49 CFR 173.185(c)(iv). (mode 1).
21139–M	KULR Technology Corporation.	172.200, 172.700(a)	To modify the special permit to increase the authorized aggregate energy content of a single inner package to 2.5 kWh. (modes 1, 2).
21163–M	United Initiators, Inc	178.345–10(b)(1)	To modify the special permit to clarify the synopsis and to authorize customers to load and unload the packagings. (mode 1).
21167–M	KULR Technology Corporation.	173.185(a)(1)	To modify the special permit to increase the authorized aggregate energy content of a single inner package to 2.5 kWh. (modes 1, 2, 3, 4).
21193–M	KULR Technology Corporation.	172.200, 172.300, 172.700(a), 172.400, 172.500, 172.600, 173.185(f).	To modify the special permit to increase the authorized aggregate energy content of a single inner package to 2.5 kWh. (modes 1, 2).

[FR Doc. 2022–00451 Filed 1–11–22; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Actions on Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before February 11, 2022.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on January 07, 2022.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
Special Permits Data—Granted			
14574–M	CMC Materials EC, Inc	180.407(c), 180.407(e), 180.407(f).	To modify the special permit to authorize an additional cargo tank.
20351–M	Roeder Cartage Company, Incorporated.	180.407(c), 180.407(e), 180.407(f).	To modify the special permit to authorize an additional cargo tank.
21069–M	Uttam Composites, LLC	173.302a, 178.71(l)(1)	To modify the special permit to authorize ISO 9712 as alternative to ISO 11515:2013 Section 9.1.1 certification.
21193–M	KULR Technology Corporation.	172.200, 172.300, 172.700(a), 172.400, 172.500, 172.600, 173.185(f).	To modify the special permit to authorize alternative inner packaging.
21216–M	Bren-Tronics, Inc	172.101(j)	To modify the special permit to authorize alternative dunnage material.
21245–N	Rivian Automotive, LLC	172.101(j)	To authorize the transportation of lithium batteries in excess of 35 kg by cargo-only aircraft.
21281–N	Highline-warren, LLC	173.156(c)(1)(iv)	To authorize the transportation in commerce of limited quantities of certain hazardous materials on pallets that weight 1,350 pounds.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
Special Permits Data—Denied			
21254–N	Praxair Distribution, Inc	173.301(f)(1)	To authorize the transportation in commerce Chlorine (UN1017) in DOT specification cylinders, UN standard cylinders prescribed in part 178 of 49 CFR, DOT special permit cylinders, or TC cylinders which are not equipped with pressure relief devices.
21290–N	Orion Engineered Carbons LLC.	171.23(b)(10)(iv)(A)	To authorize the transportation in commerce of Dinitrogen Tetroxide in non-DOT specification cylinders.
Special Permits Data—Withdrawn			
21251–N	Luxfer Inc	173.302a(a), 180.205	To authorize the manufacture, marking, sale and use of non-DOT specification fully wrapped composite cylinders with load sharing aluminum liner with either aramid fiber or carbon fiber reinforcement, for use in aircraft with a limited number of filling cycles.

[FR Doc. 2022–00452 Filed 1–11–22; 8:45 am]
BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Prompt Payment Interest Rate; Contract Disputes Act

AGENCY: Bureau of the Fiscal Service, Treasury.

ACTION: Notice of prompt payment interest rate; Contract Disputes Act.

SUMMARY: For the period beginning January 1, 2022, and ending on June 30, 2022, the prompt payment interest rate is 1⅝ per centum per annum.

DATES: Applicable January 1, 2022, to June 30, 2022.

ADDRESSES: *Comments or inquiries may be mailed to:* E-Commerce Division, Bureau of the Fiscal Service, 401 14th Street SW, Room 306F, Washington, DC 20227. Comments or inquiries may also be emailed to *PromptPayment@fiscal.treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas M. Burnum, E-Commerce Division, (202) 874–6430; or Thomas Kearns, Senior Counsel, Office of the Chief Counsel, (202) 874–7036.

SUPPLEMENTARY INFORMATION: An agency that has acquired property or service from a business concern and has failed to pay for the complete delivery of property or service by the required payment date shall pay the business concern an interest penalty. 31 U.S.C. 3902(a). The Contract Disputes Act of 1978, Sec. 12, Public Law 95–563, 92 Stat. 2389, and the Prompt Payment Act, 31 U.S.C. 3902(a), provide for the calculation of interest due on claims at the rate established by the Secretary of the Treasury.

The Secretary of the Treasury has the authority to specify the rate by which the interest shall be computed for interest payments under section 12 of the Contract Disputes Act of 1978 and under the Prompt Payment Act. Under the Prompt Payment Act, if an interest penalty is owed to a business concern, the penalty shall be paid regardless of whether the business concern requested payment of such penalty. 31 U.S.C. 3902(c)(1). Agencies must pay the interest penalty calculated with the interest rate, which is in effect at the time the agency accrues the obligation to pay a late payment interest penalty. 31 U.S.C. 3902(a). ''The interest penalty shall be paid for the period beginning on the day after the required payment date and ending on the date on which payment is made.'' 31 U.S.C. 3902(b).

Therefore, notice is given that the Secretary of the Treasury has determined that the rate of interest applicable for the period beginning January 1, 2022, and ending on June 30, 2022, is 1⅝ per centum per annum.

Timothy E. Gribben,

Commissioner, Bureau of the Fiscal Service.

[FR Doc. 2022–00391 Filed 1–11–22; 8:45 am]
BILLING CODE 4810–AS–P

DEPARTMENT OF VETERANS AFFAIRS

Loan Guaranty: Assistance to Eligible Individuals in Acquiring Specially Adapted Housing; Cost-of-Construction Index

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) announces that the aggregate amounts of assistance available under the Specially Adapted Housing (SAH) grant program will increase by .85 percent for fiscal year (FY) 2022.

DATES: The increases in the aggregate amounts outlined in this notice are effective as of October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Terry Rouch, Assistant Director for Loan Policy and Valuation, Loan Guaranty Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, 202–632–8862. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In accordance with 38 U.S.C. 2102(e), 38 U.S.C. 2102A(b)(2), 38 U.S.C. 2102B(b)(2) and 38 CFR 36.4411, the Secretary of Veterans Affairs announces for FY 2022 the aggregate amounts of assistance available to veterans and Service members eligible for SAH program grants.

Section 2102(e)(2) authorizes the Secretary to increase the aggregate amounts of SAH assistance annually based on a residential home cost-of construction index. Per 38 CFR 36.4411(a), the Secretary uses the Turner Building Cost Index for this purpose. Such increase will be equal to the percentage by which the Turner Building Cost Index for the most recent calendar year exceeds that of the next preceding calendar year. If, however, the Turner Building Cost Index for the most recent full calendar year is equal to or less than the next preceding calendar year, the percentage increase will be zero. See 38 CFR 36.4411(b).

In the most recent quarter for which the Turner Building Cost Index is available, second quarter of 2021, the index showed an increase of .85 percent over the index value listed for second quarter of 2020. *http://www.turnerconstruction.com/cost-index* (last visited August 2, 2021). Pursuant to 38 CFR 36.4411(a), therefore, the aggregate

amounts of assistance for SAH grants made pursuant to 38 U.S.C. 2101(a) and 2101(b) will increase by .85 percent for FY 2022.

Sections 2102A(b)(2) and 2102B(b)(2) require the Secretary to apply the same percentage calculated pursuant to section 2102(e) to grants authorized pursuant to sections 2102A and 2102B. As such, the maximum amount of assistance available under these grants will also increase by .85 percent for FY 2022.

The increases are effective as of October 1, 2021. 38 U.S.C. 2102(e), 38 U.S.C. 2102A(b)(2) and 38 U.S.C. 2102B(b)(2).

SAH: Aggregate Amounts of Assistance Available During FY 2022

Section 2101(a) Grants and Temporary Residence Adaptation (TRA) Grants

Effective October 1, 2021, the aggregate amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2101(a) will be $101,754 during FY 2022.

The maximum TRA grant made to an individual who satisfies the eligibility criteria under 38 U.S.C. 2101(a) and 2102A will be $40,983 during FY 2022.

Section 2101(b) Grants and TRA Grants

Effective as of October 1, 2021, the aggregate amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2101(b) will be $20,387 during FY 2022.

The maximum TRA grant made to an individual who satisfies the eligibility criteria under 38 U.S.C. 2101(b) and 2102A will be $7,318 during FY 2022.

Section 2102B Grants

Effective as of October 1, 2021, the amount of assistance available for grants made pursuant to 38 U.S.C. 2102B will be $93,356 during FY 2022; however, the Secretary may waive this limitation for a veteran if the Secretary determines a waiver is necessary for the rehabilitation program of the veteran.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on December 21,2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2022–00369 Filed 1–11–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 87 Wednesday,

No. 8 January 12, 2022

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4192–P]

RIN 0938–AU30

Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (MA) (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations to implement changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and pharmacy price concessions. This proposed rule would also revise regulations related to dual eligible special needs plans (D–SNPs), other special needs plans, and cost contract plans.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by March 7, 2022.

ADDRESSES: In commenting, please refer to file code CMS–4192–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4192–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4192–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Marna Metcalf Akbar, (410) 786–8251, or Melissa Seeley, (212) 616–2329—General Questions.
Jacqueline Ford, (410) 786–7767—Part C Issues.
PartCandDStarRatings@cms.hhs.gov—Part C and D Star Ratings Issues.
Marna Metcalf-Akbar, (410) 786–8251—D–SNP Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Acronyms

ACC Automated Criteria Check
ANOC Annual Notice of Change
ARB At-Risk Beneficiaries
BBA Bipartisan Budget Act
CAHPS Consumer Assessment of Healthcare Providers and Systems
CMS Centers for Medicare & Medicaid Services
COI Collection of Information
COVID–19 Coronavirus 2019 Disease
C–SNP Chronic Condition Special Needs Plan
DME Durable Medical Equipment
D–SNP Dual Eligible Special Needs Plan
EOC Evidence of Coverage
FFS Fee-for-Service
FIDE SNP Fully Integrated Dual Eligible Special Needs Plan
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIDE SNP Highly Integrated Dual Eligible Special Needs Plan
HOS Health Outcomes Survey
HPMS Health Plan Management System
HSD Health Service Delivery
ICR Information Collection Requirement
I–SNP Institutional Special Needs Plan
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACPAC Medicaid and CHIP Payment and Access Commission
MA–PD Medicare Advantage Prescription Drug
MCO Managed Care Organization
MCMG Medicare Communications and Marketing Guidelines
MACPAC Medicaid and CHIP Payment and Access Commission
MedPAC Medicare Payment Advisory Commission
MIPPA Medicare Improvements for Patients and Providers Act
MLR Medical Loss Ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MMP Medicare-Medicaid Plan
MOC Model of Care
MOOP Maximum Out-of-Pocket
NAMBA National Average Monthly Bid Amount
NEMT Non-emergency Medical Transportation
NMM Network Management Module
OACT Office of the Actuary
OMB Office of Management and Budget
PACE Programs of All-Inclusive Care for the Elderly
PBP Plan Benefit Package
PDE Prescription Drug Event
PDP Prescription Drug Plan
PHE Public Health Emergency
PRA Paperwork Reduction Act
RFI Request for Information
RFA Regulatory Flexibilities Act
SAE Service Area Expansion
SB Summary of Benefits
SNP Special Needs Plan
SSA Social Security Administration
TPMO Third-Party Marketing Organization

I. Executive Summary

A. Purpose

Over 27 million individuals receive their Medicare benefits through Medicare Advantage (MA or Part C), including plans that offer Medicare Prescription Drug Benefit (Part D) coverage. Over 24 million individuals receive Part D coverage through standalone Part D plans. The primary purpose of this proposed rule is to implement changes to the MA and Part D programs. The proposed provisions in this rule will reduce out-of-pocket prescription drug costs; improve price transparency and market competition under the Part D program; strengthen consumer protections to ensure MA and Part D beneficiaries have accurate and accessible information about their health plan choices and benefits; strengthen CMS oversight of MA and Part D plans; and improve the integration of Medicare and Medicaid programs for individuals enrolled in dual eligible special needs plans (D–SNPs). The proposed D–SNP provisions build on the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) (Pub. L. 111–148), the

Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123), CMS experience administering the MA and Part D programs, and the experiences of Medicare-Medicaid Plans (MMPs) to better align and integrate benefits for dually eligible beneficiaries.

B. Summary of Major Provisions

1. Enrollee Participation in Plan Governance (§ 422.107)

Managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.[1] We are proposing to require that any MA organization offering a D–SNP must establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences. We also propose that the committee include a reasonably representative sample of individuals enrolled in the D–SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. We believe that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by managed care plans and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals.

2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)

Section 1859(f)(5)(A)(ii)(I) of Social Security Act (hereafter known as the Act) requires each special needs plan (SNP) to conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs. We codified this requirement at § 422.101(f)(1)(i) as part of the model of care requirements for all MA SNPs. Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status. Many dually eligible individuals contend with multiple social risk factors such as homelessness, food insecurity, lack of access to transportation, and low levels of health literacy.[2] Building on CMS's experience with other programs and model tests, we propose to require that all SNPs include standardized questions on housing stability, food security, and access to transportation as part of their health risk assessments.

Our proposal would result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We believe this knowledge would better equip the MA organizations offering these SNPs to meet the needs of their members. Our proposal would also equip MA organizations with person-level information that would help them better connect people to covered services and social service organizations and public programs that can help resolve housing instability, food insecurity, or transportation challenges. Our proposal also would have the benefit of standardizing these data elements collected through HRAs, which we believe would eventually facilitate better data exchange among SNPs (when an individual transitions from one SNP to another) as well as facilitate the care management requirements under section 1859(f)(5) of the Act.

3. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§§ 422.2 and 422.107)

Dually eligible individuals have an array of choices for how to receive their Medicare coverage. We propose several changes to how we define fully integrated dual eligible special needs plan (FIDE SNP) and highly integrated dual eligible special needs plan (HIDE SNP) to help differentiate various types of D–SNPs, clarify options for beneficiaries, and improve integration.

We propose to require, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the State Medicaid agency. We propose to require that each HIDE SNP's capitated contract with the State apply to the entire service area for the D–SNP for plan year 2025 and subsequent years. Consistent with existing policy outlined in sub-regulatory guidance, we also propose to codify specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.

We believe these proposals will create better experiences for beneficiaries and move FIDE SNPs and HIDE SNPs toward greater integration, which we believe is a purpose of the amendments to section 1859(f) of the Act regarding integration made by section 50311(b) of the BBA of 2018.

4. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

Section 164 of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) amended section 1859(f) of the Act to require that a D–SNP contract with the State Medicaid agency in each State in which the D–SNP operates to provide benefits, or arrange for the provision of Medicaid benefits, to which an individual is entitled. States have used these contracts to better integrate care for dually eligible individuals. We propose to codify new pathways through which States can use these contracts to require that certain D–SNPs with exclusively aligned enrollment (a) establish contracts that only include one or more D–SNPs within a State, and (b) integrate materials and notices for enrollees. Where States choose to use this opportunity, it would help individuals better understand their coverage. Because Star Ratings are assigned at the contract level, this proposal would also provide the State and the public with greater transparency on the quality ratings for the D–SNP(s), helping CMS and States better identify disparities between dually eligible beneficiaries and other beneficiaries and target interventions accordingly.

We also propose mechanisms to better coordinate State and CMS monitoring and oversight of certain D–SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems. Collectively, our proposals would improve Federal and State oversight of certain D–SNPs (and their affiliated Medicaid managed care plans) through greater information-sharing among government regulators.

5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)

In order to ensure that MA plan benefits do not discriminate against higher cost, less healthy enrollees, MA plans are required to establish a limit on beneficiary cost-sharing for Medicare Part A and B services after which the plan pays 100 percent of the service costs. Current guidance allows MA plans, including D–SNPs, to not count Medicaid-paid amounts or unpaid amounts toward this maximum out-of-pocket (MOOP) limit, which results in

[1] Centers for Medicare & Medicaid Services. (n.d.). *Person & Family Engagement Strategy: Sharing with Our Partners.* Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategy-Summary.pdf.*

[2] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2020. Retrieved from: *https://www.macpac.gov/wp-content/uploads/2020/06/June-2020-Report-to-Congress-on-Medicaid-and-CHIP.pdf.*

increased State payments of Medicare cost-sharing and disadvantages providers serving dually eligible individuals in MA plans. We propose to specify that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs for Part A and Part B services) is calculated based on the accrual of all cost-sharing in the plan benefit, regardless of whether that cost sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing. The proposal would result in more equitable payment for MA providers serving dually eligible beneficiaries. We project that our proposal would result in increased bid costs for the MOOP for some MA plans. A portion of those higher bid costs would result in increased Medicare spending of $3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of $2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals $600 million over 10 years. The net 10-year cost estimate for the proposal is $614.8 million.

6. Special Requirements During a Disaster or Emergency (§ 422.100(m))

In order to ensure enrollees have uninterrupted access to care, current regulations provide for special requirements at § 422.100(m) for MA plans during disasters or emergencies, including public health emergencies (PHEs), such as requirements for plans to cover services provided by non-contracted providers and to waive gatekeeper referral requirements. The timeframe during which these special rules apply can be very limited depending on the type or scope of the disaster or emergency, while other situations, like the current PHE for COVID–19, may have an uncertain end date. Currently, the regulation states that a disaster or emergency ends (thus ending the obligation for MA plans to comply with the special requirements) the earlier of when an end date is declared or when, if no end date was identified in the declaration or by the official that declared the disaster or emergency, 30 days have passed since the declaration. This has caused some confusion among stakeholders, who are unsure whether to continue special requirements during a state of disaster or emergency after 30 days, or whether those special requirements do not apply after the 30-day time period has elapsed. This proposal would clarify the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services throughout the disaster or emergency period, especially when the end date is unclear and the period renews several times. We also propose to codify an additional condition for triggering the special requirements imposed by § 422.100(m)(1), specifically that there is a disruption in access to health care at the same time as the disaster or emergency.

7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

We are proposing to amend § 422.116 to require applicants to demonstrate that they meet the network adequacy standards for the pending service area as part of the MA application process for new and expanding service areas and to adopt a time-limited 10-percentage point credit toward meeting the applicable network adequacy standards for the application evaluation. Under our current rules, we require that an applicant attest that it has an adequate provider network that provides enrollees with sufficient access to covered services, and we will not deny an application based on the evaluation of the MA plan's network. Network adequacy reviews are a critical component for confirming that access to care is available for enrollees. As such, we believe that requiring applicants to meet network adequacy standards as part of the application process will strengthen our oversight of an organization's ability to provide an adequate network of providers to deliver care to MA enrollees. This change would also provide MA organizations with information regarding their network adequacy ahead of bid submissions, mitigating current issues with late changes to the bid that may affect the bid pricing tool. Finally, we understand that it may be difficult for applicants to have a full network in place almost one year ahead of the beginning of the contract as the proposed change for network adequacy rules would require. Therefore, the proposal includes a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for new or expanding service area applicants. Once the contract is operational, the 10-percentage point credit would no longer apply and MA organizations would need to meet full compliance.

8. Allow CMS To Calculate Star Ratings for Certain Measures for 2023 Given Impacts of the COVID–19 Public Health Emergency (§ 422.166)

Due to the scope and duration of the COVID–19 public health emergency, we codified a change to the 2022 Star Ratings methodology in the interim final rule titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (CMS–3401–IFC; 85 FR 54820), published in the **Federal Register** and effective on September 2, 2020, which included a change to our extreme and uncontrollable circumstances policy at 42 CFR 422.166(i)(11) to make it possible for us to calculate 2022 Star Ratings for MA contracts. We propose making a technical change at § 422.166(i)(12) to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey. Specifically, these measures are Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control. Without this technical change, CMS will be unable to calculate measure-level 2023 Star Ratings for these measures for any MA contract.

9. Past Performance Methodology To Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)

In the previous rulemaking cycle, CMS modified the past performance methodology, revising the elements that are reviewed to determine if CMS should permit an organization to enter into or expand an existing contract. The current regulatory language prohibits an organization from expanding or entering into a new contract if it has a negative net worth or has been under sanction during the performance timeframe. We are proposing to include an organization's record of Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.

10. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)

CMS has seen an increase in beneficiary complaints associated with and has received feedback from beneficiary advocates and stakeholders concerned about the marketing practices

of third-party marketing organizations (TPMOs) who sell multiple MA and Part D products. In 2020, we received a total of 15,497 complaints related to marketing. In 2021, excluding December, the total was 39,617. We are unable to say that every one of the complaints are a result of TPMO marketing activities, but based on a targeted search, we do know that many are related to TPMO marketing. In addition, we have seen an increase in third party print and television ads, which appears to be corroborated by state partners. Through rulemaking, we will address the concerns with TPMOs by means of the following three proposed updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V: (1) We propose to define TPMOs in the regulation at §§ 422.2260 and 423.2260 to remove any ambiguity associated with MA plans/Part D sponsors responsibilities for TPMO activities associated with the selling of MA and Part D plans, (2) we propose to add a new disclaimer that would be required when TPMOs market MA plans/Part D products (§§ 422.2267(e) and 423.2267(e)), and (3) we propose an update to §§ 422.2274 and 423.2274 to require additional plan oversight requirements associated with TPMOs, in addition to what is already required under §§ 422.504(i) and 423.505(i) if the TPMO is a first tier, downstream or related entity (FDRs).

CMS' January 2021 final rule (86 FR 5864) did not require notice and taglines, based on the HHS Office for Civil Rights repeal of certain notice and tagline requirements associated with section 1557 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). In the months since the publication of this rule, CMS gained additional insight regarding the void created by the lack of notification requirements. Based on the significant population (12.2 percent) of those 65 and older who speak a language other than English in the home and complaints CMS received through our Complaint Tracking Module, we propose to require MA and Part D plans create a multi-language insert that would inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. As a note, CMS provides plans a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S. We propose to require the inclusion of the multi-language insert whenever a Medicare beneficiary is provided a CMS required material (for example, Evidence of Coverage, Annual Notice of Change, enrollment form, Summary of Benefits) as defined under §§ 422.2267(e) and 423.2267(e). Finally, we propose codifying a number of current sub-regulatory communications and marketing requirements that were inadvertently not included during the previous updates to 42 CFR parts 422 and 423, subpart V.

11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460 and 423.2460)

To improve transparency and oversight concerning the use of Trust Fund dollars, we are proposing to reinstate the detailed medical loss ratio (MLR) reporting requirements that were in effect for contract years 2014 to 2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. In addition, we are proposing the collection of additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees under MA and Part D plans, and the impacts of recent rule changes that removed limitations on certain expenditures that count toward the 85 percent MLR requirement.

12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)

The ''negotiated prices'' of drugs, as the term is currently defined in § 423.100, must include all network pharmacy price concessions except those contingent amounts that cannot ''reasonably be determined'' at the point-of-sale. Under this exception, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a sponsor ultimately pays for a drug, based on the rationale that these amounts are contingent upon performance measured over a period that extends beyond the point of sale and thus cannot reasonably be determined at the point of sale.

We are proposing to eliminate this exception for contingent pharmacy price concessions. We are proposing to delete the existing definition of ''negotiated prices'' at § 423.100 and to adopt a new definition for the term ''negotiated price'' at § 423.100, which we are proposing to define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). To implement the proposed change at the point of sale, Part D sponsors and their pharmacy benefit managers (PBMs) would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. The proposed changes would take effect on January 1, 2023, meaning, if finalized, Part D sponsors would need to account for the changes in the bids that they submit for contract year 2023.

We are also proposing to add a definition of ''price concession'' at § 423.100. Although ''price concession'' is a term important to the adjudication of the Part D program, it has not yet been defined in the Part D statute, Part D regulations, or sub-regulatory guidance. We are proposing to define price concession in a broad manner to include all forms of discounts and direct or indirect subsidies or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors.

C. Summary of Costs and Benefits

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Summary of Major Provisions of Rule	Description	Impact
1. Enrollee Participation in Plan Governance (§ 422.107)	We propose to require that that any MA organization offering a D-SNP must establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences.	There is on average an annual impact of $0.9 million for establishing and maintaining these advisory committees with however a wide range of variability.
2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)	Building on CMS's experience with other programs and model tests, we propose to require that all SNPs include standardized questions on housing stability, food security, and access to transportation as part of their health risk assessments.	For the initial year of implementation, there is an impact on Medicare Advantage special needs plans to update systems. We are unable to reliably estimate the additional burden in subsequent years.
3. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)	We propose to require, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the State Medicaid agency. We propose to require that each HIDE SNP's capitated contract with the State apply to the entire service area for the D-SNP for plan year 2025 and subsequent years. Consistent with existing policy outlined in sub-regulatory guidance, we also propose to codify specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.	There is a one-time impact to update contracts.
4. Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107)	We propose to codify new pathways through which States can use the State Medicaid agency contracts to require that certain D-SNPs with exclusively aligned enrollment (a) apply and request to establish contracts that only include one or more D-SNP within a State, and (b) integrate materials and notices for enrollees. We also propose mechanisms to better coordinate State and CMS monitoring and oversight of certain D-SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems.	There is a one-time $1.1 million impact shared among the Federal Government, State governments, and MA organizations to create new contracts and to update systems to review the new materials.

Summary of Major Provisions of Rule	Description	Impact
5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)	We propose to specify that the maximum out-of-pocket limit in an MA plan (after which the plan pays 100 percent of MA costs) is calculated based on the accrual of all cost- sharing in the plan benefit, whether that cost sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost- sharing.	The proposal would increase Medicare spending by $3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of $2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals $600 million over 10 years. The net 10-year cost estimate for the proposal is $614.8 million.
6. Special Requirements during a Disaster or Emergency (§ 422.100(m))	This proposal would clarify the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services throughout a disaster or emergency (including PHEs) period, especially when the end date is unclear and the period renews several times. We also propose an additional condition, that there is a disruption in access to health care for enrollees, for triggering the special requirements imposed by § 422.100(m)(1).	None anticipated.
7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)	We are proposing to amend § 422.116 to require an applicant to demonstrate compliance with network adequacy standards as part of the MA application process for new and expanding service areas and to adopt a time-limited 10 percentage point credit toward meeting the applicable network adequacy standards for the application evaluation.	None anticipated.
8. Allow CMS to Calculate Star Ratings for Certain Measures for 2023 Given Impacts of the COVID-19 Public Health Emergency (§ 422.166)	We propose making a technical change at § 422.166(i)(12) to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey.	None anticipated.
9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)	We are proposing to include Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
10. Marketing and Communications Requirements on MA and Part D Plans to Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)	Through rulemaking, we will address the concerns with TPMOs by means of proposed updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V. We propose to require MA and Part D plans to create a multi-language insert that would inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. We propose to require the inclusion of the multi-language insert whenever a Medicare beneficiary is provided a CMS required material as defined under §§ 422.2267(e) and 423.2267(e). Lastly, we propose codifying a number of current sub-regulatory communications and marketing requirements.	There is an annual impact of $0.3 million to print the multi-language insert.
11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460, 422.2490, and 423.2460)	To improve transparency and oversight concerning the use of Trust Fund dollars, we are proposing to reinstate the detailed MLR reporting requirements that were in effect for contract years 2014–2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount. In addition, we are proposing the collection of additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees, and the impacts of recent rule changes.	Medicare Advantage organizations and Part D sponsors are expected to pay an additional $268.6 million in remittances to the Treasury over a 10-year period. There is an annual additional $2.3 million administrative cost to MA organizations and Part D sponsors for complying with these provisions, as well as a $0.2 million cost to the government for Federal contractors.

Summary of Major Provisions of Rule	Description	Impact
12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)	We are proposing to eliminate the exception for pharmacy price concessions that cannot reasonably be determined at the point of sale. We are also proposing to delete the existing definition of "negotiated prices" at § 423.100 and to adopt a new definition for the term "negotiated price" at § 423.100, which we are proposing to define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary. Lastly, we are proposing to add a definition of "price concession" at § 423.100.	Requiring pharmacy price concessions in the negotiated price is expected to reduce beneficiary costs by $21.3 billion over 10 years, or approximately 2 percent. In addition, the proposal is estimated to have $40 billion in Part D costs for the government over 10 years due to increases in direct subsidy and low-income premium subsidy payments, which represents a 3 percent increase. Manufacturers would save about $14.6 billion over 10 years. We expect a one-time cost to plan sponsors of $0.1 million to update systems.

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II. Provisions of the Proposed Rule

A. Improving Experiences for Dually Eligible Individuals

1. Overview and Background

Over 11 million people are concurrently enrolled in both Medicare and Medicaid. Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in: (1) Missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation.[3]

''Integrated care'' refers to delivery system and financing approaches that—

- Maximize person-centered coordination of Medicare and Medicaid services, across primary, acute, long-term, behavioral, and social domains;
- Mitigate cost-shifting incentives, including total-cost-of-care accountability across Medicare and Medicaid; and
- Create seamless experiences for beneficiaries.

There is a range of approaches to integrating Medicare and Medicaid benefits or financing for dually eligible individuals, including through demonstrations and existing programs. The most prevalent forms of integrated care use capitated financing, including capitation of health plans to cover the full range of Medicare and Medicaid services. Some States have carefully married MA dual eligible special needs plans (D–SNPs) with Medicaid managed care organizations (MCOs) to create integrated care programs for dually eligible individuals. Researchers have generally found positive results from such integrated care approaches. For example, a study in Minnesota showed that enrollees in fully integrated Medicare-Medicaid managed care plans had greater primary care physician use and lower inpatient hospital and emergency department use in comparison to service delivery when Medicare and Medicaid-funded services were delivered independently. The study also found that home and community-based service use was greater for the fully integrated Medicare-Medicaid managed care plans than the comparison population and nursing

[3] For example, see chapter 1 of Medicaid and CHIP Payment and Access Commission, *Report to Congress on Medicaid and CHIP,* June 2021, and chapter 12 of Medicare Payment Advisory Committee, *June 2019 Report to the Congress: Medicare and the Health Care Delivery System.*

facility use was no greater.[4] A study in Oregon found that dually eligible individuals enrolled in plans with aligned financial incentives for Medicare and Medicaid experienced more improvement in their care relative to those enrolled in nonaligned Medicare Advantage and Medicaid managed care plans.[5] Other studies have found that integrated care programs foster high beneficiary satisfaction,[6] perform better than non-integrated plans on certain quality metrics,[7] and provide benefit flexibility needed to allow beneficiaries to continue living in the community.[8] Overall, the number of dually eligible individuals in integrated care or financing models or both has increased over time, now exceeding 1 million beneficiaries, but it remains the exception rather than the rule in most States.[9]

An increasing number of dually eligible individuals are enrolled in managed care plans. The broader trend toward managed care presents opportunities for integrated care. It also presents risks for further fragmentation and complexity. In fact, while enrollment in integrated care has increased, it is also becoming increasingly likely that dually eligible individuals are in one sponsor's Medicaid MCO and a competitor's D–SNP. The result: Duplicative health risk assessments (HRAs); multiple ID cards, handbooks, and provider and pharmacy directories; strong incentives for cost-shifting where possible; multiple care coordinators; more complex billing processes for providers; and similar other fragmented care, burdens, or increased costs.

The Medicare Payment Advisory Commission (MedPAC), Medicaid and CHIP Payment and Access Commission (MACPAC), and a wide array of health policy organizations have long pushed for greater CMS investment in integrated care. Over the last few years, MedPAC and MACPAC have written extensively on opportunities to promote integration through managed care policies.[10]

Section 2602 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act) established the Medicare-Medicaid Coordination Office (MMCO) within CMS to better align and integrate benefits for dually eligible individuals, including specific responsibilities. Section 50311(b)(2) of the Bipartisan Budget Act (BBA) of 2018 amended that provision to also charge MMCO with—

- Developing regulations and guidance related to the integration or alignment of policy and oversight under Medicare and Medicaid regarding D–SNPs; and
- Serving as the single point of contact for States on D–SNP issues.

In two recent MA/Part D rulemakings, CMS has adopted regulations[11] to: (1) Promote better information sharing between States and D–SNPs; (2) unify appeals processes across Medicare and Medicaid for certain D–SNPs that are also capitated for Medicaid benefits; and (3) phase out ''D–SNP look-alike'' plans that enroll a high percentage of dually eligible individuals without meeting the requirements for D–SNPs.[12]

Despite this recent work, additional actions are needed to maximize the potential of D–SNPs to deliver person-centered integrated care—and ultimately better health outcomes and independence in the community—for dually eligible older adults, people with disabilities, and people with end stage renal disease.

Maximizing the potential of D–SNPs to achieve these goals will require a sustained effort over multiple years, including—

- Partnership with and technical assistance for States;
- Technical assistance and support for providers and health plans, especially among the local not-for-profit plans that disproportionately serve Medicaid beneficiaries;
- Monitoring and oversight that protects beneficiaries and promotes person-centered coordination of care; and
- Federal rulemaking to raise the bar on integration without excessive disruption for enrollees.

We are working to improve and increase options for more integrated care in a variety of ways, including through D–SNPs and Medicare-Medicaid Plans (MMPs).

a. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6) of the Act, SNPs restrict enrollment to certain populations. The most common type of SNP is a dual eligible special needs plan, or D–SNP, in which enrollment is limited to individuals entitled to medical assistance under a State plan under title XIX of the Act.

D–SNPs are intended to integrate or coordinate care for dually eligible individuals more effectively than standard MA plans or the original Medicare fee-for-service (FFS) program by focusing enrollment and care management on this population. As of January 2021, approximately 3.3 million dually eligible individuals (more than 1 of every 4 dually eligible individuals) were enrolled in 627 D–SNPs.[13]

[4] Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from: *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis.*

[5] Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. ''Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence from Oregon'', *Medical Care Research and Review,* (November 15, 2017) 1–17. Retrieved from: *https://journals.sagepub.com/doi/abs/10.1177/1077558717740206.*

[6] Health Management Associates. *Value Assessment of the Senior Care Options (SCO) Program* (July 21, 2015). Retrieved from *https://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf.*

[7] Medicare Payment Advisory Committee. ''Chapter 3, Care coordination programs for dual-eligible beneficiaries.'' In June 2012 Report to Congress: Medicare and Health Care Delivery System (June 16, 2012). Retrieved from *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun12_ch03.pdf.**COM028*

[8] Ibid.

[9] CMS Medicare-Medicaid Coordination Office FY 2020 Report to Congress, available at: *https://www.cms.gov/files/document/reportto congressmmco.pdf.*

[10] Most recently, see MACPAC's June 2021 Report to Congress and MedPAC's June 2019 Report to Congress.

[11] For a discussion of codified requirements for information sharing between States and D–SNPs and unified appeals processes, see the final rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' (84 FR 15710 through 15717 and 84 FR 15720 through 15744) at: *https://www.federalregister.gov/documents/2019/04/16/2019-06822/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.* For a discussion of codified contract limitations on D–SNP look-alike plans, see the final rule titled ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program,'' (85 CFR 33805 through 33820) at: *https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program.*

[12] For a discussion of D–SNP look-alikes, see the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' (85 FR 9018 through 9025) at: *https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf.*

[13] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (January 2021). Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

Federal statute and implementing regulations have established several requirements for D–SNPs in addition to those that apply to all MA plans to promote coordination of care, including HRA requirements as described in section 1859(f)(5)(A)(ii)(I) of the Act and at § 422.101(f)(1)(i), evidence-based models of care (MOCs) as described in section 1859(f)(5)(A)(i) of the Act and at § 422.101(f), and contracts with State Medicaid agencies as described in section 1859(f)(3)(D) of the Act and at § 422.107. The State Medicaid agency contracting requirement allows States to require greater integration of Medicare and Medicaid benefits from the D–SNPs in their markets.

Most recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs, beginning in 2021, including minimum integration standards, coordination of the delivery of Medicare and Medicaid benefits, and unified appeals and grievance procedures for integrated D–SNPs, the last of which we implemented through regulation to apply to certain D–SNPs with exclusively aligned enrollment, termed ''applicable integrated plans.'' These requirements, along with clarifications to existing regulations, were codified in the ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' final rule (84 FR 15696 through 15744) (hereinafter referred to as the April 2019 final rule).[14]

For a more comprehensive review of D–SNPs and legislative history, see the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' (85 FR 9018 through 9021) which appeared in the **Federal Register** on February 18, 2020 (hereinafter referred to as the February 2020 proposed rule).[15]

b. Medicare-Medicaid Plans

To test additional models of integrated care, we established the Medicare-Medicaid Financial Alignment Initiative (FAI) in July 2011 with the goal of improving outcomes and experiences for full-benefit dually eligible individuals while reducing costs for both States and the Federal government. Although the FAI includes two models, the model with the largest number of States participating is a capitated model through which CMS, the State, and health plans (called Medicare-Medicaid Plans or MMPs) enter into three-way contracts to coordinate the full array of Medicare and Medicaid services for members.

Certain elements of the capitated model demonstrations vary by State, but all MMPs include—

- A beneficiary advisory committee or governance board to provide ongoing input on plan operations;
- An integrated set of member materials, including provider directories, beneficiary notices, and a single ID card;
- Person-centered care planning, including HRAs and care plans;
- Care coordination and assistance with care transitions;
- Aligned Medicare and Medicaid plan enrollment and disenrollment effective dates;
- Medicare provider network adequacy standards specific to the dually eligible individual population;
- Integrated grievance and appeal processes at the plan level;
- Joint oversight by CMS and the States through contract management teams;
- Benefit flexibility, an integrated medical loss ratio (MLR), and other financing provisions intended to promote person-centeredness and mitigate incentives for cost-shifting across programs; and
- A set of CMS core and State-specific quality measures, a subset of which are part of performance-based risk through a quality withhold on the payment to the MMP.

CMS and States partnered with MMPs to create a seamless experience for beneficiaries, but MMPs operate as both MA organizations and Medicaid managed care organizations. As such, unless waived by CMS, MMPs are required to comply with Medicaid managed care requirements under 42 CFR part 438, with MA (also known as Part C) requirements in title XVIII of the Act as well as 42 CFR part 422 and, with regard to the Medicare prescription drug benefit, Part D requirements in title XVIII of the Act and 42 CFR part 423. Section 1115A of the Act (as added by section 3021 of the Affordable Care Act) authorizes waiver of certain Medicare provisions and CMS used that authority to waive several Medicare requirements for the FAI. For States participating in the capitated model, CMS typically uses authority under section 1115(a), 1915(b), 1915(c), or 1932(a) of the Act to waive or exempt the State from certain provisions of title XIX of the Act or establish the authority to deliver Medicaid services through managed care.

As of July 2021, there are 39 MMPs in nine States serving approximately 400,000 members.[16]

While an independent evaluation of the FAI is still underway, we have already gleaned several lessons regarding integrated, managed care from the capitated financial alignment model:

- *Enrollee participation in governance helps identify and address barriers to high-quality, coordinated care.* Stakeholder engagement has been an important tenet of the FAI since its inception. We required participating States to work with a variety of stakeholders, including beneficiaries and their advocates, as a condition of demonstration approval and implementation processes. Some have cultivated robust and impactful advisory bodies. For example, Massachusetts developed a One Care Implementation Council,[17] at least half of whose membership is comprised of enrollees and/or their representatives, charged with tracking quality of services, providing support and input to the State, and promoting accountability and transparency. The three-way contracts used in the capitated financial alignment model require MMPs to establish enrollee advisory committees and/or recruit enrollees to governing boards to ensure plans regularly obtain enrollee input on issues of program management. These advisory committees often provide input on enrollee materials, access to covered services, outreach campaigns, and other topics. Not every advisory committee operates at the same level, and many MMPs have had to recalibrate their approaches to ensure robust participation over time, but all have made strides toward seeking out and incorporating enrollee feedback. We believe such mechanisms help MMPs

[14] See *https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf.*

[15] See *https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf.*

[16] MMP enrollment as of December 2020. See *CMS Monthly Enrollment by Contract Report* (December, 2020). Retrieved from *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/enrollment-contract-2020-12.*

[17] For more information on the One Care Implementation Council, see the Center for Consumer Engagement in Health Innovation at Community Catalyst & the LeadingAge LTSS Center @UMass Boston. ''The One Care Implementation Council: Stakeholder Engagement Within a Duals Demonstration Initiative.'' (June, 2018). Retrieved from *https://www.healthinnovation.org/resources/publications/body/One-Care-Implementation-Council-Review-June-2018-1.pdf.*

improve the experiences of dually eligible individuals.

• *Assessment processes are a vehicle for identifying and addressing unmet need, particularly those related to social determinants of health.* MMPs are required to offer care coordination services to each beneficiary, including an HRA of the enrollee's physical, psychosocial, and functional status which meet all minimum requirements for MA plans in section 1859(f)(5)(A)(ii) of the Act but often include additional elements to assess social risk factors. As of September 2020, MMPs had performed over 1.3 million HRAs, and in doing so identified significant unmet need among members, particularly related to food insecurity and housing instability.[18] For example, we commonly learn of HRAs identifying people with no regular source of care, untreated chronic conditions, unsafe living conditions, and/or imminent eviction or homelessness. By identifying these unmet needs through the HRA process, MMPs are then able to address them with interventions from care coordinators, connections to community organizations, and by incorporating goals and actions into beneficiary care plans.

• *Medicare-Medicaid integration correlates with high levels of beneficiary satisfaction.* MMP members report high levels of satisfaction with their MMPs through member experience surveys. When asked to rate their health plan on a scale from 0 to 10 (with 0 being the worst possible and 10 being the best possible), 91 percent of respondents rated their health plan and health care a 7 or higher in 2019, the most recent year for which data are available.[19] Sixty-six percent of all respondents rated their MMP a 9 or 10 in 2019, up from 59 percent in 2016.[20] These ratings have improved continuously (by five percentage points per year on average) since the MMPs started reporting such data in 2015 and are on par with ratings in the broader Medicare Advantage program.[21]

• *Carving in Medicaid behavioral health benefits helps promote better coordination of behavioral health and physical health services.* Behavioral health conditions are pervasive among dually eligible individuals. For example, nearly one-third of individuals who are dually eligible for Medicare and Medicaid have been diagnosed with a serious mental illness, such as schizophrenia, bipolar disorder, or major depressive disorder, a rate almost three times higher than for non-dually eligible Medicare beneficiaries.[22] Fragmented physical and behavioral health care, delivered across multiple providers and funding sources, can decrease access to care and lead to poor health status.[23] MMPs in all capitated demonstration States except for California and Michigan include Medicaid behavioral health benefits in their plan benefit package. In California, specialty mental health services and substance use disorder treatment covered by Medicaid are financed and administered by county behavioral health departments, and MMPs are required to coordinate with the counties for members served by both entities. Coordination between the MMPs and the counties has varied by county and has often been difficult; challenges include confusion for plans over county-level variation on which services are covered by the county or the MMP, limited behavioral health provider resources to participate in interdisciplinary care teams, and legal and communication barriers to sharing data between county providers and MMPs.

• *Integrated beneficiary communication materials can enhance the beneficiary experience.* The Medicare and Medicaid programs have different, and sometimes inconsistent, requirements for how plans communicate with individuals. CMS and partnering States, however, require MMPs to provide a single set of integrated member materials designed to meet Federal and State requirements and convey information to members in a more streamlined fashion. CMS tested such materials with beneficiaries to maximize readability and understanding.

• *Effective joint oversight of integrated managed care products is possible.* Through the FAI, we have shown it is possible to create a successful framework for joint State and CMS oversight and contract management. Contract management teams (CMTs) consisting of State Medicaid and CMS staff work hand in hand to assure compliance with the relevant Medicare, Medicaid, and State requirements and MMP three-way contract requirements, and to promote MMP performance in meeting the needs and preferences of beneficiaries. Through each CMT, State and CMS staff coordinate to jointly issue guidance and operational clarification and, as needed, may coordinate to issue joint CMS-State compliance actions. CMTs regularly meet with State ombudsman organizations, State-convened advisory groups, and may also meet with local stakeholders, such as beneficiary advocates, enabling more rapid problem-solving and real-time feedback on plan performance and beneficiary experience.[24] CMS has also developed and refined audit protocols specific to three-way contracts between CMS, the States, and the MMPs, and CMS and State staff coordinate to avoid scheduling conflicting Medicare and Medicaid audits that can cause a plan to split resources between two regulators. Based on feedback from States and MMPs and our own experiences for the last eight years, we believe these joint oversight processes, along with having performance data specific to the local MMPs, have improved communications and driven performance improvement.

• *Integrated care and joint oversight provide a platform for quality improvement.* The capitated model demonstrations have shown it is

[18] MMP reported monitoring measure data. Measure data are provided for informational purposes only and do not constitute official evaluation results. Full measure specifications can be found in the reporting requirements documents, available at: *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPReporting Requirements.html.*

[19] Centers for Medicare & Medicaid Services. *Enrollee Experiences in the Medicare-Medicaid Financial Alignment Initiative: Results through the 2019 CAHPS Surveys.* (October 2020) Retrieved from *https://www.cms.gov/files/document/faicahps results.pdf.*

[20] Ibid.

[21] CMS analysis of MMP and Medicare Advantage CAHPS data 2015–2019.

[22] Congressional Budget Office. ''Dual-Eligible Beneficiaries of Medicare and Medicaid: Characteristics, Health Care Spending, and Evolving Policies.'' (June, 2013). Retrieved from: *https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/44308dualeligibles2.pdf.* This report classified Medicare enrollees as having a mental illness if they had a diagnosis from the previous year of schizophrenia; major depressive, bipolar, and paranoid disorders; or other major psychiatric disorders.

[23] Medicaid and CHIP Payment and Access Commission. ''Integration of Behavioral and Physical Health Services in Medicaid.'' (March, 2016). Retrieved from: *https://www.macpac.gov/wp-content/uploads/2016/03/Integration-of-Behavioral-and-Physical-Health-Services-in-Medicaid.pdf.*

[24] RTI International, ''Financial Alignment Initiative Massachusetts Once Care: Third Evaluation Report,'' (April 2019), Retrieved from: *https://innovation.cms.gov/files/reports/fai-ma-thirdevalrpt.pdf;* RTI International, ''Financial Alignment Initiative Michigan MI Health Link First Evaluation Report (Sept 2019), Retrieved from: *https://innovation.cms.gov/files/reports/fai-mi-firstevalrpt.pdf;* RTI International, ''Financial Alignment Initiative MyCare Ohio: First Evaluation Report ''(Nov 15 2018), Retrieved from: *https://innovation.cms.gov/files/reports/fai-oh-firstevalrpt.pdf;* RTI International, ''Financial Alignment Initiative South Carolina Healthy Connections Prime: First Evaluation Report (Sept 2019), Retrieved from: *https://innovation.cms.gov/files/reports/fai-sc-firstevalrpt.pdf.*

possible to effectively incentivize innovation and investment for better serving the dually eligible population. MMPs and CMTs collaborate on continuous performance improvement. Like MA plans, MMPs report quality and performance data such as Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Healthcare Effectiveness Data and Information Set (HEDIS) at the contract level. Because the MMP is the only plan under the three-way contract, CMS and the State have access to performance and quality data specific to each individual MMP. (This is similar to how States generally approach Medicaid managed care contracts and quality reporting. In contrast, a D–SNP may be one of many plan benefit packages under a single MA contract, making it difficult to get a true picture of a particular MA plan's performance.) CMS routinely shares State and national performance data on CAHPS and HEDIS metrics with States and MMPs to identify high and low performing plans. Through the CMTs, State and CMS staff have worked with MMPs to identify specific quality metrics to drive performance improvement and have developed specific quality and performance improvement projects at an MMP and/or demonstration level. These efforts have helped to drive significant year-over-year improvement in CAHPS and HEDIS measures. From 2016 to 2018, MMPs as a group improved performance on measures related to care coordination like Care for Older Adults (by an average of 17 percent across three separate measures) and Medication Reconciliation Post-Discharge (by 54 percent), and on key outcome measures like Controlling High Blood Pressure (by 16 percent) and Plan All-Cause Readmissions (17 percent reduction for beneficiaries age 65 and over).[25] Compared to MA plans as a group, MMPs improved at a higher rate on these measures over the same time period. MA plans as a group improved by an average of 5 percent across the Care for Older Adults measures (although only D–SNPs report those measures) and by 32 percent on the Medication Reconciliation Post-Discharge measure, while the Plan All-Cause Readmissions measure had a 16 percent reduction for beneficiaries age 65 and over.[26] Overall, MA plans saw no change to performance on the Controlling High Blood Pressure measure.[27]

- There is potential for market distortions in areas with multiple options targeting the same population. The MMP experience has shown that we can create a competitive market among MMPs with multiple choices for beneficiaries in the same service area and maintain high expectations for plans around care coordination and cost effectiveness. However, it has also shown the potential for beneficiary confusion and disruption in markets where MMPs are competing with other products targeting dually eligible individuals, including D–SNPs and, more recently, D–SNP look-alikes. For example, fully integrated D–SNPs (FIDE SNPs) served the same population as MMPs that were under New York's Fully Integrated Dual Advantage (FIDA) capitated model demonstration and the FIDE SNPs were offered by the same parent organization as the MMPs, creating confusion among beneficiaries and providers about each program's role.[28] Differences in Medicare capitation payments gave parent organizations a financial incentive to prioritize enrollment in FIDE SNPs over MMPs.[29] In addition to the financial challenges, the MMPs experienced low enrollment spread among a high number of MMPs [30] due to providers not wanting to meet prescriptive care coordination requirements and encouraging patients not to participate. In California, D–SNP look-alikes emerged following the State's decision to limit eligibility for D–SNPs to beneficiaries not otherwise eligible for MMPs.[31] In its June 2018 report to Congress, MedPAC describes broker commissions as another factor incentivizing enrollment in the D–SNP look-alike plans over the MMPs in States like California that prohibit MMPs from using brokers.[32] For a more thorough discussion of market dynamics in New York and California, see MedPAC's June 2018 report to Congress.[33] For a more comprehensive review of D–SNP look-alike plans, see pages 9019–9021 in the February 2020 proposed rule.[34]

- *State investment is critical to successful implementation of integrated care either through MMPs or D–SNPs.* True integration of Medicare and Medicaid requires long-term State participation. However, interest and capacity in pursuing integrated care for dually eligible individuals varies considerably from State to State, and sometimes from year to year. One of the many lessons from the MMP experience has been that standing up a demonstration of this scope requires significant State resources. However, even outside of MMPs, many of the features of integration also require significant State effort. States that have successfully utilized D–SNP contracts to integrate or align Medicare and Medicaid programmatic and administrative elements outside of the FAI have also invested in building State capacity, including establishing dedicated staff or contractors with Medicare knowledge and expertise, building technical capacity to integrate Medicare and Medicaid data, and creating analytic resources to support ongoing program operations and oversight.[35] For example, to maximize integration opportunities, D–SNP members may also enroll in the same organization's Medicaid plan. State investment in establishing enrollment and assignment processes to enable alignment of Medicare and Medicaid enrollment require upfront and ongoing monitoring resources.

[25] CMS analysis of the MMP performance on HEDIS data reported 2017–2019.

[26] CMS analysis of Medicare Advantage performance on HEDIS data reported 2017–2019.

[27] Ibid.

[28] Medicare Payment Advisory Committee. ''Chapter 9, Managed care plans for dual eligible beneficiaries.'' In *June 2018 Report to Congress: Medicare and Health Care Delivery System* (June 15, 2018). Retrieved from *https://www.medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

[29] Ibid.

[30] Per MedPAC's June 2018 report, as of June 2017, 156,000 full-benefit dually eligible individuals were eligible to participate in FIDA, but only 4,708 individuals (3 percent) were enrolled among 14 MMPs.

[31] Pursuant to Welfare and Institutions Code section 14132.277(d), for seven counties, DHCS only offered D–SNP contracts (that is, contracts between the State and the D–SNP that are required under 42 CFR 422.107 for an MA organization to offer a D–SNP) to plans that were approved as of 1/1/13 and new enrollment into those D–SNPs is limited to beneficiaries not otherwise eligible for Medicare-Medicaid plans. The State also did not permit existing D–SNPs to expand service area into the seven counties.

[32] Medicare Payment Advisory Committee. ''Chapter 9, Managed care plans for dual eligible beneficiaries.'' In *June 2018 Report to Congress: Medicare and Health Care Delivery System* (June 15, 2018). Retrieved from *https://www.medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

[33] Ibid.

[34] As finalized in § 422.514 by the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, and Medicare Cost Plan Program'' (85 FR 33796 through 33911) (hereinafter referred as the May 2020 final rule), CMS will no longer enter into a contract with a new D–SNP look-alike beginning in CY 2022 or an existing D–SNP look-alike beginning in CY 2023.

[35] A. Kruse and M. Herman Soper. State Efforts to Integrate Care for Dually Eligible Beneficiaries: 2020 Update. Center for Health Care Strategies, Inc., February 2020. Available at *https://www.chcs.org/media/State-Efforts-to-Integrate-Care-for-Dually-Eligible-Beneficiaries_022720.pdf.*

Since the outset of the FAI, our shared goal with State partners has been to develop models that promote greater Medicare-Medicaid integration that, if successful, could be implemented on a broader scale. Below we propose to incorporate into the broader MA program many of the MMP practices that successfully improved experiences for dually eligible individuals.

2. Summary of D–SNP Proposals Related to MMP Characteristics

Many of the proposals that follow would incorporate certain MMP policies into the regulations governing D–SNPs or, in several cases, certain types of D–SNPs. We describe those proposals in greater detail in this section of this proposed rule. Table 1 summarizes how our proposals relate to MMP policies.

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TABLE 1: PROPOSALS THAT WOULD APPLY MMP FEATURES INTO D-SNPs

MMP Characteristic	FIDE SNP	HIDE SNP	Coordination-only D-SNP
Enrollee advisory committee	Propose to require	Propose same as FIDE	Propose same as FIDE
HRA to include social risk factors	Propose to require	Propose same as FIDE	Propose same as FIDE
Exclusively aligned enrollment	Propose to require starting 2025	-	-
Capitation for LTSS and behavioral health	Propose to require starting 2025	-	-
Capitation for Medicare cost-sharing	Propose to specify	-	-
Unified appeals & grievances[1]	Propose to require starting 2025 for all FIDE SNPs	-	Propose to require for certain plans
Continuation of Medicare benefits pending appeal[2]	Propose to require starting 2025 for all FIDE SNPs	-	Propose to require for certain plans
Integrated member materials	Propose to create a new pathway for States to require for certain plans	Propose same as FIDE	Propose same as FIDE
Contract only includes within-State plans limited to dually eligible individuals Quality data/ratings based solely on performance in contracts that only include within-State plans limited to dually eligible individuals[3]	Propose to create a new pathway for States to require for certain plans	Propose same as FIDE	Propose same as FIDE
Mechanisms for joint Federal-State oversight	Propose to establish for States meeting proposed criteria at § 422.107(e)	Propose same as FIDE	Propose same as FIDE
State HPMS access	Propose to establish for States meeting proposed criteria at § 422.107(e)	Propose same as FIDE	Propose same as FIDE

NOTES: HPMS: Health Plan Management System; LTSS: long-term services and supports

[1]The requirement for unified appeals and grievances is currently in place for those FIDE SNPs and HIDE SNPs that qualify as applicable integrated plans, as defined at § 422.561. Our proposal to require exclusively aligned enrollment for FIDE SNPs would mean that all FIDE SNPs would be applicable integrated plans subject to the requirements for unified appeals and grievance systems. In addition, we propose to revise the definition of applicable integrated plans to extend requirements for unified appeals and grievance systems to a subset of coordination-only D-SNPs.

[2]The requirement for continuation of Medicare benefits pending appeal is codified at § 422.632 for those FIDE SNPs and HIDE SNPs that qualify as applicable integrated plans, as defined at § 422.561. Our proposal to require exclusively aligned enrollment for FIDE SNPs would mean that all FIDE SNPs would be applicable integrated plans subject to this requirement of a unified appeals system.

[3]CMS calculates Star Ratings at the contract level. Star Ratings would become specific to plans serving dually eligible individuals where the MA contract is limited to a one or more D-SNPs. We do not propose to change the Star Ratings methods *per se*. (*See* 42 CFR 422.160 through 422.166).

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3. Enrollee Participation in Plan Governance (§ 422.107)

CMS believes managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.[36] By soliciting and responding to enrollee input, plans can better ensure that policies and procedures are responsive to the needs, preferences, and values of enrollees and their families and caregivers. One of the ways managed care plans can engage dually eligible individuals is by including enrollees in plan governance, such as establishing enrollee advisory committees and placing enrollees on governing boards. Engaging enrollees in these ways seeks to keep enrollee and caregiver voices front and center in plan operations and can help plans achieve high-quality, comprehensive, and coordinated care.[37] Federal regulations for other programs, such as the Programs of All-Inclusive Care for the Elderly and Medicaid managed care plans that cover long-term services and supports (LTSS) include requirements for stakeholder engagement and committees, including input from beneficiaries. We describe these requirements later in this section.

Stakeholder engagement has been an important tenet of the FAI since its inception. As required by the three-way contracts between CMS, States, and MMPs, all MMPs established enrollee advisory committees. These enrollee advisory committees provide a mechanism for MMPs to solicit feedback directly from enrollees, assisting MMPs in identifying and resolving emerging issues, and ensuring they meet the needs of dually eligible individuals. While three-way contract terms differ by State, all three-way contracts require the enrollee advisory committees to meet at least quarterly, be comprised of enrollees, family members, and other caregivers that reflect the diversity of the demonstration population, and provide regular feedback to the MMP's governing board. MMPs have flexibility in conducting these meetings, including determining how to recruit and train enrollees, number of participants,

[36] Centers for Medicare & Medicaid Services. (n.d.). *Person & Family Engagement Strategy: Sharing with Our Partners*. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategy-Summary.pdf*.

[37] Resources for Integrated Care and Community Catalyst, "Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils", 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/Member_Engagement/Video/Listening_to_Voices_of_Dually_Eligible_Beneficiaries*.

discussion topics, and how feedback is disseminated and used.

CMS's contractor Resources for Integrated Care partnered with Community Catalyst, a non-profit advocacy organization, to offer a series of webinars and other written technical assistance to help enhance MMPs' operationalization of these committees.[38] In their work, the Resources for Integrated Care and Community Catalyst identified some practices leading to successful enrollee advisory committees. These include MMP efforts to—

- Recruit enrollees through care coordinator referrals and community outreach events;
- Listen to enrollee feedback;
- Be responsive to enrollee feedback by identifying meaningful changes made because of comments shared and, if the plan is not able to implement a suggestion, providing a rationale;
- Disseminate feedback to appropriate departments across the plan;
- Promote consistent enrollee participation through supports like transportation to the committee meetings, meals, and a stipend; and
- Provide ongoing training to enrollees to help them feel comfortable and empowered to provide feedback.[39]

In late 2018, Federal and State officials led conversations with MMPs to gain a better understanding of the enrollee advisory committees, promising practices, challenges, and how plans are using the feedback received from enrollees and caregivers. A significant number of MMPs reported value from having an advisory committee and that the committee contributes to operational improvements through: (1) Understanding challenges with community resources and potential gaps in services; (2) improving enrollee communications, including printed materials and the website enhancements; (3) identifying barriers to medication adherence and what adherence tools might be most useful to enrollees; and (4) improving delivery of non-emergency transportation, dental, vision, and over-the-counter benefits. A few MMPs reported a neutral value of the advisory committee meetings, citing benefits from enrollee feedback but also challenges in enrollee participation and willingness to engage on issues beyond their personal circumstances. Overall, though, the MMPs reported the committees provided a valuable perspective that shapes the plan's approach to recovery, wellness, and overall access to health care as well as prioritize areas where additional assistance is needed for enrollees.

More recently, MMPs have utilized enrollee advisory committees to gain insight into the effectiveness of specific enrollee materials. For example, some MMPs have shared redacted care plans with enrollee advisory committees for enrollee feedback. Other MMPs have shared draft influenza vaccination outreach materials with their enrollee advisory committees and used the quarterly meetings to discuss influenza prevention. During 2020 and 2021, MMPs have used these committees to discuss ways to educate enrollees about COVID–19 prevention and vaccines. We have had the opportunity to observe some of these meetings and found the dialogue between enrollees and their caregivers and the MMPs to be open and constructive, with all parties interested in sharing information, listening, and identifying solutions. Other programs overseen by CMS include similar committees or mechanisms for beneficiaries to provide feedback and have a role in plan administration.

a. Participant Advisory Committees in PACE Organizations

In addition to MMPs, Programs of All-Inclusive Care for the Elderly (PACE) organizations, per § 460.62(b), must establish participant advisory committees to advise the PACE organization governing body on matters of concern to participants. The majority of the 51,000 PACE participants are dually eligible individuals.[40]

CMS initially required PACE organizations to establish consumer advisory committees as part of the Federal regulations codifying the PACE program in a November 1999 interim final rule with comment period (IFC) for PACE (64 FR 66234). The November 1999 IFC noted that consumer participation through advisory committees is a ''well accepted community organization vehicle to maximize the involvement of consumers in a program designed to serve them'' and that through the use of a consumer advisory committee consumers are also ''likely to feel a greater stake in the operation of the program'' (64 FR 66242). The original regulation, codified at § 460.62, required PACE participants and participant representatives to comprise the majority of committee membership, but there was no Federal requirement relating to how frequently PACE organizations were required to convene the committees.

In a December 2006 final rule (71 FR 71244 through 71337), we made minor revisions to the PACE consumer advisory committee regulation text at § 460.62, including changing the name to participant advisory committee (71 FR 71265). We also clarified in the preamble that the final rule was not specifying the size of the participant advisory committee but that we expected each committee to be representative of the size and population of the PACE organization's participants.

The requirements at § 460.62 allow PACE organizations flexibility in determining the frequency, scope, and participation on these advisory committees. Through its many years of experience overseeing PACE organizations, CMS has learned that PACE organizations value the participant advisory committees as an important way to receive direct feedback from PACE participants to improve program policy and operations. Attendance at participant advisory committees may include PACE organization leadership, including executive directors and PACE center directors. Since PACE participants visit the PACE center at least once per week, feedback provided by PACE participants at the participant advisory committees is generally focused on challenges with transportation between the PACE center and their residences and preferences for meals and activities provided at the PACE center. Per § 460.62(c), PACE organizations must have a participant representative on their governing body. These participant representatives act in part as a liaison of the participant advisory committee to the PACE organization governing body and the participant advisory committee, presenting issues from the participant advisory committee to the governing body. The link between the participant advisory committee and the governing body helps to elevate issues raised by participants to PACE organization leadership.

[38] Resources for Integrated Care and Community Catalyst, ''Member Engagement in Plan Governance Webinar Series'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/concepts/member_engagement.*

[39] Resources for Integrated Care and Community Catalyst, ''Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/Member_Engagement/Video/Listening_to_Voices_of_Dually_Eligible_Beneficiaries.*

[40] CMS, Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report—Monthly Summary Report (Data as of June 2021). Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report.*

b. Member Advisory Committees in Medicaid Managed Care Plans

Medicaid managed care plans that cover long-term services and supports (LTSS) are also required to solicit active member and other stakeholder input through the use of a member advisory committee. Recognizing that stakeholder engagement is an important member protection and is critical to the success of Medicaid managed LTSS programs, CMS requires certain Medicaid managed care plans providing LTSS to establish and maintain a member advisory committee. Per 42 CFR 438.110, as adopted in the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (81 FR 27655 through 27658) (hereinafter referred to as the May 2016 final rule), when LTSS are covered under a risk contract between a State and a Medicaid managed care plan (that is a Medicaid managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP)), each Medicaid managed care plan must establish a member advisory committee. The committee must include at least a reasonably representative sample of the LTSS population, or other individuals representing those members, covered under the contract with the Medicaid managed care plan. CMS designed this requirement in a way that gives managed care plans covering LTSS flexibility to work with their stakeholder communities to establish the most effective member engagement process.

c. Proposal for D–SNP Enrollee Advisory Committees

We believe that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by D–SNPs and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals. Therefore, we propose at § 422.107(f) that any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees to solicit direct input on enrollee experiences. We also propose at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D–SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

We propose to establish the new paragraph at § 422.107(f) under our authority at section 1856(b)(1) of the Act to establish in regulation other standards not otherwise specified in statute that are both consistent with Part C statutory requirements and necessary to carry out the MA program and our authority at section 1857(e) of the Act to adopt other terms and conditions not inconsistent with Part C as the Secretary may find necessary and appropriate. We believe that a requirement for an MA organization offering one or more D–SNPs to establish one or more enrollee advisory committees is not inconsistent with either the Part C statute or administration of the MA program. While current law does not impose such a requirement, our experience with existing requirements for MMPs and PACE demonstrates that the use of advisory committees improves plans' ability to meet their enrollees' needs by providing plans with a deeper understanding of the communities the plans serve and the challenges and barriers their enrollees face, as well as serving as a convenient mechanism to obtain enrollee input on plan policy and operational matters. Our experience also suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees. We believe the performance of all D–SNPs would benefit from this new requirement. Further, this requirement would be consistent with the existing requirement at § 438.110 for Medicaid plans to establish member advisory committees when those Medicaid managed care plans cover LTSS.

While we describe the proposed advisory committee at § 422.107(f) as an enrollee advisory committee consistent with the use of the term ''enrollee'' in MA regulations we note that ''enrollee'' under the proposed § 422.107(f) requirement for D–SNPs has the same meaning as ''member'' under the § 438.110 requirement for Medicaid plans.

We believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement. We expect the evolution and adoption of telecommunications technology, including as experienced during the COVID–19 public health emergency, will mean that the most effective modalities for enrollee input may change over time. Therefore, we choose not to propose Federal requirements as to the specific frequency, location, format, participant recruiting and training methods, or other parameters for these committees beyond certain minimum requirements. Further, our proposal includes flexibility for MA organizations in how they structure their enrollee advisory committee(s). Though we are choosing to be nonprescriptive on meeting frequency, location, format, enrollee recruitment, training, and other parameters, we encourage D–SNPs to adopt identified best practices [41] to ensure advisory committee meetings are accessible to all enrollees, including but not limited to enrollees with disabilities, limited literacy (including limited digital literacy), and lack of meaningful access technology and broadband.

First, we propose that the MA organization offering one or more D–SNP(s) in a State must have one or more enrollee advisory committees that serve the D–SNP(s) offered by the MA organization in that State. Under our proposed rule, an MA organization would be able to choose between establishing one single enrollee advisory committee for one or multiple D–SNPs in that State or by establishing more than one committee in that State to meet proposed § 422.107(f).

Second, we propose that the advisory committee must have a reasonably representative sample of enrollees of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees. By using the phrase ''representative sample'' in the regulation text, we intend D–SNPs to incorporate multiple characteristics of the total enrollee population of the D–SNP(s) served by the enrollee committee, including but not limited to geography and service area, and demographic characteristics. An MA organization that offers separate D–SNPs in multiple counties in a State could decide to convene one enrollee advisory committee to solicit feedback across the membership of all these D–SNP plans as long as that committee's participants reasonably represent the totality of the D–SNP membership. Alternatively, this MA organization could convene an enrollee advisory committee for each D–SNP in each county where the D–SNP is offered. The MA organization could also choose to implement a combination

[41] Resources for Integrated Care and Community Catalyst, ''Engaging Members in Plan Governance'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/node/433#PlanGov.*

of the aforementioned approaches, such as establishing an enrollee advisory committee that solicits enrollees from a D–SNP offered in one county and establishing an enrollee advisory committee with enrollees representing D–SNPs offered in more than one county. For example, a MA organization that offers separate D–SNPs in Broward, Hillsborough, and Orange counties in Florida could establish one enrollee advisory committee that convenes membership representative of these distinct regions of Florida via virtual communications methods, or it could establish separate enrollee advisory committees in each county, or it could implement some combination of these approaches. Similarly, for MA organizations that offer separate D–SNPs serving full-benefit dually eligible individuals and partial-benefit dually eligible individuals in the same State, proposed § 422.107(f) provides flexibility for MA organizations to solicit enrollee input through one or more committees where separate committees might represent specific eligibility groups. Ensuring that the enrollee advisory committee is representative of the covered population of the D–SNP(s) that are served by the committee is key to achieving the goals of requiring an enrollee advisory committee.

Finally, we propose that the advisory committee must, at a minimum, solicit input on ways to improve access to covered services, coordination of services, and health equity among underserved populations, which is a CMS priority aligned with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021). CMS encourages D–SNPs to consider the CMS Office of Minority Health Disparities Impact Statement as a potential tool to improve health equity for underserved populations among their enrollment.[42] Our proposal does not specify other responsibilities or obligations for the committee, but we encourage D–SNPs to solicit input from enrollees on other topics will be part of the committee's responsibilities.

Specifically, we propose the following amendments to § 422.107:

- Revise the section heading from ''Special needs plans and dual eligible: Contract with State Medicaid Agency'' to ''Requirements for dual eligible special needs plans'' to reflect how, as amended, § 422.107 will address D–SNP requirements, such as the enrollee advisory committee, in addition to the State Medicaid agency contracts and their content; and
- Add new paragraph (f) to require that any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization, with at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

An MA organization that offers one or more D–SNPs and offers (or is under a parent organization that offers) one or more Medicaid managed care plans that cover long term services and supports—including the MA organizations associated with all FIDE SNPs and most HIDE SNPs—would be subject to our proposal and § 438.110. In some circumstances, especially among FIDE SNPs and HIDE SNPs, we expect that organizations could meet the requirements in our proposal and § 438.110 through one enrollee advisory committee. Section 438.110(b) requires the member advisory committees to include at least a reasonably representative sample of the LTSS populations covered, but it does not preclude the membership of other enrollees as well. Therefore, an advisory committee could, in some cases, be reasonably representative of both the LTSS population and the D–SNP, even if enrollment in the D–SNP is not limited to LTSS users. Some State Medicaid agency contracts, such as those in Idaho, Massachusetts, Minnesota, New Jersey, and Pennsylvania, already require member advisory committees for FIDE SNPs that operate in those States in compliance with § 438.110, because the MCOs affiliated with those FIDE SNPs cover LTSS. Therefore, based on our review of State Medicaid agency contracts, we expect that a number of FIDE SNPs and HIDE SNPs affiliated with Medicaid managed care plans that cover LTSS already operate enrollee advisory committees that would comply with our proposal and § 438.110. The proposed regulation permits an organization that operates a D–SNP that is affiliated with a Medicaid managed care plan to use one enrollee advisory committee to meet both the requirement under § 438.110 and the requirement proposed at § 422.107(f), when all the criteria in both regulations are met and the State permits this arrangement. In other circumstances, it may not be feasible for an organization to operate a single enrollee advisory committee that meets the requirements of our proposal and § 438.110. Those organizations would need to operate multiple enrollee advisory committees.

Our experience with MMPs establishing and maintaining enrollee advisory committees demonstrates that these plans have found the committees useful and carefully consider feedback provided by enrollees to inform plan decisions without prescriptive Federal requirements for the committees. As a result, we are not proposing specific prescriptive requirements for how D–SNPs must interact with and use these enrollee committees. However, we solicit comments on our proposal, including whether we should include more prescriptive requirements on how D–SNPs select enrollee advisory committee participants, training processes on creating and running a successful committee, the responsibilities of the enrollee advisory committees, and additional topics for enrollee input, and whether we should limit the enrollee advisory committee proposed at § 422.107(f) to a subset of D–SNPs. We also solicit comments on whether our approach to allow MA organizations to meet the requirements in proposed §§ 422.107(f) and 438.110 through one enrollee advisory committee could dilute the § 438.110 requirement by detracting from the focus on LTSS enrollees. Consistent with PACE, if our proposal is finalized, we would update the CMS audit protocols for D–SNPs to request documentation of enrollee advisory committee meetings. As we learn about the implementation experiences of these committees, if proposed § 422.107(f) is finalized, we would consider more prescriptive requirements in the future, if needed.

4. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessment (§ 422.101)

Section 1859(f)(5)(A)(ii)(I) of the Act requires each SNP to conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's

[42] CMS Office of Minority Health, Health Equity Technical Assistance. Retrieved from: *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/Health-Equity-Technical-Assistance.*

individualized care plan. We codified this requirement at § 422.101(f)(1)(i) as a required component of the D–SNP's MOC. In practice, we allow each SNP to develop its own HRA, as long as it meets the statutory and regulatory requirements.[43] In the final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' (86 FR 5864) (hereinafter referred to as the January 2021 final rule), we noted that D–SNPs also receiving capitation for Medicaid services may combine their Medicare-required HRA with a State Medicaid-required HRA to reduce assessment burden for enrollees (86 FR 5879). Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.[44] This is particularly true for food insecurity, housing instability, and access to transportation. The following are examples of actions that CMS has taken since 2014 to address social risk through the identification and standardization of screening for risk factors:

- *IMPACT Act of 2014.* The Improving Medicare Post-Acute Care Transformation Act of 2014 Section 2(a) (Pub. L. 113–185), hereinafter referred to as the IMPACT Act, amended the Social Security Act (the Act) by adding section 1899B to the Act. Section 1899B(b)(1) of the Act requires, in part, that the Secretary require certain post-acute care (PAC) providers to submit standardized patient assessment data with respect to certain categories of data. CMS finalized several standardized patient assessment data requirements, including on social determinants of health.[45]
- *Accountable Health Communities (AHC) Model.* The AHC Model, which is being tested under section 1115A of the Act, tests whether systematically screening for health-related social needs and referrals to community-based organizations to resolve identified unmet needs will improve healthcare utilization and reduce costs. Over a five-year period, organizations implementing the AHC Model, known as Bridge Organizations, are screening community-dwelling Medicare and Medicaid beneficiaries to identify their health-related social needs and providing navigation assistance to connect those beneficiaries with community services.[46] Some Bridge Organizations are also engaging key stakeholders in community-level continuous quality improvement activities to align the community service capacity with the community's service needs. For purposes of the model, the CMS Innovation Center developed the AHC Health-Related Social Needs (HRSN) Screening Tool. The tool asks 10 standardized questions that identify a patient's HRSNs in five core domains: Housing instability, food insecurity, transportation problems, utility help needs, and interpersonal safety.[47] [48] The first AHC Model evaluation report, assessing model implementation from 2017 to 2020,[49] demonstrated high prevalence of social risk factors among eligible high-need beneficiaries. Food insecurity was the most commonly reported social risk factor.

Many dually eligible individuals contend with multiple social risk factors such as food insecurity, homelessness, lack of access to transportation, and low levels of health literacy.[50] Nonetheless, we have not previously required that SNP HRAs specifically collect information about these issues. We believe requiring SNPs to include standardized questions about social risk factors is appropriate in light of the impact these factors may have on health care and outcomes for the enrollees in these plans and that access to this information will better enable SNPs to design and implement effective models of care.

We propose to amend § 422.101(f)(1)(i) to require that all SNPs (chronic condition special needs plans, D–SNPs, and institutional special needs plans) include one or more standardized questions on the topics of housing stability, food security, and access to transportation as part of their HRAs. These questions will help SNPs gather the necessary information in order to conduct a comprehensive risk assessment of each individual's physical, psychosocial, and functional needs as required at § 422.101(f)(1)(i) and will inform the development and implementation of each enrollee's comprehensive individualized plan of care as required at § 422.101(f)(1)(ii). Rather than include the specific questions in regulation text, we propose that the questions be specified in sub-regulatory guidance. This would afford us some flexibility to modify questions to maintain consistency with standardized questions that are developed for other programs while still providing MA organizations with clear requirements; we intend to provide ample notice to MA organizations of any changes in the questions over time. Should we finalize our proposal, SNPs would comply with the new requirement added to § 422.101(f) by

[43] In the CY 2016 Call Letter (an attachment to the Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies) released on April 6, 2015, CMS encouraged SNPs to adopt the components in the CDC's ''A Framework for Patient-Centered Health Risk Assessments'' tool but did not mandate their use. Specifically, CMS encouraged the use of elements that identify the medical, functional, cognitive, psychosocial and mental health care needs of enrollees.

[44] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/.*

[45] See the ''Medicare and Medicaid Programs: CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements'' final rule (84 FR 39151 through 39161) as an example. In the interim final rule with comment period (IFC) ''Medicare and Medicaid Programs, Basic Health Program and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27550 through 27629), CMS delayed the compliance dates for these standardized patient assessment data under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP), Long-Term Care Hospital (LTCH) QRP, Skilled Nursing Facility (SNF) QRP, and the Home Health (HH) QRP due to the public health emergency. In the ''CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities'' final rule (86 FR 62240 through 62431), CMS finalized its proposals to require collection of standardized patient assessment data under the IRF QRP and LTCH QRP effective October 1, 2022, and January 1, 2023 for the HH QRP.

[46] CMS Innovation Center, ''Findings at a Glance: Accountable Health Communities: Evaluation of Performance Years 1–3 (2017–2020).'' Retrieved from: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt-fg.*

[47] CMS Innovation Center, ''The Accountable Health Communities Health-Related Social Needs Screening Tool.'' Retrieved from: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[48] There are now Logical Observation Identifiers Names and Codes (LOINC) terms available for the AHC HRSN Screening Tool, as of June 2021. For more information, see: *https://loinc.org/loinc/96777-8/.*

[49] RTI International, ''Accountable Health Communities (AHC) Model Evaluation First Evaluation Report,'' Dec 2020. Retrieved from: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[50] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2020. Retrieved from: *https://www.macpac.gov/wp-content/uploads/2020/06/June-2020-Report-to-Congress-on-Medicaid-and-CHIP.pdf.*

including in their HRAs the standardized questions on these topics that we would specify in sub-regulatory guidance. At a minimum, we intend to align selected questions with the Social Determinants of Health (SDOH) Assessment data element [51] established as part of the USCDI v2, when finalized and where applicable.

While we are proposing that the regulation text specify that the wording of individual questions would be established through sub-regulatory guidance, we provide here examples of the questions on these topics used in other Medicare contexts to provide better context on the proposed requirement and to solicit public comment. These examples include the transportation question in the post-acute care patient/resident instruments and the housing and food insecurity questions from the AHC Model HRSN Screening Tool: [52]

Housing. What is your living situation today? [53]

- I have a steady place to live
- I have a place to live today, but I am worried about losing it in the future
- I do not have a steady place to live (I am temporarily staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, abandoned building, bus or train station, or in a park)

Food. Some people have made the following statements about their food situation. Please answer whether the statements were OFTEN, SOMETIMES, or NEVER true for you and your household in the last 12 months. Within the past 12 months, you worried that your food would run out before you got money to buy more.[54]

- Often true
- Sometimes true
- Never true

Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.

- Often true
- Sometimes true
- Never true

Transportation. Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living? [55]

- Yes, it has kept me from medical appointments or from getting my medications
- Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need
- No

Our proposal would result in SNPs having a more complete picture for each enrollee of the risk factors that may inhibit accessing care and achieving optimal health outcomes and independence. We believe that these questions are sufficiently related to and provide information on enrollees' physical, psychosocial, and functional needs to be appropriate to include the HRA. Having knowledge of this information for each enrollee would better equip MA organizations to develop an effective plan of care for each enrollee that identifies goals and objectives as well as specific services and benefits to be provided. Our proposal would also equip SNPs with person-level information that would help them better connect enrollees to covered services (for example, non-emergency medical transportation, when capitated by Medicaid or covered as a supplemental benefit) and to social service organizations and public programs that can help resolve housing instability, food insecurity, transportation needs, or other challenges. Coordinating care along these lines is consistent with the obligations under § 422.112(b)(3) for MA organizations that offer coordinated care plans.

We are not explicitly proposing that SNPs be accountable for resolving all risks identified in these assessment questions, but § 422.101(f)(1)(i) requires that the results from the initial and annual HRAs be addressed in the individualized care plan. Results of the HRAs do not require SNPs to provide housing or food insecurity supports, but having the results means that SNPs would need to consult with enrollees about their unmet social needs, which may include homelessness and housing instability, for example, in developing each enrollee's care plan. A SNP could demonstrate this in several ways, consistent with its MOC. For example, a SNP may make a referral to an appropriate community partner, consistent with the individual's goals and preferences, to assist in meeting these needs. The SNP may also adapt communication methods to fit the individual's circumstances and take steps to maximize access to covered services that may meet the individual's needs and preferences, especially for supplemental benefits that may help with housing instability, food insecurity, or transportation.

SNPs currently report to CMS the number of completed HRAs, and, as part of the Medicare Part C Program Audit Protocols for SNP Care Coordination, we currently review a sample of HRAs and ICPs.[56] However, we do not currently collect specific data elements from HRAs for all SNP enrollees, in part because the data elements vary from plan to plan. By standardizing certain data elements, our proposal would make those data elements available for collection by CMS from the SNPs for all enrollees. (States can also use their contracts with D–SNPs at § 422.107 to require reporting of these data elements in the HRA to the State or its designee.) While we continue to consider whether, how, and when we would have the SNPs actually report data to CMS, we believe having such information could help us to better understand the prevalence and trends in certain social risk factors across SNPs and further consider ways to support SNPs in promoting better outcomes for their enrollees. We believe standardizing these data elements could also eventually facilitate better data exchange among SNPs (such as when an individual changes SNPs).

We understand that some States may separately require that Medicaid managed care plans collect similar information, potentially creating inefficiencies and added assessment burden on dually eligible individuals who are asked similar, but not identical information, in multiple HRAs. We believe that the benefit gained by all SNPs having standardized information about these social risk factors outweighs this potential risk. These questions build on other work across CMS. Where States are interested in requiring

[51] For more information, see: *https://www.healthit.gov/isa/taxonomy/term/1801/uscdi-v2.*

[52] For the Accountable Health Communities Health-Related Social Needs Screening Tool, see *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.* The PAC assessment utilized the same transportation question as the AHC HRSN Tool.

[53] Adapted from National Association of Community Health Centers and partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. (2017). PRAPARE. *http://www.nachc.org/research-and-data/prapare/.*

[54] Adapted from Hager, E.R., Quigg, A.M., Black, M.M., Coleman, S.M., Heeren, T., Rose-Jacobs, R., Cook, J.T., Ettinger de Cuba, S.E., Casey, P.H., Chilton, M., Cutts, D.B., Meyers A.F., Frank, D.A. (2010). Development and Validity of a 2-Item Screen to Identify Families at Risk for Food Insecurity. Pediatrics, 126(1), 26–32. doi:10.1542/peds.2009–3146.

[55] National Association of Community Health Centers and partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. (2017). PRAPARE. *http://www.nachc.org/research-and-data/prapare/.*

[56] For more information, see: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

assessment questions, we recommend that States consider conforming to the standardized questions we implement for use under this proposed rule and, for integrated care programs, ensuring that plans do not need to ask the same enrollees similar or redundant questions. However, we also seek input from States about what questions they are using and how we can best minimize assessment burden while ensuring that SNPs and States are capturing actionable information on social risk factors.

We are considering several alternatives to our proposal. We are considering requiring fewer or more assessment questions on additional topics related to social risk factors or different combinations of questions from the post-acute care patient/resident assessment instruments and AHC Model HRSN Screening Tool. For example, we are considering requiring that SNPs use the post-acute care patient/resident assessment instruments questions on health literacy (''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'') and social isolation (''How often do you feel lonely or isolated from those around you?''). We believe these would provide valuable insight but are not proposing to require HRAs to include standardized questions in these areas out of parsimony. We focused on the proposed areas since there is a large evidence base suggesting they have a particularly significant influence on the physical, psychosocial, and functional needs of the enrollees.[57] For example, our experience with the FAI demonstrations has shown that lack of transportation can have a large impact in securing needed health care services. Our proposal would not preclude SNPs from asking additional questions related to these areas as long as the minimum standardized questions (specified in CMS sub-regulatory guidance pursuant to the regulation) are included as part of the HRA.

We considered soliciting comment in this preamble on different examples of questions on housing, food, and transportation other than the examples included above, such as the housing-related questions from the U.S. Department of Veteran Affairs' Homelessness Screening Clinical Reminder[58] or the housing-, food-, and transportation-related questions from the Medicare Current Beneficiary Survey.[59] We also considered simply proposing that all HRAs address certain domains (for example, housing), without authorizing CMS to specify the standardized questions to be used. However, we believe the benefit of flexibility for SNPs is outweighed by the challenges posed by use of multiple different questions used by different SNPs across the country. Having different questions that touch on the same topics in different ways would pose difficulties for interoperability, comparability, and reporting on these risk factors. We are considering specifying that the new questions only apply to certain enrollees and not others. For example, we are considering whether the questions on housing insecurity would be relevant for enrollees in congregate housing. However, because people may move between settings, including from an institutional placement to the community, we believe that such a proposal would add complexity without obvious benefit.

Finally, due to the processes associated with developing HRA tools, approval of MOCs, and MOC implementation, we would not enforce this requirement until contract year 2024. However, we are also considering whether to have our proposed requirement take effect at a later date, such as contract year 2025, to allow MA organizations more time to work our proposed new questions into their existing SNP HRAs. We welcome comments on our proposal and these potential alternatives including adding questions regarding health literacy, social isolation, or other areas. We also welcome comments on when CMS would need to issue sub-regulatory guidance providing the specific questions to be included in the HRA to ensure that MA organizations would have sufficient time to incorporate the required questions.

5. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§§ 422.2 and 422.107)

Dually eligible individuals have an array of choices for how to receive their Medicare coverage, including Original Medicare with a standalone prescription drug plan, non-SNP MA plans, multiple types of SNPs, and Programs of All-inclusive Care for the Elderly. Those choices can be complex and, for some, overwhelming. An average Medicare beneficiary will have access to 54 MA plans in 2022, excluding MMPs and PACE, compared to 39 MA plans in 2020.[60] In one extreme example, dually eligible individuals in Los Angeles have over 85 choices for Medicare coverage for 2022, including 70 MA plans, nine D–SNPs, two FIDE SNPs, and five MMPs—more Medicare options to choose from than Medicare-only beneficiaries.[61]

Our own terminology is complex too. While we have defined terms through rulemaking in § 422.2, there remains nuance and variation that may make it difficult for members of the public—and even the professionals who support them—to readily understand what may be unique about a certain type of plan or what a beneficiary can expect from any FIDE SNP, for example. We propose several changes to how we define FIDE SNPs and HIDE SNPs that we believe will ultimately help to differentiate various types of D–SNPs and clarify options for beneficiaries. Our proposals would lay the groundwork for potential future improvements to Medicare Plan Finder and other communications to help beneficiaries better understand their options for integrated coverage of Medicare and Medicaid benefits.

a. Exclusively Aligned Enrollment for FIDE SNPs

Section 422.2 defines the term ''fully integrated dual eligible special needs plan,'' most recently updated in the May 2020 final rule. Under the current definition, FIDE SNPs are plans that: (i) Provide dually eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization (MCO) contract under section 1903(m) of the Act with a State Medicaid agency, (ii) under the capitated Medicaid managed care contract, provide coverage, subject to some limited flexibility for carve-outs, of primary care, acute care, behavioral health, and LTSS, and coverage of nursing facility services for a period of at least 180 days during the plan year; (iii) coordinate delivery of covered Medicare and Medicaid benefits using aligned care management and specialty care network methods for high-risk beneficiaries; and

[57] See Kushel MB, Gupta R, Gee L, Haas JS. Housing instability and food insecurity as barriers to health care among low-income Americans. J Gen Intern Med. 2006;21(1):71–7. doi: 10.1111/j.1525–1497.2005.00278.x.

[58] For more information, see the U.S. Department of Veteran Affairs, VA National Center of Homelessness Among Veterans March 2014 Research Brief ''Using a Universal Screener to Identify Veterans Experiencing Housing Instability'' at *https://www.va.gov/HOMELESS/Universal_Screener_to_Identify_Veterans_Experiencing_Housing_Instability_2014.pdf.*

[59] For more information, see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS.*

[60] Information from 2022 Landscape Source Files. Retrieved from *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn.* Excludes EGWPs.

[61] Ibid.

(iv) employ policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

The current definition of a FIDE SNP does not require that the MA contract limit enrollment to the individuals who are enrolled in the affiliated MCO. One benefit of FIDE SNP designation for the MA organization is that the MA plan may qualify for a frailty adjustment as part of CMS's risk adjustment of its MA capitation payments under section 1853(a)(1) of the Act and § 422.308(c); FIDE SNPs with a similar average level of frailty (as determined by the Secretary) as the PACE program may qualify for the frailty adjustment, which may result in increased aggregate payment from CMS.

Section 422.2 also defines the term ''aligned enrollment'' as referring to when a full-benefit dually eligible individual is an enrollee of a D–SNP and receives coverage of Medicaid benefits from the D–SNP or from a Medicaid MCO that is: (1) The same organization as the MA organization offering the D–SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D–SNP's parent organization. When State policy limits a D–SNP's membership to individuals with aligned enrollment, § 422.2 refers to that condition as exclusively aligned enrollment.

Exclusively aligned enrollment is an important design feature for maximizing integration of care for all the D–SNP's enrollees. It facilitates the use of integrated beneficiary communication materials (because all beneficiaries in the D–SNP are also in the companion Medicaid MCO), clarifies overall accountability for outcomes and coordination of care, and makes feasible the requirement (effective January 1, 2021) that the plan use unified grievance and appeals procedures for both Medicare and Medicaid benefits.

All MMPs operate with exclusively aligned enrollment, and several States require exclusively aligned enrollment for FIDE SNPs that operate in the State by including this requirement in the State Medicaid agency contract that is required for D–SNPs by § 422.107(b). However, the current regulatory definition of FIDE SNP permits certain forms of unaligned enrollment between Medicare and Medicaid coverage. That is, a beneficiary may be in one parent organization's FIDE SNP for coverage of Medicare services but a separate company's Medicaid managed care plan (or in a Medicaid FFS program) for coverage of Medicaid services.

In 2021, there are 69 FIDE SNPs in 12 States, enrolling 264,146 beneficiaries as of January 2021.[62] Fifty-seven of those 69 FIDE SNPs have exclusively aligned enrollment. Only Arizona, Pennsylvania, and Virginia currently contract with FIDE SNPs without requiring exclusively aligned enrollment.

We propose to amend the definition of ''fully integrated dual eligible special needs plan'' at § 422.2 with a new paragraph (5) that requires, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment. Our proposed change would move FIDE SNPs toward greater integration in the provision of Medicare and Medicaid benefits for dually eligible individuals and make the options available to these beneficiaries simpler to understand. Requiring all FIDE SNPs to have exclusively aligned enrollment would simplify the ways we, States, and benefit counselors communicate about FIDE SNPs by eliminating some of the confusing scenarios related to unaligned enrollment that our current definition permits. It would allow all enrollees to have their Medicare and Medicaid benefits explained under the FIDE SNP clearly, which is made more difficult when some enrollees are, but others are not, also enrolled in the affiliated Medicaid MCO. Our proposed change promotes higher levels of Medicare-Medicaid integration by ensuring that that all FIDE SNPs can deploy integrated beneficiary communication materials and unify appeals and grievance procedures for all the Medicare and Medicaid benefits covered through the FIDE SNP and affiliated Medicaid MCO; such unified procedures are not feasible when some FIDE SNP members do not receive the Medicaid benefits from the same organization.

Under our proposed definition, all FIDE SNPs would (1) be capitated for Medicaid services, with some permissible exceptions proposed at § 422.107(g) and (h) and discussed later in this section, for all of their enrollees, and (2) based on meeting the definition of applicable integrated plans in § 422.561, operate unified appeals and grievance processes and continue delivery of benefits during an appeal. Ultimately, we believe this change in the definition of a FIDE SNP will help simplify options and provide a better plan experience for dually eligible beneficiaries, as they will be able to receive all their covered Medicare and Medicaid benefits through one organization.

In the absence of a State Medicaid policy change (to require or facilitate exclusively aligned enrollment) in Arizona, Pennsylvania, or Virginia, our proposal would result in 12 plans losing FIDE SNP status. However, our proposal would not prohibit those States and plans from operating as they currently do but would simply mean that the affected plans would be HIDE SNPs rather than FIDE SNPs beginning January 1, 2025. (A HIDE SNP is another type of D–SNP defined at § 422.2 which we describe in more detail in section II.A.5.d. of this proposed rule.) A consequence of this would be that these plans would not qualify for the frailty adjustment, as described in § 422.308(c)(4); however, only six of the 12 potentially-affected FIDE SNPs qualify for the frailty adjustment in 2021 because only those six plans have a similar average level of frailty (as determined by the Secretary) as the PACE program. States may also choose to require, through their State Medicaid agency contracts under § 422.107, that MA organizations create separate plan benefit packages (that is, separate D–SNPs), with one for exclusively aligned enrollment and the other for unaligned enrollment, the former of which would meet our proposed criteria and allow the organization to maintain FIDE SNP status for a share of its current FIDE SNP enrollment while using one or more new, separate D–SNPs for the unaligned enrollment. MA organizations would need to submit a request to CMS for a crosswalk exception under § 422.530(c)(4)(i), which we are proposing in section II.A.6.a. to redesignate from § 422.530(c)(4), for such enrollment transitions.

Finally, because the definition of aligned enrollment is specific to full-benefit dually eligible individuals, our proposal would newly preclude partial-benefit dually eligible individuals from enrolling in FIDE SNPs. Like with unaligned enrollees, enrollment of partial-benefit dually eligible individuals, who receive no Medicaid benefits other than coverage of Medicare premiums and—in some cases—Medicare cost-sharing, precludes a D–SNP from clearly communicating the Medicaid benefits available through the FIDE SNP or using unified appeals and grievance procedures for adjudication of both Medicare and Medicaid benefits. For CY 2021, however, no FIDE SNPs

[62] CY 2021 data is from CMS review of CY 2021 State Medicaid agency contracts submitted by FIDE SNPs. 2016 data is from Verdier, J., A. Kruse, R. Lester, et al. 2016. *State contracting with Medicare Advantage dual eligible special needs plans: Issues and options.* Washington, DC: Integrated Care Resource Center. Retrieved from *https://www.integratedcareresourcecenter.com/sites/default/files/ICRC_DSNP_Issues__Options.pdf.*

enroll partial-benefit dually eligible individuals. As such, we do not believe this would have any meaningful impact for plans currently operating as FIDE SNPs. Moving forward, we believe that the benefits to be achieved with FIDE SNPs having exclusively aligned enrollment for Medicare beneficiaries eligible for full Medicaid benefits, as proposed here, and the associated greater levels of integration in the provision and coverage of benefits and plan administration outweigh the potential negative effects for partial-benefit dually eligible individuals, who would be limited to enrollment in HIDE SNPs, coordination-only D–SNPs, other MA plans, or the original Medicare FFS program.

b. Capitation for Medicare Cost-Sharing for FIDE SNPs and Solicitation of Comments for Applying to Other D–SNPs

Section 1902(a)(10)(E) of the Act directs States to pay providers for Medicare coinsurance and deductibles for dually eligible individuals in the Qualified Medicare Beneficiary (QMB) program. Under section 1905(p)(3) of the Act, ''Medicare cost-sharing'' includes costs incurred with respect to a dually eligible individual in the QMB program,[63] ''without regard to whether the costs incurred were for items and services for which medical assistance [Medicaid] is otherwise available under the plan.'' For QMBs, Medicare cost-sharing amounts include Medicare Parts A and B premiums, coinsurance, and deductibles, and at State option, Medicare Advantage (MA) premiums. Section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid State plan payments, and third-party payments) equal to the amount a State would have paid for the service under the Medicaid State plan.[64] About 8.8 million dually eligible individuals are enrolled in the QMB program.[65] Some States also elect to cover all Medicare cost-sharing for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs. This election means the State pays Medicare cost-sharing for a non-QMB full-benefit dually eligible individual even if the Medicare service is not covered under the Medicaid State plan. Absent such an election by the State, the State would pay the Medicare cost-sharing for non-QMB full-benefit dually eligible individual only if the Medicare service, such as inpatient hospitalization, is also covered under the Medicaid State plan. [66] Typically, States allow FIDE SNP enrollment of both QMB and non-QMB full-benefit dually eligible individuals.

CMS automatically forwards claims under the original Medicare FFS program to State Medicaid agencies and other secondary payers to adjudicate the claims for payment of any Medicare cost-sharing.[67] This automatic claims crossover process greatly reduces provider burden by eliminating the need for providers to submit separate claims to both Medicare and the State Medicaid agency, or a Medicaid managed care plan, such as a Medicaid MCO, prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP), as defined at § 438.2, for payment of Medicare cost-sharing when it is covered by Medicaid. For providers serving dually eligible individuals enrolled in MA plans, including FIDE SNPs, HIDE SNPs, and other D–SNPs, there is no guarantee of an automated crossover process to State Medicaid agencies or Medicaid managed care plans to process Medicaid payment of Medicare cost-sharing. This means the providers must submit claims to the MA plan, then determine the responsible State Medicaid agency or Medicaid managed care plan, and then submit another claim to the State Medicaid agency or Medicaid managed care plan for adjudication of the claims for Medicare cost-sharing.

One way to alleviate provider burden and streamline claims processing is for the State Medicaid agency to make a capitated payment for Medicaid coverage of Medicare cost-sharing to the MA plan in which a dually eligible individual (specifically, a QMB or other dually eligible individual for which the State covers Medicare cost-sharing) is enrolled. When the State contract with the MA plan includes capitated payment for Medicaid coverage of Medicare cost-sharing, the provider submits one claim to the MA plan, and the MA plan adjudicates the claim for Medicare coverage of services and for Medicaid payment of Medicare cost-sharing without the provider submitting separate claims to the MA plan and the proper Medicaid entity (that is, State Medicaid agency or Medicaid managed care plan). Additionally, this arrangement reduces other potential obstacles, including determining the proper Medicaid entity to bill for Medicare cost-sharing, determining a beneficiary's applicable coverage of Medicare cost-sharing (for example, in States that pay Medicare cost-sharing for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs), and the potential for improper QMB billing.

We propose to specify in § 422.2 that FIDE SNPs are required to cover Medicare cost- sharing as defined in section 1905(p)(3)(B), (C) and (D) of the Act, without regard to how section 1905(n) limits that definition to QMBs, as part of the FIDE SNP's coverage of primary and acute care; this means that the proposed amendment would require FIDE SNPs to cover Medicare cost -sharing for both QMB and non-QMB full-benefit dually eligible FIDE SNP enrollees. We intend this revision to encompass all cost-sharing, whether it is in the form of coinsurance, copayments, or deductibles, for Medicare Part A and Part B benefits covered by the D–SNP. The current definition of a FIDE SNP at § 422.2 requires a FIDE SNP's capitated contract with the State Medicaid agency to provide coverage, consistent with State policy, of specified primary care, acute care, behavioral health, and LTSS, and provide coverage of nursing facility services for a period of at least 180 days during the plan year. Medicare covers most primary care and acute care services and Medicare is always the primary payer for any Medicare-covered services with Medicaid covering any Medicare cost-sharing in such cases.

[63] Under 1905(p)(1) of the Act, a QMB is an individual who is entitled to hospital insurance benefits under Part A of Medicare, with income not exceeding 100 percent of the Federal poverty level, and resources not exceeding three times the SSI limit, adjusted annually by the Consumer Price Index. For more information about QMB eligibility and benefits, see chapter 1, section 1.6.2.1 and Appendices 1.A and 1.B of the Manual for the State Payment of Medicare Premiums, found here: *https://www.cms.gov/files/document/chapter-1-program-overview-and-policy.pdf.*

[64] For example, if the Medicare (or MA) rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment. This is often referred to as the ''lesser of'' policy. Under the ''lesser of'' policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service.

[65] CMS Medicare-Medicaid Coordination Office, ''Data Analysis Brief: Medicare-Medicaid Dual Eligible Enrollment: 2006–2019''. Retrieved from: *https://www.cms.gov/files/document/medicare medicaiddualenrollmenteverenrolledtrends databrief.pdf.*

[66] See Chapter II, sections E.4 through E.6 of the Medicaid Third Party Liability Handbook at *https://www.medicaid.gov/medicaid/eligibility/downloads/cob-tpl-handbook.pdf.*

[67] State Medicaid agencies and Medicaid managed care plans enter into a Coordination of Benefits Agreement (COBA) for the purpose of coordinating health insurance benefits and facilitating the proper payment of claims for beneficiaries enrolled in the original Medicare FFS program. Within the COBA, State Medicaid agencies and Medicaid managed care plans elect which COBA claims for CMS to transfer. For more information, see: *https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/COBA-Trading-Partners/Coordination-of-Benefits-Agreements/Coordination-of-Benefits-Agreement-page.*

Under this proposal, a FIDE SNP would cover Medicare payment for primary care and acute care covered by Medicare and the Medicaid payment for any Medicare cost-sharing in such cases. In plan year 2021, all 69 FIDE SNPs include Medicare cost-sharing in their capitated contracts with the State Medicaid agency.[68] Therefore, we do not expect our proposal to have any impact on existing FIDE SNPs.

We chose to propose this change only for FIDE SNPs because FIDE SNPs are the only type of D–SNP that must cover Medicaid acute and primary care benefits and are better equipped, compared to other D–SNPs, to make improvements for coordination of benefits and adjudication of claims. This is especially true when capitation for Medicare cost-sharing is combined with a requirement for exclusively aligned enrollment (as proposed in section II.A.5.a. of this proposed rule to amend the FIDE SNP definition at § 422.2). Under our proposal, a provider serving a dually eligible individual enrolled in a FIDE SNP with exclusively aligned enrollment would submit a single claim to the FIDE SNP for both Medicare and Medicaid coverage of the service; the FIDE SNP would adjudicate the claim for a covered service for any applicable Medicare payment, Medicaid payment, and Medicaid payment of Medicare cost-sharing. In this way, the proposed additions to the definition of FIDE SNPs at § 422.2 would ensure that all FIDE SNPs include elements—capitation for Medicare cost-sharing and exclusively aligned enrollment—that result in improved beneficiary and provider experiences. This proposal furthers the level of integration required for FIDE SNPs in a way that we believe would achieve those improved experiences. In other types of D–SNPs, such as HIDE SNPs, members may participate in the HIDE SNP for their Medicare benefits and an unaffiliated Medicaid managed care plan or the State Medicaid FFS program for their Medicaid acute and primary care benefits. When Medicare and Medicaid plan enrollment is unaligned, as it is in many HIDE SNPs, a provider serving a dually eligible individual enrolled in a HIDE SNP would submit a claim to the HIDE SNP for Medicare payment of the service, then submit a second claim to the Medicaid managed care plan or the State Medicaid program for Medicaid payment of the covered benefit.

Our proposal does not include Medicare Parts A and B premiums in the requirement for FIDE SNPs to cover Medicare cost-sharing. We do not believe that it is necessary to require FIDE SNPs (or other D–SNPs) to pay premiums as there is a loss of efficiency and no additional integration of benefits to be achieved by having a State pay a capitation rate to an MA organization for the MA organization to cover Medicare premiums. The State Medicaid agency will continue to pay the Medicare Parts A and B premiums on behalf of dually eligible beneficiaries in accordance with §§ 406.26 and 406.32(g) and part 407, subpart C, of the chapter. Therefore, we propose to specifically exclude payment of Medicare premiums as a coverage requirement for dually eligible beneficiaries enrolled in FIDE SNPs.

In addition to our proposal for FIDE SNPs, we encourage States to include Medicaid coverage of Medicare Part A and Part B cost-sharing (other than Medicare premiums) for dually eligible individuals in their capitated contracts with all D–SNPs as a method of reducing provider burden and improving access. We considered proposing a requirement that *all* D–SNPs have a contract with States for capitation for Medicare cost-sharing. Unlike FIDE SNPs with our proposed requirement for exclusively aligned enrollment, applying a requirement to other D–SNPs raises a number of complicating, but we believe solvable, problems. In States that have capitated payment arrangements with Medicaid managed care plans to cover Medicaid primary and acute services and behavioral health, such coverage typically requires the Medicaid managed care plan to cover Medicare cost-sharing when Medicare covers the service. That means, when enrollment is not aligned between a D–SNP and the Medicaid managed care plan, the result is not a streamlined payment process for the provider. A contract with the D–SNP for capitated coverage of Medicare cost-sharing—and a carve-out of Medicare cost-sharing coverage from the Medicaid managed care contract—can put Medicare coverage of services and Medicaid coverage of Medicare cost-sharing under a single entity, but could be a complicated process for States to implement. For States without Medicaid managed care programs for dually eligible individuals, contracting (with capitation payments) with D–SNPs for coverage of Medicare cost-sharing can be a more straightforward process. We solicit feedback on the feasibility, implementation, estimated time to enact, and impact of requiring capitated Medicare cost-sharing for all D–SNPs to inform future rulemaking.

In the CY 2020 Medicare Parts C and D Draft Call Letter, we requested comments on the ways to extend the benefits of the automatic claims crossover process for services provided to dually eligible individuals in MA plans and discussed those comments in the CY 2020 Medicare Parts C and D Final Call Letter.[69] Commenters described the need for MA plans to have real-time Medicaid eligibility and enrollment data to facilitate better coordination of care and Medicare cost-sharing payment across MA plans and Medicaid MCOs. Therefore, we also considered proposing a requirement for States to provide real-time Medicaid managed care plan enrollment data to D–SNPs to enable better coordination between the D–SNP and the State and/or Medicaid managed care plan. We chose not to propose a requirement at this time to allow more time for us to consider the operational challenges for States. We solicit feedback on the pros and cons of requiring State Medicaid data exchanges to provide real-time Medicaid FFS program and Medicaid managed care plan enrollment data with D–SNPs, and the impact of such a requirement on States, Medicaid managed care plans, D–SNPs, providers, and beneficiaries.

c. Scope of Services Covered by FIDE SNPs

(1) Need for Clarification of Medicaid Services Covered by FIDE SNPs

CMS first defined the term ''fully integrated dual eligible special needs plan'', or FIDE SNP, at § 422.2 in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' final rule (76 FR 21432) (hereinafter referred to as the April 2011 final rule) to implement section 3205(b) of the Affordable Care Act (which amended section 1853(a)(1)(B)(vi) of the Act to add a frailty adjustment to the risk adjustment payments for certain FIDE SNPs). That definition provided that a FIDE SNP must have a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care

[68] CMS Special Needs Plan Comprehensive Report, January 2021: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data#:~:text=Special%20Needs%20Plan%20%28SNP%29%20Data%20%20%20,%20%202021-03%20%206%20more%20rows%20.*

[69] CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

benefits and services, consistent with State policy. We explained then that the term ''consistent with State policy'' recognizes the variability in the degree and extent to which Medicaid services are covered from one State to the next (76 FR 21444). Section 1859(f)(3)(D) of the Act, as added by section 164(c)(3)(D) of MIPPA, uses the phrase ''consistent with State policy'' to describe the Medicaid long-term care services that the D–SNP may include in its contract with the State Medicaid agency. As used in the definition of FIDE SNP, the term ''specifies'' acknowledges that States vary in the degree in which Medicaid services are covered by the State under its Medicaid program (encompassing the Medicaid State plan and any waivers) by only requiring the FIDE SNP to cover those services specified by the State Medicaid agency as covered in its Medicaid program. Further, in the April 2011 final rule (76 FR 21444), we explained that the FIDE SNP definition at § 422.2 requires the plan to provide all Medicaid-covered primary, acute, and long-term care services and supports (LTSS) to beneficiaries, and not some combination thereof.

Despite this discussion in the 2011 final rule that FIDE SNPs would provide all primary, acute, and long-term care services and benefits covered by the State Medicaid program, we did not operationalize review of State Medicaid agency contracts in that way. CMS determined D–SNPs to be FIDE SNPs even where the State carved out certain primary care, acute care, and LTSS benefits from the Medicaid coverage required from the D–SNP. In effect, we allowed States flexibility in the coverage provided by FIDE SNPs, not only to accommodate differences in the benefits covered under various State Medicaid programs but to accommodate differences in State contracting strategies for managed care broadly, and for FIDE SNPs in particular. In the April 2019 final rule (84 FR 15706 through 15707), we revised the FIDE SNP definition at § 422.2 to add Medicaid behavioral health services to the list of services that a FIDE SNP must include in its capitated contract with the State Medicaid agency. But, consistent with how we were operationalizing this definition, we explained that our amendment would allow plans to meet the FIDE SNP definition even where the State excluded Medicaid behavioral health services from the capitated contract.

The way we have applied the definition of FIDE SNPs has not enabled us to ensure FIDE SNPs fully integrate Medicare and Medicaid services for dually eligible individuals, which was the goal of the April 2011 final rule. We propose to revise paragraph (2) of the definition of a FIDE SNP at § 422.2 to clearly specify which services and benefits must be covered under the FIDE SNP capitated contract with the State Medicaid agency, and thus bring fuller integration of Medicaid benefits to individuals enrolled in FIDE SNPs. Our proposal would revise paragraph (2) of the existing definition into paragraphs (2)(i) through (v), with each of the new paragraphs addressing specific coverage requirements. We believe the proposed requirements described in this section strike the appropriate balance between flexibility for variations in State Medicaid policy and our goal of achieving full integration in FIDE SNPs. In addition, as discussed more fully in section II.A.5.e., our proposed revision of the definition, in conjunction with a proposal to add § 422.107(g) and (h), includes flexibility for approval of some limited carve-outs of LTSS and behavioral health services.

(2) Requiring FIDE SNPs To Cover All Medicaid Primary and Acute Care Benefits

Primary and acute care benefits for dually eligible beneficiaries are generally covered by Medicare as the primary payer rather than Medicaid. We propose revisions to the FIDE SNP definition in paragraph (2)(i) of § 422.2 to limit the FIDE SNP designation to D–SNPs that cover all primary care and acute care services and Medicare cost-sharing—to the extent such benefits are covered for dually eligible individuals in the State Medicaid program—through their capitated contracts with State Medicaid agencies. Our proposal here means that all primary and acute care services, including the Medicare cost-sharing covered by the State Medicaid program (as discussed earlier in section II.A.5.b. of this proposed rule) must be covered by the FIDE SNP under the MCO contract between the State and the organization that offers the FIDE SNP and the MCO. We seek comment on whether we should allow for specific carve-outs of some of these benefits and services. We welcome specific examples of primary and acute care benefits that are either currently carved out of FIDE SNP capitated contracts with State Medicaid agencies or should be carved out and request that comments include the reason for the existing and proposed future carve-outs.

We are clarifying here that Medicaid non-emergency medical transportation (NEMT) as defined in § 431.53 is not a primary or acute care service included in the scope of this provision. We recognize that Medicaid NEMT is a critical service for dually eligible individuals to access primary and acute care services. However, we do not consider NEMT coverage to be required for FIDE SNPs under the current or proposed definition. We note that States are able to contract with their D–SNPs, or the affiliated Medicaid managed care plans, to cover NEMT. Such contracting might provide these plans with useful tools to facilitate access to care for their members and make it easier for States to coordinate Medicaid NEMT with overlapping services provided by D–SNPs as Medicare supplemental benefits.

(3) Requiring FIDE SNPs To Cover Medicaid Home Health and Durable Medical Equipment

We propose to require that, effective beginning in 2025, each FIDE SNP must cover additional Medicaid benefits to the full extent that those benefits are covered by the State Medicaid program. Those benefits we are proposing to add are home health services, as defined in § 440.70, and durable medical equipment (DME) services, as defined in § 440.70(b)(3). We believe that FIDE SNPs should be required to cover the Medicaid home health and DME benefits because home health and DME are critical services for dually eligible individuals, necessitate coordination due to being covered by both the Medicare and Medicaid programs, and are not clearly captured under other parts of the existing definition. Based on our review of State coverage requirements for Medicaid MCOs affiliated with FIDE SNPs, all current FIDE SNPs already cover Medicaid home health services and DME, so we do not expect this proposal to impact any existing FIDE SNPs. However, we propose that this change in the scope of required coverage by FIDE SNPs would not apply until 2025 in case there are other circumstances of which we are not aware that would necessitate additional time to adapt to our proposal.

As such, we propose to add a new paragraph (2)(iv) of the FIDE SNP definition at § 422.2 related to scope of services to clarify that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid home health services as defined at § 440.70. Also, we propose to add a new paragraph (2)(v) of the FIDE SNP definition at § 422.2 related to scope of services to clarify that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid DME as defined at § 440.70(b)(3).

(4) Requiring FIDE SNPs To Cover Medicaid Behavioral Health Services

Behavioral health needs are extensive among dually eligible individuals. Nearly one-third of individuals who are dually eligible for Medicare and Medicaid have been diagnosed with a serious mental illness, such as schizophrenia, bipolar disorder, or major depressive disorder, a rate almost three times higher than for non-dually eligible Medicare beneficiaries.[70] Full-benefit dually eligible individuals experience higher rates of bipolar disorder and are more likely to use at least one Medicare or Medicaid community mental health service than partial benefit dually eligible individuals.[71] Fragmented physical and behavioral health care, delivered across multiple providers and funding sources, can decrease access to care and lead to poor health status.[72] Some studies, such as the ''Improving Mood—Promoting Access to Collaborative Treatment for Late-Life Depression'' study, provide evidence that coordinated medical and behavioral health care lead to better behavioral health outcomes.[73]

We explained earlier in this section that, consistent with how we were operationalizing the FIDE SNP definition since first adopting it at § 422.2 as established in the April 2011 final rule, we have allowed plans to meet the FIDE SNP definition even where a State excluded Medicaid behavioral health services from the capitated contract with the State Medicaid agency. In the April 2019 final rule, we added behavioral health services to the list of benefits that a D–SNP must cover, consistent with State policy, to obtain the FIDE SNP designation. We stated that complete carve out of behavioral health by a State from the scope of the Medicaid coverage provided by a FIDE SNP would be permissible (84 FR 15706–15707). We believe that a revision to that policy is appropriate and propose to establish in a new paragraph (2)(iii) in the FIDE SNP definition at § 422.2 requiring that, for 2025 and subsequent years, the capitated contract with the State Medicaid agency must include coverage of Medicaid behavioral health services. This proposal would require the Medicaid MCO that is offered by the same entity offering the FIDE SNP to cover all behavioral health services covered by the State Medicaid program for the enrollees in the FIDE SNP. Our proposal to require FIDE SNPs to cover Medicaid behavioral health services is consistent with sections 1853(a)(1)(B)(iv) and 1859(f)(8)(D)(i)(II) of the Act. We propose the 2025 date to allow time for MA organizations and States to adapt to our proposal.

Restricting FIDE SNP designation to plans capitated for Medicaid behavioral health services, as well as other benefits, has two advantages. First, it better comports with a common understanding of being ''fully integrated''—the term used in sections 1853(a)(1)(B)(iv) and 1859(f)(8)(D)(i)(II) of the Act—because of the importance of behavioral health services for dually eligible individuals. Absent coverage of Medicaid behavioral health services, a FIDE SNP would be less able to effectively coordinate overlapping behavioral health services covered by Medicare and Medicaid and would have an incentive to steer beneficiaries toward Medicaid-covered services for which it is not financially responsible. Coverage of Medicaid behavioral health services also facilitates integrating behavioral health and physical health services, which can result in improved outcomes for dually eligible beneficiaries.[74] In addition, our proposal would more clearly distinguish a FIDE SNP—which would have to cover both LTSS and behavioral health services—from a HIDE SNP—which must cover either LTSS or behavioral health services. This would reduce confusion among stakeholders.

Since codifying the definition of HIDE SNP in the April 2019 final rule, we have received many questions from MA organizations and other stakeholders about the difference between a FIDE SNP and HIDE SNP, and we attempted to further explain the distinction in a January 17, 2020 Health Plan Management System memorandum titled, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'' (January 2020 memorandum).[75] Requiring a FIDE SNP to include Medicaid behavioral health services, with the exception of limited carve-outs as proposed at § 422.107(h) and described in section II.A.5.e., would make the coordination continuum from HIDE SNP to FIDE SNP easier to explain and understand since HIDE SNP designation would allow for a carve-out in full or in part of either Medicaid behavioral health services or LTSS while FIDE SNP designation would allow for only limited carve-outs of Medicaid behavioral health services (or, as discussed in section II.A.5.e., of LTSS). As proposed, § 422.107(h) would permit limited exclusions from coverage of Medicaid behavioral health services by both FIDE SNPs and HIDE SNPs while treating those plans as providing coverage of the category of benefits. Under the proposal, the permissible carve-outs would be limited to a minority of beneficiaries eligible to enroll in the D–SNP and use Medicaid behavioral health services or constitute a small part of the total scope of behavioral health services for which Medicaid is generally the primary payer. Thus, under our proposal, FIDE SNPs would cover the vast majority of Medicaid behavioral health benefits *and* Medicaid LTSS benefits, and HIDE SNPs would cover the vast majority of Medicaid behavioral health benefits *or* Medicaid LTSS benefits (or potentially both categories of benefits).

Most FIDE SNPs already have contracts with States to cover Medicaid behavioral health benefits, indicating that the market has already moved in this direction and relatively few FIDE SNPs would be impacted by our proposal. Our review of State Medicaid agency contracts for FIDE SNPs in CY 2021 indicates that States include full coverage of Medicaid behavioral health services for 45 of the 69 FIDE SNPs.[76] The FIDE SNPs with contracts that carve

[70] Congressional Budget Office. ''Dual-Eligible Beneficiaries of Medicare and Medicaid: Characteristics, Health Care Spending, and Evolving Policies.'' (June 2013). Retrieved from: *https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/44308dualeligibles2.pdf.* This report classified Medicare enrollees as having a mental illness if they had a diagnosis from the previous year of schizophrenia; major depressive, bipolar, and paranoid disorders; or other major psychiatric disorders.

[71] Integrated Care Resources Center, Working With Medicare Webinar, *https://www.integratedcareresourcecenter.com/sites/default/files/4.15.20%20WWM%20BH%20Slide%20Deck_for%20508%20Review.pdf.*

[72] Medicaid and CHIP Payment and Access Commission. ''Integration of Behavioral and Physical Health Services in Medicaid.'' March 2016. Available at: *https://www.macpac.gov/wp-content/uploads/2016/03/Integration-of-Behavioral-and-Physical-Health-Services-in-Medicaid.pdf.*

[73] Unutzer, et al., Journal of the American Medical Association, ''Collaborative Care Management of Late-life Depression in the Primary Care Setting: A Randomized Controlled Trial'', December 11, 2002. Available at: *https://aims.uw.edu/resource-library/collaborative-care-management-late-life-depression-primary-care-setting-randomized.*

[74] Unutzer, et al., Journal of the American Medical Association, ''Collaborative Care Management of Late-life Depression in the Primary Care Setting: A Randomized Controlled Trial'', December 11, 2002. Available at: *https://aims.uw.edu/resource-library/collaborative-care-management-late-life-depression-primary-care-setting-randomized.*

[75] CMS Medicare-Medicaid Coordination Office, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'', January 17, 2020. Retrieved from: *https://www.cms.gov/httpsedit cmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

[76] CMS review of CY 2021 State Medicaid agency contracts for FIDE SNPs.

out Medicaid behavioral health include two FIDE SNPs in California, 17 FIDE SNPs in New York, and five FIDE SNPs in Pennsylvania.[77] Based on a New York State Medicaid policy change, we expect FIDE SNPs in New York to cover Medicaid behavioral health services, effective January 1, 2023, so we do not anticipate our proposal will negatively impact FIDE SNPs in New York.[78] If the remaining FIDE SNPs in California and Pennsylvania do not meet the proposed FIDE SNP definition at § 422.2, they may still meet the HIDE SNP definition proposed at § 422.2. We believe the benefit of restricting FIDE SNP designation to plans that cover Medicaid behavioral health services in the capitated contract with the State Medicaid agency outweighs the benefit of continuing to allow FIDE SNP designation for plans that do not cover these benefits.

Increasing the minimum scope of services that FIDE SNPs must cover in an integrated fashion is consistent with how section 1859(f)(8)(D) of the Act identifies Medicaid LTSS and behavioral health services as key areas for the integration of services. While the statute generally describes the increased level of integration that is required by referring to coverage of behavioral health or LTSS or both, we believe that exceeding that minimum standard is an appropriate goal for FIDE SNPs. The most integrated D–SNPs—FIDE SNPs—should cover the broadest array of Medicaid-covered services, including the behavioral health treatment and LTSS that are so important to the dually eligible population.

Further, increasing the minimum scope of services for FIDE SNPs is not inconsistent with section 1853(a)(1)(B)(iv) of the Act, which states that such plans are fully integrated with capitated contracts with States for Medicaid benefits, including LTSS. While section 1853(a)(1)(B)(iv) does not specify coverage of behavioral health services, it does not exclude coverage of behavioral health services either given that the section speaks generally to FIDE SNPs having fully integrated contracts with States for Medicaid benefits. As discussed earlier in this section, behavioral health services are critical for dually eligible individuals and benefit from coordination with Medicare services and, we believe, coverage of Medicaid behavioral health benefits by a D–SNP is key to achieving fully integrated status.

Specifically, we propose the following changes at paragraph (2) of the FIDE SNP definition at § 422.2 related to scope of services:

- Strike the words ''provides coverage consistent with State policy of'' and replace them with ''requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a FIDE SNP in the State, except as approved by CMS under § 422.107(g) and (h)'' to clarify the services the FIDE SNP must include in its capitated contract with the State Medicaid agency;
- Redesignate to a new paragraph (2)(i) the requirement that a FIDE SNP's capitated contract with the State Medicaid agency must include all primary care and acute care covered under the State Medicaid program, and newly specify that these contracts must include Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries;
- Redesignate to a new paragraph (2)(ii) the requirement that a FIDE SNP's capitated contract with the State Medicaid agency include all LTSS covered under State Medicaid policy, including coverage of nursing facility services for a period of at least 180 days during the plan year;
- Add new paragraph (2)(iii) to require that a FIDE SNP's capitated contract with the State Medicaid agency must include Medicaid behavioral health services for plan year 2025 and subsequent years;
- Add new paragraph (2)(iv) to require that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid home health services as defined at § 440.70 for plan year 2025 and subsequent years; and
- Add new paragraph (2)(v) to require that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid DME as defined at § 440.70(b)(3) for plan year 2025 and subsequent years.

d. Clarification of Coverage of Certain Medicaid Services by HIDE SNPs

CMS first defined the term ''highly integrated dual eligible special needs plan'', or HIDE SNP, at § 422.2 in the April 2019 final rule. As currently defined at § 422.2, a HIDE SNP is a type of D–SNP offered by an MA organization that has—or whose parent organization or another entity that is owned and controlled by its parent organization has—a capitated contract with the Medicaid agency in the State in which the D–SNP operates that includes coverage of Medicaid LTSS, Medicaid behavioral health services, or both, consistent with State policy. As stated in the April 2019 final rule (84 FR 15705), the HIDE SNP designation is consistent with section 1859(f)(8)(D)(i)(II) of the Act that recognizes a level of integration that does not meet the requirements of the FIDE SNP with respect to the breadth of services provided under a Medicaid capitated contract with the State.

We propose to update the HIDE SNP definition at § 422.2 consistent with proposed changes to the FIDE SNP definition described earlier in section II.A.5.c. of this proposed rule to more clearly outline the services HIDE SNPs must include in their contracts with State Medicaid agencies. Similar to our proposal for the revised FIDE SNP definition, we propose to move away from the current use of ''coverage, consistent with State policy'' language in favor of more clearly articulating the minimum scope of Medicaid services that must be covered by a HIDE SNP. Specifically, we propose the following at paragraph (2) of the HIDE SNP definition at § 422.2:

- Strike the words ''consistent with State policy, of long-term services and supports, behavioral health services, or both'' and instead require a HIDE SNP to have a capitated contract with the State Medicaid agency that requires the HIDE SNP to cover, at a minimum, Medicaid long-term services and supports or Medicaid behavioral health services;
- Reorganize paragraphs (1) and (2) into paragraphs (1)(i) and (ii) to outline that the capitated contract is between the State Medicaid agency and the MA organization or between the State Medicaid agency and the MA organization's parent organization, or another entity that is owned and controlled by its parent organization;
- Redesignate paragraph (2) into paragraphs (2)(i) and (ii) to state that the capitated contract requires coverage of LTSS, including community-based LTSS and some days of coverage of nursing facility services during the plan year, or behavioral health services to the extent Medicaid coverage of such services is available to individuals eligible to enroll in a HIDE SNP in the State; and
- To redesignated paragraph (2), add the words ''except as approved by CMS under § 422.107(g) or (h)'' such that the HIDE SNP ''requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is

[77] See *https://www.cms.gov/files/document/smacdsnpintegrationstatusesdata.xlsx.*

[78] New York State Department of Health, New York State Office of Mental Health, and New York State Office of Alcoholism and Substance Abuse Services, ''Duals Integration: Adding Behavioral Health Services into Medicaid Advantage Plus,'' December 2020.

available to individuals eligible to enroll in a HIDE SNP in the State, except as approved by CMS under § 422.107(g) or (h),'' to clarify that the HIDE SNP must cover under its capitated Medicaid contract the full scope of the Medicaid benefit for the specified LTSS or Medicaid behavioral health services, except for limited carve-outs that CMS permits under proposed § 422.107(g) or (h); and

- Add new paragraph (3) to require that the capitated Medicaid contract applies in the entire service area of the D–SNP for plan year 2025 and subsequent plan years.

Later in this section, we describe in more detail our proposal to require the capitated contract applies in the entire service area for the D–SNP. Otherwise, our proposal is generally a reorganization and clarification of the scope of Medicaid benefits that must be covered by a HIDE SNP.

e. Medicaid Carve-Outs and FIDE SNP and HIDE SNP Status

As discussed earlier, we propose to require FIDE SNPs and HIDE SNPs to cover the full scope of the Medicaid coverage under the State Medicaid program of the categories of services that are specified as minimum requirements for these plans as outlined in sections II.A.5.c. and II.A.5.d. In both definitions, we propose that coverage of the full scope of the specified categories of Medicaid benefits is subject to an exception that may be permitted by CMS under § 422.107(g) or (h). We propose to codify at § 422.107(g) and (h), respectively, current CMS policy allowing limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNPs. As discussed in section II.A.5.c.1. of this proposed rule, CMS has historically determined D–SNPs to be FIDE SNPs even where the State carved out certain primary care, acute care, LTSS, and behavioral health services from the Medicaid coverage furnished by the MCO offered by the FIDE SNP. CMS has similarly permitted carve-outs of the scope of Medicaid coverage furnished in connection with HIDE SNPs. We believe that codifying these policies would improve transparency for stakeholders and allow us to better enforce our policies to limit benefit carve-outs.

Our proposal is consistent with the policy described in a memorandum CMS issued in January 2020,[79] with some revisions to improve clarity and avoid misinterpretations of our policy that might result from language in the memorandum that differs in the allowed carve-outs for LTSS and behavioral health services. Like the memorandum, our proposal is designed to accommodate differences in State Medicaid policy—for example, the desire to retain delivery through the Medicaid FFS program of specific waiver services applicable to a small, specified population, or to retain coverage in the Medicaid FFS program for specific providers—without significantly undermining the level of Medicaid integration provided by HIDE SNPs and FIDE SNPs. While we generally favor integration and worry that Medicaid benefit carve-outs work against integration, we believe our proposal strikes a balance between the current realities of State managed care policy, applicable statutory provisions, and our implementation of those statutory provisions toward the goal of raising the bar on integration.

Currently and under our proposal to revise the definition, a D–SNP may meet the criteria for designation as a HIDE SNP if it covers either Medicaid LTSS or Medicaid behavioral health services under a State Medicaid agency contract. The Medicaid contract may be between the State and either the legal entity providing the D–SNP, the parent organization of the D–SNP, or a subsidiary owned or controlled by the parent organization of the D–SNP. As discussed in the April 2019 final rule (84 FR 15705), the breadth of Medicaid LTSS coverage under a HIDE SNP does not have to be as broad as the coverage of Medicaid benefits provided by a FIDE SNP. For example, a HIDE SNP is not required to provide at least 180 days of nursing facility coverage during the plan year. If the HIDE SNP designation is based on coverage of Medicaid LTSS, such capitated coverage must include both of the following: Community-based LTSS, subject to permissible carve-outs, and institutional LTSS. Institutional LTSS must include coverage of nursing facility services with some days for which Medicaid coverage is primary but, in contrast to a FIDE SNP, may be less than 180 days each plan year. However, if a HIDE SNP designation is based on coverage of Medicaid behavioral health services, the HIDE SNP can cover some community-based and/or institutional LTSS or no LTSS.

We currently grant FIDE SNP status despite Medicaid LTSS carve-outs of limited scope if such carved-out services (1) apply to a minority of the full-benefit dually eligible LTSS users eligible to enroll in the FIDE SNP who use long-term services and supports or (2) constitute a small part of the total scope of Medicaid LTSS provided to the majority of full-benefit dually eligible individuals eligible to enroll in the FIDE SNP who use Medicaid LTSS. Examples of permissible LTSS carve-outs for FIDE SNPs that apply to a minority of full-benefit dually eligible LTSS users may include services specifically limited to individuals with intellectual or developmental disabilities, individuals with traumatic brain injury, or children. Carve-outs of specific Medicaid LTSS would be permissible if the carved-out services would typically only be a small component of the broad array of LTSS provided to the majority of Medicaid LTSS users eligible to enroll in the FIDE SNP. We would not, however, expect to approve carve-outs for LTSS services for a specific population—for example, individuals with intellectual or developmental disabilities—if enrollment in the FIDE SNP was limited to individuals with those disabilities. For example, personal emergency response systems or home modifications may be important supports for participants in a Medicaid home and community-based waiver program. However, those specific services would rarely constitute the preponderance of an enrolled dually eligible individual's care plan because most individuals receiving such services also receive other types of in-home supports, such as personal care services. In contrast, we would not expect to approve carve-outs of in-home personal care or related services provided to older adults or people with disabilities even if such services were limited to individuals meeting a nursing home level of care.

D–SNPs can currently obtain the HIDE SNP designation with limited carve-outs of Medicaid behavioral health services from their capitated contracts. A behavioral health services carve-out would be of limited scope if such service: (1) Applies primarily to a minority of the full-benefit dually eligible users of behavioral health services eligible to enroll in the HIDE SNP; or (2) constitutes a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the HIDE SNP. We specify that only a small part of the Medicaid behavioral health services may be carved out in order to ensure that the innovative services that many Medicaid programs provide to individuals with severe and moderate

[79] CMS, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'', January 17, 2020. Retrieved from: *https://www.cms.gov/ httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

mental illness are covered through the D–SNP or the affiliated Medicaid managed care plan. We believe that level of integrated coverage is a minimum standard for a D–SNP to be considered highly or fully integrated. It would be insufficient for a HIDE SNP or FIDE SNP to solely cover the counseling services where Medicare is primary. Examples of permissible carve-outs that apply to primarily a minority of full-benefit dually eligible users of such services who are eligible to enroll in the HIDE SNP include school-based services for individuals under 21 years of age and court-mandated services. Examples of permissible carve-outs that constitute a small part of the total scope of Medicaid behavioral health services include inpatient psychiatric facilities and other residential services, such as payment of Medicare cost-sharing or coverage of days not covered by Medicare; substance abuse treatment, such as payment of Medicare cost-sharing or coverage of services not covered by Medicare; services provided by a Federal Qualified Health Center or Rural Health Clinic; and Medicaid-covered prescription drugs for treatment of behavioral health conditions. We believe such carve-outs would still allow FIDE SNPs and HIDE SNPs to meaningfully integrate Medicaid behavioral health coverage for their enrollees. We seek comment on whether we have struck the right balance in permitting such carve-outs, including for the examples cited previously.

Specifically, we propose the following language at § 422.107:

- Add new paragraph (g) to describe that a D–SNP may meet the FIDE SNP or HIDE SNP definition at § 422.2 even if the contract between the State and the plan carves out some Medicaid LTSS, as long as the carve-out, as approved by CMS, applies primarily to a minority of beneficiaries eligible to enroll in the D–SNP who use long-term services and supports or constitutes a small part of the total scope of Medicaid LTSS provided to the majority of beneficiaries eligible to enroll in the D–SNP;
- Add new paragraph (h) to describe that a D–SNP may meet the FIDE SNP or HIDE SNP definition at § 422.2 even if the contract between the State and the plan carves out some Medicaid behavioral health services, as long as the carve-out, as approved by CMS, applies primarily to a minority of beneficiaries eligible to enroll in the D–SNP who use behavioral health services or constitutes a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the D–SNP; and
- Redesignate paragraph (e) ''Date of Compliance'' as new paragraph (i) due to the proposed new paragraphs (e) through (h).

We intend to administer this proposed regulation consistent with our current policy and therefore anticipate little disruption to occur because of this proposed change.

f. Service Area Overlap Between FIDE SNPs and HIDE SNPs and Companion Medicaid Plans

MA organizations can achieve greater integration when they maximally align their FIDE SNP and HIDE SNP service areas with the service areas of the affiliated Medicaid managed care plan (meaning the entities that offer capitated Medicaid benefits for the same members under a capitated contract with the State). Service area alignment also better comports with the minimum Medicare-Medicaid integration standards established by section 50311(b) of the BBA of 2018, which amended section 1859 of the Act and is codified at § 422.2.

Currently, under § 422.2, a D–SNP can meet the requirements to be designated as a FIDE SNP and HIDE SNP even if the service area within a particular State does not fully align with the service area of the companion Medicaid plan (or plans) affiliated with their organization.[80] For FIDE SNP and HIDE SNP members outside the companion Medicaid plan's service area, this lack of alignment does little to integrate Medicare and Medicaid benefits as the D–SNP member does not have the option to join the companion Medicaid plan. In its June 2019 report to Congress, MedPAC illustrated service area misalignment between D–SNPs and companion Medicaid managed LTSS plans, finding a significant number of D–SNP members not in the same service area as the D–SNP sponsor's Medicaid managed LTSS offering.[81] In its June 2021 report to Congress, MACPAC recommended States use the State Medicaid agency contracts (required for D–SNPs by § 422.107(b)) to completely align service areas between a D–SNP and a Medicaid managed care plan to better integrate coverage and care.[82] We believe requiring service area alignment in the definitions of FIDE SNP and HIDE SNP would encourage MA organizations and States to create better experiences for beneficiaries and move toward greater integration, which would be consistent with the amendments to section 1859(f) of the Act made by section 50311(b) of the BBA of 2018.

Under our authority at section 1859(f)(8)(D) of the Act to require that all D–SNPs meet certain minimum criteria for Medicare and Medicaid integration, we are proposing to amend the definitions of FIDE SNP and HIDE SNP at § 422.2. We propose to amend the FIDE SNP definition by adding new paragraph (6) and the HIDE SNP definition by adding new paragraph (3) to require that the capitated contracts with the State Medicaid agency cover the entire service area for the D–SNP for plan year 2025 and subsequent years. Requiring the service area of the Medicaid capitated contract to include at least the service area of the D–SNP contract allows all FIDE SNP and HIDE SNP enrollees to access both Medicare and Medicaid benefits from a single parent organization. These proposed changes to § 422.2 are in addition to the other edits proposed to the definitions of FIDE SNP and HIDE SNP at § 422.2 as described in this proposed rule.

Our proposal addresses an unintended loophole to the minimum D–SNP integration criteria we have adopted as part of the definitions of FIDE SNP and HIDE SNP: Where a D–SNP can qualify as either a FIDE SNP or HIDE SNP by only having a small portion of its members in the same service area as the companion Medicaid plan. Where the overlap in the service areas for the separate MA D–SNP contract and the Medicaid capitated contract is small, the opportunity for Medicare-Medicaid integration is similarly limited as only enrollees in that overlapping area have the potential to receive benefits from an integrated plan with both MA and Medicaid managed care plan contracts under a single parent organization. In such a FIDE SNP or HIDE SNP, the members without access to the companion Medicaid plan might not benefit even from the improved care coordination possible under the notification requirement at § 422.107(d) required for a D–SNP that is not a FIDE SNP or HIDE SNP if the State has not imposed that requirement. We do not believe that is consistent with the goals and purposes

[80] CMS has acknowledged this and encouraged MA organizations to align these service areas in guidance issued on January 17, 2020, regarding D–SNPs. See *https://www.cms.gov/files/document/cy2021dsnpsmedicaremedicaidintegrationrequirements.pdf.*

[81] Medicare Payment Advisory Commission, ''Report to the Congress: Medicare and the Health Care Delivery System,'' June 2019. Retrieved from: *https://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf.*

[82] MACPAC, Report to Congress on Medicaid and CHIP, ''Chapter 6: Improving Integration for Dually Eligible Beneficiaries: Strategies for State Contracts with Dual Eligible Special Needs Plan,'' June 2021. Retrieved at: *https://www.macpac.gov/wp-content/uploads/2021/06/June-2021-Report-to-Congress-on-Medicaid-and-CHIP.pdf.*

of increasing integration for D–SNPs as a whole or particularly for FIDE SNPs and HIDE SNPs, which are supposed to have more than a bare minimum level of integration.

The proposal is not intended to limit State options for how they contract with managed care plans for their Medicaid programs, but to require the FIDE and HIDE SNPs to limit their MA service areas to areas within the service areas for the companion Medicaid plan. Our proposal would not limit the service area of the companion Medicaid plan to that of the D–SNP service area. Therefore, the companion Medicaid plan may have a larger service area than the D–SNP. States, in their contracting arrangements for Medicaid managed care programs, may wish to limit the service areas of the affiliated Medicaid managed care plans, but we recognize that States have other policy objectives better met with larger service areas in their Medicaid managed care programs.

In plan year 2021, all FIDE SNPs meet the service area requirement being proposed. Most, but not all, HIDE SNPs also meet the proposed requirement. As of June 2021, there were 1,302,505 HIDE SNP members across 16 States in 186 HIDE SNP plan benefit packages and 89 contracts.[83] In four States, 20 HIDE SNPs have service area gaps with their affiliated MCOs, leaving 97,004 members in 174 counties with no corresponding Medicaid plan.[84] Approximately half the D–SNPs with unaligned service area have over 50 percent of their enrollment in the unaligned service area, and the vast majority of HIDE SNP members and counties with unaligned service areas are concentrated in one State and one parent organization. Therefore, we believe some HIDE SNPs have only met the D–SNP integration requirements for a fraction of their enrollment due to the unintended gap in integration that is created by a lack of service area alignment.

If finalized, an MA organization impacted by our proposal would have several options. First, the organization can work with the State to expand their companion Medicaid plan service area to the full D–SNP service area, thus increasing the opportunity for integrated care and qualifying as a HIDE SNP under our proposal. Second, the MA organization can request to crosswalk enrollees (using the crosswalk exception currently at § 422.530(c)(4), which we are proposing to redesignate as § 422.530(c)(4)(i) in section II.A.6.a.) from the existing D–SNP that includes the service area outside of the companion Medicaid plan service area into a new D–SNP; the end result is two separate D–SNPs, one which qualifies as a HIDE SNP (because it has the overlapping service area with the companion Medicaid plan and meets other requirements) and another D–SNP that, because it is neither a FIDE SNP nor a HIDE SNP, would need to meet the notification requirement at § 422.107(d). Third, the MA organization can keep the existing service area for the existing D–SNP and contract with the State as a non-HIDE D–SNP by meeting the notification requirement at § 422.107(d).

These options all require the MA organization to collaborate with the State Medicaid agency. We believe that a State currently engaged with MA organizations to integrate care through a HIDE SNP would likely be willing to work with the MA organization to come into compliance with the proposed rule. However, if the State was unwilling to engage with the MA organization, the MA organization would need to end the HIDE SNP plan benefit package in the unaligned service area. We seek comment on whether this proposal would likely result in additional, unintended disruption for current HIDE SNP membership, particularly if such unintended disruption is for more than the initial year of transition. We generally believe that the additional integration—and the benefits from higher integration—outweigh the limited disruption potentially caused by realignment of FIDE SNP and HIDE SNP service areas to meet this proposed requirement by 2025.

We are considering an alternative of establishing a minimum percentage of enrollment or service area overlap between the D–SNP affiliated Medicaid plan and having FIDE SNPs and HIDE SNPs attest to meeting the minimum overlap requirement. That is, a D–SNP would qualify as a FIDE SNP or HIDE SNP if a minimum percentage of the D–SNP enrollment resides in the companion Medicaid plan (or plans) service area or if a minimum percentage of the D–SNP service area overlaps with the companion Medicaid plan (or plans). We are also considering an amendment to explicitly codify how the current requirements permit D–SNPs to be designated as a FIDE SNP or HIDE SNP even if their service area within a particular State does not fully align with the service area of the companion Medicaid plan (or plans). We are not proposing either of these alternative approaches because we believe these alternatives create greater operational complexity (in the case of establishing a minimum percentage overlap) and would fail to help us achieve our objectives of clarifying options for beneficiaries and creating better coordination of Medicare and Medicaid benefits for all enrollees of the FIDE SNP or HIDE SNP compared to current practice. We seek comment on these alternatives, including input on what an appropriate percentage threshold of overlap in the services areas should be, whether an attestation process would provide the necessary level of oversight, and whether the status quo, with a clarification in the regulation text, creates a sufficient level of integration for FIDE SNPs and HIDE SNPs. We are interested in comments on whether the alternatives create sufficient improvements in coordination of the Medicare and Medicaid benefits compared to current practice or if the alternatives would adequately address the policy goals outlined in this proposal.

6. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

Section 164 of MIPPA amended section 1859(f) of the Act to require that each D–SNP contract with the State Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, to which an enrollee is entitled. Implementing regulations are codified at § 422.107. Notwithstanding this State contracting requirement for D–SNPs, section 164(c)(4) of MIPPA does not obligate a State to contract with a D–SNP, which therefore provides States with significant control over the availability of D–SNPs in their markets. The State's discretion to contract with D–SNPs, combined with the State's control over its Medicaid program, creates flexibility to require greater integration of Medicare and Medicaid benefits from the D–SNPs that operate in the State. For example, to develop products that integrate Medicare and Medicaid coverage, several states—

[83] CMS, SNP Comprehensive report, June 2021. Retrieved at: *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldataspecial-needs/snp-comprehensive-report-2021-06.*

[84] Internal analysis based on data from: CMS, Monthly Enrollment by Contract, March 2021. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract;* CMS, Monthly Enrollment by Contract/Plan/State/County, March 2021. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract-Plan-State-County;* CMS, D–SNP Integration Levels for CY 2021. Retrieved from: *https://www.cms.gov/files/document/smacdsnpintegrationstatusesdata.xlsx;* and service area information from State Medicaid agency websites.

including Arizona, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, Pennsylvania, and Tennessee—operate Medicaid managed care programs for dually eligible individuals in which the State requires that the Medicaid MCOs serving dually eligible individuals offer a companion D–SNP product. These States also require specific care coordination or data sharing activities in their contracts with D–SNPs.[85]

Even among States that have used the State Medicaid agency contract at § 422.107 to promote integration, we believe there are additional opportunities to improve beneficiary experiences and health plan oversight. We propose addressing such opportunities in this section of this proposed rule.

We propose a new paragraph (e) at § 422.107 to describe conditions under which CMS would facilitate compliance with certain contract terms that States require of D–SNPs that operate in the State. Proposed paragraph (e)(1) provides that CMS will take the steps described in proposed paragraphs (e)(2) and (3) when a State Medicaid agency's contracts with D–SNPs require exclusively alignment enrollment and require the D–SNPs to request MA contracts that only include one or more State-specific D–SNPs and that such D–SNPs use integrated member materials. We do not believe that proposed paragraph (e)(1), in and of itself, creates or limits opportunities already available to States to contract with D–SNPs. The primary purpose of proposed paragraph (e)(1) is to establish a pathway for States with parameters for how CMS will work with the State when the State wishes to require D–SNPs with exclusively aligned enrollment in that State to operate under D–SNP-only MA contracts and use specific integrated enrollee materials. The requirements described in proposed paragraph (e)(1) require work on the part of CMS to facilitate compliance by D–SNPs with the State's requirements. Therefore, proposed paragraphs (e)(2) and (3) describe steps CMS would take when the conditions of proposed paragraph (e)(1) are met.

a. Limiting Certain MA Contracts to D–SNPs

Special needs plans, including D–SNPs, are currently included as separate plans, also known as ''plan benefit packages (PBPs),'' under the same contract number along with any other MA plans of the same product type (for example, health maintenance organization (HMO), preferred provider organization (PPO), etc.) offered by the legal entity that is the MA organization. MA organizations may offer multiple PBPs under the same contract number, and the plans under these contracts may have service areas in multiple States or regions. PBPs under one contract number may have very different benefit packages and serve different populations. MA organizations report medical loss ratios and certain quality measures—including many Star Ratings measures—at the contract level, which does not allow for differentiation of PBPs that are D–SNPs. While we capture some measures at the PBP level, unless a D–SNP is the only PBP in a contract, it is not possible to ascertain a full and complete picture of the quality performance (for example, CAHPS, HEDIS,[86] Medicare Health Outcomes Survey (HOS), Star Ratings) of the D–SNP distinguished from other PBPs in the contract. Combining data from all PBPs offered under a contract, however, ensures that there is generally a large enough sample to administer CAHPS surveys and calculate HEDIS measures; CMS has discussed the possibility of collecting data and assigning Star Ratings at the plan level in the past, such as in the April 2018 final rule (83 FR 16526 through 16528). Currently, §§ 422.162(b) and 423.182(b) provide for Star Ratings to be assigned at a contract level.

It has been a long-standing CMS policy that CMS only award a legal entity one contract for each product type (for example, HMO, PPO, RPPO, etc.) it seeks to offer for all PBPs for the totality of the States.[87] Under CMS's administration of the MA program, SNPs and non-SNPs may be PBPs in the same contract(s) so long as they are the same product type (for example, SNP HMO and non-SNP HMO PBPs can be in the same contract, but a SNP HMO and non-SNP PPO would not be). Except under our existing authority in § 422.550 where there is a change in ownership or for purposes of model tests under Section 1115A that utilized D–SNPs, CMS has not previously permitted MA organizations to create separate D–SNP contracts. If necessary, under §§ 422.504(k) and 423.504(e), CMS does have authority to sever specific PBPs from a contract and to deem a separate contract is in place for the severed PBP(s).

The majority of D–SNPs are in contracts that include other non-SNP MA plans. Of the 276 D–SNP PBPs offered in CY 2021, only 88 (32 percent) are in D–SNP-only contracts.[88] Given the important distinctions of D–SNPs in comparison to other MA plans, States and other stakeholders have expressed an interest in better understanding performance of these plans without data being combined with non-D–SNPs. Throughout our work with MMPs, we and our State partners benefited from having performance data that was specific to the MMP.

Therefore, we are proposing to codify a pathway where if a State requires an MA organization to establish a contract that only includes one or more D–SNPs with exclusively aligned enrollment within a State, the MA organization may apply for such a contract using the existing MA application process. We do not anticipate this proposal would create a large volume of new contracts, because most States do not meet the prerequisite of requiring exclusively aligned enrollment, and—among those that do—some D–SNPs are already in D–SNP-only contracts. The proposed language at § 422.107(e)(1)(i) would give States the flexibility to require an MA organization to establish one or more D–SNP-only contracts, which would provide more transparency in D–SNP plan performance within States. For example, the Florida State Medicaid agency could allow an MA organization serving South Florida and the Florida Panhandle to establish one D–SNP-only contract for South Florida and a separate D–SNP-only contract for the Florida Panhandle.[89]

[85] Verdier, J., Kruse, A., Sweetland Lester, R., Philip, A.M., and Chelminsky, D. *State Contracting with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options* (November 2016). Retrieved from *https://www.integratedcareresourcecenter.com/sites/default/files/ICRC_DSNP_Issues__Options.pdf;* MACPAC, Report to Congress on Medicaid and CHIP, ''Chapter 6: Improving Integration for Dually Eligible Beneficiaries: Strategies for State Contracts with Dual Eligible Special Needs Plan,'' (June 2021). Retrieved from *https://www.macpac.gov/wp-content/uploads/2021/06/June-2021-Report-to-Congress-on-Medicaid-and-CHIP.pdf.*

[86] Certain HEDIS measures are reported by SNPs at the PBP level and are available in public use files that can be used to review and assess D–SNP performance outside of CMS's Quality Star Rating program. These PBP-level measures are used to calculate the Care for Older Adults measures in Star Ratings, but they are not used to calculate Star Ratings to compare performance across MA plans. The public use files are available at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata?redirect=/mcradvpartdenroldata.*

[87] The following memo outlines the policy for CY2020, which has been in effect for several years: CMS HPMS Memo, ''Release of Notice of Intent to Apply for Contract Year 2021 Medicare Advantage (MA), Medicare-Medicaid Plans (MMP), and Prescription Drug Benefit (Part D) and Related CY 2021 Application Deadlines'', October 17, 2019. Retrieved from *https://www.cms.gov/files/document/2021-noia-partcpartd-mmp.pdf.*

[88] CMS, Contract Management Reports 2020, SNP Type and Subtype Report, August 7, 2020.

[89] Due to smaller enrollment compared to broader MA contracts, D–SNP-only contracts may experience sample size issues, such that certain

Where States choose to use this opportunity, it would have several benefits. First, it would provide the State and the public with greater transparency on the quality ratings for the D–SNP, reflecting outcomes and experiences specific to dually eligible individuals in the State.[90] This can help CMS and States better identify disparities between dually eligible and other beneficiaries and target interventions accordingly where the population covered by the D–SNP-only contract is of sufficient size to reliably report performance on quality measures and surveys. Second, it would improve transparency on financial experiences related to furnishing Medicare and Medicaid benefits because the contract's medical loss ratio would reflect Medicare financial experience specific to dually eligible individuals in the State that are enrolled in a companion Medicaid MCO as well as the D–SNP because this proposal is limited to D–SNPs with exclusively aligned enrollment. Exclusively aligned enrollment, as defined in § 422.2, means the Medicaid MCO that furnishes Medicaid benefits is the same as the D–SNP, the D–SNP's parent organization, or owned and controlled by the D–SNP's parent organization. Third, it would allow a D–SNP to create a MOC that is specific to the State, which would facilitate review by the State and provide opportunities for greater customization of the MOC to the State's Medicaid-related policies and priorities. Fourth, it would enable CMS to review and evaluate the provider network specific to the D–SNPs offered under that D–SNP-only contract.

We describe at proposed § 422.107(e)(2) how the CMS administrative steps to permit a new D–SNP-only contract would be initiated by receipt of a letter from the State Medicaid agency indicating its intention to include the contract requirements under § 422.107(e)(1) in its contract with specific MA organizations offering, or intending to offer, D–SNPs with exclusively aligned enrollment in the State. We will provide States with additional information on timelines and procedures in sub-regulatory guidance; we may also address our recommendations for best practices and identify considerations for States that are considering this. We would expect the following steps—which are consistent with current timeframes and procedures for submission of applications, bids and other required materials to CMS—to be taken if a State sought to include these requirements for the 2025 plan year:

- Consistent with CMS recommendations, the State consults with CMS, MA organizations, and other stakeholders beginning in early 2023 on whether to add the requirements at § 422.107(e)(1) to its State Medicaid agency contract.
- Upon reaching a decision to proceed, the State would notify CMS (by letter) and the affected MA organizations by August 2023 to enable the MA organization and CMS to start the necessary steps.
- Following existing timelines and procedures for applications, bids, and other annual submissions, and consistent with § 422.501(b), the impacted MA organizations would submit a Notification of Intent to CMS to apply for a new D–SNP-only contract in November of 2023 and an application for a new D–SNP-only contract (beginning January 2025) in February of 2024.
- CMS and the State would develop integrated SB, Formulary, and combined Provider and Pharmacy Directory model materials from January through June 2024.
- The impacted MA organizations would submit a bid for the D–SNP PBP in the new D–SNP-only contract per § 422.254 by the first Monday in June 2024.
- The impacted MA organizations would not submit a bid in June 2024 for the D–SNP PBP that had been included in the non-D–SNP-only MA contract, indicating it is non-renewing the existing PBP.
- The affected D–SNPs would submit their State Medicaid agency contracts, including the provisions described at § 422.107(e)(1), in July of 2024 and the D–SNP's request to use the proposed crosswalk exception at § 422.530(c)(4)(ii) in June of 2024 to move enrollees from the non-renewing D–SNP to the new D–SNP offered under the D–SNP-only contract.
- Subject to compliance with all Part C and Part D requirements, CMS would approve the new D–SNP PBP and its bid in the D–SNP-only contract for CY 2025 in September 2024.
- Dually eligible beneficiaries enrolled in non-renewing D–SNP PBPs could be crosswalked to the new D–SNP PBP in October 2024 for a January 1, 2025 effective date if the MA organization requests the crosswalk exception proposed at § 422.530(c)(4)(ii) and it is approved by CMS.
- The new D–SNP PBP into which individuals are crosswalked describes changes to the MA–PD benefits and provides information about the D–SNP PBP in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e) for beneficiary receipt in early October 2024.

Establishing D–SNP-specific contracts creates some new challenges. CMS would have added administrative burden to oversee a larger number of contracts. MA organizations would similarly experience new burdens, such as additional reporting to CMS, calculation of HEDIS measures, and administration of HOS and CAHPS surveys. We believe these costs are modest relative to the benefits. We solicit comments on other consequences that would flow from our proposal, both in terms of benefits for the MA organizations, States, and dually eligible individuals and potential unforeseen difficulties for these stakeholders.

Finally, to avoid any significant beneficiary disruption, we propose a new crosswalk exception to allow MA sponsors to seamlessly move D–SNP members into any D–SNP-only contract created under this proposal. Our proposed crosswalk exception would apply only for movement between plans of the same product type (HMO, PPO, etc.) under the same parent organization for the following contract year when the new D–SNP is created under a new D–SNP-only contract based on a State requirement as described in proposed § 422.107(e). It would allow transition to a D–SNP under a contract subject to proposed § 422.107(e) from a D–SNP that is non-renewing, has enrollees residing in the portion of the current service area impacted by the service area reduction, or has its eligible population newly restricted by a State contract. To add this new crosswalk exception, we propose redesignating the existing paragraph (c)(4) into new paragraphs (c)(4)(i) and (ii) in § 422.530. Under this proposal, the processes used for other crosswalk exceptions (for example, the notice to CMS and CMS' review and approval of the crosswalk exception) would apply to this new crosswalk exception.

We seek comment on this new proposed crosswalk exception and whether any additional beneficiary protections should apply.

quality measures (for example, HEDIS and CAHPS) may not have sufficient data to reliably report performance. States may want to consider this implication when contemplating whether to establish D–SNP-only contracts, particularly if a State wishes to further limit D–SNP-only contracts based on regions within the State.

[90] Star Ratings for the new D–SNP-only contracts would be calculated in accordance with § 422.166. As described at § 422.166(d)(2)(vi), new D–SNP-only contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 would be assigned Quality Bonus Payment ratings based on the enrollment-weighted average highest rating (as defined at § 422.162) of the parent organization's other MA contract(s).

b. Integrated Member Materials

Communicating information to enrollees and potential enrollees is an important function of MA plans, Part D plans, and Medicaid managed care plans—and D–SNPs with exclusively aligned enrollment must comply with all of those rules.[91] There are advantages for enrollees in D–SNPs with exclusively aligned enrollment in receiving one set of communications that integrates all of the required content, as discussed in more detail later in this section, so we are proposing a mechanism and some parameters to facilitate a State's election to have D–SNPs with exclusively aligned enrollment use certain communications materials that integrate content about Medicare and Medicaid. Under this proposal, the applicable Medicaid managed care and MA requirements and standards would continue to apply to the integrated materials. As background, we discuss in this section some of the requirements for mandatory communications materials in the MA and Medicaid programs.

CMS requires MA plans and Part D plans to furnish specific information to enrollees and potential enrollees, with some specific requirements outlined in §§ 422.111 and 423.128 and additional requirements at §§ 422.2261, 422.2267, 423.2261, and 423.2267. For information that CMS deems vital to Medicare beneficiaries, including information related to enrollment, benefits, health, and rights, CMS may develop and provide materials or content for MA organizations and Part D sponsors in either standardized or model form. Standardized materials are subject to requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) and the Office of Management and Budget (OMB) collection of information approval process no less than every 3 years.[92] While MA organizations and Part D sponsors must use *standardized* materials and content in the form and manner CMS provides, CMS *model* materials and content are examples of how to convey information to beneficiaries. MA organizations and Part D sponsors may use CMS's *model* materials or craft their own materials or content, provided the MA organization or Part D sponsor accurately conveys the vital information in the required material or content to the beneficiary and follows CMS's order of content, when specified. In §§ 422.2267 and 423.2267, we refer to such materials and content collectively as required materials.

CMS also includes similar, minimum Federal requirements in § 438.10 for Medicaid managed care plans (including MCOs) to furnish certain materials and information to enrollees and potential enrollees in a manner that is easily understood and readily accessible (OMB control number 0938–0920). However, CMS does not create standardized or model materials for use by Medicaid managed care plans. States may create such required materials and have primary responsibility for ensuring that Medicaid managed care plans comply with the minimum information requirements in § 438.10 and any additional requirements imposed by the State. Among the materials that Medicaid managed care plans must distribute are enrollee handbooks, provider directories, and formularies.

To allow MA organizations and Part D sponsors sufficient time to populate required materials with plan-specific information; submit them through the CMS Health Plan Management System (HPMS) for submission, or submission and approval, as applicable; translate them into any non-English language that is the primary language of at least 5 percent of the individuals in the service area; and make them available to beneficiaries by the required dates indicated later in this section, CMS aims to issue required materials and instructions annually by the end of May for the following plan year.

Among the required materials that MA organizations and Part D sponsors must provide to current and prospective members, and post to their websites by October 15 prior to the beginning of the plan year, are—

- Evidence of Coverage (EOC), which is a standardized communications material that tells members how to get plan-covered health care services and prescription drugs and explains member rights and responsibilities. To comply with § 422.111(b)(2)(iii), CMS expects D–SNPs to modify language in the standardized EOC, as applicable, to address and include Medicaid benefits for which enrollees are eligible, and CMS permits D–SNPs to use further modifications to explain Medicaid benefits the D–SNP furnishes to its enrollees. Plans must send the EOC, or a notice informing enrollees how to access it electronically, to current enrollees by October 15 of each year and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later). The EOC is similar to the model enrollee handbook that States are required to develop for Medicaid MCOs to send under § 438.10(c)(4)(ii).
- Annual Notice of Changes (ANOC), which is a standardized marketing material that provides information to current members about changes for the upcoming contract year. It identifies any changes to the plan's health care services, prescription drugs, cost-sharing for MA benefits (including Part A and Part B benefits and supplemental benefits), and administrative items such as contract number or grievance and appeal procedures. D–SNPs may also modify language in the ANOC, as applicable, to address and include Medicaid changes. Plans must send the ANOC to current enrollees for receipt no later than September 30 of each year, except that enrollees with an October 1, November 1, or December 1 enrollment effective date must receive the ANOC within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.
- Summary of Benefits (SB), which is a model marketing material that provides prospective members a description of health care services and prescription drugs the plan will cover in the upcoming contract year. It helps individuals determine which plans best meet their needs. D–SNPs must describe or identify their Medicaid benefits, and FIDE SNPs and HIDE SNPs may display integrated benefits where applicable. Plans are not required to send SBs to all prospective members but, in our experience, many do and make the SB available by October 15 of each year. CMS permits distribution of marketing materials as early as October 1 of each year.
- Formulary, which is a model communications material that includes the list of Medicare Part D drugs the plan covers when the drugs are medically necessary and filled at one of the plan's network pharmacies. The formulary also includes information about plan-covered over-the-counter (OTC) drugs and non-drug OTC products, any mail-order procedures, and utilization management procedures such as prior authorizations, step therapy, or quantity limits that the plan requires.[93] Plans must send the Formulary, or a notice informing how to

[91] Because D–SNPs must offer Part D benefits, they are subject to both MA requirements in part 422 and Part D requirements in part 423. *See* §§ 422.2 (definition of specialized MA plans for special needs individuals) and 422.500.

[92] Refer to *www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995* and *www.govinfo.gov/content/pkg/FR-1995-08-29/pdf/95-21235.pdf.*

[93] Refer to *www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials.*

access it electronically, for current enrollees, for receipt by October 15 of each year, and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later).

• Provider Directory, which is a model communications material that lists the number, types, and addresses for the plan's network providers and rules about access to providers, such as authorization and referral requirements. D–SNPs using this model may identify Medicare providers who also accept Medicaid.[94] Plans must send the Provider Directory, or a notice informing how to access it electronically, for current enrollees, for receipt by October 15 of each year, and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later).

• Pharmacy Directory, which is a model communications material that contains a list of the plan's network pharmacies and contact information, including all retail, mail-order, home infusion, and long-term care options.[95] Plans must send the Pharmacy Directory, or a notice informing how to access it electronically, for current enrollees for receipt by October 15 of each year, and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later).

CMS encourages D–SNPs to add related Medicaid information in the EOC, ANOC, SB, and Provider Directory. Further integrating Medicare and Medicaid information in these required materials, as well as in the Formulary and Pharmacy Directory, can improve beneficiary experiences by providing a more seamless description of health care coverage and enhancing the understanding of and satisfaction with the coverage both programs provide.

CMS conducts studies to improve the effectiveness of the model and standardized beneficiary materials and content that we provide to MA and Part D plans for their use in communicating with enrollees and potential enrollees. To test materials, we conduct individual interviews with dually eligible individuals and desk reviews by contractors, CMS subject matter experts, and advocacy organizations. Since 2015, we have tested an integrated EOC, ANOC, SB, Formulary, and combined Provider and Pharmacy Directory. For example, a 2017 study focused on beneficiary assessment of the Provider and Pharmacy Directory. Beneficiaries consistently described the CMS model directory as ''clear,'' ''simple,'' and ''easy to read.'' Beneficiaries also noted that the integrated version of the directory with the combined information on Medicare and Medicaid providers/pharmacies was comparatively better than separate Medicare and Medicaid directories they received from their current or previous insurance plans. We received similarly positive feedback from individuals with disabilities and from Spanish-speaking beneficiaries who tested a translated version.

MMPs participating in the capitated financial alignment model and the Minnesota Senior Health Options (MSHO) plans in the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience use integrated versions of these required materials. In addition, since 2019, CMS has worked with Massachusetts, New Jersey, and the FIDE SNPs in each State to develop and annually update certain integrated materials that the States require and issue to these plans. For contract years 2020 and 2021, we provided high-level assistance to New York as the State developed select integrated materials that its Medicaid Advantage Plus (MAP) plans could use. We are also working with California for contract year 2023 to develop integrated materials for those D–SNPs with exclusively aligned enrollment receiving Cal MediConnect members at the end of the California capitated FAI demonstration in 2022.

For the D–SNPs we have worked with, CMS typically begins development of integrated national templates and State-specific models with the SB; a Formulary that contains Medicare Part D, Medicaid, and OTC drugs as well as non-drug OTC products; and one combined Medicare and Medicaid Provider and Pharmacy Directory. Starting with these materials has several advantages. First, these materials integrate key Medicare and Medicaid information, which dually eligible individuals can use to make more knowledgeable decisions about their health care choices. Second, the SB, Formulary, and Provider and Pharmacy Directory are required materials but are not standardized and, therefore, are not subject to the PRA clearance process, which often takes nine months or more to complete. In contrast, D–SNPs must use standardized materials, as discussed earlier, without modification to the language, content, format, or order of information except in a few, specific instances per § 422.2267. Third, the SB, Formulary, and Provider and Pharmacy Directory models are not lengthy or overly complex. They also offer opportunities for D–SNPs in different States with different Medicaid requirements to provide prospective and current dually eligible enrollees a more seamless presentation of essential information about their Medicare and Medicaid coverage. This can contribute to increased understanding of and satisfaction with the coverage both programs provide.

To provide a more coordinated beneficiary experience, we propose at § 422.107(e) to codify a pathway by which CMS would coordinate with a State that chooses to require, through its State Medicaid agency contract, that certain D–SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory (which would have to comply with §§ 422.111, 422.2267(e)(11), 423.128, 423.2267(e), and 438.10(h)). Proposed § 422.107(e)(1) establishes factual circumstances that would commit CMS to certain actions under proposed paragraphs (e)(2) and (3). We anticipate that there would be operational and administrative steps at the CMS and State level that would be necessary before a D–SNP could implement integrated communications materials, such as collaboration and coordination by CMS and the State on potential template materials, identification of potential conflicts between regulatory requirements at 42 CFR parts 422 and 423 and State law, and setting up a process for joint or coordinated review and oversight of the integrated materials. CMS annually reviews the contracts between States and D–SNPs that are required by § 422.107(b) each July for the following plan year. There would generally be insufficient time for the necessary operational and administrative steps to implement integrated communications materials between the review of the contract and the dates by which communications materials must be provided to current enrollees and made available for prospective enrollees during the annual coordinated election period that begins October 15 each year. Therefore, proposed paragraph (e)(2) would require that CMS work in good faith with States upon receipt of a letter of intent regarding the State's inclusion of a requirement for a D–SNP with exclusively aligned enrollment to use

[94] Refer to *www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Marketng ModelsStandardDocumentsand EducationalMaterial.*

[95] Refer to *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual.*

integrated materials and apply for a D–SNP-only contract. We intend that these efforts include the work to develop model integrated materials before the State Medicaid agency contract submissions are due for the contract year for which the D–SNP would use the integrated materials.

We do not intend through this proposal to significantly change timelines for plans to prepare materials nor do we intend to require any State to mandate that D–SNPs use integrated materials. We intend for this proposal to assure interested States that CMS would do its part to make it possible for D–SNPs to comply with State Medicaid agency contract terms to use materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory if a State Medicaid Agency seeks to require D–SNPs with exclusively aligned enrollment to perform as described at § 422.107(e).

We are considering including the EOC and ANOC as part of the minimum scope of integrated materials identified in proposed § 422.107(e)(1)(ii). However, without yet navigating the PRA process for creating integrated versions of these materials, it may be better to re-assess integration of these materials at a later date. We welcome comments on this alternative and whether including these additional materials as part of the minimum scope of integration addressed in proposed § 422.107(e)(1)(ii) would better further our goals or better suit the needs of States that may use the pathway we are proposing at § 422.107(e) to achieve more integration for certain D–SNPs. Either way, our proposal would not preclude CMS and States from collaborating on other integrated materials, including an integrated EOC or ANOC. As proposed, § 422.107(e) applies only when a State requires D–SNPs with exclusively aligned enrollment to use the minimum scope of integrated materials specified in paragraph (e)(1)(ii) and to seek CMS approval of D–SNP-only contracts. While we have proposed minimum parameters, a State that wishes to require D–SNPs with exclusively aligned enrollment to do more (for example, use additional integrated materials) may do so under this proposal. Further, we do not intend to prohibit or foreclose the possibility that CMS will work with States on other potential integration efforts that are not within the scope of § 422.107(e)(1).

c. Joint State/CMS Oversight

MA organizations receiving capitated payments through MA and from the State Medicaid agency must comply with different sets of Medicare and Medicaid requirements, including requirements imposed at the State level that are not identical to Federal minimum standards for Medicaid managed care plans in part 438. CMS and States have built separate infrastructure to monitor compliance with each set of requirements. This has three drawbacks related to integrated care approaches for dually eligible individuals. First, State regulators may be unaware of important compliance or performance problems related to the delivery of Medicare services or imposed on D–SNPs (or MA plans generally), and CMS may be unaware of important compliance or performance problems related to the delivery of Medicaid services, even when both parties are monitoring the same organization's coverage of services to the same people. Second, State and CMS officials may pursue different performance improvement priorities applicable to the plan(s) that cover dually eligible individuals, even when the plan(s) are under the same parent organization and serving the same enrollees. Third, uncoordinated oversight by CMS and the States can create inefficiencies for health plans where regulators seek duplicative information or initiate Medicare and Medicaid audits at the same time. We propose to address these drawbacks by giving States the opportunity to collaborate with CMS on oversight activities for the specific D–SNPs that operate under the conditions described at proposed paragraph (e)(1).

(1) State Access to the Health Plan Management System

We propose in paragraph (e)(3)(i) a mechanism to address access by States to the CMS Health Plan Management System (HPMS) (or a successor system) to better coordinate State and CMS monitoring and oversight of D–SNPs that operate under the conditions described at proposed paragraph (e)(1). HPMS is web-enabled information system where health and drug plans, plan consultants, third party vendors, and pharmaceutical manufacturers work with CMS to fulfill the plan enrollment, operational, and compliance requirements of the MA and Prescription Drug programs. Our experience granting State access to HPMS through the FAI and a related demonstration in Minnesota suggest that HPMS access is a useful tool and that State access is without known problematic unintended consequences. Therefore, we propose that CMS would grant State access to HPMS, or any successor system, to facilitate monitoring and oversight for D–SNPs operating under the specific contract terms required by the State that are described in proposed paragraph (e)(1).

Under our proposal, approved State Medicaid officials would be able to use HPMS to conduct a number of information sharing and oversight activities for these D–SNPs including, but not limited to, reviewing marketing materials, and viewing models of care, member complaints, plan benefits, formulary, network, and other basic contract management information. This access would allow State users the ability to directly view D–SNP information without requiring or asking the D–SNP to send the information to the States and would facilitate State-CMS communication on D–SNP performance because the State users would be able to review the same data and information available to CMS. MA organizations offering D–SNPs with exclusively aligned enrollment may benefit when it reduces the need for States to separately obtain the same information that is already available in HPMS.

State access would be limited to approved users and subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. Based on the current architecture of HPMS, approved State officials would only have access specific to information related to the MA contract(s) described in proposed paragraph (e)(1)(i). This proposal would not limit CMS's discretion to make HPMS accessible in other circumstances not described in our proposal but would authorize State access, which would include access to information about the MA organization and the applicable D–SNP(s) and D–SNP-only contract, and information submitted by the MA organization through HPMS, under the specific circumstances described in the proposed regulation. We seek feedback on our proposal, including feedback from MA organizations about CMS providing approved State officials with access to HPMS as a means to share information as it relates to the provisions of this proposed rule.

(2) State-CMS Coordination on Program Audits

Proposed paragraph (e)(3)(ii) establishes that CMS would coordinate with State Medicaid officials on program audits. This coordination

would include sharing major audit findings for State awareness related to D–SNPs subject to proposed paragraph (e)(1).

CMS conducts audits of MA plans periodically to assess compliance with Federal requirements, including D–SNP-specific care coordination requirements. We believe that there are benefits for CMS, the State, and the MA organization to increasing coordination in connection with such audits. For example, providing State officials the opportunity to join the entrance and exit conference, as we have in the FAI and related demonstrations, has afforded greater transparency for State Medicaid officials into the Medicare-focused auditing process. Similarly, we would offer to work with States to attempt to avoid scheduling simultaneous State and Federal audits. For example, if State officials share a schedule of their planned Medicaid audits for MA organizations with contracts subject to proposed paragraph (e)(1) before CMS finalizes its audit schedule in October preceding the audit year, CMS may be able to adjust its program audit schedule to avoid overlapping audits. If a State official shares a schedule of planned audits with CMS after October, CMS could alternatively alert the State Medicaid agency if any of the State's planned audits are scheduled to overlap with a CMS program audit. This process would reduce the risk of concurrent Medicare and Medicaid program audits, thereby reducing the risk that an MA organization is insufficiently responsive to auditors or its performance slips because it is managing concurrent audits. We currently have the ability to coordinate with State Medicaid agencies on audits, but we are proposing to codify how CMS would commit to coordination in situations where § 422.107(e) applies. This would help in setting expectations for and provide clarity to stakeholders, especially State Medicaid agencies. While these activities are provided as examples, we do not intend to limit our discretion to coordinate with States in the audit process outside of the parameters in proposed § 422.107(e)(3)(ii); we would evaluate the extent of coordination in each circumstance relevant to the D–SNP-only contract established as a result of the State's contract requirements described in paragraph (e)(1).

(3) State Input on Provider Network Exceptions

As part of implementing the proposed policy to coordinate on program audits and providing access to HPMS, CMS expects to use existing authority and flexibility as it pertains to the review of medical provider networks, particularly the review of network exceptions, to solicit and receive input from State Medicaid agencies. CMS requires all MA organizations to maintain a network of appropriate providers that is sufficient to provide adequate access to covered services. Currently, MA organizations submit their provider networks to CMS for review at the overall contract level on a triennial basis or when there is a triggering event such as an application or a significant provider/facility termination.[96] As indicated in the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance,[97] MA organizations are required to demonstrate network adequacy by submitting data for specific contracted provider and facility specialty types via the Network Management Module (NMM) of HPMS. To the extent an MA organization offers one or more D–SNPs, State Medicaid officials may be uniquely positioned to provide relevant information to CMS during our adjudication of certain network adequacy decisions, specifically when an MA organization seeks an exception to our network adequacy standards in § 422.116. We are not proposing to adopt specific regulation text in § 422.107(e)(3) regarding potential collaboration with State Medicaid agencies in connection with adjudicating requests for an exception to network adequacy requirements for D–SNPs that operate under the conditions described at proposed paragraph (e)(1) because a regulatory amendment is not necessary to support this process; however, our proposal here outlines how we expect this type of collaboration to work.

When an MA plan fails to meet the specific network adequacy standards in § 422.116(b) through (e), the MA plan may request an exception to these network adequacy criteria. Exceptions are limited to specific situations and conditions identified in § 422.116(f)(1) and, in considering whether to grant an exception, CMS considers whether current access to providers and facilities is different from the data CMS uses to evaluate network adequacy; whether there are factors present, as identified in § 422.112(a)(10), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and whether approval of the exception is in the best interests of beneficiaries. State Medicaid agencies may have information and insight about such other factors that might be relevant in setting a standard for an acceptable health care delivery network in a particular service area. For example, State Medicaid agencies could provide information about the number and scope of providers enrolled and screened by the State Medicaid agency, local practice patterns, geographic barriers, or transportation dynamics.

In this proposed rule, CMS is proposing to amend § 422.116(a)(1)(ii) to require compliance with network adequacy standards as part of an application for a new or expanding MA service area (see section II.C. of this proposed rule). In addition, CMS intends to reach out to States when a MA organization with a D–SNP contract described in § 422.107(e)(1) submits an exception request that does not meet the requirements at § 422.116(f)(1). In those instances, CMS may collaborate with the respective State to identify if there are other factors, as described at § 422.112(a)(10), that may be relevant before making a determination on the exception request. We piloted a similar approach in the Financial Alignment Initiative and a related demonstration in Minnesota where States provided input to inform the exception review process.

Collectively, our proposed paragraph (e)(3) at § 422.107 would improve Federal and State oversight of certain D–SNPs (and their affiliated Medicaid managed care plans) through greater information-sharing among government regulators. We have successfully tested these approaches in other circumstances and believe applying them under the conditions described in proposed paragraph (e)(1) would provide greater transparency to the regulated industry while assuring States that CMS will be a willing partner. We welcome comments on our proposals.

d. Comment Solicitation on Financing Issues

In Medicare and Medicaid, benefits funded by one payer (for example, behavioral health treatment funded by Medicaid) may generate savings for the other payer (for example, reduced emergency room and inpatient admissions funded by Medicare). For dually eligible beneficiaries, each payer has an incentive to provide benefits and focus spending in a manner that promotes its own cost saving, which may not be consistent with meeting beneficiaries' overall needs. In the Financial Alignment Initiative, we tried

[96] Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (Last updated: June 17, 2020). Retrieved at Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (cms.gov).

[97] *https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf.*

to solve for this financial misalignment through integrated financial approaches, including blending Medicare and Medicaid capitation payments [98] and evaluating integrated Medicare-Medicaid medical loss ratios (MLRs).[99] Based on this experience, we are assessing whether there are ways to take two elements of MMP financial methodology and apply to D–SNPs: (1) Integrated MLRs; and (2) consideration of the expected impact of benefits provided by MA organizations on Medicaid cost and utilization in the evaluation of Medicaid managed care capitation rates for actuarial soundness. We describe each in this section.

MA organizations, including those offering FIDE SNPs and other integrated plans with both MA and Medicaid managed care plan contracts, separately report medical loss ratio (MLR) results for their Medicare experience (per subpart X of part 422) and, where applicable, their Medicaid experience (per § 438.8). MA organizations submit MLR reports in a timeframe and manner specified by CMS. As required by section 1857(e) of the Act, CMS collects remittances for MLRs below a minimum threshold of 85 percent; additionally, enrollment sanctions apply for MA contracts that fail to meet minimum MLR thresholds for three consecutive years, while contracts are terminated for those MA organizations that fail to meet these thresholds for 5 consecutive years. Medicaid managed care plans calculate and report their MLR experience for each contract year (per § 438.8), with actuarially sound rates set to achieve an MLR of at least 85 percent (per § 438.4(b)(9)). Additional Medicaid MLR requirements vary at States' discretion, including the option to impose remittance requirements.

While the MA and Medicaid managed care MLR requirements are similar, they are not identical. Areas of difference include treatment of fraud reduction expenses, credibility adjustments, the level of detail reported, and use of MLR results in ratesetting. While these differences serve program purposes in the separate Medicare Advantage and Medicaid managed care programs, they can make it challenging to compare MLRs across programs and to evaluate the performance of a plan that integrates Medicare and Medicaid benefits. For example, an integrated plan may show a low MLR for Medicare Advantage and a high MLR for Medicaid managed care if it successfully delivers more community behavioral health treatment that results in fewer emergency room visits and hospitalizations. In this example, however, even if the aggregate payment amount across Medicare and Medicaid generally matches the combined cost of furnishing covered benefits to enrollees, both Medicare and Medicaid would potentially make adjustments. For example, if the Medicare MLR was below 85 percent, CMS would recoup funds from the plan. If the Medicaid MLR exceeds a reasonable maximum threshold that would account for reasonable administrative costs, the State would evaluate that when setting future capitation rates, the result of which may be to increase the Medicaid capitation rates in subsequent years. Further, as MA plans report MLR results at the contract level (not the plan level), MLR data specific to a particular FIDE SNP is not necessarily available. In contrast, MMPs report a combined Medicare and Medicaid MLR to CMS and States, with such reporting building off MA requirements, meeting Medicaid requirements, and offering a more complete picture of these integrated plans' performance.[100]

In the rulemaking to implement the statutory requirement for an MLR for MA plans, CMS received comments requesting we allow the MLR for D–SNPs and FIDE SNPs to include Medicare and Medicaid costs and revenue, to better evaluate such plans' performance and spending. [101] While we do not believe we have the statutory authority to include Medicaid experience as part of the Medicare MLR requirement, States may require additional data to be reported, including combined Medicare-Medicaid MLRs, in addition to the MLR reporting required by § 438.8. Such reporting would be in addition to, and not a substitute for, the required MA MLR under §§ 422.2400 through 422.2490 and Medicaid managed care MLR under § 438.8.

As described in section II.A.6.a., we propose at § 422.107(e) to make an option available through which States could require D–SNPs with exclusively aligned enrollment to operate under MA contracts that only include one or more D–SNPs that operate in that State. While such D–SNPs would still have to calculate and report separate Medicare and Medicaid MLRs under the applicable program requirements (absent a waiver), having a separate contract for certain D–SNPs would better equip States to evaluate MLRs and financial performance specific to that D–SNP product. Combining MA MLR information with corresponding Medicaid MLR data could potentially provide a more complete picture of plan financial performance in an integrated environment, as compared to what may be available currently.

We are seeking feedback on the extent to which this approach would better allow States to evaluate the performance of integrated plans. We are also interested in feedback from stakeholders—including States, health plans, actuaries, and advocates—on the impact of separate Medicare and Medicaid MLR requirements on meeting integration goals, administrative burden for plans and others through separate MLR standards, and whether the current approach provides sufficient data for State decision making and policy development.

Integrated plans serving dually eligible beneficiaries receive Medicaid capitation payments from States for coverage of Medicaid-covered services. These Medicaid managed care capitation rates are subject to actuarial soundness requirements under § 438.4. Several States limit enrollment in D–SNPs to achieve exclusively aligned enrollment in which all D–SNP enrollees are also in an affiliated Medicaid managed care plan, for which these 42 CFR part 438 actuarial soundness requirements apply.

[98] For more information on the ratesetting methodology for the FAI capitated model, see *Joint Rate-Setting Process for the Financial Alignment Initiative's Capitated Model,* available at: *https://www.cms.gov/files/document/capitatedmodelratesettingprocess03192019.pdf.*

[99] Unless waived by CMS, MMPs are required to comply with Medicaid managed care requirements under 42 CFR part 438 and with MA requirements in Part C and Part D of Title XVIII of the Act and 42 CFR parts 422 and 423. While (unlike MA plans) MMPs do not submit bids, the existing payment policies for each program generally apply to MMPs, including requirements related to actuarial soundness of Medicaid capitation rates and the MLR reporting required in both the Medicare and Medicaid programs.

[100] In the FAI capitated model, CMS waived section 1857(e) of the Act, which requires MA MLR remittances, insofar as such provisions were inconsistent with the methodology for determining MLRs for the demonstration. For more information, see the signed memoranda of understanding for capitated model demonstrations available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ApprovedDemonstrationsSignedMOUs.* The MLR approach varies across capitated model demonstrations, with most demonstrations requiring remittances for MLRs below thresholds of 85 to 87 percent, while the remaining demonstrations include other risk mitigation approaches, such as risk corridors, that provide the opportunity for recoupment of MMPs' gains above specified thresholds. More information on such arrangements may be found in the MMP three-way contracts available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/CapitatedModel.*

[101] Summaries of the comments and CMS's responses may be found in the 2013 *Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* final rule (78 FR 31283).

In the FAI capitated model, CMS developed an approach to Medicaid actuarial soundness within the model to take into account the effects of Medicare payment for Medicare covered benefits, for which Medicaid is a secondary payer, as well as the opportunities for efficiencies in an integrated program, when developing the Medicaid capitation rates paid in the FAI model.[102] Since we developed this approach, CMS has expanded options for MA plans to offer a broader array of supplemental benefits than available 10 years ago.[103] This change also expands the potential that MA supplemental benefits have an impact on lowering Medicaid costs because the MA supplemental benefit must be used first to pay for any items and services that are covered by both the MA plan and Medicaid. In some cases, MA plans may offer the types of community supports or LTSS that previously were only available through Medicaid. As a result, the MA supplemental benefit may replace or be used before using the Medicaid benefit, which would lower utilization and overall costs to cover Medicaid benefits when an integrated plan covers both Medicare and Medicaid services for the same enrollees.

With this context and our FAI model experience, we believe that Medicaid managed care capitation rates can be actuarially sound as required by § 438.4 when those rates are developed in a way that considers the impact of MA supplemental benefits and any State-specific requirements in the State Medicaid agency contract, D–SNP MOC, or MMP contract on the costs and utilization of the Medicaid benefits covered by the Medicaid managed care capitation rates. MA supplemental benefits and State-specific D–SNP requirements may impact Medicaid-related costs and utilization, and Medicaid rate setting could consider the impact on both: (1) Replacing costs that would otherwise be a Medicaid responsibility, as a primary impact; and (2) affecting expenditures on other Medicaid benefits, as a secondary impact. For example, intensive care coordination, covered by MA plans through supplemental benefits or as administrative expenses, could reasonably be expected to impact Medicaid costs by (a) reducing Medicaid care coordination costs directly; and (b) indirectly reducing Medicaid expenditures through lower Medicare cost-sharing as a result of preventing avoidable hospitalizations. We seek feedback on this interpretation, including from States, health plans, and actuaries, on the extent to which consideration of the impact of Medicare-covered benefits on costs and utilization of Medicaid services as described here advances integration goals and is consistent with actuarial standards of practice. We also request input on what information States, actuaries, and others would need to evaluate actuarial soundness under this approach. Finally, we solicit feedback on other options related to financing for integrated plans CMS should evaluate and consider for future rulemaking or sub-regulatory clarification.

7. Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561)

In § 422.561, we propose to expand the universe of D–SNPs that are required to have unified grievance and appeals processes by revising the definition of an applicable integrated plan. The April 2019 final rule introduced the concept of applicable integrated plans, which we defined as FIDE SNPs and HIDE SNPs whose Medicare and Medicaid enrollment is exclusively aligned (meaning State policy limits a D–SNP's enrollment to those whose Medicare and Medicaid enrollment is aligned as defined in § 422.2) and the companion Medicaid MCOs for those D–SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. We limited the universe of potential applicable integrated plans to FIDE SNPs and HIDE SNPs with exclusively aligned enrollment to ensure, first, that all enrollees are covered with the same scope of benefits and, second, that the plans implementing unified grievances and appeals offered a sufficiently substantial range of Medicaid benefits to make the unification of Medicare and Medicaid processes meaningful for beneficiaries and worthwhile for States and plans.

Because the landscape of integrated plans has evolved in the past several years, we believe there are integrated D–SNPs other than FIDE SNPs and HIDE SNPs for which a unified grievance and appeals process is feasible and, therefore, we should require the unified process. Expanding the process to these plans would simplify the grievance and appeals steps for beneficiaries enrolled in these plans for their Medicare and Medicaid benefits and extend the protection of continuation of benefits pending appeal as described in § 422.632 to additional beneficiaries. Section 50311(b) of the BBA of 2018 amended section 1859(f)(8)(B) of the Act to direct establishment of procedures, to the extent feasible, unifying Medicare and Medicaid grievances and appeals. We believe that unified grievance and appeals procedures are feasible for the additional D–SNPs. Accordingly, we propose, effective January 1, 2023, to expand the definition of the term applicable integrated plan to include an additional type of D–SNP subject to the rule.

We propose to include as applicable integrated plans certain combinations of Medicaid managed care plans and D–SNPs that are not FIDE SNPs or HIDE SNPs but meet three other conditions. First, State policy must limit the D–SNP's enrollment to beneficiaries enrolled in an affiliated Medicaid managed care plan that provides the beneficiary's Medicaid managed care benefits. Second, each enrollee's Medicaid managed care benefits must be covered under a capitated contract between (1) the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization and (2) a Medicaid MCO or the State Medicaid agency. Under our proposal, the definition of ''applicable integrated plan'' will include (1) a D–SNP that has, by State policy, fully aligned enrollment with an affiliated Medicaid plan owned by the same parent organization, where

[102] As described in the signed memoranda of understanding for capitated model demonstrations available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ApprovedDemonstrationsSignedMOUs,* ''Assessment of actuarial soundness under 42 CFR 438.6, in the context of this Demonstration, should consider both Medicare and Medicaid contributions and the opportunities for efficiencies unique to an integrated care program. CMS considers the Medicaid actuarial soundness requirements to be flexible enough to consider efficiencies and savings that may be associated with Medicare. Therefore, CMS does not believe that a waiver of Medicaid actuarial soundness principles is necessary in the context of this Demonstration.''

[103] The BBA of 2018 (Pub. L. 115–123) amended section 1852(a) of the Act to expand the types of supplemental benefits that may be offered by MA plans to chronically ill enrollees as of plan year 2020, to specifically allow those ''supplemental benefits that, with respect to a chronically ill enrollee, have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits.'' In addition, the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' which appeared in the **Federal Register** on June 2, 2020 (June 2020 final rule) finalized provisions to allow for plans to target other chronic conditions included in the Medicare Managed Care Manual. In the January 2021 final rule, CMS codified existing policy on supplemental benefits, including the criteria for a supplemental benefit, the expanded definition of ''primarily health related,'' and the reinterpreted uniformity requirements.

the affiliated Medicaid plan has a capitated contract with a Medicaid MCO to provide all of the beneficiary's Medicaid managed care benefits (2) and its affiliated Medicaid plan. Third, the Medicaid coverage under the capitated contract must include primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C) and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and must include at least one of the following: Medicaid home health services, Medicaid durable medical equipment, or Medicaid nursing facility services.

Where each of these conditions is met, enrollees receive all of their Medicare and Medicaid benefits that are available through managed care in the State through a D–SNP and affiliated Medicaid managed care plan. We believe such plans integrate a sufficiently broad range of Medicaid benefits so as to make unifying their grievance and appeals processes worthwhile. Our proposal would not change grievance and appeals processes for any Medicaid services not covered by the Medicaid managed care plan that is affiliated with the D–SNP where the three conditions are met. We anticipate our proposal would newly require unified appeals and grievances processes in a number of plans in California following the end of the California capitated financial alignment model demonstration.

We propose to reorganize the definition of applicable integrated plan in § 422.561 by adding new subsections to the definition in § 422.561 to show separate definitions before and after January 1, 2023. The proposed definition after January 1, 2023, expands the universe of applicable integrated plans to include a D–SNP and affiliated Medicaid managed care plan that meets these three criteria. Under the proposed revisions to § 422.561, current paragraphs (1) and (2) will become paragraphs (2)(i)(A) and (B) and apply before January 1, 2023. Proposed new paragraph (2) of the definition will apply beginning January 1, 2023, and will include paragraphs (2)(i) and (ii). Proposed new paragraphs (2)(i)(A) and (B) include the current definition, and proposed new paragraph (2)(ii) includes the new category of D–SNPs and affiliated Medicaid managed care plans that would qualify as an applicable integrated plan. New proposed paragraph (2)(ii)(A) addresses enrollment requirements for the D–SNP, and new proposed paragraph (2)(ii)(B) addresses what types of contracting must be in place, and new proposed paragraph (2)(ii)(C) the minimum Medicaid benefits that must be covered by the capitated contract with the State Medicaid agency or contract with Medicaid MCO. Under our proposal, the definition of ''applicable integrated plan'' remains unchanged from the current definition for the period before January 1, 2023, and would include additional types of D–SNPs and affiliated Medicaid plans on and after January 1, 2023.

8. Permitting MA Organizations With Section 1876 Cost Contract Plans To Offer Dual Eligible Special Needs Plans (D–SNPs) in the Same Service Area (§ 422.503(b)(5))

Section 1876(h) of the Act established reasonable cost reimbursement contracts or ''cost contracts,'' as defined at § 417.401 as Medicare contracts under which CMS pays the health maintenance organization (HMO) or competitive medical plan (CMP) on a reasonable cost basis. Cost contracts arrange for Medicare services and provide members several flexibilities not offered to MA plan members, such as the ability to enroll in a plan that offers only Part B benefits and to receive health care services outside of the cost contract plan's network of providers through original Medicare. As of January 2021, approximately 173,250 beneficiaries were enrolled in seven cost contracts offered in nine States.[104]

Federal statute and regulation restrict cost contracts in several ways. First, as provided in section 1876(h)(5)(A) of the Act and § 417.402(b), CMS no longer enters into cost contracts. Second, CMS established a requirement, originally at § 422.501(b)(4), that an entity seeking to contract as an MA organization must not accept new members under a cost contract plan in any area in which it seeks to offer an MA plan when implementing the original Part C requirements in the interim final rule titled ''Medicare Program; Establishment of the Medicare+Choice Program'' (HCFA–1030–IFC) (63 FR 35014 through 35015; 35100) (hereinafter referred to as the June 1998 final rule). CMS later moved this requirement to § 422.503(b)(5). The June 1998 final rule stated that CMS established this prohibition to eliminate the potential for an organization to encourage higher cost members to enroll under its cost contract plan while healthy members were enrolled in its risk-based MA plan. Manipulating enrollment in this way would shift costs to the government away from the entity.

Third, MIPPA and the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (hereinafter referred to as MACRA) amended section 1876(h)(5)(C) of the Act by specifying that cost contract plans operating in service areas or portions of service areas with two MA plans meeting minimum enrollment requirements would be non-renewed. Implementing regulations are codified at § 417.402(c) and went into effect at the end of CY 2018, leading to a significant decrease in cost contract enrollment.[105]

The prohibition on an entity accepting new enrollees in a cost contract plan while offering an MA plan in the same service area was amended in ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (CMS–4159–F) (hereinafter referred to as the May 2014 final rule) to apply to: (1) A parent organization owning a controlling interest in a separate legal entity accepting new members under a cost contract plan, and (2) another separate legal entity owned by the same parent organization as the legal entity accepting new members under a cost contract plan (79 FR 29850; 29959). An error in the amendment in the May 2014 final rule prevented this change from being correctly codified in the CFR. This error was corrected in the January 2021 final rule (86 FR 6099).

As stated in the May 2014 final rule, CMS did not exempt entities with both cost contract plans and D–SNPs from the regulatory provision at § 422.503(b)(5) because we did not believe that the Medicare premium and cost-sharing differences in cost contract plans and MA plans, including D–SNPs, necessarily reduced the incentives an organization may have for moving an individual from one of its plans to another. We also stated that D–SNPs, which frequently serve members with greater frailty and morbidity than the general Medicare population, may have an even greater incentive to move members to a cost contract plan.

Since CMS finalized the policy in the 2014 final rule, we have gained more experience relevant to this D–SNP policy decision through the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience conducted in partnership with the State of Minnesota.[106] Three of the seven MA

[104] Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report.html.*

[105] Ibid.

[106] See *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-*

organizations offering Minnesota D–SNPs participating in the demonstration—comprising almost 60 percent of the demonstration enrollment—also sponsored cost contract plans in overlapping counties. To prevent disruption to the demonstration, we waived § 422.503(b)(5) for these entities, using our authority under section 1115A of the Act. This waiver avoided the risk that these entities would, instead of closing the cost contract plans to new enrollment where the service areas overlapped with D–SNPs, non-renew their D–SNPs during the demonstration, which would undermine our ability to carry out successfully the model test. In addition, non-renewal of these D–SNPs could potentially have led to large-scale disenrollment from Minnesota Senior Health Options, a D–SNP and Medicaid MCO program with evidence of strongly favorable outcomes for dually eligible older adults.[107]

Although the waiver and model were not designed to test this specific issue, the waiver of § 422.503(b)(5) provided an opportunity to test whether creating an exception for D–SNPs would result in substantial shifts of D–SNP members to cost contract plans offered under the same parent organization. The Minnesota demonstration, which is focused on alignment of administrative procedures, did not change the incentives for shifting of members that was the rationale for § 422.503(b)(5). In the demonstration, we required that each of the affected D–SNPs report annually the number of D–SNP members who switched to the entity's cost contract plan. If two percent or more of a D–SNP's enrollment switched to the cost contract plan, CMS would further investigate enrollment patterns, potentially require corrective actions, and rescind the waiver.

The results of this reporting have been instructive. In no year since the waiver was established has the number of D–SNP members switching to the affiliated cost contract plan approached the 2 percent threshold. The two remaining D–SNPs with cost contract plans under the same parent organization[108] which had a combined December 2020 D–SNP enrollment of 19,168, reported a total of 10 members switched to the affiliated cost contract plans during the 2020 plan year. The enrollment patterns for prior reporting periods are similar: only a small number of individuals switched from a D–SNP to a cost contract plan affiliated with the same entity.

In addition to this reporting, we reviewed current enrollment data on all cost contract plans to see if the two parent organizations offering both a cost contract plan and a D–SNP in the demonstration have a higher enrollment of dually eligible individuals than in the cost contract plans without such affiliated D–SNPs. The average enrollment of dually eligible individuals across all cost contracts in December 2020 was 3.6 percent, and ranged from 1.62 percent to 12.2 percent. In comparison, about 20 percent of Medicare Advantage enrollees are dually eligible individuals.[109] The two cost contracts operating in Minnesota that had affiliated D–SNPs were consistently on the low end of that range, with average enrollments of dually eligible individuals of 1.6 percent and 3.5 percent respectively. These averages suggest that the availability of a D–SNP that shares a parent organization with a cost contract plan may decrease such likelihood of dually eligible individuals enrolling in a cost contract plan.

The data from the Minnesota demonstration shows allowing both a D–SNP and a cost contract plan under the same parent organization has not resulted in a substantial number of members moving from the D–SNP to the cost contract plan. We believe that the number of such plan switches is likely minimal for the reasons outlined by the commenters in the May 2014 final rule: the premiums charged by cost plans are unattractive to low-income dually eligible individuals who have access to a D–SNP that charges no premium.

We also note that the cost contract plans outside of the demonstration that had more than 5 percent dually eligible enrollment included cost contract plan options with zero-dollar premiums. This indicates that the typical cost contract plan premium functions as a deterrent to enrollment by full-benefit dually eligible individuals.

Based on this evidence, we believe that allowing a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D–SNP or seeks to offer a new D–SNP will not undermine the policy goals that underlie § 422.503(b)(5)—that is, prohibiting entities from steering high-cost members to their cost contract plans and lower cost members to their risk-bearing MA plans. In addition, creating an exception to § 422.503(b)(5) for D–SNPs would allow the entities in Minnesota that currently offer both D–SNPs (through the demonstration) and cost contract plans in the same market to continue enrollment in both plans after the end of the demonstration, thus avoiding potentially significant disruption to Medicare beneficiaries that would result from each MA organization's non-renewal of one of the two types of products. More broadly, the exception removes a regulatory barrier that, in Minnesota and several other States, can impede D–SNPs from entering a market where cost contract plans remain. Without a D–SNP, States have few options to integrate Medicare and Medicaid services and improve the experience of care for dually eligible individuals. In particular, removing this barrier would allow entities offering cost contract plans in rural markets in the nine States[110] where cost contract plans are currently offered, including markets without multiple MA plan alternatives, to work with those States to offer new D–SNPs, which could further State goals for integrating Medicare and Medicaid services. We anticipate that this flexibility would provide dually eligible individuals in those States new choices for integrated coverage. Therefore, we propose to revise paragraph § 422.503(b)(5)(i) and (ii) to allow an MA organization to offer a D–SNP and also—

- Offer an 1876 reasonable cost plan that accepts new enrollees;
- Share a parent organization with a cost contract plan that accepts new enrollees;
- Be a subsidiary of a parent organization offering a cost contract plan that accepts new enrollees; or
- Be a parent organization of a cost contract plan that accepts new enrollees.

Should we finalize this proposal, we would monitor patterns of enrollment and disenrollment. To the extent we see any pattern that suggests that sponsors are persuading D–SNP members to

Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Minnesota.html.

[107] Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis.*

[108] One of the three entities offer a D–SNP and cost contract plan ceased offering a cost contract plan in the same market as its D–SNP in January 2019.

[109] CMS, ''Data Analysis Brief: Managed Care Enrollment Trends among Dually Eligible and Medicare-only Beneficiaries, 2006 through 2019''. March 2021. Retrieved from *https://www.cms.gov/files/document/managedcareenrollmenttrendsdatabrief.pdf.*

[110] For CY 2021, cost contract plans were offered in Colorado, Iowa, Illinois, Kansas, Minnesota, Nebraska, North Dakota, South Dakota, Wisconsin.

move into the cost plan, we would investigate and pursue corrective actions or additional rulemaking, potentially including the future rulemaking to remove or restrict the exemption proposed here. We seek comment on the proposed exception for D–SNPs and our process for monitoring for unintended consequences.

We are considering more limited exceptions to the requirements at § 422.503(b)(5) that may more closely fit our policy goals of removing regulatory obstacles to the availability of D–SNPs that could further Medicare-Medicaid integration. We are also considering whether additional limitations could guard against entities steering less healthy, higher cost enrollees toward their cost contract plans. Specifically, we are considering limiting the exception to:

- D–SNPs designated as highly integrated D–SNPs (HIDE SNPs), as defined at § 422.2, which are capitated for Medicaid behavioral health or Medicaid long-term services and supports, or both; and to fully integrated D–SNPs (FIDE SNPs), as defined at § 422.2, which are capitated for a comprehensive set of Medicaid long-term services and supports;
- D–SNPs that only enroll full-benefit dually eligible individuals, who qualify for full Medicaid benefits, rather than D–SNPs that also enroll partial-benefit dually eligible individuals, who are only eligible for Medicaid coverage of Medicare premiums or cost-sharing;
- D–SNPs that charge no beneficiary premium for individuals eligible for the full Part D low income subsidy;
- D–SNPs that are affiliated with cost contract plans that charge premiums for enrollees eligible for the full Part D low income premium subsidy; or
- Combinations of these types of D–SNPs.

We are concerned that these alternatives would add complexity to the regulation that we do not believe is necessary to achieve our primary aim of removing regulatory barriers that impede the availability of new D–SNPs to integrate Medicare and Medicaid services and improve care for dually eligible individuals. However, we seek comment on whether inclusion of some or all of these additional alternative criteria in the revisions to § 422.503(b)(5) would strengthen the overall policy.

9. Requirements To Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634)

In the final rule ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' which appeared in the **Federal Register** on April 16, 2019, we established procedures for unified appeals and grievances and require certain D–SNPs and Medicaid MCOs to use them beginning in 2021 (84 FR 15680). Section 50311 of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs to unify Medicare and Medicaid appeals and grievance procedures for integrated D–SNPs.

We codified the regulations for unified appeal and grievance procedures §§ 422.629 through 422.634 (84 FR 15720). These procedures apply to applicable integrated plans, which are defined at § 422.561 as FIDE SNPs and HIDE SNPs with exclusively aligned enrollment. We propose an amendment to the definition of applicable integrated plan in section II.A.7. of this proposed rule. These rules took effect for the 2021 plan year. Based on our initial implementation experience and feedback from stakeholders, we are proposing several adjustments, clarifications, and corrections to these regulations at §§ 422.629 through 422.634. We do not intend for these proposals to substantially change current policy.

a. Providing Enrollees Information on Presenting Evidence and Testimony (§ 422.629(d))

We propose adding additional language to § 422.629(d) to codify in regulation a provision from existing sub-regulatory guidance.[111] We propose to revise § 422.629(d) to require that, as part of its responsibilities pertaining to an enrollee's presenting evidence for an integrated grievance or appeal, an applicable plan provide an enrollee with information on how evidence and testimony should be presented to the plan. While we believe this requirement is within the scope of the current requirement that applicable integrated plans inform enrollees of the limited timeframe for presenting evidence as stated in § 422.629(d) and otherwise provide enrollees with reasonable assistance in taking procedural steps related to grievances and appeals as required at §§ 422.562(a)(5) (applicable to D–SNPs) and 438.406(a) (applicable to Medicaid managed care plans), revision of the regulation text will clarify this. We believe that this proposed addition will ensure that enrollees better understand the process for submitting evidence and testimony to the plan so that their information is timely considered with their appeal. In addition, our proposal would reorganize § 422.629(d) to improve the readability of the provision.

b. Technical Correction (§ 422.629(k))

We propose technical changes to § 422.629(k)(4)(ii) to correct a minor error from the April 2019 final rule. This paragraph references the integrated organization determination decision, however, the requirements in paragraph (k)(4) relate to integrated reconsideration determinations. Therefore, we are proposing to replace the word ''organization'' with ''reconsideration'' and remove the word ''decision'' from the end of the sentence in § 422.629(k)(4)(ii).

c. Accommodate State Medicaid Representation Rules (§ 422.629(l))

At § 422.629(l)(1), we propose adding additional language to codify in regulation current sub-regulatory guidance[112] regarding the appointment of a representative. The Medicare Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Section 20.2, lists several elements that should be included in an appointment of representation form. A State, in its Medicaid program, may have developed other forms or requirements for appointment of representation forms that are accepted in appeals cases. We propose to amend § 422.629(l)(1) to ensure that we are not restricting the means that an enrollee would otherwise have, outside of the integrated appeals process, to appoint a representative. We propose to add language to clarify that an enrollee's representative includes any person authorized under State law. We propose to reorganize paragraph (l)(1) as part of this amendment. Specifically, we propose to revise paragraph (l)(1)(i) to list the enrollee and to revise paragraph (l)(1)(ii) to list the enrollee's representative, including any person authorized under State law. We also propose to move the content of current paragraph (l)(1)(ii) that deals with rights of assignees to a new

[111] CMS, ''Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Applicable Integrated Plans''. Retrieved from: *https://www.cms.gov/files/document/dsnpartscdgrievancesdeterminations appealsguidanceaddendum.pdf.*

[112] CMS, ''Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Applicable Integrated Plans''. Retrieved from: *https://www.cms.gov/files/document/dsnpartscdgrievancesdeterminations appealsguidanceaddendum.pdf.*

§ 422.629(l)(4) as discussed in section II.A.9.d. of this proposed rule.

d. Clarifying the Role of Assignees and Other Parties (§ 422.629(l))

In the April 2019 final rule, we finalized § 422.629(l)(1)(ii) to include assignees of the enrollee and other providers with appealable interests in the proceedings as individuals who could file an integrated grievance, request an integrated organization determination, or request an integrated reconsideration. In so doing, we inadvertently created confusion, particularly pertaining to the rights of non-contracted providers. Like contracted providers, non-contracted providers can request an initial integrated organization determination on behalf of an enrollee if they treat or intend to treat the enrollee; this is reflected in § 422.629(l)(1)(iv) and (l)(3) and is consistent with MA rules at § 422.566(c)(1)(ii). However, our policy is that assignees (for example, a non-contracted provider to whom an enrollee has assigned their appeal rights) and other providers with appealable interests can only file an integrated reconsideration; assignees cannot file a grievance, and until the initial organization determination is completed, there is no enrollee interest to assign or other appealable interest at stake. This policy is also consistent with the MA rules which do not specifically allow anyone other than an enrollee to file a grievance (§ 422.564), and which require a provider to waive any right to payment from the enrollee for the service to be an assignee and a party to the organization determination (§ 422.574(b)) who is then able to file a request for a reconsideration under § 422.578. We are therefore proposing to move the content of § 422.629(l)(1)(ii) to new paragraph (l)(4). As noted in section II.A.9.c. of this proposed rule, we propose to add new language at § 422.629(l)(1)(ii) in its place addressing who can be an enrollee's representative.

In new paragraph (l)(4) we propose to clarify which individuals or entities can request an integrated reconsideration and are considered parties to the case but who do not have the right to request an integrated grievance or integrated organization determination. At proposed paragraph (l)(4)(i), we would permit an assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service) to request an integrated reconsideration. At proposed paragraph (l)(4)(ii), we would permit any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding to request an integrated reconsideration.

e. Timelines for Processing Payment Requests (§ 422.631)

In the April 2019 final rule, we neglected to specify explicitly how the MA ''prompt payment'' rules at § 422.520 governing payment of claims apply to applicable integrated plans. The MA organization determination timeline rules at § 422.568(c) state that the prompt payment rules at § 422.520 govern the timeline for requests for payment. However, as finalized, § 422.631 establishes the timelines for integrated reconsiderations in lieu of the timelines at § 422.568 but does not include a specific reference to the prompt payment rules at § 422.520 and does not include (in lieu of the rule in § 422.520(c) that is applicable to all MA plans) a different rule for applicable integrated plans. As a result, we have received several questions from applicable integrated plans requesting that we clarify what timeline applies to processing payment requests.

Accordingly, at § 422.631(d), we propose to add a new paragraph (d)(3) to require applicable integrated plans to process payment requests according to the prompt payment provisions set forth in § 422.520, which will mirror the current provision at § 422.568(c). We believe these prompt payment provisions are generally consistent with Medicaid prompt payment standards and therefore will not create any inconsistencies with State Medicaid policies in this area. We welcome comments on this issue.

f. Clarifying Integrated Reconsideration Request (§ 422.633(e) and (f))

We are proposing changes to § 422.633(e)(1) to clarify who may file a request for an expedited post-service integrated reconsideration (that is, one that is related to payment). Our proposal would clarify that an enrollee may request an expedited integrated reconsideration related to payment that can qualify as expedited, but a provider's right to request an expedited integrated reconsideration on behalf of an enrollee is limited to pre-service integrated reconsideration requests. In the preamble to the April 2019 final rule, we noted that there may be rare circumstances in which a dually eligible enrollee's financial need is so pressing that an enrollee's reimbursement request meets the standard for expediting a post-service integrated reconsideration request. This was a departure from the MA rule at § 422.584(a), and we intended to limit this option to requests filed by enrollees. As finalized, however, § 422.633(e) does not distinguish between pre-service and post-service expedited requests filed by the enrollee and those filed by a provider on the enrollee's behalf.

During implementation of these new unified procedures, we received several comments pointing out that § 422.633(e), as finalized, permits a provider to request an expedited post-service integrated reconsideration on behalf of an enrollee. This was not our intent, because a post-service case can only meet the expedited standard if the enrollee has already paid a provider and urgently needs reimbursement from the applicable integrated plan. We believe that a provider should not deliver a service, accept the enrollee's payment, and then argue on the enrollee's behalf that the enrollee needs an expedited decision on reimbursement. We also did not intend to place the burden on plans to accept such requests and assess whether the standard for expedited treatment is met when these post-service appeals are filed by providers. We are therefore proposing to specify in § 422.633(e)(1)(i) that expedited post-service integrated reconsideration requests are limited to those requested by an enrollee, and in § 422.633(e)(1)(ii) that providers acting on behalf of an enrollee may only request pre-service expedited integrated reconsiderations. This proposed change aligns provider appeal rights with MA regulations which do not allow expedited integrated reconsideration determinations in cases where services or items have already been furnished (see § 422.584(a)).

During implementation, we also received several questions from plans regarding the timeframe, at § 422.633(f), for applicable integrated plans to make integrated reconsideration determinations in cases involving payment requests from providers where the provider has obtained and filed a waiver of liability from the enrollee. In the April 2019 final rule, we required all integrated reconsiderations, including those involving requests for payment, be resolved within 30 days, which is consistent with Medicaid rules at § 438.408(b)(2) but shorter than the 60 days permitted under § 422.590(b)(1). In response to the sub-regulatory guidance issued subsequent to the April 2019 rule but before the effective date of the regulation, several plans commented that meeting a 30-day timeframe for all requests for payment would be difficult. We believe that the shorter 30-day timeframe is appropriate for beneficiary requests and consistent with Medicaid

rules. However, we seek comment regarding whether allowing a 60-day timeframe for non-contracted provider payment requests where the provider has obtained a waiver of liability from the enrollee would simplify plan operations without adversely affecting beneficiaries or access to care. We also seek comment regarding whether adopting such a timeframe for non-contracted provider payment requests would conflict with any State-specific Medicaid rules or processes concerning provider appeals.

Lastly, in response to several questions we have received since the regulation became effective regarding the availability of extensions for standard and expedited integrated reconsiderations, we are proposing at § 422.633(f)(3) to add language to clarify that extensions of up to 14 days are available for any integrated reconsiderations (either standard and expedited) other than those regarding Part B drugs. In our proposal at § 422.633(f)(3) we would exclude integrated reconsiderations about Part B drugs from the authority for extensions. This is consistent with current § 422.633(f), which provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2). Our current sub-regulatory guidance addresses this as well.

g. Timeframes for Service Authorization After a Favorable Decision (§ 422.634(d))

We are proposing changes to § 422.634(d) to clarify the requirements for how quickly an applicable integrated plan must authorize or provide a service after a favorable decision for an enrollee upon appeal. The current regulatory text includes timeframes for how quickly services must be put in place for an enrollee after receipt of a favorable decision on an integrated reconsideration or State fair hearing. The current regulation refers to timeframes specified in §§ 422.618 and 422.619 for implementing decisions made by the IRE and additional entities on the Medicare side. In reviewing feedback received from applicable integrated plans, we believe that these requirements should more clearly describe timeframes for authorizing services in all situations where an applicable integrated plan's decision is reversed.

We propose reorganizing § 422.634(d) to more explicitly address each scenario that an applicable integrated plan will face when effectuating a reversal. In proposed paragraph (d)(1), we propose to address cases where the applicable integrated plan reverses its own decision in an appeal for services that were not furnished while the appeal was pending. We propose that an applicable integrated plan must authorize or provide the service as expeditiously as the enrollee's condition requires and within the sooner of: (1) 72 hours from the date of the reversed decision; or (2) 30 calendar days (7 calendar days for a Part B drug) after the date that the applicable integrated plan received the integrated reconsideration request.

This would be a slight change from the current requirements, which require applicable integrated plans to authorize or provide the service as expeditiously as the enrollee's condition requires but not later than 72 hours from the date of the reversed decision. The current 72-hour rule is adopted from the Medicaid managed care rule at § 438.424(a). However, as applied in § 422.634(d), there is the possibility that in some cases an enrollee could wait longer for a determination to be effectuated by an applicable integrated plan than the enrollee would have to wait under the current MA regulation (§ 422.618(a)(1) and (3)), which requires effectuation no later than 30 calendar days after the MA plan receives the reconsideration request, or 7 calendar days for Part B drugs. If, for example, the applicable integrated plan reversed its decision on the 29th day after receiving the reconsideration request (for a request that is not a Part B drug), as allowed under § 422.633(f)(1), under the current text of § 422.634(d) it would still have another 72 hours to effectuate the determination. We also propose to include the Part B drug timeframe from § 422.618(a)(3) in § 422.634(d)(1)(ii)(B) to ensure enrollees of applicable integrated plans get the same timely effectuation for these drugs; this is consistent with how current § 422.633(f) provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing reconsidered determinations regarding Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2), which apply to other MA plans. We believe our proposal better reflects the directive in section 1859(f)(8)(B)(ii) of the Act to adopt requirements that are most protective for enrollees.

In proposed paragraph (d)(2), for the sake of clarity we propose to place in its own paragraph the requirement for the applicable integrated plan to authorize or provide a Medicaid-covered service no later than 72 hours from the date the plan is notified of a decision reversed by a State fair hearing. We propose no changes to this effectuation timeline.

Lastly, we propose to add a new paragraph (d)(3) to require the same timelines for an applicable integrated plan to effectuate reversals by the Medicare independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council as apply to other MA plans at §§ 422.618 and 422.619.

We request comment on whether the additional language provides clarity to applicable integrated plans on their responsibility to provide a service after an integrated organizational determination or integrated reconsideration is overturned.

10. Technical Update to State Medicaid Agency Contract Requirements (§ 422.107)

Section 422.107(c) lists minimum requirements for State Medicaid agency contracts. Paragraph (c)(6) requires that the contract document the verification of an enrollee's eligibility for ''both Medicare and Medicaid.'' We propose to strike the reference to Medicare in paragraph (c)(6). All MA plans, including D–SNPs, already verify Medicare eligibility as part of accepting beneficiary coverage elections under § 422.60. *See also* Chapter 2 of the Medicare Managed Care Manual for additional details.[113] Therefore, it is not essential for the contract between the State Medicaid agency and the D–SNP to document how the D–SNP verifies Medicare eligibility. Functionally, our proposal would have no impact on the responsibilities of a plan to verify eligibility. However, it would remove a detail from the State Medicaid agency contract minimum requirements, thus simplifying our review of the contracts.

11. Compliance With Notification Requirements for D–SNPs That Exclusively Serve Partial-Benefit Dually Eligible Beneficiaries (§ 422.107(d))

Section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs beginning in 2021, including minimum integration standards and coordination of the delivery of Medicare and Medicaid benefits. We codified these minimum integration requirements in the April 2019 final rule at § 422.2, stating that a D–SNP must either (i) be a HIDE SNP or FIDE SNP or (ii) meet the additional requirement specified in § 422.107(d) as required for its contract with the State Medicaid agency. When it applies,

[113] See *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/mc86c02.pdf.*

§ 422.107(d) requires that the D–SNP notify the State Medicaid agency, or individuals or entities designated by the State Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dually eligible individuals, as determined by the State Medicaid agency. We direct readers to the April 2019 final rule for a more detailed explanation of our intent and rationale for this approach (84 FR 15710 through 15717).

While implementing these minimum integration standards, CMS identified some MA organizations that have separate D–SNP PBPs for partial-benefit and full-benefit dually eligible individuals. Providing separate PBPs for full-benefit dually eligible individuals enables MA organizations to more clearly explain and coordinate the Medicaid benefits that those enrollees are entitled to receive. In addition, HIDE SNPs or FIDE SNPs that limit enrollment to full-benefit dually eligible individuals qualify to unify Medicare and Medicaid appeals and grievance processes under §§ 422.629 through 422.634. MA organizations that have D–SNPs with a combination of full-benefit and partial-benefit dually eligible enrollees can choose to ''split'' the D–SNP into two plans to take advantage of these opportunities. We codified a crosswalk exception to facilitate this process at § 422.530(c)(4) in the January 2021 final rule. (In section II.A.6.a., we are proposing to redesignate this crosswalk to § 422.530(c)(4)(i) in this proposed rule.)

However, D–SNPs that only enroll partial-benefit dually eligible individuals (hereinafter referred to as ''partial-benefit-only D–SNPs'') have no explicit pathway to meaningfully meet one of the three integration standards under § 422.2. In a partial-benefit-only D–SNP, no plan enrollees are eligible for the minimum set of Medicaid services that a D–SNP must cover to qualify as a HIDE SNP or FIDE SNP. Additionally, there are no full-benefit dually eligible individuals that the plan could identify for notification of hospital and SNF admissions (and no Medicaid services to coordinate post notification) as required by § 422.107(d).

In lieu of requiring inclusion of this notification requirement in the State Medicaid agency contract for partial-benefit-only D–SNPs during the initial CY 2021 implementation of the D–SNP integration requirements, CMS issued guidance permitting an alternative in January 2020.[114] The MAO offering the partial-benefit-only D–SNP would be considered as meeting the integration requirements in connection with the partial-benefit-only D–SNP provided that the MAO also offers a full-benefit-only D–SNP in the same State and under the same contract and that full-benefit-only D–SNP meets the integration requirements in the definition of a D–SNP at § 422.2.

We are proposing to codify this policy with the additional requirement that the service areas of the full-benefit-only D–SNP covers the entire service area of the partial-benefit-only D–SNP. That is, we propose revising § 422.107(d) to provide that partial-benefit-only D–SNPs are not required to meet the notification requirement in § 422.100(d) when the MA organization also offers a D–SNP with enrollment limited to full-benefit dually eligible individuals that meets the integration criteria at § 422.2 and is in the same State and service area and under the same parent organization. We propose to add this by reorganizing paragraph (d). The current provision in paragraph (d) would be redesignated as new paragraph (d)(1) and amended to reference exceptions listed in proposed paragraph (d)(2). Proposed paragraph (d)(2) provides that paragraph (d)(1) does not apply to any D–SNP that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries that are not entitled to full medical assistance under a State plan under title XIX if the SNP operates under the same parent organization and in the same service area as a D–SNP limited only to full-benefit dually eligible individuals that meets the requirements at (d)(1).

We believe our proposal is consistent with the minimum integration required by section 1859(f)(8) of the Act because it achieves the same level of coordination with State Medicaid agencies for partial-benefit dually eligible enrollees as would be achieved if there were one PBP including both full-benefit and partial-benefit dually eligible individuals. Additionally, for full-benefit dually eligible enrollees, the two-PBP structure facilitates a higher level of integration of Medicare and Medicaid benefits (for example, where the two-PBP structure would result in more applicable integrated plans with unified appeals processes).

We do not anticipate any negative impact for beneficiaries or partial-benefit-only D–SNPs as a result of this proposed rule. For CY 2021, nine partial-dual-only D–SNP PBPs operate under the same MA contract and same service area as a full-benefit-only D–SNP. All nine operate in either Florida or Virginia. In CY 2021, one other Virginia D–SNP enrolled partial-benefit dually eligible individuals with a corresponding D–SNP for full-benefit dually eligible individuals under the same parent organization. The proposed changes to § 422.107(d) would allow these partial-benefit-only D–SNPs to continue as they are currently operating.

12. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost-sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709 through 19711). Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. After the MOOP limit is reached, the MA plan pays 100 percent of the costs of items and services covered under Parts A and B.

In the April 2011 final rule (76 FR 21508), CMS established the approach MA organizations must use to track the enrollee's progress toward the plan MOOP limit. Under this policy, the in-network (catastrophic) and combined (total catastrophic) MOOP limits consider only the enrollee's actual out-of-pocket spending for purposes of tracking to the enrollee's progress toward the plan MOOP limit. This

[114] CMS Medicare-Medicaid Coordination Office, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'', January 17, 2020. Retrieved from: *https://www.cms.gov/ httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

approach also applies to D–SNPs. Thus, for any D–SNP enrollee, MA plans had the option to count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost-sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package. As a result, in practice the MOOP limit does not cap the amount a State could pay for a dually eligible MA enrollee's Medicare cost-sharing, nor does it cap the amount of Medicare cost-sharing that remains unpaid for providers serving dually eligible enrollees because of the prohibition on collecting Medicare cost-sharing from certain dually eligible individuals and the limits on State payments of Medicare cost-sharing under State lesser-of policies.[115] Thus, MA plans are paying amounts for non-dually eligible enrollees that they do not pay for dually eligible enrollees, even when different enrollees use the same volume of services; States, in certain circumstances, pay cost-sharing for dually eligible enrollees that is otherwise covered by the MA plans for non-dually eligible enrollees; and providers serving dually eligible MA enrollees are systemically disadvantaged relative to providers serving non-dually eligible MA enrollees, which we believe may negatively affect access to Medicare providers for dually eligible enrollees.

We propose to revise the regulations governing the MOOP limits for MA plans to require that all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit. This would ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit established by the plan (whether at the annual limit set by CMS under § 422.100(f) or some lesser amount), the MA plan must pay 100 percent of the cost of covered Medicare Part A and Part B services. As a result, the State Medicaid agency and other secondary payers would no longer be billed for any Medicare cost-sharing for the remainder of the year. To ensure clarity in the regulation text for the policy on what costs are tracked for purposes of the MOOP limit, we are proposing to amend the regulations by adding § 422.100(f)(4)(i) and (f)(5)(iii) to specify that MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached. In addition, we are proposing to amend § 422.101(d)(4) to substitute ''accrued'' for ''incurred'' in the description of how regional plans must track beneficiary out-of-pocket spending towards the MOOP limit. We intend this amendment to have only the substantive effect described here: That cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit by MA plans. This proposal is not intended to and will not change how the word ''incurred'' is otherwise used in the regulation. We believe that using a different term in the regulation text is appropriate to mark this change in policy from that first adopted in the April 2011 final rule. We note that the specific regulatory amendments may change if CMS publishes a final rule that addresses the MOOP limit provision from the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the February 2020 proposed rule).

We believe that this amendment is appropriate and necessary for several reasons. First, we believe this amendment will result in equal treatment under the MOOP limit for dually eligible MA enrollees compared to how Medicare-only enrollees are treated. Medicare-only MA enrollees receive the protection afforded by the MOOP limit after they have accrued cost-sharing under the MA plan benefit whether they have paid this cost-sharing or still owe their providers for some or all of the cost-sharing. In our experience, MA organizations do not impose additional cost-sharing liability above the MOOP limit on their Medicare-only enrollees if some of the pre-MOOP cost-sharing remains unpaid. Under our proposed amendment, dually eligible MA enrollees with unpaid cost-sharing due to limits on Medicaid payment of Medicare cost-sharing under State lesser-of policies would similarly receive 100 percent coverage of Parts A and B services under their MA plan after the MOOP limit was attained. In addition, dually eligible beneficiaries with Medicaid coverage that is secondary to Medicare would receive the same benefits from the MOOP as MA enrollees with employer or commercial insurance that is secondary to Medicare; in both cases, the Medicare cost-sharing counting towards the MOOP limit would be based on the out-of-pocket costs accrued under the MA plan benefit without regard to whether secondary coverage pays parts or all of the Medicare cost-sharing for Parts A and B services used before attainment of the MOOP.

Second, we believe this amendment will ensure that the providers serving dually eligible enrollees in MA plans receive the same benefit from the MOOP limit that providers receive when they serve Medicare-only MA enrollees, based on our understanding of how some MA plans pay providers after the MOOP limit is reached. Absent the revision we have proposed, a provider serving a dually eligible MA enrollee in a State that paid less than the full Medicare cost-sharing under the lesser-of policy (the vast majority of States) would continue to receive less than the full MA rate negotiated between the MA organization and the provider for a Part A or Part B service even after cost-sharing adds up to more than the MOOP limit during the course of the plan year. Medicare cost-sharing protections for certain dually eligible individuals prohibit providers from billing any of that unpaid Medicare cost-sharing to the beneficiary. For a Medicare-only enrollee with similarly high medical expenses, the provider can, for example, work out a payment plan for unpaid Medicare cost-sharing accumulated before attainment of the MOOP with the assurance that the MOOP amount would

[115] Section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing for QMBs to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid State plan payments, and third-party payments) equal to the amount a State would have paid for the service under the Medicaid State plan. For example, if the Medicare (or MA) rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment. See Chapter II, sections E.4 through E.6 of the Medicaid Third Party Liability Handbook at *https://www.medicaid.gov/medicaid/eligibility/downloads/cob-tpl-handbook.pdf.*

limit providers' liability for unpaid Medicare cost-sharing. If the out-of-pocket costs that counts towards the MOOP limit are calculated similarly for dually eligible enrollees with Medicare cost-sharing protections, the providers would similarly know that there was a limit on the liability for unpaid Medicare cost-sharing that they must assume. We believe this proposal to revise the method that MA organizations must use to determine when the MOOP limit has been reached will mitigate existing provider payment disincentives related to serving dually eligible MA enrollees. As a result, the proposal may improve access to providers, including specialists, who currently limit the number of dually eligible MA enrollees they serve or decline to contract with D–SNPs.

Third, our proposed amendments to §§ 422.100(f)(4) and (5) and 422.101(d)(4) are consistent with the statutory requirement at section 1902(a)(25)(G) of the Act that the State plan under title XIX must provide that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, a self-insured plan, a service benefit plan, and a health maintenance organization), in enrolling an individual or in making any payments for benefits to the individual or on the individual's behalf, from taking into account that the individual is eligible for or is provided medical assistance under Medicaid. The current method for calculating attainment of the MOOP explicitly takes into account the provision of medical assistance—specifically the payment of Medicare cost-sharing—by Medicaid in determining at what point the MA plan will begin paying 100 percent of costs for Medicare Parts A and B services. Our proposed amendments would ensure that the provision of Medicare cost-sharing assistance by the State is no longer considered in calculating attainment of the MOOP limit. In particular, this will ensure that D–SNPs that contract with State Medicaid agencies calculate attainment of the MOOP limit consistent with the Medicaid State plan requirements under the Act.

Fourth, our investigations show that D–SNPs offered by MA organizations currently differ in how they determine if the MOOP limit has been attained. Some D–SNPs calculate attainment of the MOOP as we propose, by adding up all cost-sharing accrued under the plan benefit until the MOOP limit is attained and, for the remainder of the year, paying 100 percent of the costs of covered services. Other D–SNPs do not seem to count any cost-sharing accrued under the benefit toward the MOOP for dually eligible individuals with Medicare cost-sharing protections—the D–SNPs do not count any cost-sharing amounts paid by the State and apparently assume that all cost sharing that is not paid by the State is not billed to the dually eligible enrollee because of the cost-sharing protections these beneficiaries receive. As a result, the MOOP is never attained. Our proposed amendments would bring consistency to how MA organizations determine if the MOOP limit has been attained, since it is based entirely on the claims adjudicated by the MA organization regardless of the enrollee's dual eligibility status. We believe this provides MA organizations with a straightforward method of determining when the MOOP limit has been attained based on claims data that the MA organization has in its possession.

For illustrative purposes, we provide below an example of how our proposal would change payment for services delivered after attainment of the MOOP limit in a D–SNP with cost-sharing that mirrors Original Medicare cost-sharing and where all benefits received by the enrollee are from in-network providers.

A D–SNP enrollee with unmanaged diabetes enters the hospital and has both legs amputated. After a lengthy hospital stay, followed by admission into a skilled nursing facility (SNF), the enrollee is discharged to her home with a power wheelchair. The enrollee also requires substantial follow-up care, including frequent visits with primary care and specialist physicians, physical and occupational therapy, wound care, and wheelchair modifications. The cost-sharing—inpatient charges, SNF per day charges, and the 20 percent coinsurance for the power wheelchair and follow-up care—has accrued to $7,550, the D–SNP's MOOP limit, by June. Under the lesser-of policy, the State Medicaid payment policy caps total payment at the Medicaid rate for specific services, which resulted in payment of some of the hospital cost-sharing but none of the SNF per-day charges or the 20 percent coinsurance for the power wheelchair or follow-up services. As such, providers did not receive payment for the cost-sharing amounts from the MA plan, Medicaid, or the enrollee for the SNF, power wheelchair, or other follow-up services.

Under our proposal, all of the cost-sharing, whether paid by Medicaid or unpaid, moves the beneficiary toward the $7,550 MOOP limit under the D–SNP's benefit design, after which the D–SNP would pay 100 percent of its rate for all Medicare Part A and B services provided to the enrollee for the remainder of the year. Absent the implementation of our proposal, the enrollee would not have reached the MOOP limit in June, because the D–SNP did not count either the Medicaid payments of the cost-sharing amounts or unpaid cost-sharing (which providers are prohibited from collecting from the enrollee under Medicare rules) toward attainment of the MOOP limit. Therefore, the D–SNP would continue to deduct cost-sharing amounts from payment to providers and, due to the lesser-of policy, some providers would continue to not receive payment for the cost-sharing amount at all when furnishing services to the dually eligible enrollee. In our example, assuming the enrollee only receives Part B services after June, the providers of these services would receive only 80 percent of the total payment rate for the furnished services from the D–SNP, compared with the 100 percent providers would receive under our proposal.

For the reasons described in this section, we propose to amend §§ 422.100(f)(4) and (5) and 422.101(d)(4) to provide that MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee and must alert enrollees and contracted providers when the MOOP limit is reached. For purposes of this amendment, the term accrued includes Medicare cost-sharing obligations regardless of whether the enrollee or another party or entity pays and regardless whether the provider is permitted to collect the Medicare cost-sharing from the enrollee.

13. Comment Solicitation on Coordination of Medicaid and MA Supplemental Benefits

Section 422.107 requires each MA organization offering a D–SNP to have a contract with the State Medicaid agency that describes, among other things, the organization's responsibility to coordinate Medicaid benefits. State Medicaid agencies have broad flexibility to include provisions in their D–SNP contracts. State Medicaid agencies may include provisions related to the MA supplemental benefits the D–SNP offers, how the MA organization shares information about those benefits, and processes for coordinating benefits across Medicare and Medicaid programs.

In this proposed rule, we describe a number of ways that State Medicaid agencies can use their D–SNP contracts under § 422.107 to coordinate D–SNP supplemental benefits, including

reductions in Medicare cost-sharing, with Medicaid benefits. How this coordination works varies based on whether or not the D–SNP, or an affiliated Medicaid MCO, is capitated by the State Medicaid agency to deliver Medicaid benefits, or whether those benefits are delivered through the Medicaid FFS program or an unaffiliated Medicaid MCO. We seek comments on the following examples [116] of potential coordination of Medicaid and MA supplemental benefits:

- In some States, D–SNPs offer Medicare supplemental benefits that overlap with Medicaid benefits that the State covers on an FFS basis. Under section 1902(a)(25) of the Act, State Medicaid agencies that deliver these benefits must coordinate benefits with the D–SNP to ensure that Medicaid does not pay for benefits that are covered by the D–SNP as MA supplemental benefits. For example, a State could ensure that dually eligible enrollees use up the number of non-emergency medical transportation trips provided by the D–SNP (as supplemental benefits) before using the overlapping Medicaid transportation benefits. State Medicaid agencies can also use their contracts with D–SNPs to require these plans to take specific actions, such as instructing its network providers to bill the D–SNP before billing the Medicaid program or providing information on benefits or service use to the State or its Medicaid providers, to enable successful and more seamless coordination of benefits.
- A D–SNP that is capitated by the State Medicaid agency to provide Medicaid benefits, such as dental services, can also provide dental services as a MA supplemental benefit, as long as the D–SNP (or its Medicaid MCO affiliate) is not paid twice, once by Medicare and once by Medicaid, for coverage of the identical benefit for the same enrollees in the same contract year. As noted previously, under section 1902(a)(25) of the Act, Medicaid should not pay for a benefit that Medicare or an MA plan (or a third party) covers to the same extent for the same individual. This principle applies whether the benefits are paid for on an FFS or capitation basis.

We also seek comment on other potential ways that D–SNPs and States can work together to coordinate Medicare and Medicaid benefits in order to improve D–SNP enrollee experiences and outcomes.

State Medicaid agencies can use their contracts with D–SNPs under § 422.107 to meet these requirements and ensure Medicaid funds provided to the D–SNP only pay for Medicaid benefits. These State contracts with D–SNPs, in combination with State Medicaid benefit design, can help create benefits that are in addition to Medicare benefits and complementary across programs. For example, a D–SNP that also has a Medicaid managed care contract could use both Medicare and Medicaid dollars to provide a benefit that, on an actuarial basis, equals the value of the benefit from the combination of both funding streams. The plan must be able to clearly identify, for Medicaid managed care rate setting purposes, claims that are payable under the Medicaid program after exhaustion of the Medicare benefit. In addition, § 422.254 requires the MA organization to comply with actuarial standards in developing and submitting bids, including bids for supplemental benefits.

In all cases, the capitation rate for the Medicaid benefit must be actuarially sound and based on the cost of furnishing only the Medicaid-covered benefits (§§ 438.3(c) and (e); 438.4 through 438.7). Similarly, the rebate allocated for the MA supplemental benefits must reflect the organization's estimate of the revenue required to furnish the MA supplemental benefits only and provide the actuarial basis for the bid (§§ 422.252 through 422.256; 422.266).

Coordination of overlapping benefits works differently if the State Medicaid agency has a capitated contract with a different legal entity, such as a specialty dental plan or transportation vendor for services that overlap with the D–SNP's supplemental benefits. As noted previously, Medicare or the MA plan is the primary payer whenever Medicare and Medicaid cover the same services. As such, the State Medicaid agency and its capitated vendor should take the steps necessary to avoid duplication of services or duplicate payment for services delivered as MA supplemental benefits. For example, the State can make an adjustment to the base data used for Medicaid rate development to address coordination of benefits, such as when both Medicare (or an MA plan) and Medicaid cover a benefit, to ensure Medicaid rate development appropriately accounts for Medicaid being the payer of last resort.[117] One more advantage of integrated care—capitating the same organization for all services—over fragmentated care is elimination of the administrative burden of coordinating benefits and identifying the correct payments for the secondary coverage with each service and each processed claim.

State Medicaid agencies have flexibility to determine whether a D–SNP supplemental benefit covered with Medicare funds substitutes for an identical Medicaid benefit, given that Medicare coverage is primary to Medicaid, with the Medicaid benefit not provided, or to coordinate the D–SNP benefit and Medicaid benefit to provide D–SNP enrollees with an enhanced benefit. For example, a State Medicaid agency can determine that the use of the D–SNP supplemental benefit covered with Medicare funds, such as coverage of two dental cleanings per year, will be provided first, with the same Medicaid benefit provided after the Medicare benefit has been exhausted, resulting in coverage of up to four cleanings a year, which is recommended in some cases. A State Medicaid agency may determine that provision of the Medicaid benefit in addition to the same benefit covered as a D–SNP supplemental benefit is not medically necessary or cost-effective, or coordinate the two benefits as in the example above if the State believes the additional benefits would improve the care and support received by dually eligible individuals through the two programs. The contract between the D–SNP and the State Medicaid agency required under § 422.107 can be used to document the above types of determinations, and instruct the D–SNP for how to coordinate Medicare Part A and B benefits, MA supplemental benefits, and Medicaid benefits, consistent with applicable law.

A State Medicaid agency may use the agreement required by § 422.107 between the State and the D–SNP to require a FIDE SNP to offer MA supplemental benefits that expand coverage of LTSS that are also covered under Medicaid (with the Medicaid coverage furnished by the FIDE SNP or its affiliated Medicaid MCO). For example, the State Medicaid agency may require the FIDE SNP to have coverage of an item or service that is only covered under Medicaid for certain beneficiaries by offering an MA supplemental benefit that—

- Covers the item or service as a supplemental benefit (provided the requirements for supplemental benefits are met per section 1854(c) of the Act and 42 CFR 422.2 (definition of MA plan), 422.100(d), and other regulations) for enrollees who are not eligible to receive the item or benefit under Medicaid; or

[116] These examples also appeared in a May 27, 2021 FAQ document at: *https://www.cms.gov/files/document/dsnpmedicaremedicaid coordbenefitsfaqs.pdf.*

[117] See 42 CFR 438.5 regarding rate development standards for Medicaid managed care capitation rates.

• Fills in gaps or provides coverage that exceeds the amount, duration, or scope of the Medicaid coverage of the item or service.

All MA plans, including D–SNPs, must comply with uniformity requirements in designing and offering supplemental benefits under section 1854(c) of the Act and §§ 422.2, 422.100(d), and other regulations. CMS will consider the supplemental benefits as meeting the uniformity requirements in cases where some dually eligible individuals receive the benefit under the FIDE SNP's Medicaid managed care contract while other enrollees receive the benefit as an MA supplemental benefit because they are not eligible for Medicaid benefits under State Medicaid eligibility criteria. We are considering whether an amendment to § 422.100(d)(2) would be appropriate regarding this approach to uniformity for supplemental benefits when a FIDE SNP arranges supplemental benefits this way. We welcome comments on that issue.

For example, a State can require, via the State's contract with a FIDE SNP, that the FIDE SNP offer an MA supplemental benefit that covers home and community-based services for certain, but not all, enrollees, such as enrollees who either: (1) Meet the State Medicaid criteria to receive Medicaid home and community-based services but are on waiting lists (and therefore ineligible *at the time* to receive the Medicaid services); or (2) are not eligible for the Medicaid benefits, such as because the enrollees do not receive full Medicaid benefits (that is, partial-benefit dually eligible individuals) or do not meet State Medicaid criteria to receive home and community-based services. In this case, enrollees have access to medically necessary home and community-based services when their needs are similar, even though some may be funded as an MA supplemental benefit and others through Medicaid.

Alternatively, a State Medicaid agency could contract with a FIDE SNP to use Medicare rebate dollars to pay for a supplemental benefit that the State wants the FIDE SNP to provide in addition to the Medicaid-funded benefit the FIDE SNP provides under its Medicaid managed care contract. For example, depending on the State Medicaid agency's contracting and benefit design, a D–SNP could provide its enrollees with 2 total weeks of respite care even though the Medicaid benefit is limited to 1 week, by providing an MA supplemental benefit for respite care. The FIDE SNP would provide the first week of respite care—as an MA supplemental benefit—and the second week of respite care in its role as a Medicaid managed care plan (where Medicaid is the secondary payer).

(a) Using the D–SNP MOC To Coordinate Medicaid Services

Although not a supplemental benefit, the D–SNP MOC, required by § 422.101(f), also provides a vehicle for State Medicaid agencies to work with D–SNPs to meet State goals to improve quality of care and address SDoH. State Medicaid agencies may work with D–SNPs with service areas in the State to include (and, through the State Medicaid agency contract at § 422.107, require inclusion of) specific elements in the MOC and how the D–SNP delivers covered items and services consistent with the MOC. There is no prohibition on a State Medicaid agency imposing specific requirements for the D–SNP MOC that are in addition to § 422.101(f); compliance with the approved MOC is included in the D–SNP's bid to provide basic benefits under § 422.101(f). For example, the State Medicaid agency contract under § 422.107 could require the D–SNP to have specific community-based providers involved in development of individualized care plans, deploy nurse practitioners for in-home care for high-risk enrollees when in-home services are required by the individualized care plans, use health care providers (rather than plan staff) for care coordination functions, and/or set minimum payment amounts for such providers.

(b) Coordinating Coverage of Medicare Cost-Sharing

In general, the same prohibition on duplicate Medicare and Medicaid payments for identical benefits applies when a D–SNP covers MA supplemental benefits that reduce Medicare Parts A and B cost-sharing, such as deductibles and coinsurance, as described for overlapping coverage of other Medicaid and MA supplemental benefits. How it works depends on whether the State Medicaid agency pays for Medicare cost-sharing through the Medicaid FFS program or pays the D–SNP a capitated amount to cover the State's obligation to pay MA cost-sharing. For example, if a D–SNP does not impose the Part B deductible but otherwise uses Part B cost-sharing for its coverage of Part B Medicare benefits, it would have the following effects:

• It would reduce to $0 the amount the State Medicaid FFS program pays providers serving QMBs and other full-benefit dually eligible enrollees in the D–SNP for the Part B deductible.

• If the State pays the D–SNP (or its affiliate) for coverage of MA cost-sharing otherwise payable by the State, it would eliminate any cost for coverage of the Part B deductible from those payments to the plan. D–SNPs cannot receive duplicate payments for coverage of the Part B deductible—once, in the form of the capitated payments from the State for Medicaid coverage and again by including the cost of eliminating the Part B deductible in the supplemental benefits that are paid by the Medicare beneficiary rebate under section 1854(b) of the Act.

Most States pay less than the full MA cost-sharing amount due to the application of a ''lesser-of'' [118] payment method for MA cost-sharing, and some of these States capitate D–SNPs in their States to pay this ''lesser-of'' amount to the provider. D–SNPs in these States can combine Medicaid capitated payments and Medicare rebate dollars to more fully cover MA cost-sharing—that is, the amount a dually eligible individual would pay if not subject to Medicare cost-sharing protections [119]—provided that the State Medicaid capitation payment and MA bid do not both pay for the same costs. The amount paid using MA rebates must be based on the actuarial value of the reduction in Medicare cost-sharing that is part of the MA plan benefit design, and the State Medicaid capitation payment must be based on the actuarial value of Medicare cost-sharing paid for Medicare Parts A and B services under the ''lesser-of'' payment method. The overall reduction in Medicare cost-sharing must be actuarially equivalent to the Medicare cost-sharing paid for by the Medicaid capitated payment plus the Medicare rebate dollars allocated to additional reductions in Medicare cost-sharing compared to the actuarial value of Medicare cost-sharing in the original Medicare FFS program.

We seek comments on State and MA organization experiences and challenges in coordinating benefits, CMS guidance or regulations that may warrant clarification, and whether our current policies create any unintended obstacles

[118] Under the ''lesser of'' policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service. For example, if the Medicare (or MA) rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment.

[119] Qualified Medicare Beneficiaries and full benefit Medicare beneficiaries have protections from being charged Medicare cost-sharing for Medicare Parts A and B services. See *https://www.cms.gov/files/document/medicaremedicaidenrolleecategories.pdf* for the protections that apply to different categories of dually eligible individuals.

to accessing services among dually eligible beneficiaries.

14. Converting MMPs to Integrated D–SNPs

In the 10 years since the creation of the FAI, the integrated care landscape has changed substantially. Congress made D–SNPs permanent in 2018 and established, effective beginning in 2021, new minimum integration standards and directed the establishment of unified appeals and grievance procedures (which we tested through the MMPs). Changes in MA policy have also created a level of benefit flexibility that did not previously exist outside of the capitated model demonstrations, with MA plans increasingly offering supplemental benefits that address social determinants of health and long-term services and supports.[120] These factors, in combination with the proposals discussed earlier in this proposed rule, offer the opportunity to implement integrated care at a much broader scale than existed when MMPs were first created. As a result, should we finalize the proposals in this rule that facilitate or require greater integration, we would work with the states participating in the capitated financial alignment model during CY 2022 to develop a plan for converting MMPs to integrated D–SNPs.

The process for converting MMPs to integrated D–SNPs would depend in part on each State's circumstances. States may choose to use the opportunities under our proposed § 422.107(e) to structure the integrated D–SNP products to replicate key features of MMPs. Interested States, in consultation with local stakeholders, could submit letters as described at proposed § 422.107(e)(2) indicating intent to include contract requirements under § 422.107(e)(1) and take steps toward including those new terms in their contracts with D–SNPs. Concurrently, the interested States would also notify the MMP sponsors via the transition plan required in the three-way contracts. The organizations offering the MMPs would submit a notice of intent to apply and corresponding application for an MA contract, along with the D–SNP application specific to the integrated product as part of the annual MA application process, as described in section II.A.6.a. of this proposed rule. These States would work together with CMS to take the administrative steps necessary to maintain several of the integrated processes developed as part of the capitated model demonstrations, as discussed in the previous proposals (for example, integrated materials, unified appeals and grievances, enrollment processes to support exclusively aligned enrollment, etc.). States would develop new or revise existing State Medicaid agency contracts with integrated D–SNP sponsors to reflect State-specific Medicaid-related policies and priorities. Concurrently, States may need to attain appropriate Medicaid authorities to preserve integration through Medicaid managed care plans or may need to use existing Medicaid authorities to restructure Medicaid managed care contracts.

Incorporating successful elements from MMPs into D–SNPs, using the processes and new requirements proposed in this rule, while phasing out MMPs as separate managed care products, would streamline and strengthen integrated care options for dually eligible individuals. It would allow CMS, States, and plan sponsors to concentrate quality improvement resources on a smaller number of products focused on dually eligible individuals. Now that Congress has permanently authorized SNPs, it would offer greater stability to States and sponsors and signal a longer term commitment to integration to stakeholders, including advocates, providers, and plans, than we could offer under time-limited model tests. It would also alleviate States and plans of the additional administrative burden associated with a demonstration, potentially freeing up additional resources that could be reinvested in refining and enhancing integrated care. We intend to continue—focusing now on D–SNPs—many of the technical assistance and quality improvement activities that we initially developed for MMPs, including—

- Learning communities;
- Direct work with beneficiary advocates and other stakeholders;
- Targeted efforts to improve outcomes and reduce disparities; and
- Capacity building on topics like person centeredness, disability-competent care, dementia, and behavioral health.

Converting MMPs into integrated D–SNPs would not be without downsides. While the aforementioned proposals, if finalized, would create mechanisms and new requirements to replicate much of the programmatic or administrative integration found in MMPs, other aspects of integration would be lost, including financing provisions (such as integrated risk mitigation and medical loss ratio calculations) and the ability to conduct passive enrollment at scale. States may also no longer have access to the same funding we provide to support ombudsman and options counseling as part of the current model tests. It may also be challenging to replicate the integrated enrollment processes utilized for MMPs if States no longer process all enrollments, and it is possible that we would lose some integration in beneficiary communications materials, particularly enrollment notices, in the process. In addition, converting MMPs to integrated D–SNPs also means transitioning the over 400,000 individuals currently being served by MMPs, and there is risk for beneficiary confusion and disruption of services and care coordination during such a transition.

In order to mitigate any disruptions that could result from converting MMPs to D–SNPs, we intend to work closely with States and other stakeholders to ensure the transition is as seamless as possible for MMP enrollees. To that end, we are considering use of our authority under section 1115A of the Act to facilitate the transition of MMP enrollees to D–SNPs operated by the same parent organization, subject to State approval, unless enrollees choose otherwise. This will minimize disruption of services and ensure continuity of care to the greatest extent possible. We already have experience with similar transitions at the end of the Virginia[121] and New York MMP demonstrations[122] and are working closely with the California Department of Health Care Services and MMPs to facilitate such a transition when the Cal MediConnect demonstration concludes at the end of 2022.[123] We seek comment on this contemplated approach to working with States to convert MMPs to integrated D–SNPs.

[120] ATI Advisory. *New, Non-Medical Supplemental Benefits in Medicare Advantage in 2021.* May 2021. *https://atiadvisory.com/wp-content/uploads/2021/06/2021-Special-Supplemental-Benefits-for-the-Chronically-Ill.pdf.*

[121] Centers for Medicare & Medicaid Services and Virginia Department of Medical Assistance Services. *Commonwealth Coordinated Care (CCC) Phase-Out Plan. https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/VAPhaseOutPlan.pdf.*

[122] Centers for Medicare & Medicaid Services and New York Department of Health. *New York Fully Integrated Dual Advantage Demonstration Phase-Out Plan.* September 2019. *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/NYFIDAPhaseOutPlan.pdf.*

[123] California Department of Health Care Services. *Expanding Access to Integrated Care for Dual Eligible Californians.* March 2021. *https://www.dhcs.ca.gov/provgovpart/Documents/6422/Expanding-Access-to-Integrated-Care-for-Dual-Eligible-Californians-03-01-21.pdf.*

B. Special Requirements During a Disaster or Emergency (§ 422.100(m))

In the February 12, 2015, final rule titled, ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (80 FR 7959) (hereinafter referred to as the 2015 final rule), CMS finalized a new paragraph (m) in § 422.100 to codify and clarify an MA organization's responsibilities when health plan services are affected by disasters or emergencies, including public health emergencies (PHEs), to ensure that MA enrollees continue to have access to care when normal business operations are disrupted and to ensure out-of-network providers are informed of the terms of payment for furnishing services to affected enrollees during disasters or emergencies. During the Coronavirus 2019 Disease (COVID–19) PHE, we received questions about the applicability of the special requirements at § 422.100(m), which prompted us to review the regulation and the laws related to the declaration of disasters and emergencies. In light of this review, we are proposing changes to clarify potential ambiguities in the regulation text, to further clarify the basis for determining the end of an MA organization's obligations to comply with special requirements during a disaster or emergency and to codify our previous guidance. Specifically, we are proposing to revise § 422.100(m) to more clearly specify when MA organizations must begin ensuring access to covered benefits by meeting the requirements in paragraphs (m)(1)(i) through (iv) and when MA organizations are permitted to stop meeting those requirements.

Section 1852(d) of the Act requires MA organizations to provide continued availability of and access to covered benefits, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week; the ability to limit coverage to benefits received from a plan's network of providers is contingent on fulfilling this obligation. When a disaster or emergency occurs, enrollees may have trouble accessing services through network providers or sometimes must physically relocate to locations that are outside of their MA plan's service area. Currently, § 422.100(m) requires MA organizations to ensure access, at in-network cost sharing, to covered services even when furnished by noncontracted providers when disruption in their MA plan's service area during a state of disaster or emergency impedes enrollees' ability to access covered healthcare services from contracted providers. Consistent with uniformity requirements for MA plans at § 422.100(d) and other regulations, these special requirements must be uniformly provided to similarly situated enrollees who are affected by the state of disaster or emergency.

First, we propose to amend the regulation to explicitly limit the application of the special requirements to when there is a disruption in access to health care. In the 2015 final rule, we stated in the preamble that the regulations at § 422.100(m) were added to require MA organizations to ensure access, at in-network cost sharing, to covered services even when furnished by noncontracted providers ''when a disruption of care in the service area impedes enrollees' ability to access contracted providers and/or contracted providers' ability to provide needed services.'' (80 FR 7953) We propose to revise § 422.100(m)(1) to include that there must also be a disruption of access to health care in addition to a disaster or emergency declaration for the MA organization to be required to ensure access to covered benefits consistent with the special requirements described in § 422.100(m)(1). We propose to define ''disruption of access to health care'' for purposes of these special requirements by adding a new paragraph (m)(6); as proposed, a ''disruption of access to health care'' for the purpose of § 422.100(m) is an interruption or interference in access to health care throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a). The intent of these modifications is to clarify that if there is a current state of disaster or emergency that is not contributing to a disruption in health care services, then MA organizations would not be required to follow the requirements at § 422.100(m)(1)(i)–(iv). During a state of disaster or emergency, MA organizations must continue to meet MA access and availability requirements consistent with the normal prevailing community pattern of health care delivery in the areas where the network is being offered. During a state of disaster or emergency, disruptions caused by the disaster or emergency may prevent contracted providers from providing services to enrollees. If enough contracted providers are unavailable to enrollees, then the MA plan would not have enough contracted providers consistent with the normal prevailing community pattern of health care delivery in the service area. Per the proposed definition, this would indicate that there is a disruption in access to health care in the service area, and MA organizations would be required to follow the special requirements at § 422.100(m)(1). This definition is not intended to be limited to physical barriers to access (such as electrical outages or transportation difficulties caused by hurricanes or wildfires) but to be broad enough to encompass any interruption or interference caused by a disaster or emergency such as a lack of available hospital beds or quarantine restrictions. Therefore, under our proposal, when a disaster or emergency interrupts that level of access to and availability of services, MA organizations must ensure access by covering basic and supplemental benefits furnished at non-contracted facilities; waiving, in full, requirements for gatekeeper referrals where applicable; providing in-network cost sharing even if the enrollee uses out-of-network providers; and making changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3). Limits in other regulations, such as §§ 422.204(b)(3) and 422.220 through 422.224, on which healthcare providers may furnish benefits remain in place and are not eliminated by § 422.100(m).

In the definition, we refer to the normal prevailing community pattern of health care delivery in the service area as it usually is when a state of disaster or emergency does not exist, not the prevailing community pattern of health care delivery in the service area during the state of disaster or emergency. During a state of disaster or emergency, it is possible that access to health care will be disrupted affecting more than MA enrollees, including access to care for enrollees in commercial plans and Original Medicare. To provide an extreme example, an MA organization could indicate that they are meeting the prevailing community pattern of health care delivery when all of the primary care providers in the service area are closed due to a state of disaster, and they are therefore meeting the standard because everyone in the service area, no matter the type of insurance they have, cannot access primary care providers. As explained above, this would not be acceptable, as CMS is measuring the prevailing community pattern of health care by reference to the pre-disaster period. Under the proposed regulation,

MA organizations would be required to ensure access for their enrollees by complying with the special requirements listed at § 422.100(m)(1)(i) through (iv). While we consider the standard to be the normal prevailing community pattern of health care delivery, we understand this standard broadly in the context of disasters and emergencies. Some examples that would constitute a disruption in access to health care include physical barriers to accessing health care such as road disruptions or electrical outages, as well as other barriers to accessing health care such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID–19 pandemic. This list is not intended to be exhaustive as many unforeseen circumstances may arise during states of disaster or emergencies that may cause enrollees to have trouble accessing services through normal channels or force them to move to safer locations that are outside of their plans' service areas. A disruption in access to health care could include disruptions in access to Medicare Part A or Part B services or to supplemental benefits offered by the plan, or any combination of those. Our proposal is intended to be broad and to focus on actual access to and availability of services for enrollees in a service area affected by a disaster or emergency. Whether the MA plan network continues to meet evaluation standards specified in § 422.116 is not the only relevant consideration. For example, regarding a hospital with beds or other equipment unavailable to treat additional patients (as has occurred during COVID–19 pandemic), the hospital remains part of the MA organization's network, and therefore the network may be consistent with CMS's network adequacy standards for MA plan, but enrollees would not be able to access the hospital and may need to go to out-of-network providers to access their covered benefits. Similarly, physical barriers that enrollees may experience during a disaster or emergency (road closures, flooding, etc.) may affect enrollees unevenly, preventing some enrollees from accessing in-network providers. The provider may be part of the MA organization's network and therefore the network may meet the time and distance evaluation standards in § 422.116 and appear to be capable of furnishing services consistent with the prevailing community pattern of health care, but some enrollees may experience difficulty accessing that provider to obtain needed health services. Further, if an enrollee had to leave their home to move to a safer location due to a disaster or emergency, the MA organization may still have a network that meets the prevailing community pattern of health care in the service area of the enrollee's home, but the enrollee may not be able to access health care in their safer location without being able to access out-of-network care. We request comments from stakeholders on our proposed definition to determine whether there are circumstances CMS is not considering or additional standards that we should be using to identify when a disruption of access to health care is occurring.

We propose to add a disruption of access to health care as a condition that must be met before the special requirements in § 422.100(m)(1) apply in order to ensure that this regulation is not overly broad and is appropriately tailored to address our concerns that MA enrollees have adequate access to medically necessary care and are not unduly restricted to the MA plan's network of providers. As an illustrative example of a situation where a disruption of access to health care was not present even though a state of emergency was in effect, the Governor of Hawaii issued a state of emergency [124] to fight the Zika virus in February of 2016. This state of emergency did not require all MA organizations operating in Hawaii to comply with the requirements at § 422.100(m)(1) because all provider offices were operating as usual, contracted providers continued in their ability to provide needed services, and enrollees did not face barriers in accessing needed services. The Opioid PHE, which began in 2017, is another example where there is a declared PHE by the Secretary that has been ongoing, but it does not necessarily constitute a disruption of access to health care. However, in 2017, Hurricane Maria in Puerto Rico led to substantial issues with access to covered services for MA enrollees. In connection with the Hurricane Maria, there was a Presidential declaration of a major disaster under the Stafford Act on September 20, 2017 [125] and a Public Health Emergency declaration by the Secretary as of September 17, 2017.[126] Under our proposal, MA organizations would be required to meet the special requirements at § 422.100(m)(1) for the duration of similar disasters and emergencies where access to covered benefits is disrupted.

Under this proposal, we propose that MA organizations would be initially responsible for evaluating whether there is a disruption of access to health care under § 422.100(m). We believe MA organizations are best positioned to evaluate if a state of disaster or emergency is disrupting access to health care for enrollees in their service area. MA organizations would know the status of their in-network providers (for example, whether they are operational or not, how many beds are filled, etc.) and would be in communication with their providers as issues at the provider's facilities or with an MA organization's enrollees arise. MA organizations should be guided by the explanations here, including the examples, as well as their particular and detailed knowledge and understanding of their enrollees, service areas, and networks, to reasonably assess if there is a disruption in access to health care in the service area. CMS expects that MA organizations should be aware of these and other facts regarding access to health care in the service areas where they offer plans, and should be able to evaluate those facts and apply the standard in the regulation to know when they must comply with the special requirements at § 422.100(m). CMS will closely monitor access during disasters or emergencies to ensure MA organizations are applying the standard in § 422.100(m)(1) correctly and complying with this regulation to avoid any disruptions in access to care. As we monitor, we will evaluate whether and when the standard in § 422.100(m)(1) as proposed to be amended here is met. If CMS discovers that there are problems with access for enrollees, we will direct MA organizations in an affected area to comply with § 422.100(m), but we reiterate that an MA organization should be able to apply the standard in the regulation to the relevant facts related to a potential disruption in access to care during a disaster or emergency in order for the MA organization to know when compliance is required. MA organizations are required to meet the network adequacy requirements at §§ 422.112(a) and 422.116 at all times to ensure enrollees have sufficient access to covered benefits. MA organizations that fail to meet network adequacy requirements must ensure access to specialty care by permitting enrollees to see out-of-network specialists at the individual enrollee's in-network cost

[124] *https://governor.hawaii.gov/wp-content/uploads/2016/02/160212_EmergencyProclamation_Dengue.pdf.*

[125] *https://www.govinfo.gov/content/pkg/FR-2017-10-06/pdf/2017-21649.pdf.*

[126] *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Puerto-Rico-and-US-Virgin-Islands-PHE-Determination.pdf.*

sharing level under § 422.112(a)(3). In addition, MA organizations may need to make alternate arrangements if the network of primary care providers is not sufficient to ensure access to medically necessary care under § 422.112(a)(2). This proposal would not change these existing and continuing regulatory requirements.

Similar to what we have seen during the COVID–19 PHE, CMS expects that there will be situations where there is a disruption of access to health care for some period of time during a disaster or emergency but not at other times. Under our proposed regulation, MA organizations would follow the special requirements imposed by § 422.100(m)(1) for 30 days after the disruption of access to health care ends while the disaster or emergency is ongoing and for 30 days after the end of the disaster or emergency if the disruption of access to health care, as defined in § 422.100(m)(6), continues until the end of the disaster or emergency. MA organizations may also find that at later time period during the same disaster or emergency, there is another disruption of access to health care and therefore that the MA organization must again follow the special requirements imposed by § 422.100(m)(1). We also recognize that there may be circumstances when a state of disaster or emergency is declared for an area containing multiple service areas (for example, the entire United States), but the disaster or emergency may unequally affect the various service areas contained in the larger area for which it is declared. It may be that some service areas experience a disruption of access to health care, but other service areas do not, or that the disruption in care ends for certain service areas but continues in others. Under our proposed regulation, in situations where a disruption of access to health care ends in a particular service area, but the state of disaster or emergency continues to be in effect for an area that includes that particular service area, the special requirements imposed by § 422.100(m)(1) would be in effect for the service areas in which there is a disruption of access to health care (until 30 days after the disruption of access to health care ends) and would not be in effect for services in which there has not been any disruption of access to health care.

We are also proposing two technical changes to our regulations at § 422.100(m)(2) to correct some numbering issues that occurred in the 2015 final rule. First, we are proposing to move the text from the fourth-level paragraph at (m)(2)(ii)(A) to the third-level paragraph at (m)(2)(ii), which currently does not have text associated with it. As amended, the regulation at § 422.100(m)(2)(ii)(A) would state that the Secretary of Health and Human Services (hereinafter referred to as the Secretary) may declare a PHE under section 319 of the Public Health Service Act. Second, we are proposing to remove the fourth-level paragraph at (m)(2)(ii)(B) because this paragraph only provides information about the Secretary's section 1135 waiver authority which is not an authority under which the Secretary may declare PHEs. In addition to these technical changes, we are proposing several clarifying revisions to our language in § 422.100(m) to ensure that we are consistently referring to disasters and emergencies. Currently, the language sometimes refers only to disasters (as in the introductory text to paragraphs (m)(1) and (2)), but also refers to disasters and public health emergencies (as in the text to paragraphs (m)(3) and (4) and (m)(5)(i)). We therefore propose to update the language throughout to reference disasters and emergencies with the aim of being consistent in that we refer to the various types of declarations listed at § 422.100(m)(2).

Lastly, we are proposing revisions to clarify the basis for determining when MA organizations are no longer required to comply with the special requirements for a disaster or emergency. We are proposing to modify the text at § 422.100(m)(3) to clarify that it refers to the end of the special requirements for a state of disaster or emergency stipulated at § 422.100(m)(1), not to the end of the state of disaster or emergency itself. We are also proposing to add a 30-day transition period to § 422.100(m)(3). Our current regulation at § 422.100(m)(3)(iii) provides a period of 30 days from the initial declaration for the special requirements imposed by § 422.100(m)(1) to be in effect if the initial declaration of the disaster or emergency does not contain a specific end date or if the official or authority that declared the disaster or emergency does not separately identify a specific end date, and CMS has not indicated an end date to the disaster or emergency. This means that, under the current regulation, there is usually a 30-day minimum period during which MA plans are providing access to covered benefits with the additional beneficiary protections specified in paragraphs (m)(1)(i) through (iv), unless an explicit announcement of the end of the disaster or emergency has been declared. We believe that having a minimum period for these protections is important and appropriate. A transitional period from when an MA organization must comply with the access requirements in § 422.100(m)(1) to normal coverage rules will protect enrollees who need time and assistance from the MA organization to find a contracted provider after having been treated by a non-contracted provider during the disaster or emergency. We intend for this period to serve as a protection for enrollees so they are not immediately responsible for the total cost of services received from a non-contracted provider that they have been seeing for a period of time due to the state of disaster or emergency. MA organizations may also find a transitional period helpful if they must contract with additional providers or otherwise make changes to their network to assist with the return to normal operations. We therefore propose to revise the regulation text at § 422.100(m)(3) to require a 30-day transition period after the points in time identified in the regulation for the end of the special requirements. Specifically, we propose to revise paragraph (m)(3) to provide that the applicability of the special requirements for a disaster or emergency in paragraphs (m)(1)(i) through (iv) end 30 days after the latest of the events specified in paragraph (m)(3)(i) or (ii) occur (that is, the latest end date in a case where there are multiple disasters/emergencies) or end 30 days after the condition specified in paragraph (m)(3)(iii) occurs (that is, there is no longer a disruption of access to health care).

In the 2015 final rule, we finalized three circumstances as determining the end of the special requirements for a disaster or PHE in the regulations at § 422.100(m)(3). First, as currently provided in § 422.100(m)(3)(i), the source that declared the disaster or PHE declares an end to it. As explained in § 422.100(m)(2), disasters or emergencies may be declared by the President of the United States under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) or the National Emergencies Act, by the Secretary who may declare a PHE under section 319 of the Public Health Service Act, or by Governors of States or Protectorates. We intend paragraph (m)(3)(i) to address circumstances when the initial declaration contains a specific end date or when the official or authority who declared the disaster or emergency separately identifies a specific end date. We are proposing to revise § 422.100(m)(3)(i) to address situations that may arise where there is more than one declaration of a disaster

or emergency at the same time for the same service area(s). This proposed revision clarifies that MA organizations must follow the special requirements until the latest applicable end date when multiple declarations apply to the same geographic area by specifying that all sources that declared a disaster or emergency that include the service area have declared an end. For example, if a Governor of a State declares a state of disaster or emergency and the President also later declares a state of disaster, both the state and federal disasters must be declared at an end to trigger § 422.100(m)(3)(i). If the President's disaster declaration ends after 20 days, but the Governor maintains the state of disaster for 30 days, then the special requirements imposed by § 422.100(m)(1) would apply for MA plans in that area through the end of the emergency declared by the Governor, plus an additional 30 days for the transition period we are also proposing.

Second, the regulation currently provides that CMS may declare an end to the state of disaster or PHE per § 422.100(m)(3)(ii). Upon review, we intended for this regulation text to refer to the Secretary's authority, which is consistent with the current practice of the Secretary to declare an end to PHEs. However, since the Secretary is already considered a source under § 422.100(m)(3)(i), we believe that modifying this requirement to refer to the Secretary is unnecessary and therefore we propose to remove this text.

Third, our current regulation at § 422.100(m)(3)(iii) addresses circumstances where a state of disaster or PHE is declared with no end date identified. Because § 422.100(m)(3) provides that the end of the emergency or state of disaster ends when ''any'' of the three listed, if the declaration disaster or emergency timeframe has not been identified by the authority or official who declared the disaster or emergency and CMS has not indicated an end date to the disaster or emergency, MA plans should resume normal operations 30 days from the initial declaration. However, this does not properly account for how declarations of disasters or emergencies may be renewed with continued disruptions to access to health care services for enrollees. Further, our experiences with declarations of disasters and emergencies have demonstrated that the 30-day timeframe for the special requirements in § 422.100(m)(1)(i) through (iv) may not be enough time to address concerns about enrollees being able to access benefits during disasters or emergencies, especially in cases where a disaster or emergency declaration has been renewed. There are circumstances where a 30-day time period does not cover the full length of a declared disaster or emergency and the current regulation is not well suited to ensure access for enrollees during the entire period of a disaster or emergency. For example, a PHE declared by the Secretary under section 319 of the Public Health Service Act is in effect for 90 days unless the Secretary terminates it earlier, and the Secretary may renew the declaration at the end of the 90-day period.

We propose to revise § 422.100(m)(3)(ii) to address when no end date is identified under § 422.100(m)(3)(i); in such cases, the applicability of the special requirements ends 30 days after the expiration of the declared disaster or emergency and any deadline for renewing the state of disaster or emergency. This modification clarifies that when a state of disaster or emergency is declared without an end date, § 422.100(m)(1) will continue to apply for the entire duration of the declared disaster or emergency, as determined under the relevant authority under which it was declared, if a disruption of access to health care continues. Stafford Act declarations do not have a defined end date. When the President declares a national emergency under the National Emergencies Act, the declaration of a national emergency lasts for a year unless terminated earlier by the Presidential proclamation or a joint resolution of Congress. The President can renew the declaration for subsequent one-year periods. When the Secretary declares a PHE under section 319 of the Public Health Service Act, it lasts for 90 days unless the Secretary terminates it earlier, and it can be renewed for 90-day periods. For example, if the Secretary declared a PHE under section 319 of the Public Health Service Act, then the end date of the PHE would be in 90 days, unless renewed. If the Secretary chose to declare an end before the 90-day period ended, then the public health emergency would end according to the declared end date. CMS does not have the expertise to know whether all state declarations of emergency have a defined end date. Therefore, we are not proposing specific time periods but are proposing to amend § 422.100(m)(3)(ii) to account for extensions or renewals of declarations of the type identified in paragraph (m)(2).

Lastly, we propose to add the disruption of access to health care as a limitation under revised § 422.100(m)(3)(iii) to indicate that the special requirements associated with a state of disaster or emergency may end when the disruption of access to health care ends, even if one of the circumstances in § 422.100(m)(3)(i) or (ii) to end the state of disaster or emergency has not yet occurred.

We intend to continue to issue subregulatory guidance as appropriate for MA organizations to explain how § 422.100(m) works, both through the HPMS system and through the CMS Current Emergencies web page at: *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies.-page.* Further, we note that the Secretary may exercise the waiver authority under section 1135 of the Social Security Act during an emergency period (defined in Section 1135(g) of the Act), which exists when the President declares a disaster or emergency pursuant to the National Emergencies Act or the Stafford Act, and the Secretary declares a PHE pursuant to section 319 of the Public Health Service Act. Under the Secretary's section 1135 waiver authority, CMS may authorize DME and A/B Medicare Administrative Contractors (MACs) to pay for Part C-covered services furnished to MA enrollees and seek reimbursement from MA organizations for those health care services, retrospectively. Detailed guidance and requirements for MA organizations under the section 1135 waiver, including timeframes associated with those requirements and responsibilities, would be posted on the Department of Health and Human Services website, (*https://www.hhs.gov/*) and the CMS website (*https://www.cms.hhs.gov/*). MA organizations are expected to check these sites frequently during such disasters and emergencies.

We propose the following changes to our regulations at § 422.100(m):

- Revise § 422.100(m)(1) to state that when a disaster or emergency is declared as described in § 422.100(m)(2) and there is disruption of access to health care as described in § 422.100(m)(6), an MA organization offering an MA plan must, until one of the conditions described in § 422.100(m)(3) of this section occurs, ensure access to benefits as described in § 422.100(m)(1)(i)–(iv).
- Revise § 422.100(m)(2) to refer to emergencies and disasters.
- Move the current text of § 422.100(m)(2)(ii)(A) to § 422.100(m)(2)(ii).
- Remove § 422.100(m)(2)(ii)(B).

• Revise § 422.100(m)(3) to specify to the end of the applicability of the special requirements rather than to the end of the disaster or emergency.

• Revise § 422.100(m)(3) to add a transition period of 30 days after the earlier of the conditions described in § 422.100(m)(3)(i) and (ii) occurs or after the condition described in § 422.100(m)(3)(iii) occurs; during the transition, MA organizations must continue to comply with § 422.100(m)(1).

• Revise § 422.100(m)(3)(i) to clarify that MA organizations must follow the special requirements until all of the sources that declared a disaster or emergency in the service area declare it ended.

• Revise § 422.100(m)(3)(ii) to state that no end date was identified in § 422.100(m)(3)(i) of this section, and all applicable disasters or emergencies have ended, including through expiration of the declaration or any renewal of such declaration.

• Revise § 422.100(m)(3)(iii) to state that the special requirements identified in § 422.100(m)(1) of this section may also end if the disruption in access to health care services ends.

• Revise § 422.100(m)(4) to refer to disasters and emergencies.

• Revise § 422.100(m)(5)(i) to refer to disasters and emergencies.

• Add a new paragraph at § 422.100(m)(6) to define ''disruption of access to health care'' as an interruption or interference throughout the service area such that enrollees do not have ability to access contracted providers or contracted providers do not have the ability to provide needed services, resulting in MA organizations failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

C. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

In the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' final rule, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (hereinafter referred to as the June 2020 final rule), CMS codified, with some modifications, our network adequacy criteria and access standards (previously outlined in sub-regulatory guidance) under a new regulation at § 422.116. Section 1852(d)(1) of the Act permits an MA organization to limit the providers from which an enrollee may receive covered benefits provided that the MA organization, among other standards, makes such benefits available and accessible in the service area with reasonable promptness. Using our authority under the statute to implement, interpret and enforce these requirements, we finalized § 422.116 setting forth specific requirements. The provisions at § 422.116 outline standards for measuring network adequacy and access under a contracted provider network in accordance with requirements and standards in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) of our regulations. In addition, the regulation codified our then-existing policy, that CMS does not deny an application based on the evaluation of the applicant's network for a new or expanding service area. Under our policy at the time of the June 2020 final rule and § 422.116(a)(2), an applicant is required to attest that it has an adequate network for access and availability of applicable provider and facility types at the time of the application for a new or expanding service area.

We are proposing to amend § 422.116(a)(1)(ii) to require compliance with applicable network adequacy standards set forth in § 422.116 as part of an application for a new or expanding service area. As indicated in the June 2020 final rule, we currently rely on our existing triennial network review process and timeline to evaluate compliance with network adequacy standards for organizations applying for a new or expanding service area. As discussed in the June 2020 final rule, we removed network adequacy reviews from the application process beginning in 2018 for contract year 2019. While the process of reviewing provider networks as part of the triennial review has thus far been adequate and efficient operationally, we have also experienced unintended consequences as discussed further in this section, and are therefore proposing to improve our oversight and effectiveness of network adequacy reviews for initial applicants and services area expansion (SAE) applicants by requiring provider network reviews at the time of such MA applications.

Currently, consistent with § 422.116(a)(1)(i) and our application process, applicants must attest that they meet provider network standards, but do not have to demonstrate that they meet CMS network requirements before submitting a bid for the following contract year. CMS's experience has shown that since adopting the attestation-only approach for the 2019 contract year, organizations are requesting to remove a county (or multiple counties) from their service area (that is, service area reduction) after bids are submitted because the organization realizes that it does not have a sufficient network for the entire service area. For example, five organizations have requested to make changes to the service area of a total of 10 plans after bid submission deadlines since 2019.

Bid integrity is a priority for CMS. A request by an organization to make service area reductions related to provider networks after bid submission calls into question the completeness and accuracy of the bid(s). The provider network is an important consideration in preparing the bid submission. Permitting the MA organization to make changes to the bid submission because of the inability to meet network adequacy, which is reviewed after the first Monday in June (the bid deadline), would subsequently allow the MA organization to introduce revised information into the bidding process. The introduction of this revised information after the first Monday in June implies that the initial bid submission was not complete, timely, or accurate. Requiring the submission of networks for review as part of the application will mitigate this issue, as the application review is complete before bids are due.

Furthermore, network adequacy reviews are a critical component for confirming that access to care is available for enrollees. Our network evaluations ensure that we are monitoring networks and requiring organizations to provide sufficient access to providers and facilities without placing undue burden on enrollees seeking covered services. Adding network reviews back to the application process will help ensure overall bid integrity, result in improved product offerings, and protect beneficiaries.

After we adopted the current policy, failures detected during network reviews were not a basis to deny an application and CMS expected plans to cure deficiencies and meet network adequacy standards once coverage began on January 1 of the following year. In analyzing the network adequacy review determinations for the years since removing network adequacy requirements from the application, we have observed a pattern across these network review outcomes: Organizations continue to have failures in their networks even after the contract is operational. For example, we found that 19 initial applicants who submitted provider and facility Health Service Delivery (HSD) tables since contract

year 2019 continued to have deficiencies upon review of their networks once the MA plans were operational. By changing the process and reviewing the provider networks as part of the application, CMS will be able to better understand whether the failures are due to the timing of the reviews, which we hope the 10-percentage point credit, discussed later, will account for, or whether they are failures that the organization cannot cure. Establishing and maintaining an adequate provider network capable of providing medically necessary covered services to enrollees is fundamental to participation in the MA program.

Our current process and § 422.116(a)(1)(i) do not prohibit us, when evaluating an application, from considering information related to an organization's previous failure to comply with a MA contract due to previous failures associated with access to services or network adequacy evaluations resulting in intermediate sanction or civil money penalty under to Part 422 Subpart O, with the exception of a sanction imposed under § 422.752(d). This will continue to be applicable to our evaluation of initial or SAE applications. The changes we are proposing, to require compliance with network adequacy standards during the application process, will help us assess which organizations are not capable of meeting CMS standards in a given service area. As a result, we are proposing to broaden our ability to safeguard the MA program by permitting evaluations of network adequacy in connection with review and approval of applications for new and expanding service areas. This ability will help us avoid approving organizations that could have issues providing access to care in these new or expanded service areas.

We have found that the current timing of the network adequacy reviews impact applicants' ability to make timely decisions regarding the service area in which they intend to provide coverage. The operational process for conducting network adequacy reviews is outlined in the ''Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance''.[127] The guidance currently directs initial and SAE applicants to upload their HSD tables containing pending service areas into the Health Plan Management System (HPMS) Network Management Module (NMM) in mid-June for CMS review. Regulations under § 422.254(a)(1) require organizations to submit bids no later than the first Monday in June of each year and authorize CMS to impose sanctions or choose not to renew an existing contract if the bid is not complete, timely and accurate. CMS has issued guidance to remind MA organizations of this obligation that bids be complete and accurate at the time of submission, such as in the CY 2014 through CY 2020 Final Call Letters (provided as attachments to the annual Rate Announcements [128]) and the CY 2022 MA Technical Instructions, released in an HPMS memo on May 12, 2021. Providing organizations with network adequacy determinations ahead of the bid deadline (within the application timeline) will provide them the opportunity to make decisions regarding their intended service areas before submitting bids. This practice would also help mitigate operational issues CMS has experienced related to requests for service area changes after the deadline has passed, as these kinds of requests may affect the MA organization's submissions on the bid pricing tool. For these reasons, we are proposing to revise paragraph (a)(1)(ii) of § 422.116 to require an applicant for a new or expanding service area to demonstrate compliance with § 422.116 and to explicitly authorize CMS to deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

We are also proposing to add new regulation text at § 422.116(d)(7) to provide applicants with a temporary 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for all of the combinations of county designations and provider/facility types specified in 42 CFR 422.116(d), for the proposed contracted network for a new service area or a service area expansion (SAE). Current CMS procedures (see ''The Part C—Medicare Advantage and 1876 Cost Plan Expansion and 1876 Cost Plan Expansion Application'' [129]) require completed applications to be submitted by mid-February. We understand that organizations may have difficulties meeting this timing for submission of a full provider network that the proposed change in § 422.116(a)(1)(i) would require. We previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational. In order to provide flexibility to organizations as they build their provider networks, we propose to allow the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. At the beginning of the applicable contract year (that is, January 1), the 10-percentage point credit would no longer apply, and plans would need to be in full compliance for the entire service area. This aspect of our proposal will balance the burden on applicants of having network contracts in place close to a year before the beginning of the coverage year with the need to ensure that the MA plans available to enrollees have adequate networks for furnishing covered benefits.

Under our proposal, initial and service area expansion applicants starting with the contract year 2024 application cycle would be required to submit their proposed contracted networks during the application process. Applicants would upload their HSD tables to the NMM by the application deadline, and CMS would generally follow the current operational processes for network reviews, which includes an opportunity to submit exception requests as outlined in § 422.116(f). The disposition of the exception request would be communicated as part of the opportunity to remedy defects found in the application under § 422.502(c)(2). Applicants for SAEs who are also due for a triennial review would be required to submit their pending service area during the application process, and their existing network service areas separately, during the triennial review in mid-June.

For these reasons, we propose the following changes to § 422.116:

- Revise § 422.116(a)(1)(ii) provide that beginning for contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.
- Add a new paragraph at § 422.116(d)(7), with the heading, ''New or expanding service area applicants.'' to provide that beginning for contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the

[127] *https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf.*

[128] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[129] *https://www.cms.gov/files/document/cy-2022-medicare-part-c-application-updated-1-12-2021.pdf.*

percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. At the beginning of the applicable contract year, this credit no longer applies and if the application is approved, the MA organization must be in full compliance with the section.

D. Part C and Part D Quality Rating System

1. Background

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) and Part D plans based on the requirement to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act and the collection of different types of quality data under section 1852(e) of the Act. The Star Rating system for MA and Part D plans is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of beneficiary rebates under section 1854(b) of the Act. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Rating system, as codified at § 417.472(k). We use different data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans (for example, §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156). The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186.

The Star Ratings are generally based on measures of performance during a period that is 2 calendar years before the year for which the Star Ratings are issued; for example, 2023 Star Ratings will generally be based on performance during 2021. For some measures, such as the cross-sectional measures collected through the Health Outcomes Survey (HOS), Star Ratings are based on performance up to 3 calendar years prior to the Star Ratings year. For example, the HOS survey administered in 2021 asks about care received (for example, whether a healthcare provider advised the member to start, increase, or maintain their level of exercise or physical activity) in the 12 months prior to the survey's administration—that is a period of time covering parts of the 2020 and 2021 calendar years—and the data are used for the 2023 Star Ratings.

In the interim final rule titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 19230) published in the **Federal Register** on April 6, 2020 with a March 31, 2020 effective date (hereafter referred to as the ''March 31st COVID–19 IFC''), we adopted a series of changes to the 2021 and 2022 Star Ratings to address the disruption to data collection and impact on performance for the 2020 measurement period posed by the public health emergency (PHE) for COVID–19. The Star Ratings changes adopted in that rule addressed both the needs of health and drug plans and their providers to curtail certain data collections and to adapt their current practices in light of the PHE for COVID–19 and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions. As explained in the March 31st COVID–19 IFC, we expected to see changes in measure-level scores for the 2020 measurement period due to COVID–19-related healthcare utilization, reduced or delayed non-COVID–19 care due to advice to patients to delay routine and/or elective care, and changes in non-COVID–19 inpatient utilization. The March 31st COVID–19 IFC made some adjustments to account for potential changes in measure-level scores. (See 85 FR 19269 through 19275 for a description of the various adjustments.)

The March 31st COVID–19 IFC amended, as necessary, certain calculations for the 2021 and 2022 Part C and D Star Ratings to address the expected impact of the PHE for COVID–19 on data collection and performance in 2020 that were immediately apparent. As the PHE for COVID–19 progressed in 2020 with ultimately all areas across the country eligible for Star Ratings disaster adjustments for extreme and uncontrollable circumstances under the current regulations (§§ 422.166(i) and 423.186(i)) for the 2022 Star Ratings, it became apparent that a modification to the existing disaster policy was required in order to calculate cut points for non-CAHPS measures for the 2022 Star Ratings. We adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the final rule ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' published in the **Federal Register** in April 2019 (84 FR 15680), hereafter referred to as the April 2019 final rule. Under §§ 422.166(i)(9)(i) and (i)(10)(i) and 423.186(i)(7)(i) and (i)(8)(i), the numeric scores for contracts with 60 percent or more of their enrollees living in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance are excluded from: (1) The measure-level cut point calculations for non-CAHPS measures; and (2) the performance summary and variance thresholds for the reward factor. The 60 percent rule does not apply to the calculation of cut points for CAHPS measures because those measures do not use the clustering methodology; thus, CAHPS measures were not impacted by this issue. Up until the 2022 Star Ratings, disasters for which any Star Rating adjustments had been made were localized, and the 60 percent rule had removed scores from only a small fraction of contracts (that is, less than 5 percent of contracts on average). For most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year (that is, a disaster that begins [130] during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from the HOS survey, the disaster adjustment is delayed an additional year due to the timing of the survey and 1 year recall period. In the April 2019 final rule (84 FR 15772 through 15773), we specifically gave the example of how HOS and HEDIS–HOS measures [131] for the 2023 Star Ratings would be adjusted for contracts affected by an extreme and uncontrollable circumstances in 2020. We explained how the delay for HOS measures due to the follow-up component of HOS and the adjustment for an extreme and uncontrollable circumstance would be to the Star Ratings for the year after the completion of the follow-up HOS survey (that is administered 2 years after the baseline HOS survey).

Due to the unique circumstances surrounding the PHE for COVID–19 in which all contracts operational in 2020 qualified for the extreme and uncontrollable circumstance

[130] We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

[131] The HEDIS measures derived from the HOS include *Monitoring Physical Activity, Reducing the Risk of Falling,* and *Improving Bladder Control.*

adjustments, we created special rules for the 2022 Star Ratings to be able to calculate non-CAHPS measure-level cut points and codified these special rules at §§ 422.166(i)(11) and 423.186(i)(9). Although the CAHPS surveys and HEDIS data collection were not completed in 2020 (we did conduct the HOS survey in 2020 on a later schedule than usual), CAHPS surveys and HEDIS data collection completed in 2021 would reflect performance by plans in 2020 during the COVID–19 PHE and would be used in the 2022 Star Ratings. In the interim final rule titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820), published in the **Federal Register** and effective on September 2, 2020 (hereinafter referred to as the ''September 2nd COVID–19 IFC''), we revised the disaster policy rules for calculating the non-CAHPS measure-level cut points for the 2022 Star Ratings so we would be able to calculate the 2022 Star Ratings for these measures (85 FR 54844–47). The September 2nd COVID–19 IFC also modified the calculation of the performance summary and variance thresholds for the reward factor so as not to exclude the numeric values for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds. These changes ensured that CMS was able to calculate measure-level cut points for those measures that qualified for the disaster adjustment for the 2022 Star Ratings; calculate measure-level 2022 Star Ratings; apply the ''higher of'' policy for non-CAHPS measures as described at §§ 422.166(i)(3)(iv), (i)(4)(v), (i)(5), and (i)(6)(i) and (iv) and 423.186(i)(3) and (i)(4)(i) and (iv); calculate the reward factor; and ultimately calculate 2022 overall and summary Star Ratings.

We intend to address the changes and comments we received in response to the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC in a future final rule. We are proposing here a specific provision for 2023 Star Ratings for measures derived from the HOS data collection administered in 2020.

2. Measures Calculated From the HOS Survey

In response to the September 2nd COVID–19 IFC, some commenters asked for clarification about the measures that come from the HOS survey and when the disaster policy would be applied in light of how HOS measures receive adjustment after an extreme and uncontrollable circumstance. A few commenters asked, based on previous logic for disasters and HOS measures, whether we anticipated that the impacted HOS data collection period would not be until 2021 and the ''higher of'' methodology would be applicable to reporting year 2023 for HOS measures. Another commenter noted that using the 2020 Star Ratings as an example, the contracts affected by 2018 disasters received the ''higher of'' logic for most measures; however, the HOS and HEDIS–HOS measures used the ''higher of'' logic only for contracts affected by 2017 disasters. The commenter stated if this timing applies to 2020 disasters, the HOS and HEDIS–HOS measures will receive the higher of current or prior year measure-level Star Ratings in the 2023 Star Ratings. The commenters asked for clarification since the September 2nd COVID–19 IFC adopted a regulatory change to the 60 percent rule for only the 2022 Star Ratings. We are proposing here to address the HOS measures used in the 2023 Star Ratings.

As described in the 2019 final Part C and D rule (CMS–4185–F) (84 FR 15772 through 15773), for measures derived from the HOS survey, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance. Thus, we noted in the preamble to that rule that the 2023 Star Ratings would adjust measures derived from the HOS survey for 2020 extreme and uncontrollable circumstances. (85 FR 15772 through 15773) Based on the comments received and the timing of the HOS administration, we propose to amend § 422.166(i) to specifically address the 2023 Star Ratings, for measures derived from the 2021 HOS survey only, by adding § 422.166(i)(12) to remove the 60 percent rule for affected contracts. This amendment would ensure that we are able to calculate the Star Ratings cut points for the three HEDIS measures derived from the HOS survey and are able to include these measures in the determination of the performance summary and variance thresholds for the reward factor for the 2023 Star Ratings. Without removing the 60 percent rule for HEDIS measures derived from the HOS survey, we would not be able to calculate these measures for the 2023 Star Ratings or include them in the 2023 reward factor calculation. By removing the 60 percent rule, all affected contracts (that is, contracts affected by the 2020 COVID–19 pandemic) with at least 25 percent of their enrollees in Individual Assistance areas at the time of the disaster will receive the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each of the HEDIS measures collected through the HOS survey as described at § 422.166(i)(3)(iv).

As a reminder, in a Health Plan Management System memorandum issued on August 5, 2021 (''Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings''), we explained that due to the pervasive way in which COVID–19 has undermined and continues to undermine the validity of the two HOS outcome measures for the 2020 and 2021 follow-up measurement periods, CMS will calculate the 2022 and 2023 Star Ratings without the use of the two measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. This decision was made applying the standard in § 422.164(b).

E. Past Performance (§§ 422.502, 422.504, 423.503, and 423.505)

CMS has an obligation to ensure the organizations in which we contract with will be able to provide health care services to beneficiaries in a high-quality manner. We do not want organizations entering into or expanding in MA that have shown to be poor performers. Currently, if an organization meets all of the requirements in CMS' application, CMS approves the application. However, the application requirements do not look at an organization's prior performance in existing contracts. Therefore, if an organization fails to provide key services or administers the program poorly, their application for a new contract or a service area expansion would still be approved. Allowing poor performers into the Part C and Part D programs puts beneficiaries at risk for inadequate health care services and prescription drugs. To avoid poor performers from entering or expanding, CMS first addressed this issue in the MA and Part D program regulations in 2005. CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Part D contract, including for a service area expansion, if that organization has failed to comply with the requirements of a previous MA or Part D contract. In the April 2011 final rule (75 FR 19684 through 19686), we completed

rulemaking that placed limits on the period of contract performance that CMS would review (that is, 14 months preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance. In the April 2018 final rule (83 FR 16638 through 16639), we reduced the review period to 12 months. In the January 2021 final rule (86 FR 5864), we established that CMS would only have the authority to deny applications based on an organization's past performance if an organization was subject to an intermediate sanction and/or failed to maintain a fiscally sound operation during the performance review period. Up until the January 2021 final rule (86 FR 5864) CMS issued a sub-regulatory methodology consisting of eleven areas of poor performance, including negative net worth and being under intermediate sanctions during the performance timeframe. The prior methodology assigned ''performance points'' to organizations for each area the organization failed (for example, had a negative net worth resulted in a performance point). If the total number of performance points reached CMS' threshold the organization's application would be denied based on past performance. Historically, only a handful of applications have been denied based on prior past performance, with three denials since 2017. The low number of denials has not impacted access to MA plans nor do we believe expanding the bases for denials will impact access. In fact, the average number of plans that a beneficiary has access to has been increasing since 2015 with approximately 99.7% of beneficiaries currently having access to an MA plan. In addition, 97.7 of eligible beneficiaries will have access to ten or more plans for CY 2022.

As stated in the January 2021 final rule, CMS' overall policy with respect to past performance remains the same. We have an obligation to ensure MA organizations and Part D sponsors can fully manage their current contracts and books of business before expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Part D business to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees.

The January 2021 final rule limited the bases for denial based on past performance to intermediate sanctions and failure to maintain fiscal soundness. In this proposed rule, CMS seeks to expand the bases for application denial to include Star Ratings history, bankruptcy proceedings, and certain CMS compliance actions. CMS also proposes to codify the types of compliance notices which will be used as a factor in CMS' review of an organization's past performance. These notices are Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).

We propose to codify the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(C)—Bankruptcy filing or under bankruptcy proceedings, (b)(1)(i)(D)—low Star Ratings, and (b)(1)(i)(E)—Compliance Actions. We also propose to codify CMS' compliance actions which are NONCs, WLs, and CAPs in §§ 422.504(m) and 423.505(n). We are not proposing to add a recent history of Civil Money Penalties (CMPs) as a basis for a past performance application denial at this time, but we will consider it in future rulemaking. Therefore, we are soliciting comments on how best to incorporate CMPs into CMS' methodology used to deny applications based on prior contract performance.

We are also proposing to correct a few technical issues identified since the final rule was published in January 2021. Specifically, we are proposing to correct a drafting error in § 422.502(b)(1)(i)(A) that did not include enrollment sanctions based on medical loss ratios (MLRs) as a basis for an application denial. Section 423.503(b)(1)(i)(A) already provides for the denial of an application if the organization failed to meet MLR requirements and was prohibited from enrolling new members pursuant to § 423.2410(c). The technical correction would revise § 422.502(b)(1)(i)(A) to also provide for the denial of an application if the organization failed to meet MLR requirements and was prohibited from enrolling pursuant to § 422.2410(c). The new § 422.502(b)(1)(i)(A) would read as follows, ''. . . was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).'' Secondly, we are proposing to correct a minor technical error in § 423.503(b)(1)(i)(A) to remove the word ''to'' when referencing subpart O. The revised sentence would read ''. . . was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 423.2410(c).'' Finally, we are proposing to modify §§ 422.502(b)(1) and 423.503(b)(1) by deleting ''. . . or fails to complete a corrective action plan during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications. . .'' References to CAPs in §§ 422.502(b)(1) and 423.503(b)(1) were codified more than 15 years ago. Since the original provisions, CMS' corrective action process has changed and is no longer a reason, by itself, to deny an application. Our current review for past performance does not view incomplete CAPs as a sole basis for denying an application. Nor does CMS intend to deny an application on the sole basis of an incomplete CAP. Therefore, we propose to remove the references in §§ 422.502(b)(1) and 423.503(b)(1).

As stated previously, we propose to include in §§ 422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C), as a reason for application denial, organizations that have filed for bankruptcy or are currently in bankruptcy proceedings. Currently, we have the authority to deny an application for organizations that fail to maintain a fiscally sound operation during the performance period. Failure to maintain a fiscally sound operation results in enrollees being at risk of not being able to obtain needed medical resources if the organization cannot or will not pay its providers. Similar to being fiscally unsound, an organization that will potentially be declared bankrupt may result in beneficiaries not having access to needed services as providers may terminate contracts when the plan fails to pay for their services or items. Since bankruptcy may result in the closure of an organization's operations, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the MA or Part D program. Based on this, we believe that any organization that has filed or is in bankruptcy proceedings should not be permitted to expand their current service area or enter into a new contract.

We are also seeking to include, in §§ 422.502(b)(1)(i)(D) and 423.503(b)(1)(i)(D), a recent history of low Star Ratings as a reason for application denial. We are proposing that CMS would deny an application for a new contract or a service area expansion from any organization that received 2.5 or fewer Stars. We previously proposed that low Star Ratings would be the basis for an application denial but decided not to finalize that proposal in the January 2021 final rule. In responses to comments to the January 2021 final rule,

we stated that a history of 3 consecutive years of low Star Ratings permits CMS to terminate an organization's contract, so we previously concluded it was not necessary to include one year of low ratings as a basis for a past performance application denial. However, we have re-evaluated our position, as discussed below, and believe that a history of one year of low Star Ratings merits an application denial.

CMS' Star Ratings are provided to beneficiaries to help them make informed health care choices. Moreover, MA organizations and Part D sponsors are required by §§ 422.504(b)(17) and 423.505(b)(26) to maintain summary MA and/or Part D Star Ratings of at least 3 Stars. Contracts that have 2.5 or less Stars are considered to be ''low performers.'' Regulations at §§ 422.510(a)(4) and 423.509(a)(4) permit CMS to terminate a contract for having less than 3 Stars for three consecutive years in a row for Part C summary ratings or for having less than 3 Stars for three consecutive years in a row for Part D summary ratings. Such a termination carries with it an exclusion from future MA or Part D application approvals for 38 months under §§ 422.502(b)(3) and 423.503(b)(3), a more significant consequence than the 1-year application denial we are discussing in this proposed rule. We have concluded that providing for an application denial based on a 1-year history of low Star Ratings is consistent with CMS' current practice of graduated enforcement. Furthermore, CMS does not want to provide an organization at risk of being terminated in 2 years, based on its Star Ratings history, with an opportunity to expand. Expansion would put more beneficiaries at risk of losing their health care coverage if an organization cannot improve its Star Ratings. As a note, terminating contracts based on Star Ratings rarely occurs, with the last termination being prior to 2016. Based on this, CMS is seeking to include one year of low Star Ratings as a reason to deny new applications or applications for service area expansions.

Finally, we are proposing to codify our practice of issuing compliance notices in §§ 422.504(m) and 423.505(n). CMS is also proposing, in §§ 422.502(b)(1)(i)(E) and 423.503(b)(1)(i)(E), to include the receipt of specific types of compliance notices as a reason to deny new applications or applications for service area expansions.

Prior to the January 2021 final rule, CMS included compliance letters as a category in our sub-regulatory past performance methodology. This methodology included NONCs, WLs, Warning Letters with Business Plans, and CAPs. These notices are CMS' formal way of recording an organization's failure to comply with statutory and/or regulatory requirements as well as providing notice to the organization to correct their deficiencies or risk further compliance and enforcement actions. In §§ 422.504(m) and 423.505(n), we are codifying NONCs, WLs, and CAPs as types of CMS compliance actions. CMS has been issuing compliance notices for more than 10 years. Based on our experience, we have decided that Warning Letters with Business Plans are no longer necessary. NONCs, WL, and CAPs are sufficient to record non-compliance that does not yet warrant stronger enforcement action. Based on this, we will not codify Warning Letters with Business Plans as a type of compliance action.

Of these three types of notices, Requests for CAPs are the most serious of the notice types. CMS issues these notices pursuant to §§ 422.510(c) and 423.509(c), which require CMS to afford non-compliant organizations the opportunity to develop and implement a corrective action plan prior to terminating an MA or Part D contract. CMS may request CAPs for a one-time egregious error or an organization's continued failure to correct previously identified deficiencies. The non-compliance resulting in a CAP request usually has beneficiary impact, such as failure to process appeals timely or marketing misrepresentation. In cases where CMS requests a CAP where there is no beneficiary impact, the majority are for continued non-compliance with requirements.

WLs are an intermediate level of compliance action, between a NONC and a CAP. WLs, similar to CAPs, are issued for more egregious instances of non-compliance or continued non-compliance. However, the egregiousness or continued non-compliance, at the time of the notice, would not warrant a request for a CAP. Examples include continued failure to timely send Explanation of Benefits, multiple cost/benefit errors on required beneficiary communication documents, and instances of unsolicited marketing.

NONCs are the lowest form of a compliance action issued by CMS. These notices are issued for the least egregious failures. These failures are often a first-time offense, affect a small number/percentage of beneficiaries, or issues that have no beneficiary impact. Examples may include failure to submit and/or attest to agent/broker compensation data or failure to upload or correctly upload marketing materials.

In determining the level of severity of a compliance action, CMS considers whether an organization self-reported the non-compliance. CMS considers items self-reported when CMS would not have otherwise known about the issue. In cases where we direct organizations to take a specific action, such as reviewing and reporting errors in Summary of Benefits (SB) and Evidence of Coverage (EOC) documents, CMS does not consider this self-reporting.

As mentioned above, self-reporting can affect the level of compliance action issued. CMS reviews the organization's non-compliance and whether the organization self-reported the issue or CMS found the issue through means such as, complaint reviews, notification by a State entity, or a review of requested data. Based on the issue involved, CMS determines the appropriate level of compliance that should be issued, such as a WL or a NONC. If the organization did self-report, CMS will consider lowering the level of compliance (for example, issuing a NONC instead of a WL). However, CMS is not required to lower the level of compliance action if the issue was self-reported. This is especially the case with respect to NONCs, where the non-compliance is significant enough to warrant a NONC even if self-reported.

We propose to assign points to each type of compliance action based on the type of notice and then apply a compliance action threshold to determine if the application should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. CMS will then total the points accrued for each organization, and those who are at or above a specified threshold may have applications for new contracts or service area expansions denied on the basis of past performance.

CMS is proposing a threshold of 13 compliance action points. CMS would have the right to deny applications from any organization who scored 13 or more compliance action points. This would be the equivalent of just over two CAPs. We believe any organization whose performance is such that two CAPs and a NONC are issued or a combination of compliance actions that add up to 13 points should not be permitted to expand. In determining this threshold, we reviewed compliance actions taken from 2017 through November 2021. In the review of this data no more than three organizations, out of over three hundred organizations, scored 13 or more compliance action points in any one year. When looking at a percentile,

based on historical data, an organization would need be in the top 2% of plans based on compliance action points to accrue 13 compliance action points. We solicit comments on alternative methodologies for considering compliance notices, such as calculating outlier performance based on percentages.

For these reasons, we propose to revise §§ 422.502(b), 422.504(m), 423.503(b), and 422.505(n) to read as set out in the regulatory text.

F. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267, and 423.2267)

Sections 1851(h) and (j) of the Act provide a structural framework for how MA organizations may market to beneficiaries and direct CMS to adopt standards related to the review of marketing materials and limitations on marketing activities. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) of the Act for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations. In addition, sections 1852(c) and 1860D–4(a) of the Act provide that MA organizations and Part D sponsors must disclose specific types of information to each enrollee. Based on the aforementioned authorities, CMS promulgated regulations related to marketing and mandatory disclosures by MA organizations and Part D sponsors in 42 CFR part 422, subpart C (at § 422.111) and subpart V; as well as 42 CFR part 423, subpart C (at § 423.128) and subpart V. These regulations include the specific standards and prohibitions in the statute as well as standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 apply to section 1876 cost plans. Because these proposals are applicable to MA organizations, Part D plan sponsors and cost plans, we collectively refer to these entities as ''plans.'' Finally, CMS has authority to adopt additional contract terms for cost plans (section 1876(i)(3)(D)), MA plans (section 1857(e)(1)), and Part D plans (section 1860D–12(b)(3)(D) of the Act) where such terms are not inconsistent with the Medicare statute and that we determine are necessary and appropriate.

In the January 2021 final rule (86 FR 5864), we codified much of the communications and marketing guidance previously found in the Medicare Communications and Marketing Guidelines (MCMG). In this proposed rule, we propose to codify additional guidance from the MCMG that was not part of the January 2021 final rule related to member ID card standards, the limited access to preferred cost sharing pharmacies disclaimer, plan website instructions on how to appoint a representative, and the website posting of enrollment instructions and forms. In addition, we are proposing several new communications and marketing requirements aimed at further safeguarding Medicare beneficiaries, including reinstating the requirement that plans include a multi-language insert with specified required materials. Finally, we are proposing requirements to address concerns associated with third-party marketing activities.

1. Required Materials and Content

Under § 422.111(i), MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. Likewise, under 1860D–4(b)(2)(A) of the Act and § 423.120(c)(1), a Part D plan sponsor must issue a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs. Currently, CMS guidance for additional ID card standards resides in the MCMG. We are proposing to codify existing guidance for ID card requirements under §§ 422.2267(e)(30) and 423.2267(e)(32). In addition, we will renumber the remaining required content beginning with the Federal Contracting statement, currently at §§ 422.2267(e)(30) and 423.2267(e)(32).

In the January 2021 final rule, when codifying several other required disclaimers previously provided in the MCMG, Appendix 2, at §§ 422.2267(e) and 423.2267(e), CMS inadvertently left out the disclaimer for Part D sponsors with limited access to preferred cost sharing pharmacies. The disclaimer provides important safeguards for Medicare beneficiaries enrolled in Part D plans that only provide access to preferred cost sharing through a limited number of pharmacies by alerting these beneficiaries that the preferred costs may not be available at the pharmacy they use, and by providing information to these beneficiaries about how to access the list of pharmacies offering prescription drugs at a preferred cost in the beneficiary's area. We therefore propose to codify the requirements for this disclaimer at § 423.2267(e)(40). We also note that, as required under § 422.500, MA plans that offer the Part D benefit must comply with Part 423 rules.

2. Website Requirements

The regulations at §§ 422.111(h)(2) and 423.128(d)(2) require plans to have an internet website and include requirements regarding posted content. In the January 2021 final rule, we codified additional requirements for plan websites at §§ 422.2265 and 423.2265 based on section 70.1.3 (Required Content) of the MCMG. In doing so, we inadvertently failed to include the requirement that plans post instructions about how to appoint a representative and include a link to a downloadable version of the CMS Appointment of Representative Form (Control Number 0938–0950)), as well as enrollment instructions and forms. We propose to include these two requirements under §§ 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15), respectively.

3. Multi-Language Insert

The multi-language insert (MLI) is a standardized document that informs the reader that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese; the 15 most common non-English languages in the United States. Beginning in 2012, the Medicare Marketing Guidelines (MMG) required plans to include the MLI with the Summary of Benefits (SB), Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), and the enrollment form (most recently in section 30.5.1 of the 2017 MMG, issued on June 10, 2016). The issuance of the MLI was independent of the translation requirements for any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2). However, the MLI guidance in the MMG did require plans to also include the required statement in any language that met the 5 percent threshold but was not already included on the MLI.

On May 18, 2016, the Office for Civil Rights (OCR) published a final rule (81 FR 31375) implementing section 1557 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148). Section 1557 of the PPACA provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to

discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex (including pregnancy, sexual orientation, and gender identity)), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving federal financial assistance; any health program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. Part of OCR's final rule included the requirement that all covered entities include taglines with all ''significant communications''. The sample tagline provided by the Department consisted of a sentence stating ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).'' in the top 15 languages spoken in a state or states. Because of the inherent duplication with the MLI, CMS issued an HPMS email on August 25, 2016 removing the MLI. On June 14, 2019, OCR published a proposed rule that, among other actions, proposed to repeal the requirement that notices and taglines be provided with all significant communications (84 FR 27846). Finally, on June 19, 2020, OCR published a final rule that finalized the repeal of the notice and tagline requirements while requiring that a covered entity take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals (85 FR 37160, 37210, 37245).

In the February 2020 proposed rule, CMS proposed an availability of non-English translations disclaimer. The disclaimer consists of the statement ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–XXX–XXX–XXXX (TTY: 1–XXX–XXX–XXXX).'' We proposed that the disclaimer be required in all non-English languages that met the five percent threshold for language translation under §§ 422.2267(a)(2) and 423.2267(a)(2). In addition, when applicable, we proposed the disclaimer be added to all required materials under §§ 422.2267(e) and 423.2267(e). However, we did not finalize the proposed disclaimer in January 2021 final rule. In doing so, we stated that CMS believed future rulemaking regarding non-English disclaimers, if appropriate, was best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. We also stated that deferring to OCR's oversight and management of any requirements related to non-English disclaimers is in the best interest of the Medicare program.

It is important to note that none of the actions impacting the various notifications of interpreter services changed the requirement that plans must provide these services under applicable law. Plans have long been required to provide interpreters when necessary to ensure meaningful access to limited English proficient individuals, consistent with existing civil rights laws. In fact, in the January 2021 final rule, CMS codified call center requirements under §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) that requires interpreter services be provided to non-English speaking and limited English proficient (LEP) individuals at no cost.

In the months following the publication of the January 2021 final rule, we have gained additional insight regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries. The U.S. Census Bureau's 2019 American Community Survey (ACS) 1-year estimates show that 12.2 percent of individuals sixty-five and older speak a language other than English in the home (*https://data.census.gov/cedsci/table?q=language&tid=ACSST1Y2019.S1603*). CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process. Providing a notification for beneficiaries with limited English proficiency that translator services are available provides a clear path for this portion of the population to properly understand and access their benefits. We have also reviewed Complaint Tracking Module (CTM) cases related to ''language'' and found that several cases report beneficiary confusion stemming from not fully understanding materials based on a language barrier. In retrospect, we now believe that solely relying on the requirements delineated in OCR's 2020 rulemaking for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans. We believe it is counterproductive to have regulatory requirements for interpreter services without an accompanying requirement to inform beneficiaries that the service is available.

We are proposing to reinstitute a requirement to use the MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). Similar to the previously required version, the MLI will state ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the 15 most common non-English languages in the United States. In addition, we propose to require plans to also include the required statement in any language that meets the five percent threshold for a plan's service area, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2) for translation of required materials, when not currently on the standardized MLI. Finally, we propose to require the MLI to be included with all required materials listed in §§ 422.2267(e) and 423.2267(e). If OCR were in the future to finalize broader or more robust requirements associated with interpreter services than what CMS is proposing and plans adopted those broader or more robust OCR requirements, CMS will consider plans compliant with the MLI requirements we have proposed in this rule.

4. Third-Party Marketing Organizations

As most recently expressed in an October 8, 2021 HPMS memo, we have become increasingly concerned with the activities of third-party marketing organizations (TPMOs) and the impact of those activities on Medicare beneficiaries. We have seen a significant increase in third party marketing (for example, television ads, direct mailers) in the past few years. In addition, we have seen a significant increase in marketing related complaints from beneficiaries directly attributed to the activities of TPMOs. In fact, when comparing 2020 to the first eleven months of 2021, marketing based CTM complaints have more than doubled. We believe the increase in complaints is attributed to third-party advertising that misleads beneficiaries and results in them contacting third-parties to find out how they can get the advertised benefits. Based on the CTM data, CMS also has reviewed several sales and enrollment call recordings between TPMO staff and beneficiaries. Many of these calls demonstrate that beneficiaries are confused by these TPMOs, including confusion regarding who they are speaking to, what plans the TPMOs represent, and that the beneficiary may be unaware that they

are enrolling into a new plan during these phone conversations. CMS acknowledges that in some instances TPMOs can serve a role in helping beneficiaries find a plan that best meets their needs. However, CMS believes additional regulatory oversight is required to protect Medicare beneficiaries from bad actors in this space and to ensure that Medicare health and drug plans are appropriately overseeing and maintaining responsibility for the entities that conduct marketing and, potentially, enrollment activities on their behalf. Therefore, CMS believes additional regulatory oversight is required to protect Medicare beneficiaries from confusing and potentially misleading activities. CMS is proposing several updates to various sections of parts 422 and 423, subpart V.

We first propose to define TPMOs in §§ 422.2260 and 423.2260 as being organizations that are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment, that is the steps taken by a beneficiary from becoming aware of a plan or plans to making an enrollment decision. In addition, the proposed definition includes that TPMOs may be first tier, downstream or related entity (FDRs), as defined under §§ 422.504(i) and 423.505(i), but TPMOs may also be other businesses which are customers of an MA or Part D plan or customers of an MA or Part D plan's FDRs. CMS is specifically seeking comments from stakeholders regarding the proposed TPMO definition and whether it is sufficiently broad to capture the scope of the types of entities that may be in a position of marketing Medicare health and drug plans.

We next propose a required standardized disclaimer be used by TPMOs, in §§ 422.2267(e)(41) and 423.2267(e)(41), that states ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1–800–MEDICARE to get information on all of your options.'' MA organizations and Part D sponsors will need to ensure that any TPMO with which they do business, either directly or indirectly, utilizes this disclaimer were appropriate. MA organizations and Part D sponsor may ensure TPMO's adherence with these requirements through contractual arrangements, review of materials or other appropriate oversight methods available to the MA organization or Part D sponsor such as complaint reviews or audits. Statements from TPMOs such as ''we will help pick the best plan for you'' are misleading to beneficiaries as they generally mean the TPMO's help will be limited to the plans they offer. For those TPMOs who truly offer every option in a given service area, the disclaimer will not be required. We propose the disclaimer to be prominently displayed on the TPMO's website and marketing materials, including all print materials and television advertising that meet the definition of marketing. We also propose requiring the disclaimer be provided verbally, electronically, or in writing, depending on how the TPMO is interacting with the beneficiary. In cases where the TPMO is providing information through telephonic means, this disclaimer must be provided within the first minute of the call. We believe the disclaimer will help to reduce the type of beneficiary confusion CMS observed when we listened to TPMO-based sales calls.

Finally, we are proposing new TPMO oversight responsibilities in §§ 422.2274 and 423.2274, covering agent, broker, and other third-party requirements. The proposed requirements will fall under a newly created §§ 422.2274(g) and 423.2274(g), with the heading ''TPMO oversight,'' and will work in conjunction with the current FDR requirements, when applicable, in §§ 422.504(i) and 423.505(i). We propose that, as a part of their oversight responsibilities, plans that do business with a TPMO, either directly or indirectly through an FDR, are responsible for ensuring that the TPMO adheres to any requirements that apply to the plan. In doing so, we are making it clear that an MA or Part D plan cannot purchase the services of a TPMO, and thereby evade responsibilities for compliance. This proposal includes those instances where the TPMO does not contract either directly with the MA organization or the Part D sponsor or indirectly with a plan's FDR, but where the plan or its FDR purchases leads or otherwise receives leads directly or indirectly from a TPMO. We believe it is the responsibility of the MA organization or Part D sponsor to have knowledge of how and from where leads or enrollments are obtained. We believe this requirement is necessary to address the types of confusing and potentially misleading activities that, as previously discussed, CMS understands to have resulted in hundreds of Complaint Tracking Module complaints related to TPMOs identified by CMS from 2020 and 2021. In order to ensure beneficiaries are enrolled in the plan that best meets their needs, MA organizations and Part D sponsors must have knowledge and oversee all leads and enrollments. We also propose to require plans (and their FDRs), in their contracts, written arrangements, or agreements with TPMOs, to require TPMOs to disclose to the plan any subcontracted relationships used for marketing, lead generation, and enrollment; require sales calls with beneficiaries to be recorded in their entirety; and have TPMOs report to plans any staff disciplinary actions associated with Medicare beneficiary interaction on a monthly basis. We believe these proposed reporting requirements will ensure that plans are made aware of all activities associated with the chain of enrollment.

In addition, we are proposing beneficiary notifications associated with TPMO lead generating activities. In our experience, lead generating activities are typically conducted by a TPMO who uses advertisements containing information regarding MA or Part D plans or programs as a means of enticing beneficiaries to respond, for example by calling an ''800'' number seen on TV or in a direct mail piece. When a beneficiary responds, their information is collected and becomes a ''lead'' that can then be provided to a licensed agent or broker, typically based on renumeration, who can complete an enrollment. CMS has received a number of complaints from partners such as state regulators, State Health Insurance Assistance Programs (SHIPs), and Senior Medicare Patrol (SMP) who have expressed concerns that beneficiaries are being contacted directly by agents and brokers without having knowledge of how the agent had their contact information. We have also received a number of CTM cases where beneficiaries have expressed similar concerns. Based on our review of these cases, it seems clear that it is not a case of unsolicited telephonic contact, which is currently prohibited under §§ 422.2264(a)(2)(iv) and 423.2264(a)(2)(iv); rather it is a case of a beneficiary filling out a business reply card or responding to an advertisement that does not make it clear that doing so will result in being contacted by an agent or broker. We are proposing to require that plans ensure that TPMOs conducting lead generating activities must inform the beneficiary that his or her information will be provided to a licensed agent for future contact, or that the beneficiary is being transferred to a licensed agent who can enroll him or her into a new plan. We believe this requirement will help to eliminate beneficiary confusion by making the

role of lead generating TPMOs more transparent.

Overall, we believe the proposed requirements associated with TPMOs will result in greater plan oversight of TPMOs, and in turn, result in a more positive beneficiary experience as it relates to learning about plan choices to best meet their health care needs. We also believe the proposed requirements, if implemented, would complement and strengthen existing requirements. For example, under §§ 422.2262(a)(1)(iii) and 423.2262(a)(1)(iii), plans must not engage in activities that could mislead or confuse Medicare beneficiaries. As previously discussed, we are concerned this requirement is not being met as it applies to certain TPMO activities performed on behalf of plans or in connection with marketing for plans. MA organizations and Part D sponsors are ultimately responsible for the marketing and enrollment activities done by them or on their behalf, ensuring that marketing is not misleading or confusing. The proposed disclaimers and notifications will ensure that beneficiaries are more informed. Moreover, the more robust reporting requirements and oversight proposed will create a better mechanism for plans to be made aware when beneficiary related issues to arise.

To reiterate and summarize, the proposed new and revised regulatory sections and their content are as follows:

- Sections 422.2260 and 423.2260 are revised to add a definition for Third Party Marketing Organization (TPMO).
- Sections 422.2265(b)(13) and 423.2265(b)(14) are revised to add instructions on how to appoint a representative and to add enrollment instructions and forms.
- Sections 422.2267(e)(30) and 423.2267(e)(32) are revised to add the Member ID card and requirements for the card as a model document.
- Sections 422.2267(e)(31) and 423.2267(e)(33) are revised to add the Multi-Language Insert.
- Sections 422.2267(e)(41) and 423.2267(e)(41) are revised to add the Third-Party Marketing disclaimer.
- Section 423.2267(e)(40) is revised to add the Limited Access to Preferred Cost Sharing disclaimer.
- Sections 422.2274 and 423.2274 are revised to apply MA and Part D oversight to TPMOs.

G. Proposed Regulatory Changes to Medicare Medical Loss Ratio Reporting Requirements and Release of Part C Medical Loss Ratio Data (§§ 422.2460, 422.2490, and 423.2460)

1. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 23, 2013 **Federal Register**, we published a final rule titled ''Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule), we codified the MLR requirements for MA organizations and Part D prescription drug plan sponsors (''Part D sponsors'') (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X.

Generally, the MLR for each MA and Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. For an MA contract, the MLR reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees, prescription drug costs for those enrollees in MA plans under the contract offering the Part D benefit, quality initiatives that meet the requirements at § 422.2430, and amounts used to reduce Part B premiums. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs, and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR (*see* §§ 422.2401 and 423.2401; 422.2420(b)(4) and 423.2420(b)(4); 422.2430(b) and 423.2430(b)).

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for failure to meet the statutory requirement that they have an MLR of at least 85 percent (*see* §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds, a prohibition on enrolling new members, and ultimately, contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the revenue received by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

Section 1001(5) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101(f) of the Health Care and Education Reconciliation Act (Pub. L. 111–152), also established a new MLR requirement under section 2718 of the Public Health Service Act that applies to issuers of employer group and individual market private insurance. We will refer to the MLR requirements that apply to issuers of private insurance as the ''commercial MLR rules.'' Regulations implementing the commercial MLR rules are published at 45 CFR part 158.

We propose here modifications to the MLR reporting requirements in the Medicare Part C and Part D programs and to the regulation that governs the release of Part C MLR data.

2. Proposal To Reinstate Detailed MLR Reporting Requirements (§§ 422.2460 and 423.2460)

Each year, MA organizations and Part D sponsors submit to CMS data necessary for the Secretary to determine whether each MA or Part D contract has satisfied the minimum MLR requirement under sections 1857(e)(4) and 1860D–12(b)(3)(D) of the Act. In the May 2013 Medicare MLR final rule (78 FR 31284) that established the Medicare MLR regulations, CMS codified at §§ 422.2460 and 423.2460 that, for each contract year, each MA organization and Part D sponsor must submit an MLR Report to CMS that included the data needed by the MA organization or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract such as the amount of incurred claims, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, total revenue, and any remittance owed to CMS under § 422.2410 or § 423.2410.

To facilitate the submission of MLR data, CMS developed a standardized

MLR Report template that MA organizations and Part D sponsors were required to populate with their data and upload to the Health Plan Management System (HPMS), starting with contract year (CY) 2014 MLR reporting, which occurred in December 2015. Based on the data entered by the MA organization or Part D sponsor for each component of the MLR numerator and denominator, the MLR reporting software would calculate an unadjusted MLR for each contract. The MLR reporting software would also calculate and apply the credibility adjustment provided for in §§ 422.2440 and 423.2440, based on the number of member months entered into the MLR Report, in order to calculate the contract's adjusted MLR and remittance amount (if any). In addition to the numerical fields used to calculate the MLR and remittance amount, the MLR Report template included narrative fields in which MA organizations and Part D sponsors provided detailed descriptions of the methods used to allocate expenses, including how each specific expense met the criteria for the expense category to which it was assigned.

In developing the MLR reporting format, CMS attempted to model it on the tools used to report commercial MLR data. This was in keeping with a general policy of attempting to align the Medicare MLR requirements with the commercial MLR requirements to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes. We also cited this policy when we amended our regulations to authorize the public release of the Part C and Part D MLR data that we collect for a contract year under §§ 422.2460 and 423.2460; we noted that the release of Medicare MLR data aligned with disclosures of MLR data that issuers of commercial health plans submit each year as required by section 2718 of the Public Health Service Act (81 FR 46162, 46405).

In the proposed rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56459), which appeared in the **Federal Register** on November 28, 2017 (hereinafter referred to as the November 2017 proposed rule), we proposed to modify the MLR reporting requirements by significantly reducing the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis, starting with CY 2018. As part of an initiative to reduce the regulatory burden for MA organizations and Part D sponsors, we proposed to revise the MLR reporting requirements so that MA organizations and Part D sponsors would no longer be required to report the underlying data needed to calculate and verify the MLR and remittance amount, if any, for each contract; instead, they would only have to report each contact's MLR and the remittance amount, if any.

We received numerous comments on our proposed changes to the MLR reporting requirements in the November 2017 proposed rule, which we addressed in the final rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (83 FR 16440), which appeared in the April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule). Although MA organizations and Part D plan sponsors generally supported the proposed reduction in the amount of MLR data they would be required to submit on an annual basis, some commented that they did not expect their MLR reporting burden to be significantly reduced since they would still be required to collect and analyze the same information in order to calculate the MLR percentage and remittance amount. In response to comments that contended that we would be unable to conduct meaningful compliance oversight with the minimal amount of MLR data that we proposed to collect, we noted our continued authority under § 422.2480 or § 423.2480 to conduct selected audit reviews of the data reported under §§ 422.2460 and 423.2460 for purposes of determining that remittance amounts under §§ 422.2410(b) and 423.2410(b) were calculated and reported accurately and sanctions under §§ 422.2410(c) and 423.2410(c) were appropriately applied. We expressed our belief that we could continue to effectively oversee MA organizations' and Part D sponsors' compliance by relying solely on audits (83 FR 16675) and finalized the proposed changes to the MLR reporting requirements at §§ 422.2460 and 423.2460. As a result, for CY 2018 and subsequent contract years, MA organizations and Part D sponsors are only required to report each contact's MLR and the remittance amount, if any.

In light of subsequent experience overseeing the administration of the Medicare MLR program while the simplified MLR reporting requirements have been in effect, and after further consideration of the potential impacts on beneficiaries and costs to the government and taxpayers when CMS has limited access to detailed MLR data, we have reconsidered the changes to the MLR reporting requirements that were finalized in the April 2018 final rule. We have come to recognize the limitations of our current approach to MLR compliance oversight, in which we do not collect the information needed to verify that a contract's MLR has been calculated accurately, except in the small number of cases that we can feasibly audit each year. For these reasons, which are discussed later in greater detail, we are proposing to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017. In addition, we are proposing to collect additional data on certain categories of expenditures, and to make conforming changes to our data collection tools.

One of the factors that has prompted us to reconsider our earlier decision to eliminate the detailed MLR reporting requirements is the increase both in the amount of remittances that MA organizations and Part D sponsors have reported owing, and in the number of contracts that failed to meet the MLR requirement, in the years since we changed the MLR reporting requirements. At the time we issued the November 2017 proposed rule to eliminate the detailed MLR reporting requirements, MA organizations and Part D sponsors had submitted MLR data only for CYs 2014 through 2015, when total annual remittances for all contracts averaged $29.6 million, and an average of 16 contracts failed to meet the minimum MLR requirement. Taking into account the preliminary CY 2016 MLR data that was available to CMS at the time we issued the April 2018 final rule, annual average remittances for CYs 2014 through 2016 totaled $91.8 million, and an annual average of 21 contracts failed to meet the MLR requirement. Thereafter, for CYs 2017 through 2019, the average amount of annual remittances more than doubled to $204.9 million, and the average number of contracts that failed to meet the MLR requirement nearly doubled to 40 contracts per year, even as the average number of contracts subject to the MLR requirement declined slightly.[132]

As MLR remittances have grown in scale and failure to meet the MLR requirement has become more common, the potential impact of errors that skew

[132] The average number of contracts subject to the MLR requirement was 608 per year for CYs 2014–2016 and 565 per year for CYs 2017–2019.

the MLR calculation also has grown beyond what our early experience administering the MLR requirements had led us to expect when we eliminated the detailed reporting requirement. This has become clear to us not only through observation and analysis of industry-wide changes in remittances, but also through anecdotal incidents. For example, in 2021, CMS was notified by an MA organization that it had discovered an error in one of its processes for determining the amount that it spent on prescription drugs, which caused the organization to miscalculate the MLR for 33 of its MLR submissions for CYs 2016 through 2018. For one contract, this resulted in the MA organization overstating its MLR for CY 2018 by 1.1 percent; when the error was corrected, it was determined that the contract—which the parent organization originally reported as having met the MLR requirement—had in fact failed to meet the MLR requirement, and as a result the organization was required to remit an additional $4 million to CMS for that contract alone.

Although it is possible that calculation errors such as in the above example only affect a handful of contracts, and therefore have limited impacts on the overall amount of remittances, we are mindful of how when CMS collected detailed MLR data pursuant to the reporting requirements that were in effect for CYs 2014 through 2017, we frequently detected potential errors or omissions in the reported data. When these issues were brought to the attention of the MA organization or Part D sponsor that submitted the data with a request to explain or correct the data, the MA organization or Part D sponsor often found it necessary to submit a corrected MLR Report that included changes to figures used to calculate the MLR.

In Table 2, information on the MLR submissions for CYs 2014 through CY 2017 (the contract years for which MA organizations and Part D plan sponsors reported detailed MLR data that CMS collected for CYs 2014 through 2017) is shown alongside information on the MLR submissions for CYs 2018 through 2019 (the contract years for which CMS collected minimal MLR data consistent with current §§ 422.2460 and 423.2460). Specifically, for each time period, the table shows the percentage of contracts that were flagged for potential errors during desk reviews and the percentage of contracts that submitted revisions to correct errors in the original MLR filing that had an impact on the MLR calculation. The percentage of contracts that submitted revised MLR data to correct errors in the original MLR calculation includes plan-initiated (that is, self-disclosed) resubmissions in addition to resubmissions resulting from desk reviews.

TABLE 2. COMPARISON OF PERCENTAGE OF CONTRACTS FLAGGED AND PERCENTAGE OF CONTRACTS THAT SUBMITTED CORRECTIONS THAT AFFECTED MLR CALCULATION UNDER FORMER AND CURRENT REPORTING REQUIREMENTS

	CYs 2014 to 2017 (former MLR reporting requirements)	**CYs 2018 to 2019** (current MLR reporting requirements)
% of contracts flagged during desk reviews	63% to 87%	1% to 2%
% of contracts that submitted corrections to errors that affected MLR calculation	18% to 37%	2% to 5%

As the table indicates, although we stopped collecting detailed MLR data for contract years after CY 2017, we have continued to perform desk reviews of the submitted data, although, due to the limited amount of information we receive, these are largely confined to confirming that, for contracts that reported failing to meet the 85 percent MLR requirement for a contract year and owing a remittance to CMS, the amount that the MA organization or Part D sponsor indicates it is required to remit is consistent with what we would expect based on the reported MLR and our records of the contract's revenues for the contract year. Given that we collect very little MLR data from MA organizations and Part D sponsors under current §§ 422.2460 and 423.2460, and the consequently limited nature of our current desk reviews, it is unsurprising that fewer contracts were flagged as potentially containing erroneous data for CYs 2018 and 2019 relative to CYs 2014 through 2017. We acknowledge that there may be valid explanations for the decline in the number of contracts that had to correct their MLR calculations, such as MA organizations and Part D sponsors gaining familiarity with the requirements for calculating their MLRs (although we would have expected any such decreases to be observed in the initial years of MLR reporting). However, we believe that the steep decline since CY 2017 in the number of contracts that revised and resubmitted their MLR data raises questions about whether errors or omissions affecting the calculation of the MLR that might have been flagged by CMS or discovered by MA organizations and Part D sponsors as a result of MLR desk reviews under the prior regulations are now simply going undetected. This, in turn, has led us to reconsider whether the savings we estimated would result from minimizing the MLR reporting requirements outweigh the potential cost of allowing errors that might have been discovered via desk reviews of the detailed MLR data to go undetected.

We believe the potential for costly errors in the MLR calculation should be a concern not only for the government, but also for MA organizations and Part D sponsors, for although it is possible that some may have overstated their MLRs and remitted lower amounts than were actually owed, it is also possible that others may have understated their MLRs and overpaid remittances. With respect to contract years for which MA organizations and Part D sponsors have reported the limited amount of MLR data they are required to submit under current §§ 422.2460 and 423.2460 (that is, CYs 2018 and 2019), we have been

made aware only of MLR calculation errors that resulted in the MA organization or Part D plan sponsor reporting that the MLR as originally reported for a contract was *higher* than the actual MLR, which in some cases led to CMS collecting remittance amounts that were *lower* than the amounts that were actually owed. However, with respect to contract years for which we collected detailed MLR data and conducted desk reviews (that is, CYs 2014 through 2017), MA organizations and Part D sponsors that were contacted about suspected errors in their MLR calculations would often, in the course of examining issues flagged by CMS, inform us that they had discovered that they had made other mistakes, which when corrected caused the MLR for the contract to increase.

CMS could invoke its audit authority under §§ 422.2480 and 423.2480 to require MA organizations and Part D sponsors to validate the data necessary to calculate MLRs, so that CMS is able to determine that that the MLRs and remittance amounts under §§ 422.2410(b) and 423.2410(b) and sanctions under §§ 422.2410(c) and (d) and 423.2410(c) and (d) were accurately calculated, reported, and applied. As previously noted, CMS stated in the April 2018 final rule that we believed we could continue to effectively oversee MA organizations' and Part D sponsors' compliance by relying solely on audits (83 FR 16674). In response to comments that expressed concern that the audit burden would increase once we started relying on audits to monitor compliance, we stated that we did not expect that the changes to the MLR reporting requirements would cause MLR audits to be more burdensome than the MLR audits that were conducted in previous years. However, our response was based on an assessment that the burden associated with each individual audit would not increase, as we did not intend to change our MLR audit methodology. Upon further reflection, we believe that we would need to greatly expand the number of audits we conduct if we were to rely on them as our sole means of validating the accuracy of MLR reporting. Given the minimal data we currently receive from MA organizations and Part D sponsors, we would need to conduct comparatively resource heavy audits in order to identify potentially costly errors in the calculation of the MLR and remittance amount, including errors that would have been flagged systematically during the desk review process. We believe that the increased cost to the government and the aggregate burden across all of the additional MA organizations and Part D sponsors selected for audits would negate the savings that the April 2018 final rule estimated would result from the changes to the MLR reporting requirements.[133]

Furthermore, as we have continued to administer the MLR reporting requirements, we have come to recognize the limits and potential risks of an oversight approach that requires CMS to conduct time-consuming audits as the primary mechanism for identifying any errors that might impact the calculation of the MLR, and to appreciate the unique advantages of using desk reviews of detailed MLR data to identify outliers, anomalies, and omissions in the reported data that might indicate errors in the MLR calculation. An audit-only oversight approach is potentially problematic in the context of CMS' review of the MLR submissions that MA organizations and Part D sponsors are required to submit in advance of the general MLR filing deadline when one of their contracts fails to meet the minimum MLR requirement for two or more consecutive contract years. CMS requires that the MLR data for such contracts be reported early so that we have time to implement, prior to the open enrollment period, enrollment sanctions for any contract that fails to meet the MLR threshold for 3 or more consecutive years and contract termination for any contract that fails to meet the MLR threshold for 5 consecutive years. In the May 2013 Medicare MLR final rule (78 FR 31296), we explained that we were adopting this policy because, if we were to implement enrollment and termination sanctions after the start of the annual open enrollment period, this would create disruptions for beneficiaries who are newly enrolled in plans under a contract that is subject to enrollment sanctions, or all beneficiaries enrolled in plans under a contract that is subject to termination. We have typically required that these early MLR submissions be submitted to CMS in late July, a little more than 2 months before open enrollment begins.

Given the brief amount of time between when CMS receives these early MLR data submissions and the date when open enrollment begins, and the risk of disruption to beneficiaries if it is determined after open enrollment begins that a contract for which an early MLR submission was required failed to meet the MLR requirement for a third or fifth consecutive year, we believe it is particularly important that early MLR filers submit to CMS detailed MLR data, which can then be analyzed to quickly and independently identify potential errors in the MLR calculation. We believe this will reduce the likelihood that CMS will learn that a contract must be placed under the statutorily required sanctions at a time when enforcing those sanctions will force beneficiaries to enroll in another MA plan or in Medicare fee-for-service (FFS). Although that particular concern could perhaps be addressed by only requiring that early filers submit detailed MLR reports, that would not address the concerns raised in the preceding discussion about the potential cost to the government of uncollected remittances, or to MA organizations and Part D sponsors due to overpayment of remittances, when MLR calculation errors go undetected. The MLR data submitted for CYs 2014 through 2017 does not indicate that contracts that had to early report their MLR data made up a significant portion of the contracts that submitted MLR data that later had to be revised to correct errors that impacted the MLR calculation. We discuss the concerns about potential errors in early filers' MLR submissions to further illustrate the potential consequences of CMS not receiving detailed MLR data, which we did not fully appreciate when we adopted the current MLR reporting requirements. We clarify that we believe this concern makes it necessary that all MA organizations and Part D sponsors submit detailed MLR data that CMS can use to identify suspected errors that might affect the MLR calculation in a timely manner, and without having to rely on audits or self-disclosures.

In addition to the factors we have already discussed, we believe it is appropriate that we reevaluate our alignment with the commercial MLR rules. This is particularly true as it relates to the policy considerations that underlay our rulemaking to authorize the public release of the MLR data that MA organizations and Part D sponsors submit to us on an annual basis, as codified in our regulations at §§ 422.2490 and 423.2490. The analysis in the November 2017 proposed rule did not consider the benefits CMS associated with the release of Part C and Part D MLR data to the public, which we had enumerated the previous year in the proposed rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and

[133] The April 2018 final rule (83 FR 16715) estimated that the change in the MLR reporting requirements that CMS finalized for CYs 2018 and subsequent contract years would result in annual savings of $1,446,417 per year ($490,000 to the government and $904,884 to MA organizations and Part D sponsors).

Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model'' (81 FR 46162), which appeared in the **Federal Register** on July 15, 2016 (hereinafter referred to as the CY 2017 PFS proposed rule). In that proposed rule, we stated that the release of Part C and Part D MLR data could lead to research into how managed care in the Medicare population differs from and is similar to managed care in other populations (such as the individual and group markets) where MLR data is also released publicly, and could inform future administration of these programs (81 FR 46396). We further stated that the release of this data would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner (81 FR 46397). Notably, in the final rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' (81 FR 80170), which appeared in the November 15, 2016 **Federal Register** (hereinafter referred to as the CY 2017 PFS final rule), in response to comments that requested that CMS release only the MLR percentage for a contract, CMS expressly rejected that approach because releasing only the minimum amount of MLR data for MA and Part D contracts would not align with CMS' release of the detailed MLR data submitted by commercial plans (see 81 FR 80439). However, when we amended §§ 422.2460 and 423.2460 to scale back the MLR reporting requirements starting with CY 2018 MLR reporting, we did not indicate that we had subsequently concluded that MLR data would not provide this value to the public, nor did we acknowledge that a direct consequence of CMS ending the detailed MLR reporting requirements, was that our release of Medicare MLR data would no longer align with the release of commercial MLR data, as we would only be releasing the MLR percentage and remittance amount (if any) for MA and Part D contracts, starting with MLR data submitted for CY 2018. Given this background, in proposing to reinstate the detailed MLR reporting requirements, we believe it is appropriate that we reaffirm our position that the public release of Part C and Part D MLR data provides value to the public both by increasing market transparency and improving beneficiary choice. We believe that the value in CMS releasing to the public detailed MLR data in accordance with §§ 422.2490 and 423.2490, and in alignment with the disclosure of commercial MLR data, provides further support for our proposal to require MA organizations and Part D sponsors to submit such detailed data to us on an annual basis, starting with MLR reporting for CY 2023.

3. Proposed Changes to Medicare MLR Reporting Regulations, Data Collection Instrument, and Regulations Authorizing Release of Part C MLR Data (§§ 422.2460, 422.2490, and 423.2460)

As noted throughout this section of this proposed rule, we are proposing to reinstate the MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications. Our proposed revisions to the regulation text would amend paragraph (a) of §§ 422.2460 and 423.2460 so that they are essentially as they were prior to the elimination of the detailed MLR reporting requirements as finalized in the April 2018 final rule. However, we propose to further amend § 422.2460(a) so that the regulation text explicitly provides that the MLR report submitted to CMS includes amounts paid for incurred claims for covered services (both Medicare benefits and supplemental benefits) and prescription drugs.

Under our proposed amendments, paragraph (a) of § 422.2460 would state that, except as provided in paragraph (b), for each contract year, each MA organization must submit to CMS, in a timeframe and manner that we specify, a report that includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, including the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS under § 422.2410. We propose similar amendments to paragraph (a) of § 423.2460, except § 423.2460(a) as proposed would refer to ''incurred claims for covered drugs,'' would omit any mention of ''covered services (both Medicare-covered benefits and supplemental benefits),'' and would refer to the remittance owed to CMS under § 423.2410. In addition, we propose to revise paragraph (b) of both §§ 422.2460 and 423.2460 to specify that the limited MLR data collection requirements under that paragraph only apply to MLR reporting for CYs 2018 through 2022.

In connection with our proposal to reinstate the detailed MLR reporting requirements, starting with MLR reporting for CY 2023, we intend to require MA organizations and Part D sponsors to submit their MLR data to CMS using the MLR Reporting Tool that was used to report MLR data for CYs 2014 through 2017. In the years since CMS discontinued development of the MLR Reporting Tool, we have received multiple requests to continue updating and making this software publicly available so that it can be used as an aid for calculating MLRs in accordance with the current regulations and guidance. We agree that the use of CMS-developed MLR reporting software will help MA organizations and Part D sponsors to calculate their MLRs accurately. Although the MLR reporting software is unable to prevent all errors that might cause MLRs to be calculated incorrectly, particularly errors resulting from users entering erroneous data, we believe that MLR calculation errors are less likely to occur, and less likely to go unnoticed when they do occur, when MA organizations and Part D sponsors input the data elements for the MLR calculation into a standardized data collection tool that performs the mathematical operations to compute the MLR, including any applicable credibility adjustment, and contains built-in validation checks. In addition, we believe that we can further improve the usefulness of the software if MA organizations and Part D sponsors also submit to CMS the information entered into the MLR Reporting Tool and used to calculate the MLR for a contract. As part of our desk review process, we generate reports that identify specific issues flagged during desk reviews and whether any corrections to the reported data were necessary, which we can analyze to identify areas where we can improve the reporting guidance and validations in order to prevent errors in MLR submissions. As the agency responsible for developing the requirements for calculating and reporting MLR data, receiving and processing MLR data submissions, and

identifying compliance issues, we believe that CMS is uniquely positioned to use feedback generated through the submission and review of MLR data to learn about the various types of errors that may affect MA organizations' and Part D sponsors' MLR calculations, and to make changes both in our guidance and in the data collection tool itself that can prevent or steer MA organizations and Part D sponsors away from making certain errors that are known to have affected the MLR calculations of other MA organizations and Part D sponsors.

If our proposal to amend our regulations to require reporting of detailed MLR data is finalized, we intend to make three types of changes to the MLR Reporting Tool, which we list below:

First, we will revise the MLR Reporting Tool's formulas to incorporate changes to the MLR calculation that have been finalized since CMS stopped developing the MLR Reporting Tool after CY 2017 MLR Reports were submitted. These include changes in the treatment of fraud reduction expenses to remove the cap on these amounts. We will add categories for fraud reduction expenses and medication therapy management programs in the section for Activities that Improve Healthcare Quality, consistent with changes in the April 2018 final rule that redefined these categories of expenditures as quality improvement activities (83 FR 16670 through 16673).

Second, we will separate out certain items that are currently consolidated into or otherwise accounted for in existing lines of the MLR Reporting Tool. Thus, we intend to separate out low-income cost-sharing subsidy amounts, which were previously subtracted from the MLR numerator and excluded from the denominator, into an information-only line in the MLR Reporting Tool's numerator section, which will serve as a reminder to Part D sponsors that this amount needs to be subtracted from the numerator, and which we believe will provide more accountability in ensuring this amount has been accurately determined.

Third, we will separate out the current line for claims incurred during the contract year covered by the MLR Report into separate lines for benefits covered by Medicare Parts A and B, certain additional supplemental benefits (that is, benefits not covered by Parts A, B, or D and meeting the criteria in § 422.100(c)(2), but excluding supplemental benefits that extend or reduce the cost sharing for items and services covered under Parts A and B), and Part D prescription drug benefits. As noted previously, in the CY 2017 PFS proposed rule, we explained that we believed the public release of Part C and Part D MLR data would allow the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner (see 81 FR 46396 and 46397). To date, CMS has not separated out Medicare-covered and supplemental benefits into separate lines of the MLR Reporting Tool.

We intend to require MA organizations to report all expenditures for Medicare-covered benefits, including extended A/B coverage (by which we mean, for example, coverage of additional days during an inpatient stay) and cost-sharing reductions (by which we mean the value of the difference between the cost sharing under Medicare FFS and the plan's cost sharing), on the same line of the MLR Reporting Tool, based on our assumption that it would be exceedingly difficult for MA organizations to separately identify and track spending on extended coverage of original Medicare benefits and cost-sharing reductions. We solicit comment on whether this is a reasonable assumption and whether the MLR Reporting Tool should instead mirror how MA bids are submitted under § 422.254(b).

Regarding additional supplemental benefits (supplemental benefits meeting the criteria in § 422.100(c)(2) but excluding supplemental benefits that extend or reduce the cost sharing for items and services covered under Parts A and B), we intend to have MA organizations report these expenditures on multiple lines of the MLR Reporting Tool, which would represent different types or categories of supplemental benefits. Requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will provide more transparency into how the MLR is being calculated, and it will assist CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. In addition, we believe that the public release of information on supplemental benefit spending by benefit type or category may be helpful to beneficiaries who wish to make their enrollment decisions based on a comparison of the relative value of the supplemental benefits actually provided by different MA organizations. We are not proposing to require separate reporting of Part D supplemental benefit expenditures (that is, they will continue to be reported combined with other Part D expenditures).

In developing these additional supplemental benefit categories, we recognize that requiring MA organizations to separately report expenditures that they might not already be separately tracking, or that they are tracking using categories other than the ones listed in the MLR Reporting Tool, could create an additional burden. Accordingly, where different supplemental benefits are conventionally regarded as falling into the same category of benefit offering (for example, a comprehensive dental benefit might include both extractions and dental diagnostic services), although these can be treated as separate benefit offerings in the PBP, we grouped those benefits together under the same category (for example, ''Dental'').

Based on these considerations, we intend to expand the MLR reporting requirements beyond what was required under the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, to include expenditures related to the following categories of supplemental benefits:

- Dental
- Vision
- Hearing
- Transportation
- Fitness Benefit
- Worldwide Coverage/Visitor Travel
- Over the Counter (OTC) Items
- Remote Access Technologies
- Meals
- Routine Foot Care
- Out-of-Network Services
- Acupuncture Treatments
- Chiropractic Care
- Personal Emergency Response System (PRS)
- Health Education
- Smoking and Tobacco Cessation Counseling
- All Other Primarily Health Related Supplemental Benefits
- Non-Primarily Health Related Items and Services that are Special Supplemental Benefits for the Chronically Ill (SSBCI) (as defined in § 422.102(f))

We believe that expenditures for dental, vision, and hearing should be separately reported because, in addition to being among the most widely-offered types of supplemental benefits, the amounts reported in the MLR Reporting Tool for each of those benefit types could be compared to the expenditures for each of those benefit types that are included in the base period experience section and the expected expenditures in the projected section of the Bid Pricing Tool (BPT). We believe reporting

expenditures related to the additional types and categories of supplemental benefits previously listed will increase accountability for the accuracy of the amounts used in the MLR calculation, and CMS will be able to analyze the reported data for indicators of potential inaccuracies, such as by flagging outliers for follow-up inquiries.

In compiling the previous list of supplemental benefit types and categories, we took into consideration the percentage of MA plans that offer each type of supplemental benefit in the most recent year for which data on plan benefit packages is available (that is, CY 2022), so that the lines we add to the MLR Reporting Tool are more likely to allow for comparison of MA organizations' expenditures on types of supplemental benefits that are widely offered. In addition, in deciding whether to require separate reporting of the expenditures for a particular supplemental benefit type, we considered the percentage of contracts that currently offer that supplemental benefit under just one plan, as we believe expenditures associated with benefits offered under only one plan under a contract would constitute plan-level data, which CMS proposes to exclude from public release of MLR data consistent with the exclusions for MLR data reported at the plan level and information submitted for contracts consisting of a single plan (see § 422.2490(b)(2)). Based on our review of the percentage of plans offering each type of supplemental benefit, and the percentage that are offered under only one plan under a contract, we are not proposing to require separate reporting of expenditures for supplemental benefit types or categories offered by less than 10 percent of all MA plans in 2021. The exception is SSBCI that are not primarily health related, which we include because we believe this information will help us assess the impact of our 2021 rule change that allows all amounts paid for covered services to be included in the MLR numerator as incurred claims (prior to this rule change, only amounts paid ''to providers''—which is defined in § 422.2 in terms of the provision of healthcare items and services—for covered services could be included in incurred claims, which would have excluded, for example, pest control).

We solicit comment on whether the list of supplemental benefit types and categories would be appropriate breakouts for separating out supplemental benefit expenditures in the MLR Reporting Tool. We are interested in feedback that addresses whether we should increase or decrease the number of types or categories of supplemental benefits, as well as suggestions for alternative categories or for consolidating the above benefit types or categories into larger categories.

As the preceding discussion suggests, we intend to use our authority under §§ 422.2490 and 423.2490 to release to the public the Part C and Part D MLR data we propose to collect, including the additional data we propose to collect on supplemental benefit expenditures, to the same extent that we released the information we formerly collected under the MLR reporting requirements in effect for CYs 2014 through 2017. Consistent with §§ 422.2490(c) and 423.2490(c), the release of the MLR data we propose to collect for a contract year will occur no sooner than 18 months after the end of the applicable contract year, and will be subject to the exclusions in §§ 422.2490(b) and 423.2490(b). As previously noted, we propose to amend § 422.2490(b)(2) by adding new paragraph (b)(2)(ii), which would exclude from release data on amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit. For example, if only one plan under a contract offers Dental X-rays as a supplemental benefit, and expenditures for that benefit are the only amounts reported on that line of the MLR Reporting Tool, we would exclude the entire amount reported on that line from our public data release. However, if only one plan under a contract covers Dental X-rays, and another plan under that same contract is the only plan under the contract that covers Extractions, expenditures for both benefits would be reported in the Dental line in the MLR Reporting Tool, and that combined amount (assuming both plans had expenditures in the Dental category) would not be excluded from our public data release. We believe data regarding supplemental benefit expenditures is only sensitive to the extent that the data reveals plan-level expenditures for a specific benefit offered under a single plan, and that these concerns do not exist when expenditures for multiple types of supplemental benefits or from multiple plans are included in the same line of the MLR Reporting Tool. We solicit comment on this proposed exclusion, including any suggestions for how we would implement this exclusion (for example, by adding check boxes next to the applicable lines in the MLR Reporting Tool, where users would add a check mark if their expenditures for the supplemental benefit type or category in the line by the checkbox represented expenditures for a single plan and single benefit type), and whether additional exclusions should be added to our MLR data release regulations. We solicit comment on whether there is additional sensitivity around expenditures for supplemental benefits generally or for any types of supplemental benefits in particular, such that public release of data concerning those expenditures would be harmful.

4. Proposed Technical Change to MLR Reporting Regulations (§§ 422.2460 and 423.2460)

In addition to our proposal to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications, and to add new data fields to our MLR Reporting Tool as described in the previous section of this preamble, we propose to make a clarifying amendment to our MLR reporting regulations.

Currently, §§ 422.2460(d) and 423.2460(d) state that the MLR is reported once, and is not reopened as a result of any payment reconciliation process. We propose to amend this paragraph to note that it is subject to an exception in new paragraph (e), which as proposed would provide that, with respect to an MA organization (in the case of proposed § 422.2460(e)) or Part D sponsor (in the case of proposed § 423.2460(e)) that has already submitted to CMS the MLR report or MLR data submission for a contract for a contract year, paragraph (d) does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Proposed paragraph (e) would also provide that such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, will be regarded as the contract's MLR report or data submission for the contract year for purposes of part 422, subpart X, and part 423, subpart X.

We characterize this as a clarifying amendment, as we believe it is clear from the discussion in the May 2013 Medicare MLR final rule that the provision stating that the MLR will be reported once, and will not be reopened as a result of any payment reconciliation process, was intended to codify the policy decision that the MLR for a contract year should be based on the contract year revenue figure available at the time of reporting, and should not be subject to change if the contract year

revenues increase or decrease through adjustments that take place in a future year. We note that the discussion of this policy appears in both the proposed and final rules under the heading ''Projection of Net Total Revenue'' (78 FR 12435; 78 FR 31292). The MLR final rule discusses how our policy not to reopen the MLR due to any payment reconciliation process is consistent with our view that the MLR should reflect how an MA organization or Part D plan sponsor decided to apportion the revenue it actually received for the contract year between patient care and quality improvement and other costs (78 FR 31293). The Medicare MLR final rule explains that we assume that MA organizations and Part D plan sponsors likely do not make their decisions about how to use the funds that are available to them based on an assumption that their revenue will be reduced or increased in a future year as a result of a future audit or reconciliation that changes the final Medicare payment amount. We believe that taking such future revenue adjustments into account would not be useful for assessing how a plan chose to allocate its available revenues.

In addition to our remarks in the 2013 Medicare MLR proposed and final rules, we believe it is clear based on other provisions in our MLR regulations that we have never intended to prohibit ourselves from collecting, or taking into account, additional or corrected MLR data that is submitted to address deficiencies or inaccuracies in the annual MLR submission required under §§ 422.2460 and 423.2460. For example, when MLR data submitted under § 422.2460 (for MA contracts) or § 423.2460 (for Part D contracts), calculations, or any other MLR submission required under our MLR regulations is found to be materially incorrect or fraudulent, under §§ 422.2480(d) and 423.2480(d), CMS is required to recoup the appropriate remittance amount. It would be unduly burdensome and time-consuming for both CMS and the relevant MA organization or Part D sponsor if, in lieu of requiring the MA organization or Part D sponsor to correct its MLR submission, CMS had to collect the MA organization's or Part D sponsor's relevant financial records, contracts, and other types of supporting documentation so the agency could calculate the correct MLR for a contract. That being the case, if CMS could not require the submission of corrected MLR data when deficiencies are found, whether by CMS or by the MA organization or Part D sponsor, CMS' ability to enforce the statutory MLR sanctions (codified in our regulations at §§ 422.2410(c) through (d) and 423.2410(c) through (d)) would be undermined. In addition, because our MLR data release regulations at §§ 422.2490 and 423.2490 provide that CMS releases to the public the data collected under §§ 422.2460 and 423.2460, if CMS could not require or allow resubmission of MLR data submitted under those regulations in order to correct errors in the original filing, it would be necessary for CMS to either release data that is known to contain errors, which could mislead beneficiaries who wish to use the MLR data to assess the relative value of Medicare health and drug plans, or to remove the erroneous data, which would create gaps in the dataset and limit the usefulness of MLR data as a resource for facilitating public evaluation of the MA and Part D programs (see 81 FR 46396 and 46397).

The proposed amendments to §§ 422.2460 and 423.2460 are consistent with our longstanding practice, which dates back to when CMS first began collecting Part C and Part D MLR data (for CY 2014) in December 2015, of allowing MA organizations and Part D sponsors to resubmit their MLR Data Forms for a contract year in order to correct errors and omissions in the original MLR filing without treating that resubmission as a reporting of the MLR for purposes of §§ 422.2460(d) and 423.2460(d). To date, CMS has accepted resubmission of MLR data submitted for a contract year without penalty up until the point when we collect remittances for contracts that have failed to meet the minimum MLR requirement for that contract year. CMS has typically collected remittances for a contract year through an adjustment to MA organizations' and Part D sponsors' monthly payments for July in the year that is 2 years after the contract year that is the subject of the MLR filing (for example, remittances based on CY 2015 MLR reporting were collected in July 2017). We have also required that MA organizations and Part D sponsors resubmit MLR data if it is determined that the original MLR submission contained errors that affected the calculation of the MLR or remittance amount after this date, although in such cases CMS reserves the right to issue sanctions as authorized by §§ 422.2480(d)(3) and 423.2480(d)(3). In deciding whether to issue sanctions, we will consider factors such as whether the error in the MLR filing was self-disclosed by the MA organization or Part D sponsor, whether the error appears to be the result of intentional misrepresentation, and whether any beneficiary harm (including disruptions to enrollment) occurred as a result of the error.

H. Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

1. Introduction

Under Medicare Part D, Medicare makes partially capitated payments to private insurers, also known as Part D sponsors, for covering prescription drug benefits for Medicare beneficiaries. Often, the Part D sponsor or its pharmacy benefit manager (PBM) receives compensation after the point-of-sale that serves to lower the final net amount paid by the sponsor to the pharmacy for the drug. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans. DIR includes rebates from manufacturers, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related risk-sharing settlements, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan (see § 423.308).

Total DIR reported by Part D sponsors has been growing significantly in recent years. The data Part D sponsors submit to CMS as part of the annual reporting of DIR [134] show that pharmacy price concessions (generally referring to all forms of discounts, direct or indirect subsidies, or rebates that a pharmacy pays to a Part D sponsor to reduce the costs incurred under Part D plans by Part D sponsors), net of all pharmacy incentive payments, have grown faster than any other category of DIR [135] received by sponsors and PBMs. This means that pharmacy price concessions now account for a larger share than ever before of reported DIR and a larger share of total gross drug costs in the Part D program. In 2020, pharmacy price concessions accounted for about 4.8 percent of total Part D gross drug costs ($9.5 billion), up from 0.01 percent ($8.9 million) in 2010. As shown in Table 3, the growth in pharmacy price concessions from 2010 to 2020 has been a continuous upward trend with the exception of 2011.

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TABLE 3: PHARMACY PRICE CONCESSIONS BY YEAR (2010–2020)

Contract Year	Total Pharmacy Price Concessions	% Change
2010	$ 8,869,347	–
2011	$ 8,582,354	-3.2%
2012	$ 68,086,163	693.3%
2013	$ 228,573,206	235.7%
2014	$ 538,421,239	135.6%
2015	$ 1,719,179,214	219.3%
2016	$ 2,125,460,000	23.6%
2017	$ 4,001,741,355	88.3%
2018	$ 6,339,517,817	58.4%
2019	$ 8,130,024,785	28.2%
2020	$ 9,535,197,775	17.3%

Source: Summary Direct and Indirect Remuneration Report Data, 2010–2020.

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The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 107,400 percent between 2010 and 2020. The data also show that much of this growth occurred after 2012, when the use by Part D sponsors of performance-based payment arrangements with pharmacies became increasingly prevalent. Part D sponsors and their contracted PBMs have been increasingly successful in recent years in negotiating price concessions from network pharmacies. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM. Performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.

While manufacturer rebates (a non-pharmacy price concession) account for the largest category of DIR, given the large growth in pharmacy price concessions that has resulted from the increased use of performance-based pharmacy payment arrangements, CMS is focusing on policy proposals in this section that would be applicable to pharmacy price concessions, and not non-pharmacy price concessions. Further, section 90006 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) prohibits the Secretary from implementing, administering, or enforcing the provisions of the final rule

[134] CMS collects DIR data under collection approved under OMB control number 0938–0964 (CMS–10174) (''Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment''). CMS does not release publicly the DIR data that we collect. The one exception was a highly summarized release of certain 2014 DIR data related to manufacturer rebates: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.*

[135] Sponsors report all DIR to CMS annually by category at the plan level. DIR categories include: Manufacturer rebates, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related risk-sharing settlements, etc.

published by the Office of the Inspector General of the Department of Health and Human Services on November 30, 2020, and titled ''Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees'' (85 FR 76666) (hereinafter referred to as the rebate rule) prior to January 1, 2026. While CMS has independent statutory authority, pursuant to section 1860D–2(d)(1)(B) of the Act, to regulate the application of non-pharmacy price concessions to negotiated price, given the existing moratorium on implementation of the rebate rule and the differences between performance-based pharmacy payment arrangements and non-pharmacy price concessions, we are following an incremental approach and only proposing policies related to pharmacy price concessions at this time.

The negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government cost obligations during the course of the payment year, subject to final reconciliation following the end of the coverage year. Under the current definition of ''negotiated prices'' at § 423.100, negotiated prices must include all price concessions from network pharmacies except those that cannot reasonably be determined at the point-of-sale. However, because performance adjustments typically occur after the point-of-sale, they are not included in the price of a drug at the point-of-sale.

Through comments received from the pharmacy industry in response to our Request for Information on pharmacy price concessions (included in the proposed rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56419 through 56428), which appeared in the **Federal Register** on November 28, 2017 (hereinafter referred to as the November 2017 proposed rule)), and our solicitation for comments on the potential policy approach for including pharmacy price concessions in the negotiated price discussed in the proposed rule titled ''Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses'' (83 FR 62174 through 62180), which appeared in the **Federal Register** on November 30, 2018 (hereinafter referred to as the November 2018 proposed rule), and sponsor-reported DIR data, we further understand that the share of pharmacies' reimbursements that is contingent upon their performance under such arrangements has grown steadily each year. Further, sponsors and PBMs have been recouping increasing sums from network pharmacies after the point-of-sale (pharmacy price concessions) for ''poor performance,'' sums that are far greater than those paid to network pharmacies after the point-of-sale (pharmacy incentive payments) for ''high performance.'' When pharmacy price concessions received by Part D sponsors are not reflected in lower drug prices at the point-of-sale and are instead used to reduce plan liability, beneficiaries generally see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing. Thus, beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug. Moreover, when the point-of-sale price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor.

President Biden's Executive Order (E.O.) 14036, ''Promoting Competition in the American Economy'' (86 FR 36987), section 5 (''Further Agency Responsibilities''), called for agencies to consider how regulations could be used to improve and promote competition throughout the prescription drug industry. Because variation in the treatment of pharmacy price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, and given the programmatic impacts laid out above and the charge from the E.O., CMS is proposing changes that would standardize how Part D sponsors apply pharmacy price concessions to negotiated prices at the point-of-sale.

At the time the Part D program was established, we believed, as discussed in the January 2005 final rule (70 FR 4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point-of-sale a high percentage of the price concessions they received, and that establishing a minimum threshold for the price concessions to be applied at the point-of-sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, less than 2 percent of plans have passed through any price concessions to beneficiaries at the point-of-sale. We now understand that sponsors may face market incentives to not apply price concessions at the point-of-sale because of the advantages that accrue to sponsors in terms of lower premiums (also an advantage for beneficiaries). Pharmacy price concessions reduce plan costs, and having the concessions not be applied at the point-of-sale reduces plan costs and plan premiums at the expense of the beneficiary having lower cost sharing at the point-of-sale, thus shifting some of the net costs to the beneficiary via higher cost sharing. We believe that Part D sponsors are incentivized to have lower premiums versus lower cost sharing because anecdotal evidence suggests beneficiaries focus more on premiums instead of cost sharing when choosing plans.

For this reason, as part of the November 2017 proposed rule, we published a ''Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale'' (82 FR 56419 through 56428). We solicited comment on whether CMS should require that the negotiated price at the point-of-sale for a covered Part D drug must include all price concessions that the Part D sponsor could potentially collect from a network pharmacy for any individual claim for that drug. Of the many timely comments received, the majority were from pharmacies, pharmacy associations, and beneficiary advocacy groups that supported the adoption of such a requirement claiming that it would: (1) Lower beneficiary out-of-pocket drug costs (especially critical for beneficiaries who utilize high cost drugs); (2) stabilize the operating environment for pharmacies (by creating greater transparency and allegedly making the minimum reimbursement on a per-claim level more predictable); and (3) standardize the way in which plan sponsors and their PBMs treat pharmacy price concessions. Some commenters—mostly Part D sponsors and PBMs—were against such a policy, claiming that it would limit their ability to incentivize quality improvement from pharmacies. In the November 2018 proposed rule, we solicited comment on a potential policy approach under which all pharmacy price concessions received by a plan sponsor for a covered Part D drug, including contingent price

concessions paid after the point-of-sale, would be included in the negotiated price (83 FR 62177). Specifically, we considered adopting a new definition for the term ''negotiated price'' at § 423.100, which would mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary. In the final rule titled ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' which appeared in the **Federal Register** on May 23, 2019 (84 FR 23867), we noted that we received over 4,000 comments on this potential policy approach, indicated that we would continue studying the issue, and left the existing definition of ''negotiated prices'' in place.

To address concerns about the lack of transparency in the performance measures used to evaluate pharmacy performance, in the February 2020 proposed rule (85 FR 9002), we proposed to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. We explained in the proposed rule that, once collected, we would publish the list of pharmacy performance measures in order to increase public transparency. In the final rule titled, ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the **Federal Register** on January 19, 2021 (86 FR 5684), we finalized the proposed amendment to § 423.514(a), such that, starting January 1, 2022, Part D sponsors will be required to disclose their pharmacy performance measures to CMS.

After considering the comments received on the November 2018 proposed rule, and in light of more recent data indicating that pharmacy price concessions have continued to grow at a faster rate than any other category of DIR,[136] effective for contract year 2023, we propose to amend § 423.100 to define the term ''negotiated price'' to ensure that the prices available to Part D enrollees at the point-of-sale are inclusive of all pharmacy price concessions. First, we propose to delete the current definition of ''negotiated prices'' (in the plural) and add a definition of ''negotiated price'' (in the singular) to make clear that a negotiated price can be set for each covered Part D drug. We believe this approach accommodates the different approaches to applying price concessions under sponsor and PBM payment arrangements with pharmacies, which may provide for price concessions to be applied uniformly as a percentage adjustment to the price for all Part D drugs dispensed by a pharmacy or have price concessions differ on a drug-by-drug basis. In addition, defining ''negotiated price'' in the singular is consistent with the regulations for the coverage gap discount program, which define the term ''negotiated price'' at § 423.2305, and it is compatible with our existing regulations, which at times refer to the ''negotiated price'' for a specific drug rather than ''negotiated prices'' for multiple drugs. Second, we propose to define ''negotiated price'' as the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account all pharmacy price concessions.

2. Background

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under the definition of ''negotiated prices'' at § 423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point-of-sale by the Part D sponsor. This point-of-sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Under current law, Part D sponsors can, for the most part, choose whether to reflect in the negotiated price the various price concessions they or their intermediaries receive from all sources, not just pharmacies. Specifically, section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . .'' Part D sponsors are allowed, but generally not required, to apply rebates and other price concessions at the point-of-sale to lower the price upon which beneficiary cost-sharing is calculated. Under the existing definition of negotiated prices at § 423.100, however, negotiated prices must include all price concessions from network pharmacies that can reasonably be determined at the point-of-sale.

To date, very few price concessions have been included in the negotiated price at the point-of-sale. All pharmacy and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year using the form required by CMS for reporting Summary and Detailed DIR (OMB control number 0938–0964). These data on price concessions are used in our calculation of final plan payments, which, under section 1860D–2(d)(1)(B) of the Act, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR. Reinsurance payments under section 1860D–15(b) of the Act, and risk sharing payments and adjustments under section 1860D–15(e)(2) of the Act are also required to be based on costs actually incurred by Part D sponsors. In addition, pursuant to section 1860D–2(d)(2) of the Act, Part D sponsors are required to disclose the aggregate negotiated price concessions made available to the sponsor by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers.

When price concessions are applied to reduce the negotiated price at the point-of-sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing. In contrast, when price concessions are applied after the point-of-sale, as DIR, the majority of the concession amount accrues to the plan, and the remainder accrues to the government. For further discussion on this matter, please see the CMS Fact Sheet from January 19, 2017 ''Medicare Part D Direct and Indirect Remuneration,'' found on the CMS website at *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.* As discussed later in this section of this proposed rule, pharmacy price concessions applied as DIR can lower plan premiums and increase plan revenues, result in cost-shifting to certain beneficiaries (in the form of higher cost-sharing) and the government (through higher reinsurance and low-income cost-sharing subsidies), and obscure the true costs of prescription drugs for consumers and the government.

[136] From 2018 to 2020, pharmacy price concessions increased by 50.4% while all other DIR increased by 23.5%.

a. Premiums and Plan Revenues

The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point-of-sale) is a lower plan premium. A sponsor must factor into its plan bid an estimate of the expected DIR for the upcoming payment year. That is, in the bid the sponsor must lower its estimate of plan liability by a share of the projected DIR, which has the effect of reducing the price of coverage under the plan. Under the current Part D benefit design, applying price concessions after the point-of-sale as DIR reduces plan liability (and thus premiums) more than applying price concessions at the point-of-sale.

Therefore, to the extent that plan bids reflect accurate DIR estimates, the pharmacy and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point-of-sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums. The average Part D basic beneficiary premium grew at an average rate of only about 1 percent per year between 2010 and 2020 [137] and the average basic premium actually paid by beneficiaries has declined each year since 2017 as sponsors projected in their bids that DIR growth will outpace the growth in projected gross drug costs each year. The average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 11.7 percent per year between 2010 and 2019, partly for the same reason.[138]

However, any DIR a sponsor receives that is above the projected amount factored into its plan bids increases revenues and contributes to plan profits, without necessarily being reflected in lower premiums. The risk-sharing construct established under the Part D statute at section 1860D–15(e) of the Act allows sponsors to retain as plan profit the majority of all plan revenues above the bid-projected amount. Given that plan bids, and, thus, plan revenues, are based on cost projections, the plan's actual experience may yield unexpected losses (when bid-based payments to plans—plan revenues—fall short of actual plan costs) or unexpected savings (when plan revenues exceed actual plan costs) for Part D sponsors. In order to limit Part D sponsors' exposure to unexpected drug expenses and the government's exposure to overpayments, Medicare shares risk with sponsors on the drug costs covered by their plan bids, using symmetrical risk corridors to cover or recoup a share of unexpected losses or savings.

Under the Part D risk corridors, if a plan's actual drug costs are within +/− 5 percent of the drug costs estimated in its bid, the plan assumes all of the losses or savings. If its costs are more than 5 percent above or below its bid, the government assumes a growing share of the losses or savings, and the plan assumes the remainder. Any unexpected losses or savings that a plan assumes affect its final profit margin. Thus, when a plan underestimates the amount of DIR that it will receive, any additional amount of DIR constitutes additional plan revenues. In the event that overall plan revenues exceed the amount projected in the plan sponsor's bid, the sponsor is permitted to retain most, if not all, of the excess amount, assuming that the sponsor has met the minimum MLR requirement. Our analysis of Part D plan payment and cost data indicates that in recent years, DIR amounts that Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts, by an average of 0.6 percent and as much as 3 percent as a share of gross drug costs from 2010 to 2020.

Due to the relative premium and other advantages that price concessions applied as DIR, including pharmacy price concessions, offer sponsors over lower point-of-sale prices, sponsors can have an incentive to opt for higher negotiated prices in exchange for higher DIR and, where price concessions are in the form of percentage-based fees, to prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies.

b. Cost-Shifting

Beneficiary cost-sharing is generally calculated as a percentage of the negotiated price. When pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point-of-sale (that is, are applied instead as DIR at the end of the coverage year), beneficiary cost-sharing increases, covering a larger share of the actual cost of a drug. Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug is subject to a copayment because Part D rules require that the copayment amount be at least actuarially equivalent to the coinsurance required under the defined standard benefit design. For more than half of Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR. For the millions of low-income beneficiaries whose out-of-pocket costs are subsidized by Medicare through the low-income cost-sharing subsidy, those higher costs are borne by the government. See the lowest possible reimbursement example later in this section of this proposed rule for an example of the effect the proposed change to the definition of negotiated price would have on the determination of beneficiary cost-sharing.

This potential for cost shifting to beneficiaries grows increasingly pronounced as pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price. Numerous research studies suggest that higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare overall.[139] [140] [141] Moreover, higher cost sharing can negatively impact all beneficiaries, not just those who are low income. While most low-income beneficiaries are insulated from this cost-shifting due to statutorily limited copayments, low-income subsidy (LIS) Level 4 beneficiaries pay 15 percent coinsurance in the initial coverage limit, which in an environment where the negotiated price does not include all pharmacy price concessions could be cost-prohibitive for this population. Additionally, those beneficiaries who narrowly miss the LIS eligibility criteria are particularly vulnerable to such cost shifting. Given this, we believe it is

[137] By contrast, during this same period (2010–20), the average premium for a single individual in the commercial market grew by about 4 percent per year. *See* Kaiser Family Foundation 2020 Health Benefits Annual Survey, Page 40, *https://Files.kff.org/Attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf.*

[138] Plan Payment Data, 2010–19, available at *https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Plan-Payment-Data.html.*

[139] Michele Heisler et al., ''The Health Effects of Restricting Prescription Medication Use Because of Cost,'' *Med Care,* 2004 Jul;42(7):626–634, available at *https://www.ncbi.nlm.nih.gov/pubmed/15213486.*

[140] Peter Bach, ''Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs,'' *New England Journal of Medicine* 2009, 360:626–633, available at *https://www.nejm.org/doi/full/10.1056/NEJMhpr0807774.*

[141] Sonya Blesser Streeter et al., ''Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions,'' *Journal of Oncology Practice 2011,* 7(3S):46s–51s, available at *http://ascopubs.org/doi/full/10.1200/jop.2011.000316.*

important to weigh the effects of current Part D policies, and the trade-offs between higher cost-sharing versus lower plan premiums, on beneficiaries' access to affordable prescription drugs.

Finally, beneficiaries progress through the four phases of the Part D benefit as their total gross drug costs and cost-sharing obligations increase. Because both of these values are calculated based on the negotiated prices reported at the point-of-sale, when pharmacy price concessions are not applied at the point-of-sale, the higher negotiated prices result in more rapid movement of Part D beneficiaries through the Part D benefit phases. This, in turn, shifts more of the total drug spend into the catastrophic phase, where Medicare liability is at 80 percent (paid as reinsurance) and plan liability is at 15 percent (which is much lower than the 75 percent plan liability for drugs in the initial phase and generic drugs in the coverage gap phase; plan liability with respect to ''applicable drugs'' in the coverage gap phase is 5 percent). With such cost-shifting to the government under current rules, Part D sponsors may have weak incentives, and, in some cases no incentive, to lower prices at the point-of-sale. See the Regulatory Impact Analysis in section V.D.8. of this proposed rule for a discussion of cost impacts to beneficiaries, the government, and plan sponsors of requiring all pharmacy price concessions to be included in the negotiated price at the point-of-sale.

c. Transparency and Competition

The significant growth in pharmacy price concessions in recent years and inconsistency in how pharmacy price concessions are treated by different Part D sponsors (that is, they are applied to the point-of-sale price to differing degrees or estimated and factored into plan bids with varying degrees of accuracy) has resulted in plans that are not consistent with each other with respect to the aggregate share of drug costs covered by the plan versus the beneficiary. Moreover, the disparate ways that Part D sponsors manage pharmacy price concessions reduces transparency of the point of sale cost to the beneficiary and can increase beneficiary confusion. For example, a beneficiary facing a choice between a plan offering a 10 percent coinsurance tier versus a plan offering $50 copay for a given drug, would have difficulty assessing the true cost at the point of sale and, as a result, may inadvertently select the more costlier option. This undermines beneficiaries' ability to make meaningful price comparisons and efficient choices when considering the combined cost sharing and premiums plans offer when choosing a plan. Second, if a sponsor's bid is based on an estimate of net plan liability that is lowered because the sponsor has been applying pharmacy price concessions as DIR at the end of the coverage year rather than using them to reduce the negotiated price at the point-of-sale, it follows that the sponsor may be able to submit a lower bid than a competitor that applies pharmacy price concessions at the point-of-sale. This lower bid results in a lower plan premium, which could allow the sponsor to capture additional market share. The competitive advantage accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of pharmacy price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency.

3. Proposed Changes to the Definition of Negotiated Price (§ 423.100)

As previously discussed, Part D sponsors and PBMs have been recouping increasing sums from network pharmacies after the point-of-sale in the form of pharmacy price concessions. We addressed concerns about these pharmacy payment adjustments when we established the existing requirements for negotiated price reporting in the May 2014 final rule (79 FR 29844). In that rule, we amended the definition of ''negotiated prices'' at § 423.100 to require Part D sponsors to include in the negotiated price at the point-of-sale all pharmacy price concessions and incentive payments to pharmacies—with an exception, intended to be narrow, that allowed the exclusion of contingent pharmacy payment adjustments that cannot reasonably be determined at the point-of-sale (the reasonably determined exception). However, when we formulated these requirements in 2014, the most recent year for which DIR data was available was 2012, and we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years.

We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards contingent pharmacy payment arrangements. As suggested by numerous stakeholders in response to the Request for Information in the November 2017 proposed rule (82 FR 56419 through 56428), nearly all performance-based pharmacy payment adjustments may be excluded from the negotiated price on the grounds that they cannot reasonably be determined at the point-of-sale. Specifically, several stakeholders have suggested to us that sponsors apply the reasonably determined exception to all performance-based pharmacy payment adjustments. These stakeholders assert that the amount of these adjustments, by definition, is contingent upon performance measured over a period of time that extends beyond the point-of-sale and, thus, cannot be known in full at the point-of-sale. Therefore, performance-based pharmacy payment adjustments cannot ''reasonably be determined'' at the point-of-sale as they cannot be known in full at the point-of-sale. These assertions are supported by the information plan sponsors report to CMS as part of the annual DIR reports. As a result, the reasonably determined exception prevents the current policy from having the intended effect on price transparency, consistency (by reducing differential reporting of pharmacy payment adjustments by sponsors), and beneficiary costs.

Given the predominance of the use of performance-contingent pharmacy payment arrangements by plan sponsors, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves the goals previously discussed: Meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and preventing cost-shifting to beneficiaries and taxpayers. Therefore, to establish a requirement that accomplishes these goals while better reflecting current pharmacy payment arrangements, we propose to delete the existing definition of the term ''negotiated prices'' at § 423.100 and add a definition of the term ''negotiated price'' at § 423.100 to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum possible reduction that could result from any contingent pharmacy payment arrangement). Specifically, as noted previously, we propose to delete the current definition of ''negotiated prices'' (in the plural) and to add a new definition of ''negotiated price'' (in the singular) in order to make clear that a negotiated price can be set for each covered Part D drug, and the amount of

pharmacy price concessions may differ on a drug-by-drug basis. Our proposed definition of negotiated price would specify that the negotiated price for a covered Part D drug must include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts (such as incentive fees) if these amounts increase prices. Under our proposal, we would not change Part D sponsors' ability to pass-through other, non-pharmacy price concessions and other direct or indirect remuneration amounts (for example, legal settlement amounts and risk-sharing adjustments) to enrollees at the point-of-sale. These proposed provisions are discussed in the following sections.

Requiring that all pharmacy price concessions be included in the negotiated price, as proposed, will lead to more accurate comparability of drug prices, Part D bid pricing, and plan premiums. This increased level of accuracy should center the beneficiary by allowing them to better compare between plans' cost sharing and premiums, so that beneficiaries are able to identify the plan that best meets their individual needs. Moreover, when negotiated prices and plan premiums more accurately reflect relative plan efficiencies, there would not be unfair competitive advantages accruing to one sponsor over another based on a technical difference in how costs are reported. In short, because Part D is a market-based approach to delivering prescription drug benefits, and relies on healthy market competition, we believe the proposed changes to cost reporting could make the Part D market more competitive and efficient by allowing for a more consistent, accurate, ''apples to apples'' comparison of prices in the market.

a. All Pharmacy Price Concessions

In this proposed rule, we propose to adopt a new definition of ''negotiated price'' at § 423.100 that would include all pharmacy price concessions received by the plan sponsor for a covered Part D drug. The proposed definition would omit the reasonably determined exception, meaning that all price concessions from network pharmacies, negotiated by Part D sponsors and their contracted PBMs, would have to be reflected in the negotiated price that is made available at the point-of-sale and reported to CMS on a PDE record, even when such price concessions are contingent upon performance by the pharmacy.

Section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . .'' We have previously interpreted this language to mean that some, but not all, price concessions must be applied to the negotiated price (see, for example, 70 FR 4244 and 74 FR 1511). Although we continue to believe that the prior interpretation of ''take into account'' was permissible, we believe that our initial interpretation may have been overly definitive with respect to the intended meaning of ''take into account.'' We believe that a proper reading of the statute supports requiring that all pharmacy price concessions be applied at the point-of-sale. As proposed, requiring that all pharmacy price concessions be applied at the point-of-sale would ensure that negotiated prices ''take into account'' at least some price concessions and, therefore, would be consistent with and permitted by the plain language of section 1860D–2(d)(1)(B) of the Act.

The regulatory change we propose to adopt changes the reporting requirements for Part D sponsors; it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point-of-sale. We clarify this point because in comments on the solicitation in the November 2018 proposed rule (83 FR 62179) regarding a potential policy approach under which all pharmacy price concessions received by a plan sponsor for a covered Part D drug would be included in the negotiated price at the point-of-sale, some commenters posited that CMS requiring that all pharmacy price concessions be passed through at the point-of-sale, as opposed to being reported as DIR, would violate the statutory ''non-interference clause,'' at section 1860D–11(i) of the Act, which specifies that ''the Secretary . . . may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors.'' We disagree. Mandating that all pharmacy price concessions be included in the negotiated price at the point-of-sale does not interfere with the negotiations between plan sponsors, their PBMs, and pharmacies. Contracts between sponsors or their PBMs and pharmacies can continue to provide for performance-based payment adjustments. The requirement that pharmacy price concessions be passed through to the point-of-sale price only directly impacts the price that is used to determine beneficiary cost-sharing and the information that is populated and reported on the PDE record, but it does not dictate the amount that is ultimately paid to the pharmacy or the timing of payments and adjustments.

b. Lowest Possible Reimbursement

To effectively capture all pharmacy price concessions at the point-of-sale consistently across sponsors, we propose to require that the negotiated price reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point-of-sale would need to include all price concessions that could potentially flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow to network pharmacies and thus increase prices over the lowest possible reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that drug under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR as part of the annual report on DIR following the end of the year. For an illustration of how negotiated prices would be reported under such an approach, see the lowest cost reimbursement example provided later in this section of this proposed rule.

By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point-of-sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point-of-sale. We believe, based on the overwhelming support received from commenters on the Request for Information in the November 2017 proposed rule and the potential change to the definition of negotiated price discussed in the November 2018

proposed rule, that this is the best approach to achieve our goals, as noted previously, of—(1) consistency (standardized reporting of negotiated prices and DIR); (2) preventing cost-shifting to beneficiaries; and (3) price transparency for beneficiaries, the government, and other stakeholders.

Regarding consistency in reporting, we believe that the proposed requirement that the negotiated price reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug would, if implemented, provide a clearer reporting standard for Part D sponsors relative to the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception. We expect this increased clarity would reduce sponsor burden in terms of the resources necessary to ensure compliance. Finally, we believe that requiring all pharmacy price concessions be included in the negotiated price at the point-of-sale would improve the quality of drug pricing information available across Part D plans and thus improve market competition and cost efficiency under Part D.

Requiring the negotiated price to reflect the lowest possible pharmacy reimbursement as proposed would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements, and thus closer to the actual cost of the drug for the Part D sponsor. We have learned from the DIR data reported to CMS and feedback from numerous stakeholders that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties.

Finally, we propose that all contingent incentive payments (that is, an amount that is paid to the pharmacy instead of a price concession from the pharmacy) be excluded from the negotiated price. As noted previously, we understand that such incentive payments are rare. Furthermore, even in those instances in which a pharmacy may qualify for such a payment, including the amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a ''high performing'' pharmacy, which receives an incentive payment, than at a ''poor performing'' pharmacy, which is assessed a penalty, and would also reduce price transparency. This pricing differential could create a perverse incentive for beneficiaries to choose a ''lower performing'' pharmacy for the advantage of a lower price. Additionally, Part D sponsors and their intermediaries previously asserted in public comments on the 2017 and 2018 rules that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition as proposed would mitigate this concern by allowing sponsors and their intermediaries to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per claim. Further, we emphasize that the proposed changes would not require pharmacies to be paid in a certain way; rather we would be requiring standardized reporting to CMS of drug prices at the point-of-sale.

c. Lowest Possible Reimbursement Example

To illustrate how Part D sponsors and their intermediaries would report costs under our proposal, we provide the following example. Suppose that under a performance-based payment arrangement between a Part D sponsor and its network pharmacy, the sponsor will implement one of three scenarios: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy $100 at the point-of-sale, the pharmacy's final reimbursement under this arrangement would be: (1) $95 for poor performance; (2) $100 for average performance; or (3) $101 for high performance. Under the current definition of negotiated prices, the reported negotiated price is likely to be $100, given the reasonably determined exception for contingent pharmacy payment adjustments. However, under the proposed definition, for all three performance scenarios, the negotiated price reported to CMS on the PDE record at the point-of-sale for this drug would be $95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of $95, or $23.75, which is less than the $25 the enrollee would pay today (when the negotiated price is likely to be reported as $100). Finally, any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. Under this requirement, the sponsor would report $0 as DIR under the poor performance scenario ($95 minus $95), −$5 as DIR under the average performance scenario ($95 minus $100), and −$6 as DIR under the high-performance scenario ($95 minus $101), for every covered claim for this drug purchased at this pharmacy.

d. Additional Considerations

In order to implement the proposed change, we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point-of-sale. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to also collect the amount of point-of-sale pharmacy price concessions. We also would likely use fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession data at the plan and national drug code (NDC) levels. Differences between the amounts applied at the point-of-sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year. To implement the proposed change at the point-of-sale, Part D sponsors and their PBMs would load revised drug pricing tables that reflect the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies.

e. Negotiated Prices of Applicable Drugs in the Coverage Gap

The negotiated price of an applicable drug is also the basis by which manufacturer liability for discounts in the coverage gap is determined. Section 1860D–14A(g)(6) of the Act provides that, for purposes of the coverage gap discount program, the term ''negotiated price'' has the meaning it was given in § 423.100 as in effect as of the enactment of the Patient Protection and Affordable Care Act (PPACA), except that it excludes any dispensing fee for the applicable drug. Under that definition, which is codified in the

coverage gap discount program regulations at § 423.2305, the negotiated price is the amount the Part D sponsor (or its intermediary) and the network dispensing pharmacy (or other network dispensing provider) have negotiated as the amount such network entity will receive, in total, for a covered Part D drug, reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale, and net of any dispensing fee or vaccine administration fee for the applicable drug.

In the November 2018 proposed rule (83 FR 62179), we solicited comment on whether to require sponsors to include pharmacy price concessions in the negotiated price in the coverage gap. Under such an approach, the negotiated price of the applicable drug for purposes of determining manufacturer coverage gap discounts, would include all pharmacy price concessions as in all other phases of the Part D benefit under the proposed revision to the definition of negotiated price at § 423.100. Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has *elected* to pass through at the point-of-sale, we explained that we did not believe it would be appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, we indicated our belief that there would be authority under the statute to require sponsors to include all *pharmacy* price concessions in the negotiated price for purposes of the coverage gap discount program because such concessions necessarily affect the amount that the pharmacy receives in total for a particular applicable drug. We also noted that pharmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor were required to include all pharmacy price concessions in the negotiated price of an applicable drug at the point-of-sale, the plan sponsor must still make an election as to how much of the overall price concessions (including non-pharmacy price concessions) it receives will be passed through at the point-of-sale.

In the November 2018 proposed rule, we also sought comment on an alternative approach under which Part D sponsors would determine how much of pharmacy price concessions to pass through at the point-of-sale for applicable drugs in the coverage gap, and beneficiary, plan, and manufacturer liability would be calculated using this alternate definition of negotiated price.

The majority of the comments that addressed the possible inclusion of pharmacy price concessions in the negotiated price of applicable drugs in the coverage gap expressed support for applying the same definition of negotiated price in all phases of the Part D benefit, as they believed maintaining the same definition for all phases of the benefit would provide more transparency and consistency at the point-of-sale, minimize beneficiary confusion, and avoid the operational challenges of having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit. Some commenters disagreed with our assessment that CMS has the legal authority to require that all pharmacy price concessions be included in the negotiated price of applicable drugs in the coverage gap, as they felt this was at odds with the reference to ''price concessions that the Part D sponsor had elected to pass-through to Part D enrollees at the point-of-sale'' in the regulatory definition of ''negotiated price'' at § 423.100 as in effect when the PPACA was enacted. Commenters noted that if CMS were to adopt the alternative approach under which sponsors would be required to include pharmacy price concessions in the negotiated price for applicable drugs in all phases of the Part D benefit other than the coverage gap, it would be necessary for CMS to issue very specific guidance explaining how to operationalize different definitions of ''negotiated price'' for the coverage gap versus the non-coverage gap phases of the Part D benefit.

Although we continue to believe that section 1860D–14A(g)(6) of the Act would not preclude us from revising the definition of negotiated price at § 423.2305 to require Part D sponsors to apply all pharmacy price concessions for applicable drugs at the point-of-sale, we are not proposing to adopt such a mandate at this time. As demonstrated in the Regulatory Impact Analysis of this proposed rule (sections IV.D.8. and IV.E.2.), allowing plans flexibility with respect to the treatment of pharmacy price concessions for applicable drugs in the coverage gap will moderate increases to beneficiary premiums and government costs.

In summary, under our proposed approach, for non-applicable drugs in the coverage gap, and during the non-coverage gap phases of the Part D benefit for applicable drugs, claims would be adjudicated using the negotiated price determined using the lowest possible reimbursement to the pharmacy. In contrast, for applicable drugs during the coverage gap, plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point-of-sale, and beneficiary, plan, and manufacturer liability in the coverage gap would be calculated using this alternate negotiated price. Based on comments we received on the November 2018 proposed rule, we anticipate that if CMS adopts the proposed approach, we will need to provide technical or operational guidance to Part D sponsors regarding the calculation of the gap discount, PDE reporting, and straddle claim processing. We solicit comment on whether there are other topics CMS will need to address in new guidance if we finalize the proposed approach. We also request that commenters with concerns about the feasibility of sponsors having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit provide detailed explanations of their concerns, with specificity and examples.

In addition, we solicit comment on whether, as an alternative to our proposed approach, we should require that Part D sponsors apply pharmacy price concessions to the negotiated price of applicable drugs in the coverage gap. As noted above, we believe that such a requirement would also be consistent with section 1860D–14A(g)(6) of the Act.

4. Pharmacy Administrative Service Fees

As noted in the November 2018 proposed rule (83 FR 62179 and 62180), we are aware that some sponsors and their intermediaries believe certain fees charged to network pharmacies—such as ''network access fees,'' ''administrative fees,'' ''technical fees,'' and ''service fees''—represent valid administrative costs and, thus, do not believe such fees should be treated as price concessions. However, pharmacies and pharmacy organizations report that they do not receive anything of value for such administrative service fees other than the ability to participate in the Part D plan's pharmacy network.

Thus, we restate the conclusion we provided in the May 2014 final rule (79 FR 29877): When pharmacy administrative service fees take the form of deductions from payments to pharmacies for Part D drugs dispensed to Part D beneficiaries, they clearly represent charges that offset the sponsor's or its intermediary's operating costs under Part D. We believe that if

the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis.

The regulations governing the Part D program require that price concessions be fully disclosed. If not reported at all, these amounts would result in another form of so-called PBM spread in which inflated prices contain a portion of costs that should be treated as administrative costs. That is, even if these amounts did represent costs for services rendered by an intermediary organization for the sponsor, then these costs would be administrative service costs, not drug costs, and should be treated as such. Failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements (as required at section 1860D–11(e)(2)(C) of the Act and at § 423.272(b)(1) of the regulations) relative to another sponsor that accurately reports administrative costs consistent with CMS instructions.

5. Defining Price Concession (§ 423.100)

Section 1860D–2(d)(1)(B) of the Act stipulates that the negotiated price shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs. Section 1860D–2(d)(2) of the Act further requires that Part D sponsors disclose to CMS the aggregate negotiated price concessions by manufacturers that are passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. While ''price concession'' is a term important to the adjudication of the Part D program, it has not yet been defined in the Part D statute or in Part D regulations and subregulatory guidance. Therefore, to avoid confusion among Part D sponsors and other stakeholders of the Part D program resulting from inconsistent terminology, we propose to add a regulatory definition for the term ''price concession'' at § 423.100 that is consistent with how that term is used in paragraphs (d)(1)(B) and (d)(2) of section 1860D–2 of the Act.

In considering how to define price concession, we believe it is important to define the term in a broadly applicable manner, while maintaining clarity. Accordingly, we propose to define price concession to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors. The proposed definition would note that price concessions include but are not limited to discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

We believe the proposed approach would be consistent with the statute, support consistent accounting by Part D sponsors of amounts that are price concessions, and ensure that certain forms of discounts are not inappropriately excluded from being considered price concessions. An alternative would be not to define ''price concession'' at all. However, this option would not support consistent accounting of amounts that are price concessions among Part D sponsors, which we believe is particularly important in light of the proposed change to the definition of negotiated price.

We note that adopting the proposed definition of price concession would not affect the way in which price concessions must be accounted for by Part D sponsors in calculating costs under a Part D plan. Defining the term ''price concession'' as proposed would not require the renegotiation of any contractual arrangements between a sponsor and its contracted entities. Therefore, the proposed definition of price concession has no impact under the federal requirements for Regulatory Impact Analyses.

III. Requests for Information

A. Request for Information: Prior Authorization for Hospital Transfers to Post-Acute Care Settings During a Public Health Emergency

We are committed to ensuring that hospitals, post-acute care facilities (including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), and skilled nursing facilities (SNFs)), physicians, and MA organizations have the tools necessary to provide access to appropriate care to patients without unnecessary delay during a public health emergency (PHE). Throughout 2020 during the Coronavirus Disease 2019 Public Health Emergency (COVID–19 PHE), we consistently issued guidance to address permissible flexibilities for MA organizations as part of an ongoing effort to help MA enrollees, and the health care systems that serve them, avoid delays and disruptions in care. We recognize that any delays or disruptions in care that might transpire within the MA program could have a ripple effect and also negatively impact the timely provision of appropriate care to patients covered under payer systems external to MA (for example, employer-sponsored insurance). Additionally, we recognize the positive impact that payers in general can have through the adoption of flexibilities that support hospitals' ability to effectively manage resources when a hospital experiences a substantial uptick in hospitalizations.

As a result of the guidance and clarification that we issued throughout 2020, a large proportion of MA organizations opted to relax or completely waive their prior authorization requirements with respect to patient transfers between hospitals and post-acute care facilities during plan year 2020, consistent with our guidance encouraging flexibility to ensure access to care. However, as the PHE continued into 2021, many MA organizations reinstated prior authorization requirements, which some stakeholders reported contributed to capacity issues and delays in care within hospital acute care settings. For example, one stakeholder reported that only 5 percent of intensive care unit (ICU) beds were open in their state during the month of August 2021, and stated that the scarcity of available beds could be mitigated if more MA organizations reinstated waivers on prior authorization requirements for patient transfers. Another stakeholder reported that it was not uncommon for a hospital to wait up to 3 business days to receive a decision from an MA organization for a request for a patient transfer—a delay which prevented hospitals from moving patients to the next appropriate care setting in a timely manner and forced the unnecessary use of acute-care beds. The same stakeholder reported that a high rate of initial denials from MA organizations also contributed to delays in patient transfer. We acknowledge our responsibility to ensure that our programs' policies do not hinder access to care, especially during a public health emergency. Therefore, in response to these reports and the uptick in COVID–19 hospitalizations across the country, we are seeking information from stakeholders in order to assess the impact of MA organizations' use of prior authorization or other utilization management criteria during certain

PHEs. Through this request for information (RFI), CMS seeks additional information from all affected stakeholders, especially MA organizations, hospitals, post-acute care facilities, professional associations, states, and patient advocacy groups regarding the effects of both the relaxation of and reinstatement of prior authorizations on patient transfers during a PHE.

We remain mindful of the impact the MA program's policies have on the health care system as a whole, and strongly encourage MA organizations to continuously re-assess the need for flexibilities in their utilization management practices. We note that with regard to prior authorization and other utilization management practices, we permit MA organizations the choice to uniformly waive or relax plan prior authorization requirements at any time in order to facilitate access to care, even in the absence of a disaster, declaration of a state of emergency, or PHE. Generally, MA organizations are required to ensure that enrollees are notified of changes in plan rules of this type in accordance with § 422.111(d); however, when the provisions under § 422.100(m)(1) go into effect during a disaster or emergency as they did during the COVID–19 PHE, MA organizations are permitted to immediately implement plan changes that benefit enrollees, including a waiver of prior authorization requirements, without the 30-day notification requirement at § 422.111(d)(3).

We invite the public to submit comments for consideration as CMS assesses the impact of MA organizations' prior authorization requirements for patient transfer on a hospital's ability to effectively manage resources and provide appropriate and timely care during a PHE. The primary objective of this RFI is for us to glean information from stakeholders about the effects of MA organizations' prior authorization requirements for patient transfers on a hospital's ability to furnish the appropriate care to patients in a timely manner in the context of a PHE. This is a general RFI related to prior authorizations on patient transfers during any PHE. While many commenters may choose to provide information in the context of the COVID–19 PHE, we welcome and encourage commenters to provide information in the context of any PHE.

Responses to this RFI may include, but are not limited to the following:

- The overall impact of both the relaxation and reinstatement of prior authorization requirements for patient transfer by MA organizations on the provision of appropriate patient care in hospital systems.
- The overall impact of both the relaxation and reinstatement of prior authorization requirements for patient transfer on MA organizations.
- Wait times for receiving a response from an MA organization about the authorization of a patient transfer.
- Information pertaining to industry guidelines that are used to inform prior authorization, including the extent to which such guidelines are evidence-based, the degree of transparency that exists for such guidelines, and the extent to which such guidelines are standardized.
- With respect to MA organizations, the denial rates and associated burden, including rates at which denials are upheld and overturned, for prior authorizations for patient transfer from hospitals to post-acute care facilities.
- Any consequences of delayed patient transfer from hospitals to post-acute care facilities.
- Recommendations for how CMS can accommodate hospital systems that face capacity issues through policy changes in the MA program.
- Examples of any contrast in a state's policies for payers (for example, Medicaid managed care) with respect to prior authorizations for patient transfer that do not pertain to MA organizations, and the effects of such policies on hospitals systems' ability to effectively manage resources.

We request that all respondents provide complete, clear, and concise comments that include, where practicable, data and specific examples.

B. Request for Information: Building Behavioral Health Specialties Within MA Networks

CMS is dedicated to ensuring that MA beneficiaries have access to provider networks sufficient to provide covered services in accordance with our standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1). Accordingly, CMS strengthened network adequacy rules for MA plans by codifying our network adequacy standards at § 422.116 through the June 2020 final rule.

Currently, we require MA organizations to submit data for behavioral health providers, specifically psychiatry (provider-specialty type) and inpatient psychiatric facility services (facility-specialty type), using the Health Service Delivery (HSD) tables. The HSD tables are submitted to CMS during an organization's formal network review and are utilized to demonstrate compliance with network adequacy standards. The HSD tables must list every provider and facility with a fully executed contract in the organization's network, and are uploaded to the Health Plan Management System (HPMS) for an automated review. MA plans must have sufficient providers with a certain time and distance of 85 or 90 percent of beneficiaries residing the plan's service area, depending on the type of counties in the service area, under § 422.116. We also encouraged plans to provide more choices for enrollees to access care using telehealth for certain specialties, including psychiatry, through our policy under § 422.116(d)(5), while maintaining enrollees' right to access in person care for these specialty types. To encourage and account for telehealth providers in contracted networks, § 422.116(d)(5) provides MA plans a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards when the plan includes in its network telehealth providers for certain specialties. However, despite requiring a minimum number of behavioral health providers and encouraging use of telehealth providers, CMS understands that MA organizations may experience difficulties when building an adequate network of behavioral health providers.

In order to increase our understanding of issues related to access to behavioral health specialties for enrollees in MA plans, we are interested in comments from industry stakeholders related to the challenges MA organizations face when building an adequate network of behavioral health providers for MA plans. Therefore, we invite comment from interested stakeholders regarding these issues. Comments for this RFI can include, but are not limited to:

- Challenges related to a lack of behavioral health provider supply in certain geographic regions for beneficiaries, health plans, and other stakeholders;
- Challenges related to accessing behavioral health providers for enrollees in MA health plans, including wait times for appointments;
- The extent to which a behavioral health network affects a beneficiary's decision to enroll in an MA health plan;
- Challenges for behavioral health providers to establish contracts with MA health plans;
- Providers' inability or unwillingness to contract with MA plans, including issues related to provider reimbursement;
- Opportunities to expand services for the treatment of opioid addiction and substance use disorders;
- The overall impact of potential CMS policy changes as it relates to

network adequacy and behavioral health in MA health plans, including in rural areas that may have provider shortages;

• Suggestions from industry stakeholders on how to address issues with building adequate behavioral health networks within MA health plans.

C. Request for Comment on Data Notification Requirements for Coordination-Only D–SNPs (§ 422.107(d))

Section 50311(b) of the BBA of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(i)(I) to require that the Secretary establish additional integration requirements for D–SNPs' contracts with State Medicaid agencies. In the April 2019 final rule, we implemented section 1859(f)(8)(D)(i)(I) of the Act by establishing at § 422.107(d) that any D–SNP that is not a FIDE SNP or HIDE SNP is subject to an additional contracting requirement effective January 1, 2021. Under this new requirement for the contract that is required between the D–SNP and the State Medicaid agency, the D–SNP is required to notify the State Medicaid agency, or individuals or entities designated by the State Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the State Medicaid agency.

These data notification requirements have only been in effect for a few months, all of which coincided with the COVID–19 public health emergency. Through this proposed rule we invite MA organizations, States, and other stakeholders to submit comments on their experience implementing the data notification requirements thus far and any suggested improvements for CMS consideration in future rulemaking.

D. Collection of Information Requirements

This proposed rule contains several requests for information. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that these RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposals (RFPs), applications, proposal abstracts, or quotations. These RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through these RFIs and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. We note that not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential respondents to monitor these RFI announcements for additional information pertaining to these requests. In addition, we note that we will not respond to questions about the policy issues raised in these RFIs.

We will actively consider all input as we develop future plans and policies. We may or may not choose to contact individual respondents. Such communications would be for the sole purpose of clarifying statements in the respondents' written responses. Contractor support personnel may be used to review responses to these RFIs. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's implementing regulations.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

A. Wage Data

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*), which, at the time of drafting of this rule, provides May 2020 wages. In this regard, Table 4 presents BLS' mean hourly wage along with our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 4—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Business Operation Specialists, All Other	13–1198	40.53	40.53	81.06
Compliance Officers	13–1041	36.35	36.35	72.70
Computer and Information Systems Managers	11–3021	77.76	77.76	155.52

TABLE 4—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES—Continued

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Lawyer	23–1011	71.59	71.59	143.18
Software and Web Developers	15–1250	52.86	52.86	105.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent to account for fringe benefits and overhead costs that vary from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within section II. of this proposed rule.

1. ICRs Regarding Enrollee Participation in Plan Governance (§ 422.107)

The proposed requirement and burden for D–SNPs to create one or more enrollee advisory committees will be submitted to OMB for review under control number 0938–TBD (CMS–10799). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

The proposed requirement and burden for D–SNPs to update audit protocols to require documentation of the enrollee advisory committees will be submitted to OMB for review under control number 0938–1395 (CMS–10717).

a. Creating One or More Enrollee Advisory Committees

At § 422.107(f), we propose that any MA organization offering a D–SNP must establish one or more enrollee advisory committees at the State level or other service area level in the State to solicit direct input on enrollee experiences. We also propose at § 422.107(f) that the committee include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan, or plans, or other individuals representing those enrollees and solicit input from these individuals or their representatives on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

The burden of establishing and maintaining an enrollee advisory committee is variable due to the flexibilities MA organizations would have to implement the proposed requirements. We believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement, and therefore, we chose not to propose the specific: (1) Frequency; (2) location; (3) format; (4) participant recruiting and training methods; (5) number of committees (for example, one committee at the State level to serve all of the MA organization's D–SNPs in that State or more than one committee); (6) utilization of existing committees which would meet the requirements of both §§ 438.110 and 422.107(f) (we expect this approach to be used by FIDE and HIDE SNPs); (7) use and adoption of telecommunications technology; and (8) other parameters. Instead, the only requirements proposed in this rule for an MA organization offering one or more D–SNPs in a State would be to establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization and for that committee to solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the D–SNP(s), or other individuals representing those enrollees. The enrollee advisory committee may also advise managed care plans under title XIX of the Act offered by the same parent organization as the MA organization offering a D–SNP.

To determine the burden for MA organizations to establish the proposed enrollee advisory committees, we reviewed two estimates from similar committees.

First, the May 2016 final rule (81 FR 27778) estimated it will take 6 hours annually for a business operations specialist to establish and maintain the LTSS member advisory committee requirement codified at § 438.110 for Medicaid managed care plans.

Second, in 2021 we conducted an informal survey of the three South Carolina MMPs under the capitated FAI demonstration that are required to conduct meetings quarterly and highly value their advisory committees. The MMPs surveyed estimated an annual average of 240 hours (or 60 hours per meeting) to recruit members and establish and maintain the committee. We expect these efforts to include outreach and communication to members, developing meeting agendas, scheduling participation of presenters, preparing meeting materials, identifying meeting location and technology, D–SNP staff attendance at the meeting, and disseminating enrollee feedback to D–SNP and MA organization staff.

Due to the variety of flexibilities in creating the proposed enrollee advisory committee, detailed in the opening paragraph of this ICR, we expect the average time and annual cost for a MA organization to establish and hold an enrollee advisory committee meeting to be somewhere between 6 hours estimated for the requirement at § 438.110 and 240 hours as reported by MMPs. We believe this large difference in the time spent comes from two sources: (1) the requirement that the committee created by MMPs meet quarterly rather than annually and (2) MMPs find value in their committees and have invested more staff and resources to recruit enrollees, and prepare for and hold meetings. For example, MMPs often provide transportation to meetings, refreshments, and nominal incentives for participation, none of which is required by the capitated FAI demonstration or this proposed rule. We have used a 40-hour estimate and the services of a business compliance officer to assess burden with the understanding that a wide variety of approaches would probably be used.

Each MA organization offering one or more D–SNPs in a State would decide how to establish an enrollee advisory committee based on the MA organization's approach to obtaining maximal input from enrollees leading to the highest quality enrollee experience. Because of this wide variability, we

solicit stakeholder comments on our assumptions and burden estimates.

For purposes of this proposed rule for establishing an enrollee advisory committee, we are estimating each MA organization would spend 40 hours at a cost of $3,242 (40 hr × $81.06/hr for a business operation specialist).

We believe all FIDE SNPs and HIDE SNPs that provide LTSS currently have an enrollee advisory committee since they have a Medicaid managed care plan that must comply with § 438.110. Of the 596 D–SNP PBPs for CY 2021, we estimate 478 do not have a corresponding Medicaid managed care plan that provides LTSS. Several of these D–SNP PBPs are in the same State and under the same contract, which means only one enrollee advisory committee is necessary to meet the proposed requirement. Therefore, we estimate MA organizations operating D–SNPs will need to establish 260 new enrollee advisory committees.

Thus, the aggregate minimal annual burden for MA organizations operating D–SNPs to meet the proposed requirements of § 422.107(f) is 10,400 hours (260 new committees × 40 hr per committee) at a cost of $843,024 (10,400 hr × $81.06/hr). As stated above, the proposed requirement and burden will be submitted to OMB for review under control number 0938–TBD (CMS–10799).

b. Updates to Audit Protocols

As noted in section II.A.3. of this proposed rule, we anticipate updating the CMS SNP Care Coordination audit protocols [142] for MA organizations offering one or more D–SNPs to require documentation, such as a committee member list and meeting minutes, of the enrollee advisory committee meetings. Currently, control number 0938–1395 (CMS–10717) estimates the audit protocol and data request burden at 701 hours per MA organization at an average hourly cost of $87.00/hr, totaling $60,987 per MA organization (701 hr × $87.00/hr). We believe MA organizations offering D–SNPs would retain a committee member list and meeting minutes as part of customary business practices; therefore, we do not believe reporting this documentation on the enrollee advisory committee would impact our currently approved 701 hr audit protocol estimate.

While we do not anticipate any changes to our active time estimates, if this proposal is finalized we would revise the SNP Care Coordination audit protocol prior to the effective date of the rule to provide stakeholders the ability to comment on the contents of the document. The CMS–10717 package would be made available to the public for review/comment under the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

2. ICRs Regarding Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessment (§ 422.101)

The following proposed HRA question changes will be submitted to OMB for review under control number 0938–TBD (CMS–10799). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

The proposed changes to our SNP audit protocols will be submitted to OMB for review under control number 0938–1395 (CMS–10717). Subject to renewal, the control number is currently set to expire on May 31, 2024. It was last approved on May 8, 2021, and remains active.

a. Added HRA Questions

As described in section II.A.4. of this proposed rule, we propose requiring that SNPs include specific questions on housing stability, food security, and access to transportation specified in sub-regulatory guidance as part of their HRAs. This proposal, if finalized, would result in SNPs having a more complete picture of the risk factors that may inhibit beneficiaries from accessing care and achieving optimal health outcomes and independence. We do not believe that collecting this information would require any additional efforts from SNPs outside of customary updates to the HRA tools. Due to the current requirement at § 422.101(f) that the HRA include an assessment of the individual's physical, psychosocial, and functional needs, we believe that many SNPs are already including questions related to housing stability, food security, and access to transportation in their HRA tools. Therefore, if this proposal is adopted, most SNPs would revise their HRA tools to use our standardized questions. If a SNP is not already asking these questions, we do not predict the addition of questions on these three topics would lengthen the time to administer a typical HRA.

CMS does not currently collect specific data elements from HRAs for all SNP enrollees. By standardizing HRA questions in our proposed rule, CMS would be able to collect those specific data elements; however, CMS will not be collecting data elements from the HRA as part of this collection of information.

We estimate a one-time burden (over the next three years) for the parent organizations offering SNPs to update their HRA tools in their care management systems and adopt our standardized questions on housing stability, food security, and access to transportation. It is possible that we would change the standardized questions in the future, thereby making the burden of our proposal more than a one-time burden. However, we have no plans at this point to change the standardized questions once we establish them. Therefore, we are unable to reliably estimate the additional burden in subsequent years.

We assume that each parent organization with one or more SNPs would update the care management system where an enrollee's HRA responses are recorded. We believe that it would take a software programmer 3 hours at $105.72/hr to update the care management system resulting in a cost of $317 (3hr × $105.72/hr) per parent organization. For CY 2021, there are 123 parent organizations with a SNP PBP. In aggregate, we estimate a one-time burden for updating the HRA tool of 369 hr (123 parent organizations × 3 hr) at a cost of $39,011 (369 hr × $105.72/hr). After the finalization and implementation of our proposed rule, we will reassess the impact of future updates to these HRA questions. As stated above, the proposed requirements and burden will be submitted to OMB for review under control number 0938–TBD (CMS–10799).

b. Updates to Audit Protocols

The proposed change to the HRA would also require an update to the CMS SNP Care Coordination audit protocols [143] that ensure the completed HRA includes the assessment of housing stability, food security, and access to transportation. Currently, audit protocol and data request burden are estimated at 701 hours per MA organization at an average hourly cost of $84.00/hr, totaling $58,884 per MA organization.

We do not believe the changes to SNP audit protocols would add more time to the 701-hour audit protocol estimate as

[142] See *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

[143] See *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

we are adding a confirmation that the SNP's HRA includes the proposed changes as part of the SNP Care Coordination Audit protocols.

While we do not anticipate any changes to our active time estimates, if this proposal is finalized, we would revise the audit protocol documents prior to the effective date of the rule to provide stakeholders the ability to comment on the contents of the document. The CMS–10717 package would be made available to the public for review/comment under the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

As stated in section II.A.4. of this proposed rule, CMS will consider collecting data from the SNPs on responses to the specified HRA questions. However, we are not proposing such requirements at this time. We welcome comment on our assumptions regarding the collection of information burden for this proposal.

3. ICRs Related to Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§ 422.2)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD2 (CMS–10796). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

As described in section II.A.5. of this proposed rule, we propose several changes to the definitions of FIDE SNPs and HIDE SNPs at § 422.2 that we believe will ultimately help to differentiate various types of D–SNPs and clarify options for beneficiaries and stakeholders. Our proposal for the FIDE SNP definition requires these plans to have exclusively aligned enrollment, cover Medicare cost-sharing, and cover the Medicaid benefits of home health, DME, and behavioral health through a capitated contract with the State Medicaid agency. We propose to require that each FIDE SNP's and HIDE SNP's capitated contract with the State Medicaid agency apply to the entire service area for the D–SNP for plan year 2025 and subsequent years. We also propose to codify existing policy outlined in sub-regulatory guidance to permit, subject to CMS approval, specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs through the State Medicaid agency contract submission process.

Due to the proposed changes in the definition of FIDE SNP and HIDE SNP, a D–SNP may need to update its contract with the State Medicaid agency to come into compliance with the proposed changes at § 422.2. The currently approved annual burden estimate for updating the State Medicaid agency contract is 30 hours per D–SNP as described in OMB control number 0938–0753 (CMS–R–267). While the proposed changes may result in a one-time change to the contract, we believe the changes to the contract language would be relatively minor (even though the changes are substantive in nature) and part of routine updates to contracts such as changes of dates. We also believe that the contract changes would be subsumed in the 30-hour burden estimate for updating the contract annually. Therefore, we do not estimate our proposed changes to these definitions at § 422.2 would impact our currently approved annual 30 hr contracting burden estimate for D–SNPs.

The proposed changes to the FIDE SNP and HIDE SNP definitions may change how D–SNPs attest when submitting their State Medicaid agency contract to CMS. The burden is currently estimated under OMB control number 0938–0935 (CMS–10237). We do not estimate D–SNPs would experience an increase in their per response time or effort to submit the State Medicaid agency contract to CMS.

However, if proposed changes to the FIDE and HIDE definitions are finalized, then we would update the content of the collection of information to reflect the changes to § 422.2. If this proposal is finalized, we would revise the 5.11 D–SNP State Medicaid Agency Contract Matrix and 5.12 D–SNP State Medicaid Agency Contract Matrix documents connected to control number 0938–0935 (CMS–10237) and move these documents to control number 0938–TBD2 (CMS–10796). We believe including these forms in a separate OMB control number 0938–TBD2 (CMS–10796) exclusively for the D–SNP State Medicaid agency contracts is more operationally consistent with the collection of information required from MA organizations.

a. Service Area Overlap Between HIDE SNPs and Companion Medicaid Plans

Besides the updates to the documents currently under control number 0938–0935 (CMS–10237) described in this section, section II.A.5.f. of this proposed rule would require the service area of a FIDE SNP or HIDE SNP to overlap with companion Medicaid plans; therefore, the 20 HIDE SNPs that have service area gaps with their affiliated MCOs would make a business decision regarding how to comply with the requirement in addition to updating the State Medicaid agency contract with the D–SNP. We believe that only one-third of the 20 impacted D–SNPs, or 7 D–SNPs, would choose to remain a HIDE SNP. The remaining 13 D–SNPs would contract with the State as a non-HIDE D–SNP and not incur additional burden.

A D–SNP that wishes to remain a HIDE SNP would submit a new D–SNP PBP for the service area that does not overlap with the D–SNP's companion Medicaid plan during the annual bid submission process (OMB control number 0938–0763 (CMS–R–262)). Also, under the annual bid submission process, the existing HIDE SNP would reduce their MA service area to that which overlaps with the companion Medicaid plan.

The currently approved annual burden estimate for D–SNPs to update PBPs is 35.75 hours per MA contract as described in OMB control number 0938–0763 (CMS–R–262). We do not estimate D–SNPs would experience an increase in their response time or effort to submit the bid to CMS.

Alternatively, to remain a HIDE SNP, the MA organization can work with the State Medicaid agency to expand the service area of the companion Medicaid plan to align with the D–SNP service area. However, State Medicaid procurement time frames and contracting strategies may not provide the 20 D–SNPs impacted by the proposed the opportunity to expand the service area of the companion Medicaid plan in CY2025.

In section II.A.5.f. of this proposed rule, we discuss alternatives to the proposed changes to the FIDE SNP and HIDE SNP definitions regarding service area overlap with the companion Medicaid plan. For example, we are considering requiring a minimum level of service area overlap for the FIDE SNP or HIDE SNP and the companion Medicaid plans rather than full overlap. We request comment on how these alternatives may change the estimates for impacted D–SNPs if they were finalized.

4. ICRs Related to Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

As described in section II.A.6. of this proposed rule, we propose to add a new paragraph (e) at § 422.107 to describe conditions through which States may require certain contract terms for D–SNPs and how CMS would facilitate

compliance with those contract terms. Proposed paragraph (e)(1) would allow States, through the State Medicaid agency contract with D–SNPs, to require that certain D–SNPs with exclusively aligned enrollment (a) establish MA contracts that only include one or more D–SNPs within a State, and (b) integrate materials and notices for enrollees. A more detailed discussion of the proposed requirements and associated burden follows:

a. State Medicaid Agency Contract Requirements

The following proposed changes will be submitted to OMB for review under control number 0938–TBD2 (CMS–10796). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

For States that opt to require the contract requirements at proposed § 422.107(e), States and plans would be required to modify the existing State Medicaid agency contract. These modifications would document the D–SNP's responsibility to only enroll dually eligible individuals who receive coverage of Medicaid benefits from the D–SNP, integrate member materials, and request that CMS establish an MA contract limited to D–SNPs within the State.

(1) State Burden

Section 1903(a)(7) of the Act requires the Federal government to pay a match rate for administrative expenses. Since cost is split between the State Medicaid agency and the Federal government, we split in half the total costs, half of which the States incur and half of which the Federal government incurs, associated with administering the Medicaid program. The Federal government's cost is presented in the RIA section of this rule (see section V.D.3).

For each State Medicaid agency, it would take a total of 24 hours at $143.18/hr for State staff to update the State Medicaid agency's contract with the D–SNPs in its market to address the changes in this proposed rule. This estimate includes the cost to negotiate with the D–SNPs on contract changes and engage with CMS to ensure contract changes meet the proposed requirements at § 422.107(e).

Based on our experience, we expect that each State Medicaid agency will establish uniform contracting requirements for all D–SNPs operating in their market. We are uncertain of the exact number of States that would opt to require these proposed contract changes over the course of the first 3 years after the effective date (contract years 2025 to 2027). Based on our previous work with States as part of the capitated FAI demonstration and implementing the D–SNP integrations requirements established by the BBA of 2018, we estimate as few as five and as many as 20 States may opt to make these changes in their contracts with D–SNPs and their administration of their programs. Based on the number of States currently collaborating with CMS on Medicare and Medicaid integration and the States likely to transition from MMP-based to D–SNP-based integrated care approaches, we believe there will be 12 states that implement this rule in the first 3 years. We further expect these 12 States to implement this one-time change during the first year it is effective.

Section 1903(a)(7) of the Act requires the Federal government to pay half the States' administrative costs. Therefore, for purposes of the COI we interpret that the states will incur costs for only 12 hours (0.5 × 24 hours); the other 12 hours of work are paid for by the Federal government and therefore we account for these other 12 hours in the RIA. This division of the 24 hours into two 12-hour parts is also consistent with COI requirements that aggregate amounts reflect hour and wage/hr burden. Thus, the cost to each State would be $1,718 per State (1 State × 12 hr × $143.18/hr). The aggregate burden to 12 States would be 144 hours (12 States × 12 hours/State) at an aggregate one-time cost of $20,618 (144 hr × $143.18/hr). After this first-year one-time requirement is satisfied, and given the uncertainty involved in estimating State behavior, we are estimating zero burden in subsequent years on States.

As mentioned previously, the other half of the burden will be presented in the RIA.

(2) MA Organization Burden

For the initial year, we expect each affected D–SNP would take 8 hours at $143.18/hr for a lawyer to update the contract with the State Medicaid agency to reflect the revised and new provisions proposed in this rule at § 422.107(e). Based on our assumptions of States likely to opt to require the proposed contract changes, we estimate between 40 to 80 MA organizations would be impacted in the first three years. Since we are uncertain of which extreme to use, we use the average, 60 MA organizations per year. We further expect the updates to be done in the first year these regulations are effective. In aggregate we estimate a one-time burden of 480 hours (60 MA organizations × 8 hr) at a cost of $68,726 (480 hr × $143.18/hr).

b. Limiting Certain Medicare Advantage Contracts to D–SNPs

The following proposed changes regarding additional Part C application respondents will be submitted to OMB for review under control number 0938–0935 (CMS–10237). Subject to renewal, the control number is currently set to expire on January 31, 2024. It was last approved on January 19, 2021 and remains active.

The following proposed changes regarding additional Part D application respondents will be submitted for OMB approval under control number 0938–0936 (CMS–10137). Subject to renewal, the control number is currently set to expire on July 31, 2024. It was last approved on July 27, 2021 and remains active.

We propose at § 422.107(e) to codify a pathway by which States would require and CMS would permit MA organizations—through the existing MA application process—to establish MA contracts that only include one or more D–SNPs with exclusively aligned enrollment within a State. This action would allow dually eligible individuals to ascertain the full quality performance of a D–SNP and better equip States to work with their D–SNPs to improve health equity.

We note that creating a new D–SNP-only contract would have several downstream collection of information impacts for an MA organization that are captured under the two aforementioned control numbers, the most immediate of which is the MA organization would need to complete a new application for Parts C and D.

Our estimate is that 60 D–SNPs will be impacted by our proposed changes to § 422.107(e). Currently, 32 percent of D–SNPs are in D–SNP-only contracts; [144] therefore, we estimate that 19 of the 60 D–SNPs (60 D–SNPs × 0.32) impacted would already have a D–SNP-only contract and not need to submit a new Part C and D application. The remaining 41 D–SNPs (60—19 D–SNPs) would need to submit both a new Part C and a new Part D application.

The burden for an initial Part C application for a SNP is currently approved by OMB under control number 0938–0935 (CMS–10237) at 10 hours at $72.70/hr for a compliance officer to review instructions and complete the proposal (including

[144] HPMS, Contract Management Reports 2020, SNP Type and Subtype Report, August 7, 2020.

submission) at a cost of $727 per contract (10 hr × $72.70/hr). Under this proposed rule, the currently approved burden for one-time Part C applications would increase by 410 hours (10 hr × 41 D–SNPs) and $29,807 (410 hr × $72.70/hr).

The burden for an initial Part D application for an MA–PD plan is currently approved by OMB under control number 0938–0936 (CMS–10137) at 6.41 hours for a compliance officer to review instructions and complete the proposal (including submission) at a cost of $466 per contract (6.41 hr × $72.70/hr). The aggregate one-time burden for 41 D–SNPs to complete an initial Part D application for an MA–PD plan is 263 hours (6.41 hr × 41 affected D–SNPs) at a cost of $19,120 (263 hr × 72.70/hr).

We acknowledge there may be additional downstream collection of information impacts for new contracts related to Part C and D reporting and CMS monitoring at the contract level. For example, MA organizations would experience additional reporting to CMS, calculation of HEDIS measures, and administration of HOS and CAHPS surveys. We are uncertain of the extent of the additional burden incurred for reporting as a separate contract. We request comments on these impacts for a new contract under an already existing MA organization and if they should be included in our estimates.

c. Integrated Member Materials

As described in section II.A.6.b. of this proposed rule, to provide a more coordinated beneficiary experience, we propose at § 422.107(e) to codify a pathway by which States and CMS would collaborate to establish model materials when a State chooses to require through its State Medicaid agency contract that certain D–SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. Proposed § 422.107(e)(1)(ii) establishes factual circumstances that would commit CMS to certain actions under paragraphs (e)(2) and (3).

We do not estimate any additional burden for States or plans to implement integrated member materials at proposed § 422.107(e) due to existing State efforts to work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D–SNPs to populate Medicaid benefits for Medicare member materials. Since requirements imposed on the Federal government are not subject to the PRA, we describe costs to the Federal government's burden to develop integrated member materials in section V.D.3.a. of this preamble.

5. ICRs Related to Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561)

The following proposed changes would be submitted to OMB for review under control number 0938–TBD2 (CMS–10796). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request. In § 422.561, we propose to expand the universe of D–SNPs with unified grievance and appeals processes by revising the definition of the term ''applicable integrated plan,'' which establishes the scope of plans that are subject to the requirement to use those unified processes. Unified grievance and appeals processes were originally limited to FIDE SNPs and HIDE SNPs; however, after our implementation experience, we believe that there are models of integrated D–SNPs other than FIDE SNPs and HIDE SNPs that are also amenable to the unified grievance and appeals processes.

If finalized, additional D–SNPs would be implementing the unified grievance and appeals procedures under §§ 422.629 through 422.634. We anticipate that the D–SNPs impacted by this rule would be D–SNPs in California with exclusively aligned enrollment, including those plans receiving Cal MediConnect members at the end of the California capitated FAI demonstration.

Consistent with our currently approved burden estimates, we continue to estimate a one-time burden for each new applicable integrated plan to update its policies and procedures to reflect the new integrated organization determination and grievance procedures under § 422.629. We anticipate this task would take a business operation specialist 8 hours at $81.06/hr. In aggregate, we estimate a one-time burden of 104 hours (8 hr × 13 D–SNPs) at a cost of $8,430 (104 hr × $81.06/hr).

While new D–SNPs would use the CMS–10716 denial notice at OMB control number 0938–1386 rather than the CMS–10003 MA denial notice under OMB control number 0938–0829, neither of the notices nor burden estimates would be revised as a result of this rule's proposal. As indicated above, the rule's proposed changes will be submitted to OMB under control number 0938– TBD2 (CMS–10796).

The CMS–10716 denial notice required under § 422.631(d)(1) includes information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights would be a new requirement for the impacted D–SNPs, we note that the timeframe for sending a notice and the content of the notice are largely the same as the current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)); therefore, impacted D–SNPs are not incurring additional burden to send the notification. Setting out such burden would be duplicative.

6. ICRs Related to Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

As described in section II.A.12. of this proposed rule, we are proposing a revision to which costs accumulate toward the MOOP limit for dually eligible enrollees with cost-sharing protections under § 422.101 for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. CMS proposes that all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit. This would ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit, the MA plan must pay 100 percent of the cost of covered Medicare Part A and Part B services. MA plans are currently tracking all costs accrued as part of preparing to submit an accurate plan benefit package bid (OMB control number 0938–0763 (CMS–R–262)); therefore, this proposal does not add additional requirements or burden.

This proposal would update current guidance governing MA organization bid requirements, which are captured under our active OMB control number 0938–0763 (CMS–R–262). We do not believe there is additional material burden resulting to plans that would arise from the proposed changes. As such, non-PRA related burden can be found in section V.D.4 of this preamble.

7. ICRs Related to Network Adequacy (§ 422.116(a)(i)(ii) and (d)(7))

The following proposed changes, although carrying no burden, will be submitted to OMB for review under control number 0938–1346 (CMS–10636).

In this rule we propose to require compliance with CMS' network adequacy standards for initial and service area expansion (SAE) applicants as part of the MA application process. Therefore, our proposal would require that initial and SAE provider networks be submitted and reviewed in February instead of June (with plans being reviewed for the triennial review).

Consequently, the number of reviews and the amount of work is the same; rather, it is being re-distributed.

8. ICRs Related to the Disclaimer for Preferred Pharmacy (§ 423.2267(e)(40))

The following proposed disclaimer changes carry no burden. Section 423.2267(e)(40) would require Part D sponsors to insert CMS standard disclaimer on materials that mention preferred pharmacies. The burden associated with this requirement would be the time and effort to copy the disclaimer on plan documents during document creation. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(c)(2). We believe that the time, effort, and financial resources to comply with the information collection requirements would be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practice.

This disclaimer is currently described in CMS's sub-regulatory guidance, the MCMG, and would be codified in this proposed regulation. The disclaimer provides an important safeguard to Medicare beneficiaries enrolled in a Part D plan that only provide access to preferred cost sharing through a limited number of pharmacies by alerting them that the preferred costs may not be available at the pharmacy they use, as well as providing information on how to access the list of pharmacies offering prescription drugs as a preferred cost in the beneficiary's area.

9. ICRs Related to Member Identification Cards (§§ 422.2267(e)(30) and 423.2267(e)(32))

The following proposed changes carry no burden. Although subject to PRA, Member Identification Cards are exempt since the issuance of Medicare Identification Cards is a normal and customary practice throughout the insurance industry. Health plans, whether commercial, through Medicare or Medicaid, or Original Fee-For-Service issue cards that inform providers of the enrollees insurance. Based on the exemption we will not be submitting this to OMB for review.

This proposal is a codification of previously issued sub-regulatory guidance in the MCMG defining standards for member identification cards issued by MA plans and Part D plan sponsors.

CMS created this subregulatory guidance to reduce Medicare beneficiary confusion through bringing consistency to member ID card requirements by applying standards so that ID cards from plan to plan contained the same information in the same locations.

The member identification card standard provided in the previously issued sub-regulatory guidance was created using an industry standard for ID cards; these industry standards reflected best practices and consequently plans found the previously issued sub-regulatory guidance implementable with minimal burden. Because of the minimal burden, plans would have no incentive to avoid using them. Additionally, we have received no enrollee complaints on member cards since issuing the sub-regulatory guidance.

Because of the reasons listed previously, we believe plans are following the standards described in this subregulatory guidance and therefore no further burden is imposed by codifying these standards in regulation.

10. ICRs Related to the Creation of a One-Page Multilanguage Insert (§§ 422.2267(e)(31) and 423.2267(e)(33))

The following proposed changes would be submitted to OMB for review under control number 0938–TBD2 (CMS–10802). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request. This provision requires that plans add in their postings or mailings of CMS required materials a one-page document written in the top 15 non-English languages in the U.S. informing enrollees that interpreter services are available at no cost.

We previously required plans to provide this document to enrollees. However, based on section 1557 of the Affordable Care Act, the Office for Civil Rights (OCR) created their own version. Because of the inherent duplication between CMS' MLI requirement and OCR's requirement, CMS issued an HPMS email on August 25, 2016, that removed the MLI requirement. OCR later vacated their requirement, leaving a gap. Consequently, we are proposing to require that MA plans and Part D plan sponsors provide the one-page document.

In estimating the burden of this one-page document we assume plans have retained their templates consistent with the record retention requirements at § 422.504(e)(4). Consequently, there is no burden to create the template, as plans will either use their existing templates or a template that will be provided by CMS to new plans based on the previously created MLI without change.

The cost of placing an extra page on the plan's web page is incurred by plans as part of their normal course of fluctuating business activities and hence excluded from the PRA (5 CFR 1320.3(b)(2)). For those beneficiaries who request a paper copy, the proposed regulations require sending it with other CMS required materials (§§ 422.2267(e) and 423.2267(e)). We believe it is reasonable to assume that adding one page (at 0.1696 ounces) to a bulk mailing cost is de minimis and therefore does not create additional postage costs.

Similar estimates have been made in previous final rules where we identified the major burden as paper and toner. We have checked the following assumptions of cost and beneficiary interest in receiving paper copies found in the April 2018 final rule (83 FR 16695), and found them to still be reliable for the purpose of this proposed rule.

A 10-ream box (of 5,000 sheets) of paper costs approximately $50. Hence the cost per sheet is $50/5,000 sheets = $0.01 per page.

Standard toner cartridges which last for about 10,000 pages also cost $50. Hence the cost per sheet is $50/10,000 = $0.005 per page.

Thus, the total paper and toner cost is $0.015 per page.

As of September 2021, there are 52 million beneficiaries enrolled in MA PD or stand-alone PDP plans.[145]

Of these 52 million beneficiaries we estimate that two fifths or 20,800,000 beneficiaries (52 million beneficiaries × 0.40) will request paper copies.

It follows that the aggregate cost of providing one extra sheet of paper is

[145] *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2021-09.*

$312,000 (20,800,000 enrollees × $0.015/sheet).

There is no labor cost. Had we assumed that each extra sheet will incur postage costs we would have to add about $43,333 (52 million enrollees × 2/5 requesting paper copies × 1/6 once per sheet × 1/16 ounces per pound × $0.20/pound). However, it is not clear the extent to which every sheet will bear a cost. We solicit stakeholder input on all assumptions including the estimate that 40 percent of enrollees request paper copies and that the major costs are paper and toner.

11. ICRs Related to Third-Party Marketing Organizations (TPMOs) Agent (§§ 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2274(g))

The following proposed disclaimer changes carry no burden submitted to OMB for review. Sections 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2275(g) would require MA organizations and Part D sponsors to insert CMS standard disclaimer on materials created by Third Party Marketing Organizations and would require MA organizations and Part D sponsor update training materials. The burden associated with this requirement would be the time and effort to copy the disclaimer on marketing materials during document creation. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(c)(2). We believe that the time, effort, and financial resources to comply with the information collection requirements would be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practice.

The major cost associated with these requirements is the burden of updating policies and training. We note that many TPMOs such as field marketing organizations (FMOs), or other companies that a plan uses for marketing, lead generation, and enrollment functions already perform similar training in order to ensure compliance with their FDR requirements.

We estimate that it would take a business operation specialist 2 hours at $81.06/hr for a one-time update of procedures and training at a cost of $162 ($81.06/hr × 2 hr) per contract. In aggregate the one-time burden for 961 current contracts is 1,922 hours (2 hr × 961 contracts) at a cost of $155,797 (1,922 hr × $81.06/hr).

The major update is procedures and training. The burden of adding just one itm to the required disclosures is not being estimated since it is part of the normal varying disclosures done and as such is exempt from the PRA (5 CFR 1320.3(b)(2)).

12. ICRs Related to the Medicare MLR Reporting Requirements (§§ 422.2460 and 423.2460)

The proposed changes to the Medicare MLR Reporting Requirements will be submitted to OMB for review under control number 0938–1232 (CMS–10476).

In section II.G.2. of this proposed rule, we note that under current §§ 422.2460 and 423.2460, for each contract year, MA organizations and Part D sponsors must report to CMS only the MLR and the amount of any remittance owed to us for each contract with credible or partially credible experience. For each non-credible contract, MA organizations and Part D sponsors are required to report only that the contract is non-credible. In this rule, our proposed amendments to §§ 422.2460 and 423.2460 would increase the MLR reporting burden by requiring that MA organizations and Part D sponsors report, for each contract year, the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, such as the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS under § 422.2410 or § 423.2410.

Our analysis of the estimated administrative burden related to the MLR reporting requirements is based on the average number of MA and Part D contracts subject to the reporting requirements for each contract year. For contract years (CYs) 2014 to 2020, the average number of such contracts is 601. The total number of MA and Part D contracts is relatively stable year over year.

Another amount used in our calculations is the total number of hours spent on administrative work related to the Medicare MLR requirements that applied with respect to MLR reporting for contract years CY 2014 through CY 2017. In the information collection request that was previously approved by OMB under 0938–1232 (CMS–10476), CMS estimated that, on average, MA organizations and Part D sponsors would spend 47 hours per contract on administrative work related to Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting internal review, submitting the reports to the Secretary, and conducting internal audits. This 47-hour figure was also used in the final rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (83 FR 16701), which appeared in the **Federal Register** on April 16, 2018 (hereinafter referred to as the April 2018 final rule), and revised the MLR reporting requirements that apply with respect to MLR reporting for CY 2018 and subsequent contract years, and it will be used in this proposed rule.

In calculating burden, we contrast the proposed requirements with those in the April 2018 final rule, which revised the MLR reporting requirements for all MA and Part D contracts, and the June 2020 final rule (84 FR 33796, 33850), which added a deductible-based adjustment to the MLR calculation for MA medical savings account (MSA) contracts. In reviewing the April 2018 final rule, we identified an overestimation in the calculations.

To explain the overestimation and to account for it in our burden calculation for this proposed rule, we present three tables: One table for the estimates of hourly burden per contract included in the April 2018 final rule, which established the current MLR reporting requirements (Table 5); a second table for our revised estimates of hourly burden in the April 2018 final rule (Table 6); and a third table for our estimates of the hourly burden of the proposed changes to the MLR reporting requirements. Having the calculated hourly burden per contract, we can then estimate dollar burden per contract and also aggregate hourly and dollar burden per contract.

We believe that presenting these 3 tables will aid the reader in navigating a set of calculations that are complicated by (1) the contrast between the burden estimate for the current MLR reporting requirements, as published in the April 2018 final rule, and our revised burden estimate for the current reporting requirements, which we provide here, and (2) the contrast between our revised burden estimate for the current reporting requirements and our burden estimate for the proposed reporting requirements. To provide further clarity, we number each row in the tables with a row ID so that appropriate narrative can be tied to overall calculation. For this reason, we initially focus on hourly burden. Once the hourly burden of this proposed rule is established, we calculate the per

contract and aggregate hourly and dollar burden.

In the April 2018 final rule (83 FR 16701), we estimated that it would take an MA organization or Part D sponsor 11.5 hours to complete the MLR reporting form that was used to collect MLR data for CYs 2014 through 2017. We explained that we developed this estimate by considering the amount of time it would take an MA organization or Part D sponsor to complete *each* of the following tasks:

- Review the MLR report filing instructions and external materials referenced therein and to input all figures and plan-level data in accordance with the instructions.
- Draft narrative descriptions of methodologies used to allocate expenses.
- Perform an internal review of the MLR report form prior to submission.
- Upload and submit the MLR report and attestation.
- Correct or provide explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report.

The calculations for hourly burden per contract that were included in the April 2018 final are summarized in Table 5.

TABLE 5: TIME PER CONTRACT USED IN APRIL 2018 FINAL RULE (HOURS)

Row ID	Item	Estimate	Notes
(1)	Total administrative burden (assuming use of MLR form for CYs 2014-2017) (hr)	47	Estimate used in former approved Information Collection Request that included MLR form used for CYs 2014-2017
(2)	Original estimate of burden for completing MLR form used for CYs 2014-2017 (hr)	11.5	Assumption in April 2018 final rule about amount of time needed to complete MLR form used for CYs 2014-2017
(3)	Burden for administrative tasks other than completing MLR form (hr)	35.5	(3)=(1)-(2)
(4)	Estimate of burden for completing current MLR form (hr)	0.5	Assumption in April 2018 final rule
(5)	Total administrative burden for current MLR form (hr)	36	(5)=(3)+(4)

The following explanations apply to the rows in Table 5:

Row(1): The 47-hour figure, as explained in the opening paragraphs of this ICR, is CMS' estimate for the total amount of time MA organizations and Part D sponsors would spend per contract on administrative work related to Medicare MLR reporting when the MLR was reported using the MLR form for CYs 2014 through 2017, including: Collecting data, populating the MLR reporting form, conducting internal review, submitting the report to the Secretary, and conducting internal audits.

Row (2): The 11.5-hour burden is the portion of the burden in Row (1) that the April 2018 final rule assumed was associated with completing the MLR form used for CYs 2014 through 2017. This burden is discussed in the paragraph immediately preceding Table 5.

Row (3): 35.5 hours, the administrative burden associated with the MLR requirements, excluding the April 2018 final rule's estimate of the burden for completing and submitting the MLR form used for CYs 2014 through 2017. This number represents the difference between total per contract burden, 47 hours, and the form burden per contract, 11.5 hours.

Row (4): Estimated burden to complete the current MLR data form, which is vastly simplified and is estimated to take only a half-hour to complete.

Row (5): The total burden per contract, as written in the 2018 and 2020 rule, and as adjusted for the current number of contracts is 36.00 (35.5 hours non-form burden + 0.5 hours current form burden).

After further consideration, we believe that the April 2018 final rule overstated the burden of completing the detailed MLR reporting form because it did not take into account the number of MA organizations and Part D sponsors that were actually required to provide explanations for suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report. Unlike the first four tasks previously listed (the first four of the bullets immediately listed prior to Table 5), the need to correct or provide explanations for errors and omissions discovered by CMS or our contractor during desk reviews and estimated at 11.5 hours (row (2)) was not applicable to all plans when our detailed MLR data reporting requirements were in effect.

Based on the percentage of contracts per CY (for CYs 2014 through 2017) for which the annual MLR filing was flagged for potential errors during desk reviews, the number of MA organizations and Part D sponsors that were required to correct or explain suspected errors during desk reviews, and a review of the correspondence between such organizations or sponsors and CMS or our contractor, we estimate the last task previously listed (to correct or provide explanations for suspected errors or omissions flagged in desk reviews) would take an MA organization or Part D sponsor an average of 3 hours per affected contract, depending on the number and complexity of issues that

required additional explanation, whether the MA organization or Part D sponsor had to recalculate any of the figures included in its original MLR submission, and whether the MA organization or Part D sponsor had to submit a corrected MLR Report to address any of the errors or omissions in its original submission.

This refinement to our prior 11.5-hour time estimate does not affect our estimate that MA organizations and Part D sponsors spent 47 hours per contract on administrative work under the MLR reporting requirements in effect for CYs 2014 through 2017 (Row (1) in Table 5). Instead, it causes the estimated time to complete the detailed MLR reporting form to decrease from 11.5 hours to 10.75 hours (Row (2) in Table 5 and Row (7) in Table 6), with the remaining administrative tasks now estimated as taking the other 36.25 hours (47 hours − 10.75 hours). (Row (8) in Table 6). Table 6 presents a revision of Table 5 with the primary change being replacing 11.5 (Row (2) in Table 5) with 10.75 (row (7) in Table 6), with the other rows following by computation. Table 6 also differs from Table 5 is the addition of the per contract burden of calculation of the MSA deductible factor. This is explained in the narrative to Table 6.

TABLE 6: TIME PER CONTRACT IN APRIL 2018 FINAL RULE REVISED (HOURS)

Row ID	Item	Estimate	Notes
(6)	Total administrative burden (assuming use of MLR form for CYs 2014-2017) (hr)	47	(1)
(7)	Revised estimate of burden for completing MLR form used for CYs 2014-2017 (hr)	10.75	Reduced from original 11.5 hr estimate
(8)	Burden for administrative tasks other than completing MLR form (hr)	36.25	(8)=(6)-(7)
(9)	Estimate of burden for completing current form (hr)	0.5	(4)
(10)	Burden for calculation of MSA deductible factor (hr)	0.00055	Burden per contract of calculation of MSA deductible factor. This is explained in the narrative below.
(11)	Total administrative burden for current MLR form (hr)	36.75055	(11)=(8)+(9)+(10)

We now explain row (10), calculation of the deductible factor. In the June 2020 final rule, CMS estimated that it would take 5 minutes (1/12 hour) to calculate and verify the deductible factor for an MSA contract. At the time of the 2020 rule, there were 8 MSA contracts. As of 2021, there are only 4 MSA contracts. However, the calculations presented in Table 6 are per contract, not aggregate. Thus, the hourly burden for calculation of the MSA deductible factor adjusted for the number of current contracts is 0.00055 hours (1/12 hour per contract × 4 MSA contracts divided by 601 total contracts). We round to 5 decimal places because if we had rounded to two decimal places the burden would be 0. This burden is eliminated under the current proposal because the software tool that will be used to report the detailed MLR data that CMS proposes will now calculate and apply the deductible factor, making it unnecessary for MA organizations to perform this calculation. The sole purpose of discussing this burden here is to illustrate the flow of logic in determining hourly burden as written in the previous rules.

This proposed rule introduces three items affecting per contract hourly burden. First, as noted in section II.G.3. of this proposed rule, if the proposed changes to the MLR reporting requirements are finalized, CMS expects to resume development of the MLR reporting software, and to update the data collection fields and built-in formulas so that the MLR reporting software calculates the MLR consistent with all amendments to the MLR regulations that CMS has finalized since CY 2017. In making these updates, CMS would revise the programming of the MLR reporting software so that it automatically calculates and applies the appropriate deductible factor for MA MSA contracts, as determined under § 422.2440. Because MA organizations would no longer be responsible for calculating the deductible factor, the burden associated with performing that calculation would be eliminated.

Second, as discussed in section II.G.2. of this proposed rule, CMS proposes to reinstate the detailed MLR reporting requirements in effect for CYs 2014 through 2017.

Third, we propose to require that MA organizations provide more detailed information on the portion of the incurred claims component of the MLR numerator that represents expenditures for supplemental benefits. As discussed

in section II.G.3. of this proposed rule, to collect this information, we intend to add 18 additional fields to the MLR Report template in which MA organizations would enter their total expenditures for different types or categories of supplemental benefits. We also anticipate adding narrative fields in which users would describe the methodologies used to allocate supplemental benefit expenditures.

In total, we estimate that the addition of these fields, as well as an information-only field in which MA organizations and Part D sponsors would enter the low-income cost sharing subsidy amount that they deducted when calculating the amount of prescription drug costs to include in the MLR report, would increase the number of fields that would require user input and validation by approximately one-third, or 33.3 percent. We believe this increase would cause a proportional increase in the amount of time needed both to complete and submit the MLR Report to CMS, and to perform the data collection activities that make up the remaining portion of the 47 hours per contract that we previously estimated MA organizations and Part D sponsors would spend on administrative work related to the MLR reporting requirements.

However, because the new supplemental benefits fields do not affect the MLR reporting burden for sponsors of standalone Part D contracts, we calculate the MLR reporting burden separately for MA contracts and standalone Part D contracts. Thus, we estimate the burden to stand-alone Part D contracts would only increase 5 percent.

To aggregate this increase on a per-contract level, we take a weighted average of the 33 percent increase and the 5 percent increase. The weights correspond to the percentage of contracts that represent MA contracts (about 89 percent) and standalone Part D contracts (about 11 percent). This aggregate net increase per contract is 29.92 percent (89% × 33% + 11% × 5%). The computations are presented in Table 7. As previously indicated, it is simpler to use one aggregate figure (29.92 percent) for all contracts rather than estimate each contract type separately and then adding them together.

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TABLE 7: CALCULATION OF (WEIGHTED) AVERAGE INCREASE IN TIME PER CONTRACT

Row ID	Contract Type	Percent of contracts	Increase for new fields	Product of Increase and Percent (weight) of contract type	Notes
(12)	Stand-alone prescription drug contracts	11%	5%	0.55%	Rounded to 4 decimal places. Rounding to two decimal places would make this 1, a misleading increase.
(13)	MA (including MA-PD and MSA) contracts	89%	33%	29.37%	Rounded to 4 decimal places for consistency with previous row.
(14)	Aggregate burden increase per contract			29.92%	(14)=(12)+(13)

TABLE 8: BURDEN (AGGREGATE and PER CONTRACT)

Row ID	Item	Burden	Notes
(15)	Total administrative burden (hr) per contract	47	(6)
(16)	Revised (2018 rule) burden (hr) per contract for then current form	10.75	(7)
(17)	Admin burden (hr) per contract for non-form items	36.25	(17)=(8) or (17)=(15)-(16)
(18)	Per contract burden for return to form used for CYs 2014-2017	10.75	Removal of current form; return to form used for CYs 2014-2017 (See row (7))
(19)	Per contract burden for calculation of deductible factor for MSA contracts (hr)	0	Software now automatically calculates the MSA deductible factor
(20)	Per contract revised hourly burden (hr) for return to form used for CYs 2014-2017 and removal of calculation of MSA deductible factor	47	(20)=(17)+(18)
(21)	Per contract burden (hr) for proposed form with new fields, this proposed rule	61.1	(21)=(20)+(14)*(20)
(22)	Current per contract burden (hr)	36.75055	(22) = (11)
(23)	Average increase (hours)/contract	24.34945	(23) = (21) - (22)
(24)	Wage/hr	$155.52	Wage Table
(25)	Per contract burden ($) for proposed form, this rule, with new fields	$3,787	(25)=(24)*(23)
(26)	Number of current contracts affected by MLR provisions	601	Estimate explained in opening paragraph of this ICR
(27)	Aggregate burden (hr), all contracts, with new fields, this rule	14,634	(27)=(26)*(23)
(28)	Aggregate burden ($), all contracts, with new fields, this rule	$2,275,880	(28)=(27)*(24)

Table 8 incorporates these three proposed changes—removing the deductible factor calculation burden, reinstating the form used for MLR reporting for CYs 2014 through 2017, and increasing the fields in the form—to arrive at a final hourly burden per contract, and then calculates dollar burden per contract as well as aggregate burden (hourly and dollar) for all contracts. The rows of Table 8 are explained in the narrative following the table. The following presents explanations of the rows in Table 8.

- *Rows (15)–(17)* are identical to rows (6)–(8). This provides the per-contract administrative hours on non-form items connected with the MLR provisions before adding the form-related burdens.
- *Row (18):* The 0.5 hours in Row (9) is replaced by the 10.75 hours in Row (16) since this proposed rule requires returning to the detailed form used for MLR reporting for CYs 2014 through 2017 whose cost is estimated in Row (7).
- *Row (19):* Row (10), the time for calculation of the MSA deductible factor, is replaced with 0 hours, since the proposal would entail having CMS-developed software automatically calculate and apply the deductible factor.
- *Row (20):* The total hourly burden per contract, 47 hours, reflecting returning to the detailed form used for CY 2014 through 2017 MLR reporting and removal of calculation of the MSA deductible factor (but not yet reflecting additional fields) is obtained by adding 10.75 (form burden) + 36.25 (non-form burden), (Rows (17) and (18)).
- **ROW (21):** The total hourly burden per contract, 61.1 hours under the current proposal, is obtained by increasing the 47 hours (Row (20)) by 29.92 percent, which is the weighted effect of adding new fields (Row (14)). (61.1 = 47 + 29.92 percent × 47).
- *Row (22):* The current contract burden of 36.75055 hours is obtained from Row (11). The five decimal places assure that the effect of the provision on MSAs is not removed.
- *Row (23):* The average increase in burden (hours) due to the proposed regulation of 24.34945 is obtained by subtracting from the total burden under the proposed regulation of 61.1 hours on Row (21) the current burden of 36.75055 hours on Row (22).
- *Row (24):* The $155.52/hr wage is obtained from the wage table.
- *Row (25):* The increased contract burden ($) $3,787 on Row (25) is obtained by multiplying the average increase in burden (hours) of 24.34945 on Row (23) by the wages per hour ($155.52) on Row (24).

• *Row (26):* The total number of contracts is presented in the opening paragraphs of this ICR.

• *Row (27)*: The aggregate increase in burden (hours) across all contracts of 14,634 is obtained by multiplying the 601 contracts (Row (26)) by the per contract increase in burden (hours) of 24.34945 on Row (23).

• *Row (28):* The aggregate increase in burden ($) across all contracts, $2,275,880, is obtained by multiplying the increase in burden (hours) of 14,634 on Row (27) by the wages per hour on Row (24).

We estimate that MA organizations and Part D sponsors will incur minimal one-time start-up costs associated with developing processes for capturing the necessary data, as they should already have been allocating their expenses by line of business and contract in order to comply with our current regulations regarding the calculation of the MLR, and they should already have been tracking their supplemental benefit expenditures for purposes of bid development. We estimate that MA organizations and Part D sponsors will incur ongoing annual costs relating to data collection, populating the MLR reporting form, conducting an internal review, submitting the MLR reports to the Secretary, and conducting internal audits.

Table 9 summarizes the relevant calculations in traditional COI format as one combined line item.

TABLE 9: BURDEN ASSOCIATED WITH THE MLR PROVISIONS

Respondent	Number of Respondents	Responses per Respondent	Time per Response (hours)	Total Annual Time (hours)	Hourly Labor Cost ($/hr)	Total Cost ($)
Contracts subject to MLR reporting requirement	601	1	24.34945	14,634	155.52	2,275,880

The average burden per contract as given on Row (25) of Table 8 is $3,787. We note that this is a weighted average. Stakeholders may be interested in a more careful analysis based on contract type. We do this for 3 types of contracts.

MA MSA contracts have reduced burden since the new software automatically calculates the deductible factor and uses that to adjust the applicable credibility factor, relieving them of the need to perform this calculation and adjustment on their own.

For each MA contract (including MA–PD and MA MSA contracts), we estimate, on average, 25.92 hours of additional burden at an additional cost of $4,032. Row (11) (which excludes the burden on Row (10) associated with calculating the MSA deductible factor) shows the current hour burden to be 36.75 hours. (The removal of the 0.00055 hours has negligible effect and is appropriate for the majority of contracts which are non-MSAs). Row (20) shows that the new burden without considering the additional fields is 47 hours. Row (13) shows that this would result in 62.67 hours total burden (47 hours × 1.33 due to increased fields). Comparing the 62.67 total burden under the proposed MLR reporting requirement with the 36.75 hours under the current reporting requirements shows an increase in burden of 25.92 hours (62.67 − 36.75) at a cost of $4,031 (25.92 hours × $155.52/hr).

For Part D contracts, we estimate 12.6 additional hours of burden at an additional cost of $1,960. As in the preceding analysis for MA contracts, Row (11) (which excludes burden on Row (10) associated with calculating the MSA deductible factor) shows the current hour burden to be 36.75 hours. Row (20) shows that the new burden without taking into effect the new fields is 47 hours. Row (12) shows a 5 percent increase for new fields for Part D contracts, such that this would result in a total burden of 49.35 hours (47 hours + 47 hours × 5 percent). Thus, there is an additional hour burden of 12.6 hours (49.35 hours − 36.75 hours) at an additional cost of $1,960 (12.6 hours × $155.52/hr) per contract.

ICRs Related to Pharmacy Price Concessions in the Part D Negotiated Price (§ 423.100)

The proposed requirement and burden for Part D Sponsors to implement provisions related to pharmacy price concessions, discussed below, will be submitted to OMB for review under control number 0938–0982 (CMS–10174), as needed.

This provision would require that Part D sponsors apply all pharmacy price concessions to the point of sale price in all phases of the Part D benefit excluding for applicable drugs dispensed to applicable beneficiaries in the coverage gap. Under this proposal, beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder, beginning immediately in the year the policy would take effect, 2023. We anticipate that this proposed change would require Part D sponsors to make certain system changes related to the calculation of the amounts they report in one or two fields in the PDE data collection form. We anticipate that this would cause sponsors to incur one-time administrative costs.

To estimate the administrative costs associated with submission of PDE data, we consider the following factors: (1) The number of plan sponsors (or sponsors' intermediaries) submitting data; (2) the amount of data that must be submitted; and (3) the time required to complete the data processing and transmission transactions. This information is summarized in Table 10. Throughout the narrative, the row references refer to this Table.

Number of Part D Contracts (Respondents): The average number of Part D contracts per year (Row (B)) is 856 (based on 2019–2021 internal CMS data).

PDE Data Submission: The number of prescription drug events (PDE) for 2020 is 1.5 billion (Row (C)). The average number of Part D contracts for the past 3 years (2019–2021) is 856 (Row (B)). To compute the average number of responses per respondent, that is, the number of PDEs per contract (D), we divide the average number of PDEs per year (Row C) by the average number of contracts (Row B). This computation leads to an average of 1,752,336.45 PDEs/contract (Row (D)) (1.5 billion divided by 856). A similar computation shows that the average number of PDEs per Part D enrollee is 30.5 (1.5 billion

PDE (Row (C)) divided by 49,229,626 enrollees (as of November 2021) (Row (A)).

Time Required to Process Data: The third factor that contributes to the burden estimate for submitting PDE data depends upon the time and effort necessary to complete data transaction activities. Since our regulations require Part D sponsors to submit PDE data to CMS that can be linked at the individual level to Medicare Part A and Part B data in a form and manner similar to the process provided under § 422.310, the data transaction timeframes will be based on risk adjustment and prescription drug industry experiences. Moreover, our PDE data submission format only supports electronic formats.

The drug industry's estimated average processing time for electronic data submission is 1 hour for 500,000 records (Row F). The drug industry further estimates that on average it costs $35.50/hr (for 2020) to process PDEs (Row E).

Using these numbers, we can compute individual contract and aggregate burden.

It would take 3.5 hours (Row G) on average for each respondent (contract) to process its 1,752,336.45 PDEs at a rate of 500,000 per hour (1,752,336.45 PDEs per contract (Row D) divided by 500,000/hr (Row (F)). The aggregate hours to process all 1.5 billion claims is therefore 2,996 hours (Row H) (3.5 hours/contract Row (G) × 856 contracts (Row (B)).

The average cost per contract (Row (I)) is $124.25 (3.5 hours (Row G) × $35.50/hr (Row E)). The aggregate one-time cost for all contracts is $106,358 (Row J), which can be obtained either by multiplying total hours (2,996 (Row (H)) by total contracts (856 (Row (B)) or by multiplying the cost per contract ($124.25 (Row I)) by the number of contracts (856 (Row B)).

TABLE 10: ESTIMATED ADMINISTRATIVE COSTS RELATED TO SUBMISSION OF PRESCRIPTION DRUG EVENT (PDE) DATA

Row ID	Item	Estimate	Source/Derivation	Description
A		49,229,626	Internal CMS Data	Number of Part D Enrollees as of November 2021
B	Number of respondents	856	Internal CMS Data	Average Number of Contracts 2019-2021
C	Total responses	1,500,000,000	Internal CMS data	PDEs per year
D	Average responses per respondent	1,752,336.45	(C) / (B)	Average PDEs per contract
E	Wage per hour (Non labor)	$35.50/hr	Drug industry's estimated cost/hr of electronic processing	Cost/hr of processing PDEs electronically
F		500,000	Drug industry's estimated average processing volume per hour	Number of Electronic PDEs processed per hour
G	Hours/respondent	3.5	(D) / (F)	Number of hours needed to process one contract's PDEs
H	Aggregate hours	2,996	(G) x (B)	Total hours to process all contracts
I	Cost per respondent	$124.25	(G) x (E)	Cost per contract to process PDEs
J	Total cost all contracts	106,358	Either (H) x (E) or (I) x (B)	Total cost for all contracts

C. Summary of Proposed Information Collection Requirements and Associated Burden Estimates

TABLE 11. SUMMARY OF ANNUAL INFORMATIO COLLECTION REQUIREMENTS AND BURDEN

Regulation Section in Part 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondent	Number of Respondents	Responses per Respondent	Total Responses	Time per Response (hours)	Total Time (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.107(f)	Solicit committee members	0938-INSERT (CMS-10799)	D SNPS	260	1	260	40	10,400	81.06	843,024	843,204
422.101	Update HRA System	0938-INSERT (CMS-10799)	SNP Parent Organizations	123	1	123	3	369	105.72	39,011	0
422.107(e)	Update Contracts with D-SNPs	0938-INSERT (CMS-10796)	State	12	1	12	12*	144	143.18	20,618*	0
422.107(e)	Update Contracts	0938-0935	D SNPS	60	1	60	8	480	143.18	68,726	0
422.107(e)(1)	Part C Contracts with only D SNPS	0938–0935	D SNPS	41	1	41	10	410	72.7	29,807	0
422.107(e)(1)	Part D Contracts with only D SNPS	0938–0936	D SNPS	41	1	41	6.41	263	72.7	19,120	0
422.561	Update Contracts	0938-INSERT (CMS-10796)	D SNPS	13	1	13	8	104	81.06	8,430	0
422.2267(e)(31) and 423.2267(e)(33))	1 pager multi-lanaguage insert	0938-INSERT	MA Plans and Part D Sponsors	961	21,644	20,800,000	0	0	0.015	312,000	312,000
422.2274(g) and 423.2274(g)	Update policies on 3rd party marketing	0938-INSERT	MA Plans	961	1	961	2	1,922	81.06	155,797	0
422.2460 and 423.2460	MLR	0938-1232	MA and Part D Contracts	601	1	601	24.34945	14,634	155.52	2,275,880	2,275,880
423.100	Part D Pharmacy Price Concessions	0938-0982	Part D Sponsors	856	1,752,336	1,500,000,000	3.5	2,996	35.5	106,358	106,358
	Totals			1,096		*Varies*	*Varies*	31,722	*Varies*	3,878,771	3,537,442

NOTES:

*For States, burdens, reflect 50 percent reduction to Federal Matching program (hours are halved)

**Includes MA only, MA PD, and PDP plans.

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D. Submission of Comments

We have submitted a copy of this rule to OMB for its review of the rule's proposed information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at *https://www.cms.gov/Regulations andGuidance/Legislation/Paperwork ReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on the proposed information collection requirements and burden. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–4192–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

V. Regulatory Impact Statement

A. Statement of Need

This proposed rule would revise the MA and Part D program regulations to improve transparency in, and oversight of, these programs and to revise regulations to improve the integration of Medicare and Medicaid programs for individuals enrolled in dual eligible special needs plans (D–SNPs). This proposed rule would also revise regulations related to MA and Part D plans, D–SNPs, other special needs plans, and cost contract plans. Additional proposed revisions would implement changes related to requirements during disasters or public emergencies, past performance, MLR reporting, pharmacy price concessions, marketing and communications, Star Ratings, and network adequacy.

Through proposals that apply to D–SNPs, we intend to improve beneficiary experiences, by amplifying the voices of dually eligible individuals in health plan governance and operations by requiring an enrollee advisory committee and requiring assessment of certain social risk factors. Additionally, our proposals will improve partnership with States through better Federal-State collaboration on oversight and performance improvement activities and establishing new pathways for CMS and States to collaborate to integrate care for dually eligible individuals.

The proposed past performance proposals hold plans more accountable for their performance under MA and Part D and protect the best interest of the Medicare program by preventing those with poor past performance from entering new MA or Part D applications or service area expansions. The proposed Star Ratings provisions allow CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey; due to the COVID–19 PHE in place nationwide during 2020, applying the 60 percent rule in the current regulations would result in removal of all contracts from threshold calculations and CMS would be unable to calculate ratings for these three measures.

Due to a rule change that took effect with CY 2018 MLR reporting, MA organizations and Part D sponsors only submit to CMS the MLR percentage and amount of any remittance that must be repaid to CMS for failure to meet the 85 percent minimum MLR requirement. CMS is proposing to change our regulations to reinstate the former requirement for MA organizations and Part D sponsors to submit the underlying information needed to calculate, and verify the accuracy of, the MLR and remittance amount. We believe reinstating this detailed data submission requirement and the desk review process will allow us to detect errors in the MLR calculation which can result in significant losses to the government.

We are proposing to delete the existing definition of ''negotiated prices'' at § 423.100 and to adopt a new definition for the term ''negotiated price'' at § 423.100, which we are proposing to define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). To implement the proposed change at the point-of-sale, Part D sponsors and their PBMs would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. This proposed provision would reduce out-of-pocket prescription drug costs, improve price transparency and market competition under the Part D program.

We have proposed to clarify our regulations regarding the special requirements for disasters and emergencies at § 422.100(m) to address stakeholder concerns about the end of a disaster or emergencies and to codify previous guidance. We also proposed updates to them to allow smoother transitions for enrollees who during a disaster or emergency may have been obtaining services from out-of-network providers.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. While the total annualized costs for this rule are about $3.5 million a year, as indicated in Table 20, the net transfers

from the Trust Fund to enrollees and manufacturers exceed $100 million annually. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule will not mandate on an unfunded basis any requirements for State, local, or tribal governments nor would it result in expenditures by the private sector meeting that threshold in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Under Executive Order 13132, this proposed rule will not significantly affect the States. It follows the intent and letter of the law and does not usurp State authority beyond what the Act requires. This rule describes the processes that must be undertaken by CMS, the States, and D–SNPs in order to implement and administer the requirements of the MA program. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by OMB.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. As of November 2021, there are 962 contracting organizations with CMS (which includes MA, MA–PD, and PDP contracts). Additionally, there are 55 state Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major PBMs). A reasonable maximal number is 1,500 total entities who will review this rule. We note that other assumptions are possible. We assume each organization will designate two people to read the rule.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is $114.24 per hour, which includes 100 percent increase for fringe benefits and overhead costs (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for each person to review this entire proposed rule. For each person that reviews this proposed rule, the estimated cost is therefore $900 (8 hours × $114.24). Therefore, we estimate that the maximum total cost of reviewing this entire proposed rule is $2.7 million ($900 × 1,500 entities × 2 reviewers/entity).

We note that this analysis assumed two readers per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we expect it is more reasonable to estimate review time based on the number of contracting organizations because a parent organization might have local reviewers assessing potential region-specific effects from this proposed rule.

C. Regulatory Flexibility Act (RFA)

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA). If a proposed rule may have a significant economic impact on a substantial number of small entities, then the proposed rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a ''significant'' impact to be 3 to 5 percent or more of the affected entities' costs or revenues.

For purposes of the RFA, we estimate that many affected payers are small entities as that term is used in the RFA, either by being nonprofit organizations or by meeting the SBA definition of a small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The North American Industry Classification System (NAICS) is used to classify businesses by industry and is used by the United States, Canada, and Mexico. While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category.[146] Note that the most recent update to the NAICS classifications went into effect for the 2017 reference year. The latest size standards are for 2019.

As can be seen from the Summary of Annual Information Collection Requirements and Burden table (Table 11) in section IV.C. of this proposed rule, as well as Table 20 of this section, on average, the net cost to each plan to implement all provisions is significantly below $10,000 (The annualized cost over 10 years of $3.5 million divided by the number of contracts, about 1,000, is significantly below $10,000). Additionally, not all provisions apply to all plans. We do not believe this to be excessive burden even to small entities. Nevertheless, a more complete analysis is provided immediately below supporting the position that burden is not excessive.

Although States are also affected by these provisions, States are not classified as small entities and in any event the burden as just indicated is small.

The relevant NAICS category is Direct Health and Medical Insurance Carriers, NAICS 524114, with a $41.5 million threshold for ''small size,'' with 75 percent of insurers having under 500 employees meeting the definition of small business.

MA organizations and Medicaid managed care plans have their costs funded by the Federal government or State and therefore there is no significant burden. We discuss the details of this in this section. This discussion will establish that there is no significant burden to a significant number of entities from this proposed rule for these provisions.

1. Medicare Advantage

Each year, MA plans submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay a basic premium, thus this percentage of plans is not ''significant'' as defined by the RFA and as justified below).

[146] North American Industry Classification System (2017). Retrieved from: *https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf. https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019.pdf.*

MA and MA–PD plans can also offer supplemental benefits, that is, benefits not covered under Original Medicare (or under Part D). These supplemental benefits are paid for through enrollee premiums, extra government payments or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a ''beneficiary rebate.'' The rebate must be used to provide supplemental benefits (that is, benefits not covered under Original Medicare) and/or lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the government's payments to plans for the bid plus the rebate exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the supplemental coverage available in many MA plans.

Part D plans, including MA–PD plans, submit bids and those amounts are paid to plans through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries Part D plans receive government funds to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this proposed rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, MA plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either—(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from Original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

If an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is two percent, this is not considered substantial for purposes of the RFA.

The preceding analysis shows that meeting the direct cost of this proposed rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal government. However, the government additionally pays the plan a ''beneficiary rebate'' amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) It would follow that if the provisions of this proposed rule cause the MA bid to increase and if the benchmark remains unchanged or increases by less than the bid does, the result would be a reduced rebate and, possibly fewer supplemental benefits, or higher premiums for the health plans' enrollees. However as noted above, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this rule would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

2. Medicaid

We include Medicaid in this section since it is relevant to the proposed change to the applicable integrated plan (AIP) definition at § 422.561. At § 422.561, we propose to expand the universe of D–SNPs that are required to have unified grievance and appeals processes by revising the definition of an applicable integrated plan. Section 50311(b) of the BBA of 2018 amended section 1859(f)(8)(B) of the Act to direct establishment of procedures, to the extent feasible, unifying Medicare and Medicaid grievances and appeals. The April 2019 final rule introduced the concept of applicable integrated plans, which we defined as FIDE SNPs and HIDE SNPs whose Medicare and Medicaid enrollment is exclusively aligned (meaning State policy limits a D–SNP's enrollment to those whose Medicare and Medicaid enrollment is aligned as defined in § 422.2) and the companion Medicaid MCOs for those D–SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. We believe that unified grievance and appeals procedures are feasible for the additional D–SNPs. While we are not imposing new Medicaid requirements, the proposed AIP definition change would expand the universe of Medicaid managed plans subject to the unified appeals and grievances provisions codified in the April 2019 final rule. However, the burden imposed by this proposed rule on Medicaid managed care plans is the one-time requirement to update their grievance and appeals procedures, which as estimated in Table 11, is a one-time cost of $8,430. Consequently, the Secretary has determined that this proposed rule will not have a significant impact on Medicaid managed care plans.

Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. Based on the above, we conclude that the requirements of the RFA have been met by this proposed rule.

3. Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This rule however is directed to plans and enrollees. Providers

including hospitals receive the contracted rate or at least the original Medicare rate depending on whether the providers are contracted or not. Consequently, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

D. Anticipated Effects

1. Enrollee Participation in Plan Governance (§ 422.107)

As described in section II.A.3. of this proposed rule, at § 422.107(f), we propose that any MA organization offering a D–SNP must establish one or more enrollee advisory committees at the State level or other service area level in the State to solicit direct input on enrollee experiences. We also propose at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D–SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. This proposal intends to ensure enrollees are engaged in defining, designing, participating in, and assessing their care systems. Section IV.B.1. presents the collection of information burden for this provision.

To support D–SNPs in establishing enrollee advisory committees that meet the objective of this proposed rule in achieving high-quality, comprehensive, and coordinated care for dually eligible individuals, CMS would provide technical assistance to D–SNPs to share engagement strategies and other best practices. CMS can leverage the body of technical assistance developed for MMPs. For example, the CMS contractor Resources for Integrated Care partnered with Community Catalyst, a non-profit advocacy organization, to offer a series of webinars and other written technical assistance to help enhance MMPs' operationalization of these committees.[147] CMS will be able to realize efficiencies by repurposing and building on these resources. Based on the existing technical assistance contracts held by CMS, we estimate an annual cost to the federal government of $15,000.

2. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§ 422.2)

We have presented a discussion of collection of information burden associated with this provision in section IV.B.3. of this proposed rule. In this section, we describe the impacts of our proposed definition changes of: (1) Requiring exclusively aligned enrollment for FIDE SNPs; (2) capitation of Medicare cost-sharing; (3) clarifying the scope of services covered by a FIDE or HIDE; (4) Medicaid carve-outs; and (5) requiring service area overlap with the corresponding Medicaid plan. We anticipate all proposed changes to the definition of FIDE SNP and HIDE SNP will result in additional time for CMS staff to review D–SNPs' contracts with State Medicaid agencies. We estimate that a GS level 13, step 5 (GS–13–5), employee will take an additional 20 minutes per State to confirm the contract meets the updated definitions. For CY 2022, 21 States have FIDE SNPs, HIDE SNPs, or both. Therefore, we estimate that the proposed rule would result in 7 hours (20 minutes × 21 State contracts) of additional work for a GS–13–5 Federal employee. The 2021 hourly wage for a GS–13–5 Federal employee for the Baltimore Washington Area, which is close to the average hourly wage over all localities, is $56.31.[148] We allow 100 percent for fringe benefits and overtime, increasing the hourly wage to $112.62. Thus, the expected additional annual cost for reviewing the contract is $788.

a. Exclusively Aligned Enrollment for FIDE SNPs

Under the proposal to require exclusively aligned enrollment for FIDE SNPs described in section II.A.5.a. of this proposed rule, we note that 12 D–SNPs may lose FIDE SNP status and no longer qualify for the frailty adjustment described in section 1853(a) of the Act and the regulation at § 422.308(c)(4). Of these 12 FIDE SNPs, six are currently receiving the frailty adjustment. We believe that these six FIDE SNPs are likely to have exclusively aligned enrollment by CY 2025 as only a small fraction of their current enrollment is currently unaligned and there are multiple options through which MA organizations can meet the proposed requirement. Therefore, we do not believe the proposal will result in a significant reduction of Medicare payments from FIDE SNPs losing the frailty adjustment.

b. Capitation for Medicare Cost-Sharing for FIDE SNPs

We do not anticipate any cost transfers from the State to FIDE SNPs resulting from the proposals at § 422.2 to require that the capitated contract with the State Medicaid agency for a FIDE SNP must include coverage of Medicare cost-sharing (that is, payment by Medicaid of Medicare cost-sharing for the dually eligible individual), where applicable, and Medicaid behavioral health services. Currently, all 69 FIDE SNPs include coverage of Medicare cost-sharing in their capitated contracts with the State Medicaid agency.[149] As noted in section II.A.5.b. of this proposed rule, most FIDE SNPs already include Medicaid behavioral health benefits in their capitated contracts with the State Medicaid agency. The remaining FIDE SNPs in California and Pennsylvania that do not currently cover Medicaid behavioral health benefits would likely become HIDE SNPs under the definition proposed at § 422.2. These impacted D–SNPs would not experience a direct impact on costs when becoming a HIDE SNP as benefits covered by the impacted D–SNP would not change. Nor would impacted D–SNPs experience a change to revenue, as none of the impacted D–SNPs receive the frailty adjustment.

3. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

As described in section II.A.6. of this proposed rule, we propose a new paragraph (e) at § 422.107 to describe conditions through which States may require certain contract terms for D–SNPs and how CMS would facilitate compliance with those contract terms. This proposal allows States to further promote integration using the State Medicaid agency contract with D–SNPs, with the goal of improving beneficiary experiences and health plan oversight. Proposed paragraph (e)(1) applies only for State Medicaid agency contracts through which the State requires exclusively alignment enrollment, as defined in § 422.2, and establishes that States may choose to require and CMS would permit MA organizations—through the existing MA application process—to establish MA contracts that only include one or more State-specific D–SNPs and require that all such D–SNPs use integrated member materials.

[147] Resources for Integrated Care and Community Catalyst, ''Member Engagement in Plan Governance Webinar Series'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/concepts/member_engagement.*

[148] See the locality pay tables for 2021 at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/general-schedule/.*

[149] CMS Special Needs Plan Comprehensive Report, January 2021. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data#:~:text=Special%20Needs%20Plan%20%28SNP%29%20Data%20%20%20,%20%202021-03%20%206%20more%20rows%20.*

a. State Medicaid Agency Contract Requirements

Section IV.B.4. of this proposed rule describes the total cost for the State to update the State Medicaid agency's contract with the D–SNPs in its market to address the changes in this proposed rule and consult with CMS to ensure contract changes meet the proposed requirements at § 422.107(e). Half of the cost ($20,618) could be claimed by the State as Federal financial participation for administrative costs of the Medicaid program, born by the Federal government. In addition to updating the State Medicaid agency contract, a State choosing to further integration through proposed § 422.107(e) would need to determine readiness and make changes to State policy. The State's time and cost for adopting this proposed rule would depend on the State's current level of integration. For example, 11 States currently have a policy for exclusively aligned enrollment, and Massachusetts, New Jersey, and New York have worked with CMS to integrate some member materials. These States that have taken steps toward integration may use less time and resources to take advantage of the new processes proposed at § 422.107(e) than States just beginning to integrate Medicare and Medicaid using D–SNPs. Given the uncertainty involved in estimating State behavior and levels of existing integration, we are not estimating any additional burden outside of updating the State Medicaid agency contract with D–SNPs. We request comment on what State resources are needed to use the pathway for requiring or achieving higher integration and collaboration with CMS as described in proposed § 422.107(e) in a State with limited D–SNP integration (for example, a State with no FIDE SNPs or HIDE SNPs).

b. Limiting Certain MA Contracts to D–SNPs

We propose at § 422.107(e) to codify a pathway that would result, in certain circumstances, in contracts that only include one or more D–SNPs with exclusively aligned enrollment within a State. Because Star Ratings are reported at the contract level, having a contract with only the D–SNPs in a particular State would allow dually eligible individuals in that State to ascertain the full quality performance of a D–SNP and better equip States to work with their D–SNPs to improve health equity.

We describe the collection of information burden for MA organizations resulting from establishing a D–SNP-only contract in section IV.B.4.b. of this proposed rule. However, the additional Part C and D applications necessary to create separate contracts covering only D–SNPs in a particular state also result in additional Federal costs. While the collection of information packages lay out the Federal burden to process Part C and D applications, they do not list out the cost per contract application. We estimate the additional contract submissions for D–SNP only contracts would at most cost an additional $50,000 in labor burden for the Federal government annually.

We note impacted D–SNP contracts may have changes to their quality bonus payments (QBP), as the new contract's payment will initially be calculated from the parent organization's enrollment-weighted average quality rating and eventually only on the performance under the new contract. We are unable to predict if QBPs will increase or decrease for these MA organizations due to separating D–SNPs from the original contracts into separate contracts.

c. Integrated Member Materials

As described in section II.A.6.b. of this proposed rule, to provide a more coordinated beneficiary experience, we propose at § 422.107(e) to codify a pathway by which States and CMS would collaborate to establish model materials when a State chooses to require through its State Medicaid agency contract that certain D–SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. Proposed § 422.107(e)(1) establishes factual circumstances that would commit CMS to certain actions under paragraphs (e)(2) and (3).

In section IV.B.4.c. of this proposed rule, we note that we do not intend through this proposal to significantly change timelines for D–SNPs to prepare materials, nor do we intend to mandate that States require D–SNPs to use integrated materials. We do not estimate any additional costs for States or plans to implement integrated member materials as proposed at § 422.107(e) due to existing State efforts to work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D–SNPs to populate Medicaid benefits for Medicare member materials. Our proposal, if finalized, would simply assure interested States that, under the conditions of proposed paragraph (e), CMS would do its part to make it possible for D–SNPs to comply with State Medicaid agency contract terms for D–SNP-only contracts and integrated enrollee materials. Further, States already work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D–SNPs to populate Medicaid benefits for Medicare member materials. Therefore, we do not estimate any additional burden for States or plans to implement integrated member materials as proposed at § 422.107(e).

We anticipate costs to CMS will be similar to past work done to collaborate with States to improve the integration and effectiveness of beneficiary materials. To test materials, we conducted individual interviews with dually eligible individuals and desk reviews by contractors, CMS subject matter experts, and advocacy organizations. Since 2015, we have tested an integrated EOC, ANOC, SB, Formulary, and combined Provider and Pharmacy Directory.

We estimate that each of the model documents under proposed § 422.107(e)—the SB, Formulary, and combined Provider and Pharmacy Directory—will require 40 hours of work from CMS staff (a GS–13–5 Federal employee) working at $112.62/hr. The projected cost to the Federal government for 120 hours (40 hours × 3 documents) of a GS–13–5 employee is $13,500.

In our experience, a desk review from a contractor is approximately $10,000 per document and a study of the documents consisting of dually eligible individuals interviews costs $25,000 per document. Therefore, we anticipate the contractor costs for integrated member materials to be $105,000 ($10,000 × 3 documents + $25,000 × 3 documents). Therefore, the total cost to the Federal Government of our proposal on integrating member materials is $118,500.

d. Joint State/CMS Oversight

In section II.A.6.c. of this proposed rule, we discuss our proposals at § 422.107(e)(3) to better coordinate State and CMS monitoring and oversight of D–SNPs that operate under the conditions described at proposed paragraph (e)(1). These coordination mechanisms include sharing relevant plan information, coordinating program audits, and consulting on network exception requests. We cannot estimate the cost of uncoordinated State and federal oversight, but we believe this provision would result in a reduction in administrative burden for D–SNPs. States will have the ability to determine what level of resources is needed for their related work, and we believe States likely to elect to use the pathway described in proposed § 422.107(e) would already have resources invested in coordinating care between MCOs and

D–SNPs and would otherwise make choices that avoid significant increases in State burden.

At paragraph (e)(3)(i), we propose that CMS would grant State access to HPMS, or any successor system, to facilitate monitoring and oversight for a D–SNP with exclusively aligned enrollment in an MA contract that only includes one or more D–SNPs operating within the State. Our proposal would require the State officials and employees accessing HPMS to comply with applicable laws and CMS policies and standards for access to that system, including keeping information confidential and maintaining system security. This access would allow State users the ability to directly view D–SNP information without requiring or asking the D–SNP to send the information to the States and would facilitate State-CMS communication on D–SNP performance since more people are able to review the data and information. MA organizations may benefit when it reduces the need for States to separately obtain the same information that is already available in HPMS.

Providing this HPMS access to State users would require HPMS contractors to update several modules, including user access and coding changes needed to implement the necessary access. HPMS contractors estimated that there would be a one-time update costing approximately $750,000.

4. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

As described in section II.A.12. of this proposed rule, CMS proposes a revision to which costs are tracked and accumulate toward the MOOP limit for dually eligible enrollees in MA plans under § 422.101 for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. Our proposal would result in MA organizations that, under current policy, rarely or never pay cost-sharing above the MOOP limit for dually eligible enrollees being held responsible for payment of cost-sharing amounts above the MOOP limit. As a result, our proposal may lead to an increase in the plan bids relative to the benchmark for dually eligible individuals who would receive the same cost-sharing protection provided by the MOOP that is now afforded non-dually eligible individuals. However, in the short term, as we note above, MA organizations may prefer to reduce their profit margins, rather than substantially raise their bids and thereby reduce the rebate dollars available for supplemental benefits.

Specifically, CMS proposes that all cost-sharing for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under the lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit. This would ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit, the MA plan must pay 100 percent of the cost of covered Medicare Part A and Part B services. As a result, the State Medicaid agency would no longer be responsible for any Medicare cost-sharing for the remainder of the year. In addition, providers serving dually eligible MA enrollees with Medicare cost-sharing above the MOOP limit would be fully reimbursed for this cost-sharing for the remainder of the year. Now, some of that cost-sharing is unpaid because of limits on State payment of Medicare cost-sharing and prohibitions on collection of Medicare-cost sharing from certain dually eligible beneficiaries. We believe this proposed change to the cost-sharing that MA organizations must use to determine when the MOOP limit has been reached will mitigate existing provider payment disincentives related to serving dually eligible MA enrollees. As a result, the proposal may improve access to providers, including specialists, who currently limit the number of dually eligible MA enrollees they serve or decline to contract with D–SNPs. However, we are unable to quantify the extent to which any improved access would affect utilization of services by dually eligible MA enrollees and thereby affect Medicare spending.

Our proposal would increase the amount of MA organization payments to providers serving dually eligible individuals enrolled in MA plans after the MOOP limit is reached. As a result, our proposal may lead to an increase in the plan bids relative to the benchmark for dually eligible individuals who would receive the same cost-sharing protection provided by the MOOP that is now afforded non-dually eligible individuals.

To estimate the costs of the proposal, we started with CY2022 bid data to estimate the Medicare cost-sharing accrued by dually eligible beneficiaries with cost-sharing protections (full benefit dually eligible individuals and QMB enrollees) above the mandatory MOOP level ($7,550 in 2022). We estimated the cost of Medicare cost-sharing above this MOOP level to be on average $22.99 per person per month. Then we multiplied this amount by 41 percent to reflect the portion of dually eligible enrollees in MA organizations that already accrue cost sharing towards the MOOP level to arrive at $9.43 as the additional per person per month bid cost. Based on projected MA enrollment of dually eligible beneficiaries and other factors described in this section, this proposal would result in additional payments from MA organizations to health care providers serving high cost dually eligible MA enrollees, represented in the annual MA bid costs shown in column 2 of Table 12.

Only a portion of the projected higher MA organization bids for MOOP benefits represent higher costs to Medicare. MA rebates are calculated as an average of 68 percent of the difference between the bids and benchmarks. The additional cost to the Medicare Trust Funds is estimated to be the remaining 32 percent increase in bids. After reflecting the change in rebates, the per member per month cost to Medicare of the proposed policy is 32 percent of $9.43, or $3.

To project annual costs, we used projected enrollment by dually eligible beneficiaries in MA plans, as well as Trustee's Report USPCC cost and utilization trends. We also projected annual increases in the mandatory MOOP amounts under current regulations. The cost to Medicare based on our proposed changes would be partly offset by the savings to Medicaid for payment of Medicare cost-sharing over the MOOP limit for dually eligible individuals. While some State Medicaid agencies may save as much as the projected increase in bid costs per dually eligible MA enrollee in their State, the savings from this proposal will likely be less for most States. The majority of States have a ''lesser-of'' policy, under which the State caps its payment of Medicare cost-sharing so that the sum of Medicare payment and cost-sharing does not exceed the Medicaid rate for a particular service. We estimate that, based on average differences in State Medicaid and Medicare provider contracted rates, 39 percent of the costs of MOOP coverage under our proposal represents Medicaid savings. Of those savings, 57 percent accrue to the Federal government based on the average FMAP rate of 57 percent. Those annual savings are shown in column 4 of Table 12.

Finally, 25 percent of the additional Medicare costs that represent Part B

costs (Part B accounts for 60 percent of the costs of Parts A and B benefits provided by Medicare Advantage organizations) are offset by beneficiary premiums for Part B, as shown in column 6 of Table 12. The total Federal costs of the proposal, net of Federal Medicaid savings and the Part B premium offset are shown in column 7 of Table 12.

We note that there is uncertainty inherent in this analysis. In using the bid data, we made some assumptions about the extent to which MA organizations are already counting all cost-sharing in the plan benefit, including amounts paid by Medicaid programs, towards the MOOP limit. In addition, MA organizations may prefer to reduce their gain/loss margins, rather than substantially change their benefit package, when rebates are reduced in the short term. However, our estimate of the added bid benefit costs does not assume that MA organizations will absorb any portion of these costs by reducing their gain/loss margins.

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TABLE 12: 10-YEAR AGGREGATE PROJECTED COSTS (MILLIONS $) FROM PROPOSED MOOP PROVISION*

Year	Additional Bid Benefit Costs for MA Organizations for Cost Sharing Above the MOOP	Total Medicare-Only Benefit Costs	Federal Savings to Medicaid from MOOP Provision	Medicare Costs minus Medicaid Savings	Part B Premium Offsets	Impact of MOOP Provision
(1)	(2)	(3) = 32% * (2)	(4) =39% * 57% * (2)	(5) = (3) - (4)	(6) = 60% * 25% *(3)	(7) = (5) - (6)
2023	805.8	257.9	179.1	78.7	38.7	40.0
2024	879.5	281.4	195.5	85.9	42.2	43.7
2025	963.2	308.2	214.1	94.1	46.2	47.9
2026	1,052.5	336.8	234.0	102.8	50.5	52.3
2027	1,145.8	366.7	254.7	111.9	55.0	56.9
2028	1,279.2	409.3	284.4	125.0	61.4	63.6
2029	1,391.1	445.2	309.2	135.9	66.8	69.1
2030	1,502.2	480.7	333.9	146.8	72.1	74.7
2031	1,619.7	518.3	360.1	158.2	77.7	80.5
2032	1,730.6	553.8	384.7	169.1	83.1	86.0
Totals	12,369.5	3,958.2	2,749.7	1,208.5	593.7	614.8

*Explanatory equations in the second row of the table are further elaborated on in the narrative.

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No additional goods or services are being created. Rather, the money that States would pay or that would remain unpaid for Parts A and B services is now being paid by the plans and hence by the Trust Fund. Hence these amounts are considered transfers from the Trust Fund to the States.

5. Special Requirements During a Disaster or Emergency (§ 422.100(m))

We are not scoring the proposed revisions to § 422.100(m) Special Requirements during a Disaster or Emergency. As stated in the February 12, 2015 final rule (80 FR 7953), we recognize that disasters can create unavoidable disruptions and increased costs for MA organizations. Our primary goal during a disaster is the provision of continued and uninterrupted access to medically necessary plan-covered services for all enrollees. Our intention is to facilitate achievement of this goal by ensuring that plans facilitate increased access to providers from whom enrollees in the disaster area may seek high quality services at in-network cost-sharing. We do not believe that these temporary and unusual episodes of increased access will incentivize enrollees in a negative way or result in significant cost increases for affected MA organizations. We believe this is still relevant as most of our proposed revisions clarify our current policy. More detailed arguments for not scoring are presented below after a discussion of the proposal.

Our proposed amendments to § 422.100(m) include codifying our

current practice of imposing the special requirements at § 422.100(m)(1) on MA organizations only when there is a disruption of access to health care as stated in the preamble to the February 12, 2015 final rule (80 FR 7953) and in our responses to inquiries. We receive many questions and inquiries during a disaster or emergency so we believe this has been fully complied with; because we are clarifying through notice and comment rulemaking, these clarifications may result in enhanced compliance with this requirement and may contribute to reduced costs. Consequently, we do not believe the disruption of access proposal has an impact because it is already complied with.

We also proposed adding a transition period of 30 days between a disaster or emergency ending and the end of the special requirements to § 422.100(m)(3). We do not believe these provisions would create impact. Some MA organizations may already allow flexibilities to enrollees following a disaster or emergency, such as a transition period to allow additional time for enrollees to return to in-network providers. Additionally, many plans have experience with disasters or other changes in cost that arise annually. The nature of the business cycle shows that plans may experience losses due to disasters or emergencies in certain years, which may be offset with profits in the following years. Although the cost burden for a longer disaster or emergency is different than that for a shorter disaster, our recent experience with the COVID–19 PHE shows that CMS is aware of this cost burden and as each specific situation develops, is responding with certain flexibilities.

For these reasons, we are not further scoring the special requirements during a disaster or emergency provision.

6. Provisions Relating to Past Performance (§§ 422.504 and 423.505)

We propose to update the past performance measures at 42 CFR 422.504 and 423.505 in order to better ensure CMS' capacity to limit new applications and applications for service area expansions by low performers when these new plans and/or service area expansions would not be in the best interest of the Medicare program.

- To perform the calculations, we estimate—

++ 2 staff at the GS 13–5 level working at $112.62/hr would have to perform a total of 24 hours of work (12 hours for each staff); and

++ 2 staff at the GS 14–9 level working at $148.74/hr would have to perform 10 hours of work.

- To notify plans, we estimate that 1 staff at the GS–13–5 level working at $112.62/hr will have to perform 3 hours of work.

The aggregate annual cost to the government is therefore $4,528.

7. Proposed Revisions to the Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

Our proposal to reinstate the detailed MLR reporting requirements in effect for CYs 2014 through 2017, and to require separate reporting of amounts spent on supplemental benefits, would impose additional costs on the Federal Government.

The paperwork burden associated with these provisions, $2.3 million, is estimated in section IV.B.12. of this proposed rule, and is included in the summary table below. There is also additional anticipated impact to the Federal Government. Most of the impact will arise from projections of future increases or decreases in MLR remittances, which are amounts that were originally paid from CMS to MA organizations or Part D sponsors, which they have to return to CMS (although the remittances go to the Treasury General Fund and not the Medicare Trust Funds from which they originated).

If our proposal to reinstate and add to the detailed MLR reporting requirements is finalized, we will pay a contractor to perform desk reviews and analyses of the reported data in order to identify omissions or suspected inaccuracies and to communicate its findings to MA organizations and Part D sponsors in order to resolve potential compliance issues. In the Regulatory Impact Analysis for the April 2018 final rule in which we eliminated the detailed MLR reporting requirements, we assumed that by significantly reducing the amount of MLR data that MA organizations and Part D sponsors would be required to report to CMS annually starting with CY 2018, we had also eliminated the need for CMS to continue paying a contractor approximately $390,000 each year in connection with desk reviews of the detailed MLR reports. However, the April 2018 final rule indicated that the entire amount we paid to our desk review contractor would no longer be necessary once we stopped collecting detailed MLR data on an annual basis. This has not been the case, as in the years since we scaled back the reporting requirements, we have continued to find value in having our contractor perform MLR-related administrative tasks. Prior to CY 2018, the funding for these administrative tasks was included in the $390,000 figure that the April 2018 final rule identified as representing payment for desk reviews only. These administrative tasks include sending reminders to MA organizations and Part D Sponsors to submit their MLR data and attestations by the applicable deadlines, following up with MA organizations and Part D sponsors about their questions regarding their MLR submissions, and triaging communications to CMS so that matters requiring additional input from us are brought to our attention timely. CMS currently pays the contractor approximately $230,000 per year to perform these services.

We anticipate that, if the proposed detailed MLR reporting requirements are finalized and CMS resumes conducting desk reviews of the detailed MLR data, we will increase the amount that we pay our contractor for desk reviews and MLR-related administrative services so that the total payment amount is approximately equal to the total amount we paid to our contractor for those services prior to the elimination of the detailed MLR reporting requirements (that is, $390,000). In other words, we expect that we will need to pay our contractor an additional $160,000 per year to perform MLR desk reviews of the detailed MLR data that CMS is proposing to require MA organizations and Part D sponsors to submit to us on an annual basis, starting with CY 2023.

In addition, CMS currently pays a contractor $300,000 each year for software development, data management, and technical support related to MLR reporting. The Regulatory Impact Analysis for the April 2018 final rule estimated that we would be able to reduce this amount by $100,000 because we would no longer need to maintain and update the MLR reporting software with validation features, to receive certain data extract files, or to provide support for desk review functionality. However, contrary to our expectations, since CY 2018, CMS has continued to require technical support related to submission of the MLR Data Forms, such that, even without requiring significant updates to the MLR reporting software, we have continued to pay a contractor $300,000 for data management and technical support services. We anticipate that we will continue to pay this amount for software development, data management, and technical support related to MLR reporting if the proposed changes to the MLR reporting requirements are finalized.

Table 14 presents expected additional payments (transfers) from MA

organizations and Part D sponsors to the Treasury arising because they are projected to pay more in MLR remittances to the Treasury. These additional payments are transfers since no goods or services are being created. The impact to the Medicare Trust Funds is $0.

Based on internal CMS data, the raw average of total remittances for CYs 2014–2019 is $153 million. As discussed in section II.G.2. of this proposed rule, when CMS collected detailed MLR data pursuant to the reporting requirements that were in effect for CYs 2014–2017, the desk review contractor frequently detected potential errors or omissions in the reported data, which were brought to the attention of the MA organization or Part D sponsor that submitted the data, with a request to explain or correct the data. This process often resulted in the MA organization or Part D sponsor finding it necessary to resubmit the contract's MLR Report after revising the figures in the Report or attaching supplementary materials to explain details of its expense allocation methodology. A summary of the MLR remittances for the initial MLR submission versus the final MLR submission for CYs 2014–2017 can be found in the table below. These 4 years represent the time period when detailed MLR data was submitted to CMS and subjected to desk reviews.

TABLE 13: CHANGE IN MLR REMITTANCES BETWEEN INITIAL AND FINAL MLR SUBMISSION

Contract Year (CY)	Initial MLR Submission	Final MLR Submission	Change	Percent Change
2014	36,884,719	37,074,217	189,498	0.5%
2015	28,128,535	22,064,688	(6,063,847)	-27.5%
2016	200,308,358	242,402,915	42,094,557	17.4%
2017	223,244,933	222,058,179	(1,186,754)	-0.5%
2014–2017	488,566,545	523,599,999	35,033,454	6.7%
2018	92,639,916	94,502,390	1,862,474	-----
2019	298,124,406	298,124,406	-----	-----
Average (2016–2019):[1]		204,045,022	-----	-----

[1]The average remittance is calculated using the initial MLR submission for CYs 2016 and 2017 and the final MLR submission for CYs 2018 and 2019.

The percent change in MLR remittances increased on average 6.7 percent between the initial and final MLR submissions during the MLR desk review periods for CYs 2014–2017. We anticipate that, if finalized, the proposed amendments to §§ 422.2460 and 423.2460 would increase future remittance amounts by an average of 6.7 percent due to CMS receiving detailed MLR data and conducting desk reviews of the detailed MLR data.

To estimate the amount of additional remittances under the proposed regulations, we evaluated the MLR for those contracts that failed to meet the 85 percent minimum MLR requirement for CYs 2016–2019. The MLR remittances for CYs 2014 and 2015 were much lower than those for the more recent years and so these older years were excluded from the base period that is used to project future remittances. For CYs 2016 and 2017, we examined the MLR prior to desk reviews, or in the Initial MLR Submission. For CYs 2018 and 2019, when there were not desk reviews of detailed MLR data, we examined the finalized total MLR remittances. The average remittances for these years (CYs 2016 and 2017 prior to desk reviews and CYs 2018 and 2019) equaled $204.0 million. In order to project the increase in remittances for CYs 2023–2032, the $204.0 million was inflated using estimated enrollment and per capita increases based on Tables IV.C1. and IV.C3. of the 2021 Medicare Trustees Report, with ordinary inflation (Table II.D1. of the 2021 Medicare Trustees Report) carved out of the estimates. We continued to assume that remittance amounts would increase by 6.7 percent for the entire projection period due to the restatement of desk reviews of detailed MLR data, after the application of enrollment and per capita increases.

Table 14 is based on data from the Office of the Actuary, some of which may be found in the annual Trustees Report. The calculations started with a $13.7 million additional cost to MA organizations and Part D sponsors in CY 2019 (This amount is not shown in the table which is a 10 year table starting from CY 2023). The cost in each successive contract year is obtained by adding the MA enrollment increases expressed as a percentage in column (2), then adding the average annual per capita increase in expenditures, expressed as a percentage in column (3), and then dividing by ordinary inflation expressed as a percentage column (4). The calculations can be illustrated starting with the CY 2023 net cost ($20.3 million) and deriving the $21.5 million CY 2024 cost. We have $20.3 million *(1 + 3.8%) * (1 + 4.8%)/(1 + 2.5%) = $21.5 million.

TABLE 14: MLR COST (TRANSFERS) FROM MA ORGANIZATIONS AND PART D SPONSORS (MILLIONS) TO THE TREASURY

Contact Year	MA Enrollment Increase	Average Annual Per Capita Increase in Expenditures	Ordinary Inflation	Net Cost (Savings) ($ millions)
(1)	(2)	(3)	(4)	(5)
2023	4.1%	4.8%	2.5%	20.3
2024	3.8%	4.8%	2.5%	21.5
2025	3.7%	5.4%	2.5%	22.9
2026	3.6%	5.4%	2.5%	24.4
2027	3.3%	5.3%	2.5%	25.9
2028	3.1%	5.5%	2.5%	27.5
2029	2.8%	5.5%	2.5%	29.1
2030	2.6%	4.4%	2.5%	30.4
2031	2.3%	7.2%	2.4%	32.6
2032	1.8%	4.9%	2.4%	34.0
Totals				268.6

8. Pharmacy Price Concessions in the Part D Negotiated Price (42 CFR 423.100)

As discussed in section II.H.3. of this proposed rule, at § 423.100, we propose to adopt a new definition of ''negotiated price'' to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug. As part of this proposal, we first propose to delete the current definition of ''negotiated prices'' (in the plural) and add a definition of ''negotiated price'' (in the singular) to make clear that a negotiated price can be set for each covered Part D drug, and the amount of the pharmacy price concessions may differ on a drug by drug basis. Then, we propose a definition of ''negotiated price'' that is intended to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all pharmacy price concessions. The proposed requirement to apply pharmacy price concessions to the negotiated price at the point-of-sale would apply in all phases of the Part D benefit except with respect to applicable drugs dispensed to applicable beneficiaries in the coverage gap.

Plan sponsors may attempt to mitigate the effects from this change by modifying their benefits, such as making more frequent use of copay structures rather than coinsurance. There are limits to how much this can change, however, given that they must maintain actuarial equivalence to the defined standard design, where lower prices would result in lower cost sharing.

The proposal would have several impacts on prescription drug costs for government, beneficiaries, Part D sponsors, and manufacturers. Tables 15 and 16 summarize these impacts, which are discussed in more detail in the narrative that follows. We note that this proposal would also have one-time administrative costs for Part D sponsors. This cost is discussed in the Collection of Information section of this proposed rule.

a. Impact on Prescription Drug Costs for Government, Beneficiaries, Part D Sponsors, and Manufacturers

Table 16 summarizes the 10-year impacts we have modeled for requiring that sponsors apply all pharmacy price concessions to the negotiated price in all phases of the Part D benefit except for applicable drugs in the coverage gap. We estimate a modest potential indirect effect on pharmacy payment as a result of pharmacies' independent business decisions. Specifically, our estimates assume that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow and we assume that these business decisions will result in a slight increase in pharmacy payments of 0.1–0.2 percent of Part D gross drug cost. We solicit comment on the potential indirect impact estimates of the pharmacy price concessions provision included in this rule. Table 16 reflects 10-year row sums of Table 15. For example, the second row of Table 15 lists a $33.1 billion savings to beneficiaries. The row header references row (I) of Table 15. The sum of the numbers in row (I) of Table K4 is $33.1 (1.7+1.9 . . . +5.7 = 33.1). Throughout this narrative, quantitative aspects of the discussion may be found in the corresponding labeled rows of Table 16.

Under this proposal, we anticipate that beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder for most drugs, beginning immediately in the year the proposed change would take effect (2023). (This is summarized in Table 16 in the row ''Beneficiary Costs'' which reflects a sum of the rows ''Cost sharing'' and ''Premiums.'' Lower point-of-sale prices would result directly in lower cost-sharing costs for non-low-income beneficiaries, and on average we expect these cost-sharing decreases

would exceed the premium increases. While the amounts will vary depending on an individual beneficiary's prescriptions, plan sponsor benefits, and contractual arrangements, we expect more than half of the non-low-income, non-employer group beneficiaries to see lower total costs, inclusive of cost-sharing decreases and premium increases. For example, a beneficiary who takes no medications will probably see a premium increase and no cost-sharing decreases, whereas a beneficiary who takes several medications each month is likely to see cost-sharing decreases that are greater than the premium increase. For low-income beneficiaries, whose out-of-pocket costs are funded through Medicare's low-income cost-sharing payments, cost-sharing savings resulting from lower point-of-sale prices would accrue to the government.) Plan premiums would likely increase as a result of the proposed change to the definition of negotiated price—if pharmacy price concessions are required to be passed through to beneficiaries at the point of sale as proposed, fewer such concessions could be apportioned to reduce plan liability in the bid, which would have the effect of increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations for the average beneficiary would be large enough to lower their overall out-of-pocket costs. The increasing cost of coverage under Part D plans as a result of pharmacy price concessions being applied at the point of sale as proposed would likely have a more significant impact on Government costs, which would increase overall due to the significant growth in Medicare's direct funding of plan premiums and low-income premium payments.

Partially offsetting the increase in direct funding and low-income premium payment costs for the government would be decreases in Medicare's reinsurance and low-income cost-sharing payments. Decreases in Medicare's reinsurance payments result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the Government's 80 percent reinsurance payments for allowable drug costs incurred in the catastrophic phase are based on lower negotiated prices. Similarly, low-income cost-sharing payments would decrease if beneficiary cost-sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower progression of beneficiaries through the Part D benefit would also have the effect of reducing aggregate manufacturer gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it.

These impacts assume that the proposed definition of ''negotiated price'' would apply for all Part D drugs in all phases of the Part D benefit, except for applicable drugs in the coverage gap. While this exclusion would increase the complexity of the point-of-sale transaction, pharmacies and PBMs have experience with similar elements of the program today, such as accounting for the coverage gap discount program. Given the significance of these amounts to overall premiums and their competitive position, we expect that pharmacy price concessions after the point of sale will remain in place during the coverage gap. The alternative section demonstrates how requiring the price concessions in the coverage gap could lead to larger premium increases, which would not be desirable for plan sponsors.

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TABLE 15*: IMPACT (BILLIONS) OF CONCESSIONS EXCLUDES APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP

Label	Item/Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
(A)	Gross Drug Cost (GDCC)	-$14.4	-$15.8	-$17.2	-$19.0	-$20.9	-$22.9	-$25.0	-$27.3	-$29.8	-$32.4
(B)	Drug Cost Covered by Plan (Supplemental and non-Part D) CCP	-$10.5	-$11.6	-$12.7	-$13.6	-$14.6	-$15.6	-$16.7	-$17.9	-$19.1	-$20.3
(C)	OOP including Gap Discount	-$3.9	-$4.2	-$4.6	-$5.4	-$6.3	-$7.2	-$8.3	-$9.4	-$10.7	-$12.1
(D)	General Premium Payment	$4.8	$5.2	$5.6	$6.3	$7.0	$7.8	$8.6	$9.5	$10.4	$11.4
(E)	Reinsurance	-$1.4	-$1.6	-$1.7	-$1.7	-$1.7	-$1.7	-$1.6	-$1.6	-$1.5	-$1.4
(F)	LIS Cost-Sharing	-$1.2	-$1.3	-$1.4	-$1.7	-$2.1	-$2.4	-$2.8	-$3.3	-$3.8	-$4.3
(G)	LIS Premium	$0.2	$0.2	$0.2	$0.3	$0.3	$0.4	$0.4	$0.5	$0.5	$0.6
(H)	Total Government	**$2.3**	**$2.5**	**$2.7**	**$3.1**	**$3.6**	**$4.0**	**$4.5**	**$5.1**	**$5.7**	**$6.3**
(I)	Enrollee Cost Sharing	-$1.7	-$1.9	-$2.0	-$2.4	-$2.8	-$3.3	-$3.8	-$4.4	-$5.0	-$5.7
(J)	Enrollee Premiums	$0.6	$0.7	$0.7	$0.9	$1.0	$1.2	$1.4	$1.6	$1.8	$2.0
(K)	Total Enrollee Costs	-$1.1	-$1.2	-$1.3	-$1.5	-$1.8	-$2.1	-$2.5	-$2.8	-$3.2	-$3.6
(L)	Total Benefits	2.9	3.2	3.5	4.0	4.6	5.2	5.9	6.7	7.5	8.4
(M)	Gap Discount	-$0.9	-$1.0	-$1.1	-$1.2	-$1.4	-$1.5	-$1.6	-$1.8	-$1.9	-$2.1

*Negative numbers indicate savings. Positive numbers indicate costs. Row totals are found in Table 16.

TABLE 16*: TOTAL IMPACTS FOR 2023 THROUGH 2032 WITHOUT APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

	Total (in billions)	Per Member-Per-Year 2023–2032[1]	Percent Change
Beneficiary Costs (K)	($21.30)	($36.66)	-2%
Cost Sharing (I)	($33.10)	($57.03)	-6%
Premium (J)	$11.80	$20.37	5%
Government Costs	$40.00	$69.17	3%
Direct Payment (D)	$76.70	$132.47	83%
Reinsurance (E)	($15.80)	($27.27)	-2%
LI Cost-Sharing (F)	($24.40)	($42.15)	-5%
LI Premium (G)	$3.50	$6.13	7%
Manufacturer Gap Discount (M)	($14.60)	($25.19)	-6%

*Negative numbers indicate savings; positive numbers equal costs. Minor discrepancies between the sums in Tables 15 and 16 are due to rounding.

Note: These values represent the annualized average impacts divided by the average total Part D projected enrollees. Actual impacts will vary depending on beneficiary status and plan.

E. Alternative Analysis

The major drivers of cost and transfers in this rule include the MLR and Part D pharmacy price concessions provisions. The aggregate impact of each of these over 10 years exceeds $100 million. Alternative analysis is provided below for these provisions.

1. Proposed Alternatives Related to the Medical Loss Ratio Reporting Requirements (42 CFR 422.2460, 423.2460)

As an alternative to our proposal to reinstate and add to the detailed MLR reporting requirements in effect for CYs 2014–2017, we considered continuing to collect minimal MLR data, as required under current §§ 422.2460 and 423.2460, and to use our authority under §§ 422.2480 and 423.2480 to require that entities selected for MLR audits provide us with more detailed MLR data, and with any underlying records that can be used to substantiate amounts included in the calculation of each contract's MLR and the amount of any remittance owed to CMS. In addition to their primary function as a mechanism for obtaining information that can be used to validate audited MA organizations' and Part D sponsors' compliance with the applicable requirements for calculating and reporting MLR information to CMS, we believe that audits are in general well-suited for examining matters such as where and how calculation errors occur, and identifying areas where we might be able to reduce the incidence of errors through revisions to our regulations and guidance. By contrast, desk reviews of detailed MLR data are more useful for quickly reviewing large amounts of data in order to identify possible errors or omissions that might affect the MLR calculation, and for identifying market-wide trends in how MA organizations and Part D sponsors might be adjusting their expenditures in response to rule or policy changes that affect how MLRs are calculated. Given CMS' interest in better understanding how MA organizations and Part D sponsors' are calculating their MLRs in general, and in flagging areas where calculation errors might be impacting the MLR calculation so that they can be addressed promptly, we decided that our goals would be better served if we were to require MA organizations and Part D sponsors to report detailed MLR data to us directly, and to subject that data to desk reviews, rather than to attempt to collect the same or similar MLR data using our audit authority.

An additional reason we chose at this time not to rely solely on MLR audits to identify errors in MA organizations' and Part D sponsors' MLR submissions is that we believe this approach would result in a greater burden for the Federal government and cumulatively across all MA organizations and Part D sponsors than would the proposed reinstatement of the detailed MLR reporting requirements. We note that, in the April 2018 final rule, CMS indicated that we did not believe that eliminating the detailed MLR reporting requirements would weaken MLR compliance oversight, and in connection with this we noted that had not changed our authority under § 422.2480 or § 423.2480 to conduct selected audit reviews of the data reported under §§ 422.2460 and 423.2460 for purposes of determining that remittance amounts under §§ 422.2410(b) and 423.2410(b) and sanctions under §§ 422.2410(c) and (d) and 423.2410(c) and (d) were accurately calculated, reported, and applied (73 FR 16675). However, in that rule, we did not account for the increased cost to CMS, or the additional cumulative burden across all MA organization and Part D sponsors, if we were to scale up our MLR audit operations to a sufficient degree to perform effective compliance oversight in the absence of detailed MLR reporting requirements.

Based on CMS' historical costs in auditing MLRs, we estimate that individual audits would cost the government approximately $71,000 per audit. We anticipate that, in order to effectively monitor MLR compliance using audits, we would need to audit one-third of MA and Part D contracts, or an average of 194 contracts per year, at a cost of approximately $13.8 million per year. By contrast, we estimate that the proposed reinstatement of the detailed MLR reporting requirements would result in a relatively small increase in burden for MA organizations and Part D sponsors, as we expect that they would already need to be tracking most of the information included in the

detailed MLR Report template in order to calculate their MLRs in accordance with current requirements.

2. Proposed Alternatives Related to Pharmacy Price Concessions in the Part D Negotiated Price (§ 423.100)

As discussed in section II.H.3. of this proposed rule, we propose to adopt a new definition of ''negotiated price'' to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug.

In the analysis provided in section IV.D.8. of this proposed rule, we estimate the impact of our proposal to require application of pharmacy price concessions to the negotiated price at the point-of-sale in all phases of the Part D benefit except with respect to applicable drugs in the coverage gap. In this alternative analysis, we consider the added impact of requiring application of pharmacy price concessions to the negotiated price of applicable drugs in the coverage gap also.

Table 17 shows the increased savings to enrollees. Ten-year total savings to enrollees increase 37 percent from $21.3 billion as indicated in Table 16 to $29.1 billion. As explained in the previous narratives, the total savings to enrollees accounts for both cost-sharing savings and expected premium increases.

TABLE 17. TOTAL IMPACTS TO ENROLLEES FOR 2023 THROUGH 2032 WITH APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total With Gap	Total Without Gap
Beneficiary Costs (in billions)	$0.0	-$1.6	-$1.7	-$1.8	-$2.2	-$2.5	-$2.9	-$3.3	-$3.8	-$4.3	-$4.9	**-$29.1**	**-$21.3**
Cost-Sharing	$0.0	-$2.4	-$2.6	-$2.8	-$3.3	-$3.8	-$4.4	-$5.1	-$5.8	-$6.6	-$7.5	**-$44.3**	**-$33.1**
Premium	$0.0	$0.8	$0.9	$1.0	$1.1	$1.3	$1.5	$1.8	$2.0	$2.3	$2.6	**$15.2**	**$11.8**

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of $

Table 18 shows increased savings to pharmaceutical manufacturers if pharmacy price concessions are applied to applicable drugs in the coverage gap. As can be seen, savings to manufacturers increase by 23 percent since as presented in Table 16, the savings are $14.6 billion without application in the coverage gap while with application to applicable drugs in the coverage gap the savings are $17.9 billion.

TABLE 18: TOTAL IMPACTS TO MANUFACTURERS FOR 2023 THROUGH 2032 WITH APPLICATION IN COVERAGE GAP

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total With Gap	Total Without Gap
Manufacturer Gap Discount (in billions)	$0.0	-$1.1	-$1.3	-$1.4	-$1.5	-$1.7	-$1.8	-$2.0	-$2.2	-$2.4	-$2.6	-$17.9	-$14.6

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars ($).

Table 19 shows the impact to the Government. The Federal expenditures increase 27 percent, from the $40.0 billion presented in Table 16 without application in the coverage gap, to $50.7 billion if the pharmacy price concessions are applied to the point-of-sale price of applicable drugs in the coverage gap. As explained in the narrative of section IV.D.8. of this proposed rule, the total Government cost reflects four separate components including direct payments, reinsurance, low income cost-sharing payments, and low-income premium payments. We note, that this $50.7 billion is a transfer. More specifically, the identical Rx that was formerly paid for by enrollees is now being paid for by the Government.

TABLE 19: TOTAL IMPACTS TO GOVERNMENT FOR 2023 THROUGH 2032 WITH APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP

	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	TOTAL With Gap	Total Without Gap
Government Costs (in billions)	$0.0	$2.9	$3.3	$3.5	$4.0	$4.5	$5.1	$5.8	$6.4	$7.2	$8.0	$50.7	$40.00
Direct Payments	$0.0	$6.1	$6.7	$7.2	$8.1	$8.9	$9.9	$10.9	$12.0	$13.2	$14.5	$97.6	$76.70
Reinsurance	$0.0	-$1.7	-$1.9	-$2.1	-$2.1	-$2.1	-$2.0	-$2.0	-$1.9	-$1.8	-$1.7	-$19.3	-$15.80
LI Cost-Sharing	$0.0	-$1.7	-$1.8	-$1.9	-$2.3	-$2.7	-$3.2	-$3.7	-$4.3	-$4.9	-$5.6	-$32.2	-$24.40
LI Premium	$0.0	$0.3	$0.3	$0.3	$0.4	$0.4	$0.5	$0.5	$0.6	$0.7	$0.7	$4.6	$3.50

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars ($).

F. Accounting Statement and Table

In accordance with OMB Circular A–4, Table 20 depicts an accounting statement summarizing the assessment of the benefits, costs, and transfers associated with this regulatory action.

TABLE 20: ACCOUNTING STATEMENT (MILLIONS OF DOLLARS)

Category	Estimate at 7% (In 2022 Dollars)	Estimate at 3% (In 2022 Dollars)	Years Covered	Affected Stakeholders
Net Annualized Monetized Cost	3.5	3.5	CYs 2023-2032	MA organizations, Part D sponsors, and contractors for the Federal Government
Net transfers from the Medicare Trust Fund	(3790.0)	(3930.1)	CYs 2023-2032	The transfers in this row combine: (i) transfers arising from the pharmacy price concessions provision from the Medicare Trust Fund to plan enrollees and pharmaceutical manufacturers; and (ii) transfers arising from the MOOP provision from the Medicare Trust Fund to States and providers of duals.
Transfers to the United States Treasury	26.0	26.5	CYs 2023-2032	The transfers in this row arising from the MLR provision are from MA organizations and Part D sponsors to the United States Treasury.

Table 20 is based on the summary of costs presented in Tables 21 and 22. Tables 21 and 22 reflect all costs in both the COI and RIA sections. This summary table allocates impact by year and by whether it is a cost or transfer (no provisions of this rule have a savings impact). In all tables, costs are expressed as positive amounts.

However, in the transfer row negative numbers correspond to payments by the government (which in the provisions of this rule may come from the Treasury or Medicare Trust Fund) while positive numbers indicate savings. There are 5 transfers in this rule: The MOOP provision is a cost to the Medicare Trust Fund (TF) (the corresponding gain to States and providers of duals in equal amounts is not shown in Tables 21 and 22). The MLR provision is a savings to the Treasury (the corresponding loss in equal amount to the plans is not shown in the Tables 21 and 22). The pharmacy price concessions provision incurs a cost to the Medicare Trust Fund, and savings to enrollees and manufacturers. However, there is a small difference between what the Trust Fund pays and what beneficiaries and manufacturers gain. The difference is due to the assumption that pharmacies will seek to retain a small portion of the current DIR to compensate for differences in cash flow and pricing risk. Therefore, Tables 21 and 22 list separately the impacts on the Trust Fund, the enrollees, and the manufacturers. However, the row ''Total transfers from the Trust Fund'' only reflects the sum of the Trust Fund payments for the pharmacy price concessions provision and the MOOP provision (it does not offset this amount by the savings to enrollees and manufacturers) Similarly, Table 20 reflects annualized transfers to the Treasury and annualized transfers from the Trust Fund for the MOOP and pharmacy price concessions provision but these annualized amounts do not reflect the savings to enrollees and manufacturers. Thus, complete detailed amounts on all provisions may be found in Tables 21 and 22.

TABLE 21: SUMMARY TABLE OF COSTS and TRANSFERS BY PROVISION AND YEAR (MILLIONS OF DOLLARS)

	2023 Cost	2023 Transfers	2024 Cost	2024 Transfers	2025 Cost	2025 Transfers	2026 Cost	2026 Transfers	2027 Cost	2027 Transfers
Total Costs	2.4		2.5		4.8		3.6		3.6	
Total transfers to the United States Treasury		20.3		21.5		22.9		24.4		25.9
Total Transfers from the Medicare Trust Fund		(2,340.0)		(2,543.7)		(2,747.9)		(3,152.3)		(3,656.9)
MOOP		(40.0)		(43.7)		(47.9)		(52.3)		(56.9)
Enrollee Advisory Committee					0.9		0.9		0.9	-
HRA			0.0							
HIDE, FIDE Definition					0.0					
D-SNP contracts					1.0					
Past Performance					0.0					
Unified Appeals/Grievances	0.0									
Third Party Marketing					0.2					
Marketing Multi-lanaguage insert					0.3		0.3		0.3	
MLR Paperwork	2.3		2.3		2.3		2.3		2.3	
MLR Treasury		20.3		21.5		22.9		24.4		25.9
MLR Contractor	0.2		0.2		0.2		0.2		0.2	
Rx cost to TF		(2,300.00)		(2,500.00)		(2,700.00)		(3,100.00)		(3,600.00)
Rx Savings Enrollees		1,100.0		1,200.0		1,300.0		1,500.0		1,800.0
Rx Savings Manufacturers		900.0		1,000.0		1,100.0		1,200.0		1,400.0

NOTE: Entries of $0.0 reflect rounding to tenths of a million. However, the sum of these numbers adds a total of about $0.1 million and hence these numbers were included. The numbers are obtained by dividing the corresponding numbers in the Summary COI table by 1,000,000. Positive numbers in the cost columns represent costs. In the transfer columns, positive numbers reflect savings, and negative numbers reflect costs.

TABLE 22: SUMMARY TABLE OF COSTS AND TRANSFERS BY PROVISION AND YEAR (MILLIONS OF DOLLARS)

	2028 Costs	2028 Transfers	2029 Cost	2029 Transfers	2030 Cost	2030 Transfers	2031 Cost	2031 Transfers	2032 Cost	2032 Transfers	Raw 10 Year Totals
Total Costs	3.6		3.6		3.6		3.6		3.6		32.1
Total transfers to the United States Treasury		27.5		29.1		30.4		32.6		34.0	268.6
Total Transfers from the Medicare Trust Fund		(4,063.6)		(4,569.1)		(5,174.7)		(5,780.5)		(6,386.0)	(40,414.8)
MOOP		(63.6)		(69.1)		(74.7)		(80.5)		(86.0)	(614.8)
Enrollee Advisory Committee	0.9		0.9		0.9		0.9		0.9		6.9
HRA											0.0
HIDE, FIDE Definition											
D-SNP contracts											1.0
Past Performance											
Unified Appeals/Grievances											-
Third Party Marketing											0.2
Marketing Multi-lanaguage insert	0.3		0.3		0.3		0.3		0.3		2.1
MLR Paperwork	2.3		2.3		2.3		2.3		2.3		20.5
MLR Treasury		27.5		29.1		30.4		32.6		34.0	268.6
MLR Contractor	0.2		0.2		0.2		0.2		0.2		1.6
Rx cost to TF		(4,000.00)		(4,500.00)		(5,100.00)		(5,700.00)		(6,300.00)	(40,000.00)
Rx Savings Enrollees		2,100.00		2,500.00		2,800.00		3,200.00		3,600.00	21,300.00
Rx Savings Manufacturers		1,500.00		1,600.00		1,800.00		1,900.00		2,100.00	14,600.00

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F. Conclusion

The previous analysis, together with the preceding preamble, provides an RIA. This rule at an annual cost of $ 3.5 million, during the first 10 years after implementation, provides efficiencies and improves marketing and communications, past performance measures, Star Ratings, network adequacy, medical loss ratio reporting, requirements during disasters or public emergencies, D–SNP program, MOOP, as well as cost-efficiencies to enrollees for prescription drugs. Additionally, there are a variety of transfers to and from the Federal Government (the Medicare Trust Fund and the United States Treasury) which in aggregate will increase dollar spending by $3.8 to $3.9 billion annually. We estimate that this rule generates $2.4 million in annualized costs, discounted at 7 percent relative to year 2016, over an infinite time horizon.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 14, 2021.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended by—
■ a. In the definition of ''Fully integrated dual eligible special needs plan'':
■ i. Revising paragraphs (2) and (3);
■ ii. Removing the period at the end of paragraph (4) and adding a semicolon in its place; and
■ iii. Adding paragraphs (5) and (6); and
■ b. Revising the definition of ''Highly integrated dual eligible special needs plan''.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Fully integrated dual eligible special needs plan * * *

(2) Whose capitated contract with the State Medicaid agency requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a fully integrated dual eligible special needs plan (FIDE SNP) in the State, except as approved by CMS under § 422.107(g) and (h):

(i) Primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries.

(ii) Long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the plan year.

(iii) For plan year 2025 and subsequent years, behavioral health services.

(iv) For plan year 2025 and subsequent years, home health services as defined in § 440.70.

(v) For plan year 2025 and subsequent years, durable medical equipment as defined in § 440.70(b)(3);

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries;

* * * * *

(5) For plan year 2025 and subsequent years, that has exclusively aligned enrollment; and

(6) For plan year 2025 and subsequent years, whose capitated contract with the State Medicaid agency covers the entire service area for the dual eligible special needs plan.

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract that meets the following requirements—

(1) The capitated contract is between the State Medicaid agency and—

(i) The MA organization; or

(ii) The MA organization's parent organization, or another entity that is owned and controlled by its parent organization.

(2) The capitated contract requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State, except as approved by CMS under § 422.107(g) or (h):

(i) Long-term services and supports, including community-based long-term services and supports and some days of coverage of nursing facility services during the plan year; or

(ii) Behavioral health services; and

(3) For plan year 2025 and subsequent years, the capitated contract covers the entire service area for the dual eligible special needs plan.

* * * * *

■ 3. Section 422.100 is amended by—
■ a. Adding paragraphs (f)(4)(i) and (ii) and (f)(5)(iii);
■ b. Revising paragraphs (m)(1) introductory text, (m)(2) introductory text, (m)(3) and (4), and (m)(5)(i); and
■ c. Adding paragraph (m)(6).

The additions and revisions read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(4) * * *

(i) *Tracking of deductible and catastrophic limits and notification.* MA plans are required to track the maximum out-of-pocket limit described in paragraph (f)(4) of this section based on accrued out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the limit has been reached.

(ii) [Reserved]

(5) * * *

(iii) MA plans are required to track the maximum out-of-pocket limit described in paragraph (f)(5) of this section based on accrued out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the limit has been reached.

* * * * *

(m) * * *

(1) *Access to covered benefits during disasters or emergencies.* When a disaster or emergency is declared as described in paragraph (m)(2) of this section and there is disruption of access to health care as described in paragraph (m)(6) of this section, an MA organization offering an MA plan must, until one of the conditions described in paragraph (m)(3) of this section occurs, ensure access to covered benefits in the following manner:

* * * * *

(2) *Declarations of disasters or emergencies.* A declaration of a disaster or emergency will identify the geographic area affected by the event and may be made as one of the following:

* * * * *

(3) *End of the special requirements for the disaster or emergency.* An MA organization must continue furnishing access to benefits as specified in paragraphs (m)(1)(i) through (iv) of this section for 30 days after the conditions described in paragraph (m)(3)(i) or (ii) of this section occur with respect to all applicable emergencies or after the condition described in paragraph (m)(3)(iii) of this section occurs, whichever is earlier:

(i) All sources that declared a disaster or emergency that include the service area declare an end.

(ii) No end date was identified as described in paragraph (m)(3)(i) of this section, and all applicable emergencies or disasters declared for the area have ended, including through expiration of the declaration or any renewal of such declaration.

(iii) There is no longer a disruption of access to health care as defined in paragraph (m)(6) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the disaster or emergency as described in paragraph (m)(3)(i) or (ii) of this section must notify CMS.

(5) * * *

(i) Indicate the terms and conditions of payment during the disaster or emergency for non-contracted providers furnishing benefits to plan enrollees residing in the affected service area(s).

* * * * *

(6) *Disruption of access to health care.* A disruption of access to health care for the purpose of paragraph (m) of this section is an interruption or interference throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services to enrollees resulting in MA plans failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

■ 4. Section 422.101 is amended by—

■ a. In paragraph (d)(4), removing the word ''incurred'' and adding in its place the word ''accrued''.

■ b. Revising paragraph (f)(1)(i).

The revision reads as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) * * *

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individuals' individualized care plan as required under paragraph (f)(1)(ii) of this section. Beginning in 2024, the comprehensive risk assessment tool must include standardized questions specified by CMS in subregulatory guidance as follows:

(A) One or more questions on housing stability.

(B) One or more questions on food security.

(C) One or more questions on access to transportation.

* * * * *

■ 5. Section 422.107 is amended by—

■ a. Revising the section heading and paragraphs (c)(6) and (d);

■ b. Redesignating paragraph (e) as paragraph (i); and

■ c. Adding new paragraph (e) and paragraphs (f) through (h).

The revisions and additions read as follows:

§ 422.107 Requirements for dual eligible special needs plans.

* * * * *

(c) * * *

(6) The verification of an enrollee's Medicaid eligibility.

* * * * *

(d) *Additional minimum contract requirement.* (1) For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, except as specified in paragraph (d)(2) of this section, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arranges for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with the requirement in this paragraph (d)(1).

(2) For a dual eligible special needs plan that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries who are not entitled to full medical assistance under a State plan under title XIX of the Act, paragraph (d)(1) of this section does not apply if the SNP operates under the same parent organization and in the same service area as a dual eligible special needs plan limited to beneficiaries with full medical assistance under a State plan under title XIX of the Act that meets the requirements at paragraph (d)(1) of this section.

(e) *Additional opportunities in certain integrated care programs.* (1) CMS facilitates operationalization as described in paragraphs (e)(2) and (3) of this section if a State Medicaid agency requires MA organizations offering dual eligible special needs plans with exclusively aligned enrollment to do both of the following:

(i) Apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more dual eligible special needs plans with a service area limited to that State.

(ii) Use required materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets MA requirements consistent with § 422.2267(e) and §§ 423.2267(e) and 438.10(h) of this chapter.

(2) The requirements, processes, and procedures applicable to dual eligible special needs plans and the MA program, including for applications, bids, and contracting procedures under §§ 422.250 through 422.530, remain applicable. Because implementation of the contract provisions described in paragraph (e)(1) of this section may require administrative steps that cannot be completed between reviewing the contract and the start of the plan year, CMS begins good faith work following

receipt of a letter from the State Medicaid agency indicating intent to include the provisions described in paragraph (e)(1) of this section in a future contract year and collaborate with CMS on implementation.

(3) When the conditions of paragraph (e)(1) of this section are met—

(i) Following a State request, CMS grants access for State Medicaid agency officials to the Health Plan Management System (HPMS) (or its successor) for purposes of oversight and information-sharing related to the MA contract(s) described in paragraph (e)(1)(i) of this section, as long as State Medicaid agency officials agree to protect the proprietary nature of information to which the State Medicaid agency may not otherwise have direct access. State access to the Health Plan Management System (or its successor) is subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. CMS may terminate a State official's access to the Health Plan Management System (or its successor) if any policy is violated or if information is not adequately protected; and

(ii) CMS coordinates with States on program audits, including information-sharing on major audit findings and coordination of audits schedules for the D–SNPs subject to paragraph (e)(1) of this section.

(f) *Enrollee advisory committee.* Any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization in that State.

(1) The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

(2) The enrollee advisory committee may also advise managed care plans that serve D–SNP enrollees under title XIX of the Act offered by the same parent organization as the MA organization offering the D–SNP.

(g) *Permissible carve-outs of long-term services and supports for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of long-term services and supports, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use long-term services and supports; or

(2) Constitute a small part of the total scope of long-term services and supports provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(h) *Permissible carve-outs of behavioral health services for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of behavioral health services, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use behavioral health services; or

(2) Constitute a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

* * * * *

■ 6. Section 422.116 is amended by revising paragraph (a)(1)(ii) and adding paragraph (d)(7) to read as follows:

§ 422.116 Network adequacy.

(a) * * *

(1) * * *

(ii) Beginning with contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

* * * * *

(d) * * *

(7) *New or expanding service area applicants.* Beginning with contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. At the beginning of the applicable contract year, this credit no longer applies and if the application is approved, the MA organization must be in full compliance with this section.

* * * * *

■ 7. Section 422.166 is amended by adding paragraph (i)(12) to read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(i) * * *

(12) *Special rules for the 2023 Star Ratings only.* For the 2023 Star Ratings only, for measures derived from the Health Outcomes Survey only, CMS does not apply the provisions in paragraph (i)(9) or (10) of this section and CMS does not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

■ 8. Section 422.502 is amended by revising paragraphs (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Received 2.5 or less on CMS Star Ratings, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions.

(*1*) CMS determines the number of points each MA organization accumulated during the performance

period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(*2*) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold.

* * * * *

■ 9. Section 422.503 is amended by revising paragraphs (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(5) * * *

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

* * * * *

■ 10. Section 422.504 is amended by revising paragraph (m) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(m) *Issuance of compliance actions for failure to comply with the terms of the contract.* The MA organization acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (m)(3) of this section if it determines that the MA organization has not complied with the terms of a current or prior Part C contract with CMS.

(i) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the MA organization.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization.

(iv) The history of prior offenses by the MA organization or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of non-compliance.* A notice of non-compliance may be issued for any failure to comply with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued non-compliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are requested for particularly serious or continued non-compliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the MA organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

* * * * *

■ 11. Section 422.530 is amended by revising paragraph (c)(4) to read as follows:

§ 422.530 Plan crosswalks.

* * * * *

(c) * * *

(4) When—

(i) A renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interest of the enrollees to move to the new or renewing D–SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For the crosswalk exception in this paragraph (c)(4), CMS does not permit enrollees to be moved between different contracts; or

(ii) An MA organization creates a new MA contract when required by a State as described in § 422.107(e), eligible enrollees may be moved from the existing D–SNP that is non-renewing, reducing its service area, or has its eligible population newly restricted by a State, to a D–SNP offered under the D–SNP-only contract, which must be of the same plan type operated by the same parent organization.

* * * * *

■ 12. Section 422.561 is amended by revising the definition of ''Applicable integrated plan'' to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means either of the following:

(1) *Before January 1, 2023.* (i) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(ii) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

(2) *On or after January 1, 2023.* (i)(A) A fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(B) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization; or

(ii) A dual eligible special needs plan and affiliated Medicaid managed care plan where—

(A) The dual special needs plan, by State policy has enrollment limited to those beneficiaries enrolled in a Medicaid managed care organization as described in paragraph (2)(ii)(B) of this definition;

(B) There is a capitated contract between the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization; and

(*1*) A Medicaid agency; or

(*2*) A Medicaid managed care organization as defined in section 1903(m) of the Act that contracts with the Medicaid agency; and

(C) Through the capitated contract described in paragraph (2)(ii)(B) of this definition, Medicaid benefits including primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and at a minimum, home health services as defined in § 440.70 of this chapter, durable medical equipment as defined in § 440.70(d)(3) of this chapter, or nursing facility services are covered for the enrollees.

* * * * *

■ 13. Section 422.629 is amended by—

■ a. Revising paragraph (d);

■ b. In paragraph (k)(4)(ii), removing the phrase ''integrated organization determination decision'' and adding in its place the phrase ''integrated reconsideration determination'';

■ c. Revising paragraph (l)(1); and

■ d. Adding paragraph (l)(4).

The revisions and addition read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(d) *Evidence.* The applicable integrated plan must do the following:

(1) Provide the enrollee—

(i) A reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations; and

(ii) Information on how evidence and testimony should be presented to the plan.

(2) Inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

* * * * *

(l) * * *

(1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee.

(ii) The enrollee's representative, including any person authorized under State law.

* * * * *

(4) The following individuals or entities may request an integrated reconsideration and are parties to the case:

(i) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service).

(ii) Any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding.

■ 14. Section 422.631 is amended by adding paragraph (d)(3) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(d) * * *

(3) *Timeframe for requests for payment.* The applicable integrated plan must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

* * * * *

■ 15. Section 422.633 is amended by revising the section heading and paragraphs (e)(1) and (f)(3)(i) introductory text to read as follows:

§ 422.633 Integrated reconsiderations.

* * * * *

(e) * * *

(1) Applicable integrated plans must accept requests to expedite integrated reconsiderations from either of the following:

(i) An enrollee.

(ii) A provider, making the request on behalf of an enrollee, that is not a request for expedited payment.

* * * * *

(f) * * *

(3) * * *

(i) The applicable integrated plan may extend the timeframe for resolving any integrated reconsideration other than those concerning Part B drugs by 14 calendar days if—

* * * * *

■ 16. Section 422.634 is amended by revising paragraph (d) to read as follows:

§ 422.634 Effect.

* * * * *

(d) *Services not furnished while the appeal is pending.* (1) If an applicable integrated plan reverses its decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than the earlier of—

(i) 72 hours from the date it reverses its decision; or

(ii)(A) With the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

* * * * *

■ 17. Section 422.2260 is amended by adding the definition of ''Third-party marketing organization (TPMO)'' in alphabetical order to read as follows:

§ 422.2260 Definitions.

* * * * *

Third-party marketing organization (TPMO) means organizations who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.504(i), but may also be entities that are not FDRs but provide services to customers including an MA plan or an MA plan's FDR.

■ 18. Section 422.2265 is amended by adding paragraphs (b)(13) and (14) to read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(13) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form–1696).

(14) Enrollment instructions and forms.

* * * * *

■ 19. Section 422.2267 is amended by—

■ a. Redesignating paragraphs (e)(30) through (38) as paragraphs (e)(32) through (40).

■ b. Adding new paragraphs (e)(30) and (31) and paragraph (e)(41).

The additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(30) *Member ID card.* The member ID card is a model communications material that plans must provide to enrollees as required under § 422.111(i). The member ID card—

(i) Must be provided to new enrollees within ten calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later;

(ii) Must include the plan's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under § 422.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a PPO and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member; and

(vi) Is excluded from the translation requirement under paragraph (a)(2) of this section.

(31) *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. The disclaimer consists of the statement ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1–800–MEDICARE to get information on all of your options.'' The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization unless the TPMO sells all commercially available MA plans in a given service area.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

■ 20. Section 422.2274 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 422.504(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, MA plans must implement the following as a part of their oversight of TPMOs:

(1) When a TPMO is not otherwise an FDR, the MA organization is responsible for ensuring that the TPMO adheres to any requirements that apply to the MA plan.

(2) Contracts, written arrangements, and agreements between the TPMO and an MA plan, or between the TPMO and an MA plan's FDR, must ensure the TPMO:

(i) Discloses to the MA organization any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Records all calls with beneficiaries in their entirety, including the enrollment process.

(iii) Reports to plans monthly any staff disciplinary actions associated with beneficiary interaction to the plan.

(iv) Uses the TPMO disclaimer as required under § 422.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for an MA organization, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided as follows:

(A) Verbally when communicating with a beneficiary through telephone.

(B) In writing when communicating with a beneficiary through mail or other paper.

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) Disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

■ 21. Section 422.2460 is amended by revising paragraphs (a), (b) introductory text, and (d) and adding paragraph (e) to read as follows:

§ 422.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the MA organization to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS under § 422.2410.

(b) For contract years 2018 through 2022, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

* * * * *

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to an MA organization that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

■ 22. Section 422.2490 is amended by redesignating paragraph (b)(2) as paragraph (b)(2)(i) and adding paragraph (b)(2)(ii) to read as follows:

§ 422.2490 Release of Part C MLR data.

* * * * *

(b) * * *

(2) * * *

(ii) Amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 23. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 24. Section 423.100 is amended by removing the definition of ''Negotiated prices'' and adding in alphabetical order definitions for ''Negotiated price'' and ''Price concession'' to read as follows:

§ 423.100 Definitions.

* * * * *

Negotiated price means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(2) Meets all of the following:

(i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers;

(ii) Includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

* * * * *

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

* * * * *

■ 25. Section 423.503 is amended by revising the section heading and paragraphs (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(2) through (4) of this section, if a Part D plan sponsor fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(C) Filed for or is currently under state bankruptcy proceedings.

(D) Received 2.5 or less on CMS Star Ratings, as identified in § 423.186.

(E) Met or exceeded 13 points for compliance actions.

(*1*) CMS determines the number of points each Part D plan sponsor accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 423.505(n) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 423.505(n) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 423.505(n) counts for 1 point.

(*2*) CMS adds all the point values for each Part D plan sponsor to determine if any organization meets CMS' identified threshold.

* * * * *

■ 26. Section 423.505 is amended by revising paragraph (n) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(n) *Issuance of compliance actions for failure to comply with the terms of the contract.* The Part D plan sponsor acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (n)(3) of this section if it determines that the Part D plan sponsor has not complied with the terms of a current or prior Part D contract with CMS.

(i) CMS may determine that a Part D plans sponsor is out of compliance with a Part D requirement when the organization fails to meet performance standards articulated in the Part D statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining

noncompliance, CMS may determine that a Part D plan sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D plan sponsors.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the Part D plan sponsor.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the Part D plan sponsor.

(iv) The history of prior offenses by the Part D plan sponsor or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the Part D plan sponsor's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of non-compliance.* A notice of non-compliance may be issued for any failure to comply with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued non-compliance with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are issued for particularly serious and/or continued non-compliance with the requirements of the Part D plan sponsors' current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the Part D plan sponsor has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, and/or must implement a detailed plan to correct the underlying causes of the noncompliance.

* * * * *

■ 27. Section 423.2260 is amended by adding the definition of ''Third-party marketing organization (TPMO)'' in alphabetical order to read as follows:

§ 423.2260 Definitions.

* * * * *

Third-party marketing organization (TPMO) are organizations who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of a Part D plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.504(i) of this chapter, but may also be entities that are not FDRs but provide services to customers including an Part D sponsor or an Part D sponsor's FDR.

■ 28. Section 423.2265 is amended by adding paragraphs (b)(14) and (15) to read as follows:

§ 423.2265 websites.

* * * * *

(b) * * *

(14) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form-1696).

(15) Enrollment instructions and forms.

* * * * *

■ 29. Section 423.2267 is amended by—

■ a. Redesignating paragraphs (e)(32) through (37) as paragraphs (e)(34) through (39); and

■ b. Adding new paragraphs (e)(32) and (33) and paragraphs (e)(40) and (41).

The additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(32) *Member ID card.* The member ID card is a model communications material that plans must provide to enrollees as required under § 423.128(d)(2). The member ID card—

(i) Must be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later;

(ii) Must include the Part D sponsor's—

(A) Website address;

(B) Customer service number (the Member ID card is excluded from the hours of operations requirement under § 423.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a preferred provider organization (PPO) and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member; and

(vi) Is excluded from the translation requirement under paragraph (a)(2) of this section.

(33) *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(40) *Limited access to preferred cost sharing pharmacies.* This is standardized content that must—

(i) Be used on all materials mentioning preferred pharmacies when there is limited access to preferred pharmacies; and

(ii) Include the following language ''<insert organization/plan name>'s pharmacy network includes limited lower-cost, preferred pharmacies in <insert geographic area type(s) and state(s) for which plan is an outlier)>. The lower costs advertised in our plan

materials for these pharmacies may not be available at the pharmacy you use. For up-to-date information about our network pharmacies, including whether there are any lower-cost preferred pharmacies in your area, please call <insert Member Services phone number and TTY> or consult the online pharmacy directory at <insert website>.''

(41) *Third-party marketing organization disclaimer.* This is standardized content. The disclaimer consists of the statement ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1–800–MEDICARE to get information on all of your options.'' The Part D sponsor must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 423.2260, that sells plans on behalf of more than one Part D sponsor unless the TPMO sells all commercially available Part D plans in a given service area.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any TPMO marketing materials, including print materials and television advertising.

■ 30. Section 423.2274 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 423.505(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, Part D sponsor must implement the following as a part of their oversight of TPMOs:

(1) When TPMOs is not otherwise an FDR, the Part D sponsor is responsible for ensuring that the TPMO adheres to any requirements that apply to the Part D sponsor.

(2) Contracts, written arrangements, and agreements between the TPMO and a Part D plan, or between a TPMO and a Part D plan's FDR, must ensure the TPMO:

(i) Discloses to the plan any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Record all calls with beneficiaries in their entirety, including the enrollment process.

(iii) Report to plans monthly any staff disciplinary actions associated with beneficiary interaction to the plan.

(iv) Use the TPMO disclaimer as required under § 423.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for a Part D sponsor, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided:

(A) Verbally when communicating with a beneficiary through telephone;

(B) In writing when communicating with a beneficiary through mail or other paper; and

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) When applicable, disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

■ 31. Section 423.2460 is amended by revising paragraphs (a), (b) introductory text, and (d) and adding paragraph (e) to read as follows:

§ 423.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the Part D sponsor to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for prescription drugs, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract years 2018 through 2022, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:

* * * * *

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to a Part D sponsor that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

Dated: January 4, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–00117 Filed 1–6–22; 4:15 pm]

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Part III

Securities and Exchange Commission

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to Security-Based Swaps; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93914; File No. SR–FINRA–2021–008]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to Security-Based Swaps

January 6, 2022.

I. Introduction

On April 26, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to clarify the application of its rules to security-based swaps (''SBS'') following the Commission's completion of its rulemaking regarding SBS dealers (''SBSDs'') and major SBS participants (''MSBSPs'') (collectively, ''SBS Entities'').

The proposed rule change was published for comment in the **Federal Register** on May 12, 2021.[3] On June 14, 2021, FINRA consented to an extension of the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to August 10, 2021.[4] The Commission received two comments on the proposed rule change during the initial comment period.[5] On August 9, 2021, FINRA responded to the comment letters received in response to the Notice and filed an amendment to the proposed rule change (''Amendment No. 1'').[6] On August 9, 2021, the Commission issued an Order Instituting Proceedings (''OIP'') to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No.1.[7] The Commission received an additional four comments in response to the OIP.[8] On September 30, 2021, the FINRA consented to an extension of the time period in which the Commission must approve or disapprove the proposed rule change to January 7, 2022.[9] This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change

A. Background

Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Title VII'' or ''Dodd-Frank Act'') [10] established a comprehensive new regulatory framework for over-the-counter (''OTC'') derivatives, commonly known in the industry as ''swaps.'' It divided regulatory jurisdiction over swap products between the Commodity Futures Trading Commission (''CFTC'') and the Commission, with the CFTC regulating ''swaps'' and the SEC regulating SBS, and the SEC and the CFTC regulating mixed swaps.[11] The Dodd-Frank Act directed the SEC to promulgate rulemakings implementing the new regulatory framework for SBS, including rules requiring SBS Entities to register with the Commission and to be subject to requirements related to business conduct and supervision, documentation standards; recordkeeping and financial reporting; and capital, and margin and segregation. The Dodd-Frank Act also directed the Commission to promulgate rules applicable to all market participants including requiring regulatory reporting and public dissemination of SBS transaction information; and those creating processes to require SBS to become subject to mandatory clearing and execution on a registered or exempt execution facility or exchange.[12] The Commission has now finalized a majority of these rulemakings.[13] As of October 6, 2021, SBS Entities are permitted to register with the Commission and are required to comply with the Title VII rulemakings.[14] The deadline for the initial wave of SBS Entity registrations was November 1, 2021.

Title VII also amended the definition of ''security'' under the Exchange Act to expressly encompass SBS.[15] Therefore,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 91789 (May 12, 2021), 86 FR 26084 (May 12, 2021) (File No. SR–FINRA–2021–008) (''Notice'').

[4] Letter from Robert McNamee, Assistant General Counsel, Office of General Counsel, FINRA to Daniel Fisher, Division of Trading and Markets, Commission dated June 14, 2021.

[5] Letter from Kyle L. Brandon, Managing Director, Head of Derivatives Policy, Securities Industry and Financial Markets Association (''SIFMA'') to Vanessa A. Countryman, Secretary, Commission, dated June 2, 2021 (''SIFMA Letter'') and Matthew R. Cohen, Chief Executive Officer and Richard C. Chase, Chief Compliance Officer, Provable Markets LLC to Jill M. Peterson, Assistant Secretary, Commission, dated June 7, 2021 (''PML Letter''). Letters are available at the Commission's website at *https://www.sec.gov/comments/sr-finra-2021-008/srfinra2021008.htm.*

[6] *See* letter from Robert McNamee, Associate General Counsel, Office of General Counsel, FINRA, to Vanessa Countryman, Secretary, Commission, dated Aug. 9, 2021 (''FINRA Letter''). The FINRA Letter is available at the Commission's website at *https://www.sec.gov/comments/sr-finra-2021-008/srfinra2021008-9125111-247215.pdf.* Amendment No. 1 is available at *https://www.finra.org/sites/default/files/2021-08/SR-FINRA-2021-008-Amendment_1.pdf.*

[7] *See* Exchange Act Release No. 92617 (Aug. 9, 2021), 86 FR 44761 (Aug. 13, 2021) (File No. SR–FINRA–2020–008) (''OIP'').

[8] *See* Letters from Anonymous dated Aug. 10, 2021; Blake Daniels dated Aug. 10, 2021, Tristan Kifer dated Aug. 10, 2021; and Eileen Loh dated Aug. 10, 2021 (''Letters''). Letters are available at the Commission's website at *https://www.sec.gov/comments/sr-finra-2021-008/srfinra2021008.htm.*

[9] Letter from Robert McNamee, Assistant General Counsel, Office of General Counsel, FINRA to Daniel Fisher, Division of Trading and Markets, Commission dated September 30, 2021.

[10] Public Law 111–203, 124 Stat. 1376 (2010).

[11] The terms ''swap'' and ''security-based swap'' are defined in Sections 721 and 761 of the Dodd-Frank Act. The Commission and the CFTC have jointly promulgated rules further defining these terms. *See* Exchange Act Release No. 67453 (Jul. 18, 2012), 77 FR 48208 (Aug. 13, 2012) (Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping) (''Product Definitions''). Very generally, SBS are swaps referencing a single security or loan, or a narrow-based security index. Certain products sharing characteristics of both swaps and SBS are regulated as ''mixed swaps'' subject to both CFTC and SEC jurisdiction.

[12] *See* Dodd-Frank Act Section 763.

[13] *See* Exchange Act Release No. 74244 (Feb. 11, 2015), 80 FR 14564 (Mar. 19, 2015) (Final Rule: Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information) (''Regulation SBSR Release''); Exchange Act Release No. 75611 (Aug. 5, 2015), 80 FR 48964 (Aug. 14, 2015) (Final Rule: Registration Process for Security-Based Swap Dealers and Major Security-Based Swap Participants) (''Registration Process Release''); Exchange Act Release No. 77617 (Apr. 14, 2016), 81 FR 29960 (May 13, 2016) (Final Rule: Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants) (''Business Conduct Standards Release''); Exchange Act Release No. 78011 (Jun. 8, 2016), 81 FR 39808 (Jun. 17, 2016) (Final Rule: Trade Acknowledgment and Verification of Security-Based Swap Transactions) (''Trade Acknowledgment and Verification Release''); Exchange Act Release No. 86175 (Jun. 21, 2019), 84 FR 43872 (Aug. 22, 2019) (Final Rule: Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers) (''Capital, Margin, and Segregation Release''); Exchange Act Release No. 87005 (Sep. 19, 2019), 84 FR 68550 (Dec. 16, 2019) (Final Rule: Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers) (''Recordkeeping Release''); Exchange Act Release No. 87780 (Dec. 18, 2019), 85 FR 6270 (Feb. 4, 2020) (Final Rules; Guidance: Rule Amendments and Guidance Addressing Cross-Border Application of Certain Security-Based Swap Requirements) (''Cross-Border Release''); Exchange Act Release No. 87782 (Dec.18, 2019), 85 FR 6359 (Feb. 4, 2020) (Final Rule: Risk Mitigation Techniques for Uncleared Security-Based Swaps) (''Risk Mitigation Release'').

[14] *See* Notice at 26085.

[15] *See* Dodd-Frank Act Section 761(a)(2) (inserting ''security-based swap'' in the definition of ''security'' in Section 3(a)(10) of the Exchange Act); *see also* 15 U.S.C. 78c(a)(10).

in addition to the comprehensive new SBS-specific regulatory framework discussed above, SBS are now also defined as securities under the Exchange Act and the rules thereunder. As a result, according to FINRA, any FINRA rule applicable to FINRA members' activities involving a security, securities business, a transaction involving a security or a securities position would apply to those activities involving SBS.[16] Consistent with the SEC's actions in this area, on July 8, 2011, FINRA filed for immediate effectiveness FINRA Rule 0180, which, with certain exceptions noted below, temporarily limits the application of FINRA rules with respect to SBS.[17] This rule is currently set to expire on February 6, 2022.[18]

Current FINRA Rule 0180 broadly excepts SBS activities from most FINRA rules. Specifically, FINRA Rule 0180(a) provides that FINRA rules shall not apply to members' activities and positions with respect to SBS, except for: (i) FINRA Rule 2010 (Standards of Commercial Honor and Principles of Trade); (ii) FINRA Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices); (iii) FINRA Rule 3310 (Anti-Money Laundering Compliance Program); and (iv) FINRA Rule 4240 (Margin Requirements for Credit Default Swaps).[19] In addition, FINRA Rule 0180(b) provides that the following rules apply to members' activities and positions with respect to SBS only to the extent they would have applied as of July 15, 2011 (*i.e.,* the day before the effective date of Title VII): (i) NASD Rule 3110 (Supervision) and all successor FINRA Rules to such NASD Rule; (ii) the FINRA Rule 4500 Series (Books, Records, and Reports); and (iii) the FINRA Rule 4100 Series (Financial Condition). Finally, FINRA Rule 0180(c) provides that certain other rules apply as necessary to effectuate members' compliance with paragraphs (a) and (c) of the rule.

In light of the Commission's October 6, 2021, registration compliance date, FINRA proposed in April 2021 to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to clarify the application of FINRA rules to members' SBS activities after the Commission's registration compliance date. These proposed amendments would: (1) Adopt a permanent FINRA Rule 0180 to replace the temporary rule set to expire on February 6, 2022; (2) amend FINRA's financial responsibility and operational rules to conform to the SEC's amendments to its capital, margin and segregation requirements for SBSDs and broker-dealers, and to otherwise take into account members' SBS activities; (3) adopt a new margin rule specifically applicable to SBS, replacing the expiring interim pilot program establishing margin requirements for CDS; and (4) amend Rule 9610 to permit FINRA to exempt members from Rule 0180 under the process set forth in FINRA's Rule 9600 series (Procedures for Exemptions).

B. Proposed Rule 0180 (Application of FINRA Rules to Security-Based Swaps)

Proposed Rule 0180(a) would provide that FINRA rules generally apply to members' SBS activities unless otherwise specifically excepted. This would reverse the presumption of the applicability of FINRA rules to members' SBS activities in the current, expiring temporary Rule 0180, which generally does not apply FINRA rules unless otherwise specified.

Proposed Rule 0180 paragraphs (b) through (g) would then specify the exceptions from the general presumption of applicability of FINRA rules in proposed Rule 0180(a). These proposed exceptions fall into three general categories: (1) General exceptions based on impracticability or operational burdens; (2) exceptions for SBS Entities already registered with the Commission and associated persons of SBS Entities; and (3) exceptions in connection with the conditions to the SEC's cross-border SBS counting exception. Proposed FINRA Rule 0180(i) would further authorize FINRA to exempt a person from the application of specific FINRA rules to SBS on a case-by-case basis, pursuant to the existing procedural framework set forth in the FINRA Rule 9600 series and as FINRA deems appropriate consistent with the protection of investors and the public interest.

C. Proposed Rule 0180(b) (General Exceptions From Applicability of FINRA Rules)

Proposed Rule 0180(b) would provide that the following FINRA rules shall not apply to members' activities and positions with respect to SBS: (1) The Rule 6000 Series (Quotation, Order, and Transaction Reporting Facilities); (2) the Rule 7000 Series (Clearing, Transaction, and Order Data Requirements, and Facility Charges); and (3) the Rule 11000 Series (the Uniform Practice Code or ''UPC''). The Rule 6000 and 7000 Series include rules relating to trading, quoting, clearing, and reporting for securities other than SBS (*e.g.,* NMS stocks and over-the-counter equity securities), and therefore are not applicable to members' SBS activities.

According to FINRA, the UPC, contained in the Rule 11000 Series, is a series of rules, interpretations and explanations designed to make uniform, where practicable, custom, practice, usage, and trading technique in the investment banking and securities business, particularly with regard to operational and settlement issues.[20] The Rule 11000 Series contains, for example, rules addressing matters relating to the delivery of securities, certificated security matters, delivery of bonds, and close-out procedures.[21] According to FINRA, the UPC was created to simplify and facilitate cash securities transactions.[22]

By its terms, the UPC applies to all OTC secondary market transactions in securities between members, with enumerated exceptions.[23] FINRA believes that, as a result, the UPC could be interpreted as applying to SBS transactions in a limited set of circumstances—*e.g.,* an SBS transaction between two FINRA members.[24] FINRA further believes that because the UPC could only be invoked for a small portion of the SBS market—particularly

[16] *See* Notice at 26085.

[17] *See* Exchange Act Release No. 64884 (Jul. 14, 2011), 76 FR 42755 (Jul. 19, 2011) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2011–033). To allow sufficient time to consider the complex interpretative issues resulting from defining SBS as securities, the Commission also issued a number of temporary exemptive orders relating to the regulation of SBS as securities, all of which have either expired or been made permanent now that the October 6, 2021, registration compliance date for the Commission's SBS regulatory framework has passed. *See* Exchange Act Release No. 92837 (Sep. 1, 2021), 86 FR 50391 (Sep. 8, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2021–021) (''Extension Notice'').

[18] FINRA has extended the expiration date of FINRA Rule 0180 a number of times, most recently in September 2021. *See, e.g.,* Extension Notice, *supra* note 17.

[19] FINRA Rule 4240 establishes an interim pilot program with respect to margin requirements for any transactions in credit default swaps (''CDS'') held in an account at a FINRA member. The interim pilot program under FINRA Rule 4240 will expire on April 6, 2022. *See id.; see also* FINRA Rule 4240(a). FINRA Rule 4240 Supplementary Material .02 clarifies that the rule does not apply to a member that is registered with the Commission as an SBSD. *See id.*

[20] *See* Notice at 26088.

[21] *Id.*

[22] *See id.*

[23] *See* FINRA Rule 11100(a). Under FINRA Rule 11100(a)(1), transactions in securities between members which are compared, cleared or settled through the facilities of a registered clearing agency are not subject to the UPC, except to the extent that the rules of the clearing agency provide that rules of other organizations shall apply. Paragraphs (a)(2) through (a)(5) of FINRA Rule 11100 also provide exceptions for specific types of securities, including exempted securities, municipal securities, redeemable securities issued by investment companies and Direct Participation Program Securities.

[24] *See* Notice at 26088.

given that FINRA expects only a small number of its members to register as SBSDs or otherwise engage in SBS activities—applying the UPC to members' SBS activities has the potential to create confusion and uncertainty in the SBS market.[25] Because SBS transactions involve bilateral contractual negotiations, often utilizing industry-standard SBS documentation, FINRA believes that the operational and settlement risks of SBS transactions are more appropriately addressed through other means, including standardized contractual provisions in that industry documentation, as well as, where applicable, the Commission's risk mitigation requirements.[26]

D. Proposed Rule 0180(c) and (d) (Exceptions for Registered SBS Entities and Associated Persons)

As discussed above, the Title VII rulemakings completed by the Commission, including business conduct standards, trade acknowledgement and verification requirements, risk mitigation techniques for uncleared SBS, and recordkeeping rules for SBS Entities, are now in effect for SBS Entities, which are now required to be registered with the Commission unless their dealing activity is below the *de minimis* registration threshold.[27] As described below, certain of these new SBS-specific Commission rules are analogous to existing, generally applicable FINRA rules. Where the Commission has promulgated analogous rules applicable to registered SBS Entities, FINRA has proposed to provide exceptions from its rules for SBS Entities registered with the Commission and, in certain circumstances, associated persons of those SBS Entities.[28]

Proposed Rules 0180(c) and (d) would provide exceptions to specified FINRA rules for FINRA members that are also registered as SBS Entities with the Commission or the associated person of the member, where two conditions are satisfied: (1) The SBS Entity or associated person is acting in the capacity of an SBS Entity or associated person of that SBS Entity; and (2) the activities or positions relate to the business of the SBS Entity within the meaning of Exchange Act Rule 15Fh–3(h)(1) (addressing supervisory obligations of SBS Entities).[29] The proposed exceptions are for FINRA rules that FINRA believes are analogous to SEC business conduct requirements,[30] and are limited to the members' SBS business and conditioned upon the application of the SEC's supervision rule for SBS Entities.[31]

Under proposed FINRA Rules 0180(c) and (d), these proposed exceptions would be available for eight FINRA rules that FINRA believes are analogous to SEC rules, subject to the conditions described above. Specifically, proposed FINRA Rule 0180(c) would provide exceptions for the following five FINRA rules, for registered SBS Entities and their associated persons: [32]

- FINRA Rule 2210(d) (Communications with the Public—Content Standards). Among other things, FINRA Rule 2210(d) requires that member communications be based on principles of fair dealing and good faith, be fair and balanced, and not omit any material facts or make false or exaggerated claims. FINRA believes that this rule is analogous to Exchange Act Rule 15Fh–3(g), which requires SBS Entities to, among other things, communicate with counterparties in a fair and balanced manner.[33]
- FINRA Rule 2232 (Customer Confirmations) generally requires members to provide customers with written confirmations in conformity with Exchange Act Rule 10b–10,[34] along with specified additional disclosures for certain types of securities. FINRA believes this is analogous to Exchange Act Rule 15Fi–2, which requires SBS Entities to provide trade acknowledgements and to establish, maintain and enforce written policies and procedures reasonably designed to obtain prompt verification of the terms of such trade acknowledgments.[35]
- FINRA Rules 3110 (Supervision), 3120 (Supervisory Control System) and 3130 (Annual Certification of Compliance and Supervisory Processes) require, among other things, each member to establish and maintain a supervisory system; establish, maintain and enforce written supervisory procedures; designate principals to establish, maintain and enforce a system of supervisory control policies and procedures; designate a chief compliance officer; and submit annual certifications to FINRA related to the member's compliance policies and written supervisory procedures. FINRA believes this is analogous to the supervision rule for SBS Entities in Exchange Act Rule 15h–3(h), which requires, among other things, an SBS Entity to establish and maintain a system to supervise, and to diligently supervise, its business and the activities of its associated persons; designation of at least one person with authority to carry out supervisory responsibilities; and establishment, maintenance and enforcement of written policies and procedures addressing supervision of the SBS Entity's SBS business.[36] Additionally, Exchange Act Rule 15Fk–1 requires each SBS Entity to designate a chief compliance officer and submit annual compliance reports to the SEC.[37]

In addition, proposed FINRA Rule 0180(d) would provide exceptions for the following three FINRA Rules for registered SBSDs and their associated persons, but not MSBSPs: [38]

- FINRA Rule 2030 (Engaging in Distribution and Solicitation Activities with Government Entities) is FINRA's ''pay-to-play'' rule, which imposes restrictions on member firms engaging in distribution or solicitation activities with government entities. FINRA believes that Exchange Act Rule 15Fh–6 imposes analogous restrictions.[39]
- FINRA Rule 2090 (Know Your Customer) generally requires that each member use reasonable diligence to know and retain essential facts concerning every customer and the authority of each person acting on behalf of such customer. FINRA believes this rule is analogous to: Exchange Act Rule 15Fh–3(a), which generally requires SBS Entities to verify the status of their SBS counterparties, including verification that the counterparty is an eligible contract participant and whether the counterparty is a ''special entity;'' [40] and to Exchange Act Rule 15Fh–3(e), which requires each SBSD to

[25] *Id.*

[26] *Id.* at 26089.

[27] *See* Business Conduct Standards Release; Trade Acknowledgment and Verification Release; Risk Mitigation Release; Recordkeeping Release, *supra* note 13.

[28] *Id.* at 26089.

[29] *See* 17 CFR 240.15Fh–3(h)(1). The exceptions in Rule 0180(c) would apply to both SBSDs and MSBSPs or their associated persons, while the exceptions in Rule 0180(d) would apply only to SBSDs or their associated persons (and not MSBSPs or their associated persons).

[30] *See* Notice at 26089.

[31] 17 CFR 240.15Fh–3(h)(1).

[32] *See* Notice at 26089.

[33] *See* Notice at 26089–90; *see also* 17 CFR 240.15Fh–3(g); Business Conduct Standards Release at 30000–02.

[34] *See* 17 CFR 240.10b–10; *see also* Notice at 26089–90.

[35] *See* 17 CFR 240.15Fi–2; *see generally* Trade Acknowledgment and Verification Release, *supra* note 13.

[36] *See* Notice at 26089–90.

[37] *See* 17 CFR 240.15Fk–1.

[38] *See* Notice at 26089.

[39] *See id.* at 26089–90; *see also* 17 CFR 240.15Fh–6; Business Conduct Standards Release at 30045–50.

[40] *See* Notice at 26089–90. ''Special entity'' is defined in Exchange Act Rule 15Fh–2(d) and includes certain government entities, employee benefit plans and endowments. *See* 17 CFR 240.15Fh–2(d).

establish, maintain and enforce written policies and procedures reasonably designed to obtain and retain a record of the essential facts concerning each counterparty whose identity is known to the SBSD that are necessary for conducting business with such counterparty.[41]

• FINRA Rule 2111 (Suitability) generally requires a member or associated person to have a reasonable basis that a recommended transaction or investment strategy is suitable for at least some investors as well as for the customer receiving the recommendation. FINRA believes it is analogous to Exchange Act Rule 15Fh–3(f), which imposes suitability obligations on SBSDs with respect to recommendations of SBS or trading strategies involving SBS.[42] In addition, Exchange Act Rule 15Fh–5 applies special, enhanced requirements when SBS Entities act as counterparties to special entities.[43]

E. Proposed Rule 0180(e) (Exceptions in Connection With Arranging, Negotiating, and Executing Activity)

Proposed Rule 0180(e) would provide that the following FINRA rules shall not apply to members' activities and positions with respect to SBS, to the extent that the member or the associated person of the member, as applicable, is arranging, negotiating or executing SBS on behalf of a non-U.S. affiliate pursuant to, and in compliance with, the conditions of, Exchange Act Rule 3a71–3(d)(1):[44] (1) FINRA Rule 2111 (Suitability); (2) FINRA Rule 2210(d) (Communications with the Public—Content Standards); and (3) FINRA Rule 2232 (Customer Confirmations).[45] The availability of the exceptions under proposed FINRA Rule 0180(e) would require the member's compliance with the conditions specified in Exchange Act Rule 3a71–3(d)(1)(ii)(B) as if the member were the counterparty to the SBS transactions (as opposed the non-U.S. affiliate).[46]

In connection with finalizing certain Title VII rulemakings, the SEC also adopted a number of rules and provided guidance to address the cross-border application of various SBS requirements. One of these rules, Exchange Act Rule 3a71–3(d), provides a conditional exception to the provisions of Exchange Act Rule 3a71–3 that otherwise would require non-U.S. persons to count—against the thresholds associated with the *de minimis* exception to the SBSD definition—SBS dealing transactions between non-U.S. counterparties when U.S. personnel arrange, negotiate or execute those transactions.[47] To qualify for this exception, all such arranging, negotiating or executing activity must, among other things, be conducted by U.S. personnel in their capacity as persons associated with a registered broker that meets certain capital requirements, or a registered SBSD, in each case so long as such entity is a majority-owned affiliate of the non-U.S. person relying on the exception (the ''U.S. Registered Affiliate'').[48] The U.S. Registered Affiliate also must comply with certain rules applicable to SBSDs with respect to such SBS transactions as if the counterparties to the non-U.S. person relying on the exception also were counterparties to the U.S. Registered Affiliate and as if the U.S. Registered Affiliate were registered as an SBSD, if not so registered.[49]

Specifically, Exchange Act Rule 3a71–3(d)(1)(ii)(B) requires the U.S. Registered Affiliate to comply with, as a condition of the exception: (1) Section 15F(h)(3)(B)(i) and (ii) of the Exchange Act and Rule 15Fh–3(b) thereunder (disclosures of material risks and characteristics and material incentives or conflicts of interest), (2) Exchange Act Rule 15Fh–3(f)(1) (recommendations and suitability),[50] (3) Section 15F(h)(3)(C) of the Exchange Act and Rule 15Fh–3(g) thereunder (fair and balanced communications); and (4) Exchange Act Rule 15Fi–2 (acknowledgement and verification of SBS transactions) and the underlying definitions in Exchange Act Rule 15Fi–1.[51] FINRA believes it is appropriate to provide exceptions from the parallel FINRA rules to provide clarity and avoid unnecessary regulatory duplication, but only where the member is in fact complying with the rules specified in Exchange Act Rule 3a71–3(d)(1)(ii)(B).[52]

F. Proposed Rule 0180(f) (Exceptions From Rules 2231, Customer Account Statements, and 4512, Customer Account Information)

Proposed FINRA Rule 0180(f) would provide that FINRA Rules 2231 (Customer Account Statements) and 4512 (Customer Account Information) shall not apply to members' activities and positions with respect to SBS, to the extent that the member is acting in its capacity as an SBS Entity and the customer's account solely holds SBS and collateral posted as margin in connection with such SBS, provided that the member complies with the portfolio reconciliation requirements of Exchange Act Rule 15Fi–3 with respect to such account and that such portfolio reconciliations include collateral posted as margin in connection with SBS in the account. FINRA Rule 2231 generally requires each member to provide, on at least a quarterly basis, an account statement to each customer containing a description of any securities positions, money balances or account activity during the period since the last customer account statement. FINRA Rule 4512 generally requires each member to maintain specified information for each customer account, including specified identifying information about the customer.

FINRA believes that the customer account statements required under FINRA Rule 2231 generally should reflect a holistic view of a member's relationship with its customer, including SBS transactions, positions and related collateral, if applicable.[53] Therefore, to the extent that a customer's account includes SBS along with other securities positions or activity, or related money balances, then FINRA believes that the account statement under FINRA Rule 2231 should include SBS.[54] However, FINRA understands that members that are also registered as SBS Entities may have customer accounts that hold solely SBS and related collateral, and do not hold any other securities positions or have

[41] *See* Notice at 26089–90; *see* 17 CFR 240.15Fh–3(e).

[42] *See* Notice at 26090; *see* 17 CFR 240.15Fh–3(f).

[43] *See* Notice at 26091; *see* 17 CFR 240.15Fh–5.

[44] *See* 17 CFR 240.3a71–3(d)(1). Rule 3a71–3(d)(1) provides an exception from counting certain SBS transactions against the thresholds associated with the *de minimis* exception to the SBSD definition. *See id.*

[45] FINRA believes these proposed exceptions are appropriate for similar reasons as the proposed exceptions for SBS Entities in proposed FINRA Rules 0180(c) and (d). *See* Notice at 26093, n.64.

[46] A member acting as the U.S. Registered Affiliate under Exchange Act Rule 3a71–3(d) would remain subject to all other FINRA rules applicable to such SBS brokerage activity. *See supra* note 44.

[47] *See* 17 CFR 240.3a71–3(d); Cross-Border Release at 6276–92.

[48] *See* 17 CFR 240.3a71–3(d)(1)(i).

[49] *See* 17 CFR 240.3a71–3(d)(1)(ii)(A).

[50] Rule 3a71–3(d)(1)(ii)(B)(2) does contain a limited exception from the requirement to comply with Exchange Act Rule 15Fh–3(f)(1). Specifically, if the U.S. Registered Entity reasonably determines that the counterparty to whom it recommends an SBS or trading strategy involving an SBS is an ''institutional counterparty'' as defined in Exchange Act Rule 15Fh–3(f)(4), the registered entity instead may fulfill its obligations under Rule 15Fh–3(f)(1)(ii) if it discloses to the counterparty that it is not undertaking to assess the suitability of the SBS or trading strategy involving an SBS for the counterparty.

[51] *See* 17 CFR 240.3a71–3(d)(1)(ii)(B).

[52] *See* Notice at 26093.

[53] *Id.* at 26091.

[54] *Id.*

any other securities activity.[55] While SBS Entities are not subject to a customer account statement requirement with respect to SBS, Exchange Act Rule 15Fi–3 includes requirements applicable to SBS Entities with respect to engaging in portfolio reconciliation with applicable counterparties on a periodic basis, which the Commission adopted as part of a broader set of risk mitigation requirements for SBS Entities.[56]

Exchange Act Rule 15Fi–3(a) generally requires SBS Entities to engage in portfolio reconciliation for all SBS with their SBS Entity counterparties, with the frequency of such portfolio reconciliations based on the size of the SBS portfolio with the applicable counterparty, ranging from once each business day (for SBS portfolios that include 500 or more SBS), to once each week (for SBS portfolios that include more than 50 but fewer than 500 SBS on any business day during the week), to once each calendar quarter (for SBS portfolios that include no more than 50 SBS at any time during the calendar quarter).[57] Exchange Act Rule 15Fi–3(b) requires each SBS Entity to establish, maintain, and follow written policies and procedures reasonably designed to ensure that it engages in portfolio reconciliation for all SBS with non-SBS Entity counterparties, with the frequency of such portfolio reconciliations ranging from once each calendar quarter (for SBS portfolios that include more than 100 SBS at any time during the calendar quarter) to once annually (for SBS portfolios that include no more than 100 SBS at any time during the calendar year).[58]

FINRA acknowledges that the portfolio reconciliation requirements in Exchange Act Rule 15Fi–3 differ in some respects from the customer account statement requirements under FINRA Rule 2231.[59] For example, the frequency of portfolio reconciliations varies as described above, while customer account statements must be delivered at least quarterly. In addition, as described above, an SBS Entity must have policies and procedures in place to ensure that it engages in portfolio reconciliation with non-SBS Entity counterparties, while a member must provide a customer account statement to each customer unless a specific exception under FINRA Rule 2231(b) applies. However, FINRA believes that, while not identical, Exchange Act Rule 15Fi–3 serves analogous purposes to FINRA Rule 2231, such that requiring members that are SBS Entities to also provide customer account statements for accounts holding solely SBS and related collateral would be unnecessarily duplicative.[60] Accordingly, FINRA believes to promote regulatory clarity and avoid unnecessary duplication, proposed FINRA Rule 0180(f) would provide an exception from FINRA Rule 2231 in the limited circumstances where the member is acting in its capacity as an SBS Entity and the account holds solely SBS and collateral posted as margin in connection with such SBS.[61] FINRA states that collateral in a customer's account would be included in account statements provided under FINRA Rule 2231.[62] Therefore, in FINRA's view, the proposed rule change includes as a condition to the proposed exception that the member comply with Exchange Act Rule 15Fi–3 with respect to an account qualifying for the exception and include collateral in the portfolio reconciliation and dispute resolutions requirements as applied to such an account.[63]

SBS Entities also are subject to Exchange Act Rule 15Fi–5, which requires them to establish, maintain, and follow written policies and procedures reasonably designed to ensure that it executes written SBS trading relationship documentation with each of its counterparties prior to, or contemporaneously with, executing an SBS with any counterparty.[64] In addition, SBS Entities that are also registered broker-dealers are subject to the SEC's recordkeeping requirements under Exchange Act Rule 17a–3, which require, among other things, certain records to be kept for each SBS account.[65] These SEC rules generally require SBS Entities to obtain and keep records of certain information in connection with their SBS accounts, including SBS-specific identifying information. FINRA believes that, while not identical to FINRA Rule 4512, these SEC rules serve analogous purposes, and that also applying FINRA Rule 4512 to SBS-only accounts would be duplicative.[66] Accordingly, in order to promote regulatory clarity and avoid unnecessary duplication, FINRA believes it is appropriate to provide an exception from FINRA Rule 4512 in the limited circumstances where the member is acting in its capacity as an SBS Entity and the account solely holds SBS and collateral posted as margin in connection with such SBS.[67] Both exceptions under proposed FINRA Rule 0180(f) would not apply to accounts holding SBS together with other securities or to members that are not also registered SBS Entities.

G. Proposed Rule 0180(g) (Exception From FINRA Registration for Certain Associated Persons of Registered SBS Entities)

Proposed FINRA Rule 0180(g) would provide that persons associated with a member whose functions are related solely and exclusively to SBS, and undertaken in such person's capacity as an associated person of an SBS Entity, are not required to be registered with FINRA.[68] Generally, FINRA Rule 1210 requires that each person engaged in the investment banking or securities business of a member must be registered with FINRA as a representative or principal in each category of registration appropriate to his or her functions and responsibilities as specified in FINRA Rule 1220. Individuals seeking to become registered with FINRA generally must pass an appropriate qualification examination, and registered individuals are subject to continuing education (''CE'') requirements under FINRA Rule

[55] *Id.*

[56] *See* 17 CFR 240.15Fi–3; Risk Mitigation Release at 6362–70. For purposes of Exchange Act Rule 15Fi–3, ''portfolio reconciliation'' is defined as ''any process by which counterparties to one or more SBS'' (1) exchange the material terms of all SBS in the SBS portfolio between the counterparties, (2) exchange each counterparty's valuation of each SBS in the SBS portfolio between the counterparties as of the close of business on the immediately preceding day and (3) resolve any discrepancy in valuations or material terms. *See* 17 CFR 240.15Fi–1(l).

[57] *See* 17 CFR 240.15Fi–3(a).

[58] *See* 17 CFR 240.15Fi–3(b).

[59] *See* Notice at 26091.

[60] *Id.*

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *See* 17 CFR 240.15Fi–5; Risk Mitigation Release at 6372–6377. Such documentation also must include all terms governing the trading relationship between the SBS Entity and its counterparty, including, without limitation, certain terms specified in the rule. SBS Entities are also required to maintain records of SBS trading relationship documentation. *See* 17 CFR 17a–4(e)(12)(ii).

[65] *See* 17 CFR 240.17a–3; *see generally* Recordkeeping Release, *supra* note 13. FINRA states in particular Exchange Act Rule 17a–3(a)(9)(iv), which requires an SBS Entity to keep a record, for each SBS account, of the unique identification code of the counterparty, the name and address of the counterparty, and a record of the authorization of each person the counterparty has granted authority to transact business in the SBS account. *See* 17 CFR 240.17a–3(a)(9)(iv).

[66] *See* Notice at 26092.

[67] *Id.*

[68] This proposed exception is structured similarly to existing exceptions from registration for persons associated with a member whose functions are related solely and exclusively to certain other product types (such as municipal securities, commodities or security futures), as found in FINRA Rule 1230.

1240.[69] The exception from registration would apply only to individuals engaged solely in SBS activities on behalf of the SBS Entity (and potentially non-securities activities, such as swaps).[70] Under FINRA's proposed exception, if an associated person of the SBS Entity engaged in any other securities activities in addition to SBS, that individual must register with FINRA in accordance with FINRA Rule 1210.[71] Associated persons of members that are not registered SBS Entities would also still be required to register with FINRA, even if those individuals engage solely in SBS activities.[72] Additionally, although individuals qualifying for the proposed exception would not be required to register with FINRA, they would remain associated persons of the member subject to all FINRA and SEC rules applicable to such associated persons, including fingerprinting requirements under Exchange Act Rule 17f–2.[73]

FINRA stated that it structured this exception similarly to existing exceptions from registration for persons associated with a member whose functions are related solely and exclusively to certain other product types (such as municipal securities, commodities or security futures).[74] FINRA also stated that it based the proposed exception in Rule 0180(g) on its analysis of existing registration and related requirements, and its understanding that the number of associated persons that would qualify for the exception is limited.[75] FINRA stated that it will monitor developments with respect to the SBS activities of its members and will continue to consider whether it would be appropriate to tailor the registration and related requirements to SBS, for example through targeted SBS-related registration categories or the addition of SBS-specific content to qualification examinations or CE content.[76] FINRA stated that it will consider whether it would be appropriate to rescind the exception under proposed FINRA Rule 0180(g) in such circumstances.[77]

H. Proposed Rule 0180(i) (Authority To Grant Exemptions From the Application of Rule 0180 Upon Member Application) and 9610 (Application for Exemptive Relief)

Proposed FINRA Rule 0180(i) would provide that, pursuant to the FINRA Rule 9600 Series (Procedures for Exemptions), FINRA may, taking into consideration all relevant factors, exempt a person unconditionally or on specified terms from the application of FINRA rules (other than an exemption from the general application of proposed FINRA Rule 0180(a)) to the person's SBS activities or positions, as it deems appropriate, consistent with the protection of investors and the public interest.[78] FINRA believes it is appropriate and in the public interest to provide this exemptive authority so that FINRA can account for specific situations that may arise with respect to SBS in the future on a case-by-case basis.[79] In formulating the proposed rule change, FINRA stated that it consulted with its members and reviewed its rulebook to determine whether continuing exceptions from any of its rules are appropriate.[80] FINRA stated that it is proposing FINRA Rule 0180(i) in recognition that the SBS market continues to evolve and that particular circumstances may arise in which applying specific FINRA rules not otherwise covered by the proposed exceptions to SBS activities may not be appropriate or feasible.[81]

As proposed, FINRA would consider written applications for exemptive relief, on a rule-by-rule and member-by-member basis, under the existing process set forth in FINRA Rule 9610.[82] Rule 9610 requires a member seeking exemptive relief to file a written application with the appropriate department or staff of FINRA containing, among other things, a detailed statement of the grounds for granting an exemption from the application of a specific FINRA rule.[83] Pursuant to FINRA Rule 9620, FINRA staff is then required to issue a written decision setting forth its findings and conclusions, which may be made publicly available.[84] A member would have the ability to appeal such a decision pursuant to FINRA Rule 9630.[85] FINRA stated that it expects to apply heightened scrutiny to applications for exemptive relief from members that are not also registered with the SEC as SBS Entities, and therefore not subject to the SEC's regulatory framework for SBS.[86] FINRA believes it is appropriate and in the public interest to provide this exemptive authority so that FINRA can account for specific situations that may arise with respect to SBS in the future on a case-by-case basis.[87]

Finally, FINRA proposed a conforming change to Rule 9610 to add Rule 0180 to the list of over 30 rules pursuant to which FINRA already has exemptive authority.[88]

I. Financial Responsibility and Operational Requirements

In June 2019, the Commission adopted final capital, margin and segregation requirements for SBS Entities, along with amendments to the existing capital and segregation requirements for broker-dealers, in the Capital, Margin, and Segregation Release.[89] As with other Title VII rulemakings, the SEC aligned the compliance date for the amendments under the Capital, Margin, and Segregation Release with the SBS Entity registration compliance date.[90] Among other things, the Capital, Margin, and Segregation Release amended the existing net capital rule for broker-dealers, Exchange Act Rule 15c3–1,[91] in two key respects relevant to FINRA's rules:

- First, the SEC adopted new minimum net capital requirements for broker-dealers that are also registered as SBSDs, but that do not operate pursuant to the alternative net capital (''ANC'') requirements of Exchange Act Rule 15c3–1 (''Non-ANC Firms'').[92] Non-

[69] *See* Notice at 26092.

[70] *Id.*

[71] *Id.*

[72] FINRA states that associated persons of SBS Entities are not independently subject to registration, licensing or CE requirements. *See id.* at 26109, n.58. However, an SBS Entity is prohibited from permitting an associated person that is subject to a statutory disqualification to effect or be involved in effecting SBS on behalf of the SBS Entity. *See* 15 U.S.C. 78*o*–10(b)(6). The SEC's SBS Entity registration rules also require an SBS Entity to certify that it neither knows, nor in the exercise of reasonable care should have known, of any such statutory disqualification. Such certifications must be supported by questionnaires or employment applications serving as the basis for background checks. *See* 17 CFR 240.15Fb6–2; Registration Process Release at 48973–79.

[73] *See* 17 CFR 240.17F–2.

[74] *See* Notice at 26092, n.57; *see also* FINRA Rule 1230.

[75] *See* Notice at 26092.

[76] *Id.*

[77] *Id.*

[78] *See* Notice at 26093.

[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *See* FINRA Rule 9610(a) and (b).

[84] *See* Notice at 26093. FINRA would consider any such application based on the specific circumstances described in the application and whether the requested exemptive relief would be consistent with the protection of investors and the public interest. *Id.* at 26093, n.66.

[85] *Id.* at 26093.

[86] *Id.*

[87] *Id.*

[88] *See* FINRA Rule 9610(a); *see also* Notice at 26093.

[89] *See* Capital, Margin, and Segregation Release, *supra* note 13.

[90] *See id.* at 43954.

[91] *See* 17 CFR 240.15c3–1.

[92] Generally, a broker-dealer may apply to the SEC for authorization to use the alternative method for computing net capital contained in Appendix E to Exchange Act Rule 15c3–1. *See* 17 CFR 240.15c3–1(a)(7). Such broker-dealers are known as

Continued

ANC Firms that are also registered as SBSDs must comply with a new minimum dollar net capital requirement and a new component for determining their minimum capital requirement that is based on a percentage of initial margin computed for SBS (in addition to other minimum requirements applicable to the broker-dealer).[93] These changes do not apply to broker-dealers that operate pursuant to the ANC requirements of the rule (''ANC Firms''). These new minimum net capital requirements also do not impact Non-ANC Firms that are not also registered as SBSDs, regardless of whether such Non-ANC Firms engage in SBS activities.[94]

• Second, the SEC changed the minimum net capital requirements for ANC Firms, regardless of whether they transact in SBS. For ANC Firms, the SEC increased the minimum dollar net capital requirement, added a new component for determining the minimum capital requirement that is based on a percentage of initial margin computed for SBS (in addition to other minimum requirements applicable to the broker-dealer), increased the minimum tentative net capital requirement and amended the early warning notification requirement for tentative net capital.[95]

FINRA Rule 4120 (Regulatory Notification and Business Curtailment) sets forth certain early warning notification and business curtailment requirements if a member's capital falls below certain thresholds. Specifically, FINRA Rule 4120(a) requires each carrying or clearing member to notify FINRA if its net capital falls below certain specified levels.[96] FINRA Rule 4120(b) allows FINRA to restrict a member from expanding its business in certain circumstances and FINRA Rule 4120(c) allows FINRA to require a member to reduce its business if its net capital falls below certain specified levels (generally lower than those required for notification under FINRA Rule 4120(a)). According to FINRA, these requirements are based on the minimum capital requirements applicable to a member broker-dealer under Exchange Act Rule 15c3–1.[97] FINRA believes it is necessary to amend FINRA Rule 4120 to conform the rule to the new and increased minimum capital requirements for Non-ANC Firms that are also registered as SBSDs and for ANC Firms, as described above.[98]

FINRA Rule 4120(a) requires each carrying or clearing firm to promptly, but in any event within 24 hours, notify FINRA in writing if its net capital falls below any of the percentages specified in subparagraphs (A) through (F) of FINRA Rule 4120(a)(1). The proposed rule change would modify subparagraph (D), which applies to ANC Firms, and also add new subparagraph (E), applicable to Non-ANC Firm members that are also registered as SBSDs.[99]

Prior to the amendments in the Capital, Margin and Segregation Release, Exchange Act Rule 15c3–1(a)(7)(i) required an ANC Firm to maintain minimum tentative net capital of not less than $1 billion and minimum net capital of not less than $500 million. In addition, Exchange Act Rule 15c3–1(a)(7)(ii) required an ANC Firm to provide an ''early warning'' notice to the Commission when its tentative net capital fell below $5 billion (or a lower threshold, if the Commission has granted an ANC Firm's application to use such lower threshold). Subparagraph (D) of FINRA Rule 4120(a) is based on these net capital requirements, requiring notification to FINRA if the member is an ANC Firm and (i) its tentative net capital under Exchange Act Rule 15c3–1(c)(15) is less than 50 percent of the early warning notification amount required by Exchange Act Rule 15c3–1(a)(7)(ii) or (ii) its net capital is less than $1.25 billion. In other words, notification to FINRA is required if an ANC Firm's tentative net capital falls below $2.5 billion (or a lower amount, if the ANC Firm has been permitted to use a lower early warning notice threshold), which is half of the SEC's early warning notification amount, or its net capital falls below $1.25 billion, which is 2.5 times the SEC's net capital requirement for ANC Firms.[100]

In the Capital, Margin, and Segregation Release, the Commission amended the net capital requirements for ANC Firms in three ways. First, the Commission raised the tentative net capital requirement for ANC Firms from $1 billion to $5 billion. Second, the Commission raised the minimum net capital requirement for ANC Firms from $500 million to the greater of $1 billion or the sum of the applicable ratio requirement under Exchange Act Rule 15c3–1(a)(1)[101] and two percent of the risk margin amount.[102] Third, the Commission raised the tentative net capital early warning notification threshold from $5 billion to $6 billion. In light of these increased capital requirements under the Commission's net capital rule, FINRA believes it is appropriate to also modify the thresholds for required notification to FINRA for ANC Firms under FINRA Rule 4120(a)(1)(D).[103] Specifically, under the proposed rule change, an ANC Firm would be required to notify FINRA if, in addition to the conditions currently prescribed under FINRA Rule 4120(a)(1)(A), (E) and (F):[104]

''ANC broker-dealers.'' There are currently five approved ANC broker-dealers. *See* SEC, Broker-Dealers Using the Alternative Net Capital Computation under Appendix E to Rule 15c3–1, available at *https://www.sec.gov/tm/broker-dealers-alternative-net-capital-computation.* Other broker-dealers are known as non-ANC broker-dealers and must compute net capital pursuant to the provisions of Exchange Act Rule 15c3–1. *See* Notice at 26093.

[93] *See* 17 CFR 240.15c3–1(a)(10).

[94] For example, the new minimum net capital requirements do not apply to a Non-ANC Firm engaged in SBS dealing activity below the *de minimis* threshold for SBSD registration, or to a Non-ANC Firm engaged in SBS brokerage activity or entering into non-dealing SBS transactions (*e.g.,* hedging). FINRA stated that the SEC also adopted new minimum capital requirements for MSBSPs, including that such entities must at all times have and maintain a tangible net worth. *See* Capital, Margin, and Segregation Release at 43906–07. FINRA does not believe any changes to FINRA rules are necessary with respect to the new MSBSP capital requirements. *See* Notice at 26094, n.71.

[95] *See* 17 CFR 240.15c3–1(a)(7).

[96] As discussed below, FINRA also proposed to apply all requirements in the FINRA Rule 4000 Series applicable to carrying or clearing firms to members that act as principal counterparty to an SBS, clear or carry an SBS, guarantee an SBS or otherwise have financial exposure to an SBS. *See* Notice at 26094, n.73.

[97] *See* Notice at 26094.

[98] As noted above, the SEC did not amend Exchange Act Rule 15c3–1 to apply increased minimum capital requirements to Non-ANC Firms that engage in SBS activities but that are not registered SBSDs. FINRA is therefore not proposing to amend FINRA Rule 4120 to impose any additional minimum thresholds on such members. However, FINRA states that, as a general matter, FINRA Rule 4120 would apply to all members that engage in SBS transactions (and any related transactions) because net capital is a holistic calculation based on a firm's liquid net worth, which includes all of a firm's activities. *See* Notice at 26094, n.74.

[99] The proposed rule change would also make non-substantive and conforming changes to other subparagraphs of FINRA Rule 4120(a) to reflect the insertion of new subparagraph (E), update cross-references to SEC rules that have been amended and reflect FINRA rulebook format conventions.

[100] *See* Notice at 26094.

[101] *See* 17 CFR 240.15c3–1(a)(7)(i)(A). Under Exchange Act Rule 15c3–1(a)(1)(i), a broker-dealer generally may not permit its aggregate indebtedness to exceed 1500 percent of its net capital. A broker-dealer may elect not to be subject to the aggregate indebtedness standard if it complies with an alternative method of computing net capital. *See* 17 CFR 240.15c3–1(a)(1)(ii).

[102] The ''risk margin amount'' means the total initial margin for SBS. *See* 17 CFR 15c3–1(c)(17). Exchange Act Rule 15c3–1(a)(7)(i)(A) provides that initially the requirement will be two percent of the risk margin amount. However, the SEC may issue an order raising the requirement to four percent on or after the third anniversary of the amended rule's compliance date and to eight percent on or after the fifth anniversary of the amended rule's compliance date. *See* 17 CFR 15c3–1(a)(7)(i)(A)(2) and (3) and 15c3–1(a)(7)(i)(B).

[103] *See* Notice at 26094.

[104] *Id.*

• Its tentative net capital is less than 150 percent of the minimum tentative net capital amount required by Exchange Act Rule 15c3–1(a)(7)(i)(A) (*i.e.,* $5 billion, such that the notification amount would be $7.5 billion),

• the member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/10th of its aggregate indebtedness and 150 percent of the required percentage of the risk margin amount, or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of the level specified in Exchange Act Rule 17a–11(b)(2) [105] and 150 percent of the required percentage of the risk margin amount.

FINRA believes these modified thresholds are appropriately calibrated to provide FINRA with sufficient early warning that an ANC Firm's capital levels may be deteriorating.[106] By revising the early warning levels as proposed, FINRA believes the proposed rule change aligns the historical thresholds in FINRA Rule 4120(a) for early warning notification for ANC Firms with the revised capital requirements applicable to such firms under the Commission's amended rules.[107] Additionally, according to FINRA, ANC Firms historically maintain capital far in excess of the proposed amounts, so FINRA does not expect these levels to be problematic for firms to maintain.[108]

In the Capital, Margin, and Segregation Release, the Commission also adopted a new minimum net capital requirement for Non-ANC Firms that are also registered as SBSDs.[109] Specifically, a Non-ANC Firm that is registered as an SBSD must maintain minimum net capital of not less than the greater of $20 million or the sum of the ratio requirements under Exchange Act Rule 15c3–1(a)(1) and two percent of the risk margin amount.[110] Accordingly, FINRA believes it is necessary to add corresponding new thresholds for required notification to FINRA for Non-ANC Firms that are also registered as SBSDs under new FINRA Rule 4120(a)(1)(E).[111] Specifically, under the proposed rule change, a Non-ANC Firm that is also a registered SBSD would be required to notify FINRA if, in addition to the conditions currently prescribed under FINRA Rule 4120(a)(1)(A), (E) and (F):

• The member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/10th of its aggregate indebtedness and 150 percent of the required percentage of the risk margin amount, or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of the level specified in Exchange Act Rule 17a–11(b)(2) and 150 percent of the required percentage of the risk margin amount.[112]

FINRA believes it is appropriate to include specific thresholds for early notification to FINRA based on the new minimum net capital requirements for Non-ANC Firms that are registered SBSDs.[113] FINRA also believes that the thresholds described above are appropriately calibrated to provide FINRA with sufficient early warning that such a firm's capital levels may be deteriorating.[114] By defining the early warning levels as proposed, the proposed rule change, in FINRA's view, aligns the historical thresholds in FINRA Rule 4120(a) for early warning notification with the new capital requirements applicable to Non-ANC Firms that are registered SBSDs under the SEC's amended rules.[115]

FINRA Rule 4120(b) allows FINRA to require a member that carries customer accounts or clears transactions to not expand its business during any period in which any of the conditions described in paragraph (a)(1) of FINRA Rule 4120 continue to exist for more than 15 consecutive business days, provided that such condition(s) has been known to FINRA or the member for at least five consecutive business days. Since the proposed rule change would modify the conditions specified in FINRA Rule 4120(a)(1) as described above, the triggers for the application of restrictions under FINRA Rule 4120(b) would be similarly affected. However, FINRA does not believe that any conforming changes are needed at this time to the restrictions on business expansion requirements under FINRA Rule 4120(b).[116] FINRA states that FINRA Rule 4120(b)(3)(A)–(G) includes a non-exclusive list of activities that may constitute an ''expansion of business'' for these purposes, and FINRA Rule 4120(b)(3)(H) provides that the term ''expansion of business'' may include such other activities as FINRA deems appropriate under the circumstances, in the public interest or for the protection of investors. FINRA believes that a member firm's SBS activities would be within the scope of ''other activities'' contemplated by FINRA Rule 4120(b)(3)(H).[117]

FINRA Rule 4120(c) allows FINRA to require a member to reduce its business if its net capital falls below any of the percentages specified in subparagraphs (A) through (F) of FINRA Rule 4120(c)(1). Similar to the proposed modifications to FINRA Rule 4120(a) described above, the proposed rule change would modify subparagraph (D) of FINRA Rule 4120(c)(1), which applies to ANC Firms, and also add new subparagraph (E), applicable to Non-ANC Firm members that are also registered as SBSDs.[118]

Current subparagraph (D) of FINRA Rule 4120(c)(1) permits business curtailment if the member is an ANC Firm and (i) its tentative net capital under Exchange Act Rule 15c3–1(c)(15) is less than 40 percent of the early warning notification amount required by Exchange Act Rule 15c3–1(a)(7)(ii) or (ii) its net capital is less than $1 billion. These thresholds are based on the broker-dealer net capital rule prior to the amendments in the Capital, Margin, and Segregation Release. As described above, the Commission amended the net capital requirements for broker-dealers in the Capital, Margin, and Segregation Release.[119] Accordingly, under the proposed rule change, a member that is an ANC Firm would be subject to the business curtailment provisions of FINRA Rule 4120(c)(1) if, in addition to the conditions currently prescribed under FINRA Rule 4120(c)(1)(A), (E) and (F):

[105] *See* 17 CFR 240.17a–11(b)(2). Exchange Act Rule 17a–11 requires broker-dealers to promptly notify the SEC after the occurrence of certain events. Exchange Act Rule 17a–11(b)(2) requires such notification for broker-dealers using the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii) when net capital is less than five percent of aggregate debit items under the Exchange Act Rule 15c3–3 reserve formula.

[106] *See* Notice at 26094.

[107] *See* Notice at 26094–95.

[108] *Id.* at 26095.

[109] *See* 17 CFR 15c3–1(a)(10).

[110] *See* Notice at 26095.

[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] *Id.*

[118] The proposed rule change would also make non-substantive and conforming changes to other subparagraphs of FINRA Rule 4120(c)(1) to reflect the insertion of new subparagraph (E), update cross-references to SEC rules that have been amended and reflect FINRA rulebook format conventions. Similar non-substantive changes would be made to paragraph (b)(1) and Supplementary Material .01 to FINRA Rule 4120 to reflect FINRA rulebook format conventions. *See id.,* n.87.

[119] *See* Capital, Margin, and Segregation Release, *supra* note 13.

• Its tentative net capital is less than the amount specified under Exchange Act Rule 15c3–1(a)(7)(ii) (*i.e.,* the early warning amount, $6 billion),

• The member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/12th of its aggregate indebtedness and 125 percent of the required percentage of the risk margin amount, or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of one percentage point below the level specified in Exchange Act Rule 17a–11(b)(2) and 125 percent of the required percentage of the risk margin amount.[120]

FINRA believes these modified thresholds are appropriately calibrated to provide FINRA with the ability to require ANC Firms to reduce their business when their capital levels have deteriorated to a level that may jeopardize their ability to continue to comply with their capital requirements.[121]

As described above, in the Capital, Margin, and Segregation Release, the Commission also added a new minimum net capital requirement for Non-ANC Firms that are also registered as SBSDs. Accordingly, the proposed rule change would add corresponding new thresholds for business curtailment for Non-ANC Firms that are also registered as SBSDs under new FINRA Rule 4120(c)(1)(E). Specifically, under the proposed rule change, a Non-ANC Firm that is also a registered SBSD would be subject to the business curtailment provisions of FINRA Rule 4120(c)(1) if, in addition to the conditions currently prescribed under FINRA Rule 4120(c)(1)(A), (E) and (F):

• The member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/12th of its aggregate indebtedness and 125 percent of the required percentage of the risk margin amount,[122] or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of one percentage point below the level specified in Exchange Act Rule 17a–11(b)(2) [123] and 125 percent of the required percentage of the risk margin amount.[124]

FINRA believes it is appropriate to include specific thresholds for business curtailment based on the new minimum net capital requirements for Non-ANC Firms that are registered as SBSDs.[125] FINRA also believes that the thresholds described above are appropriately calibrated to provide FINRA with the ability to require such firms to reduce their business when their capital levels have deteriorated to a level that may jeopardize their ability to continue to comply with their capital requirements.[126]

Lastly, FINRA states that FINRA Rule 4120(c)(3)(A)–(J) includes a non-exclusive list of activities that may constitute a ''business reduction'' for these purposes, and FINRA Rule 4120(c)(3)(K) provides that the term ''business reduction'' may include such other activities as FINRA deems appropriate under the circumstances, in the public interest or for the protection of investors.[127] FINRA believes that a member firm's SBS activities would be within the scope of ''other activities'' contemplated by FINRA Rule 4120(c)(3)(K).[128]

In addition to these conforming changes to FINRA Rule 4120, the proposed rule change would apply FINRA's financial and operational rules more broadly to firms that enter into, or otherwise have exposure to, SBS. Specifically, certain rules in the FINRA Rule 4000 Series (Financial and Operational Rules) include provisions that impose higher standards, or provide FINRA the authority to impose additional requirements, on firms that carry or clear transactions or accounts (generally referred to as ''carrying or clearing firms''). This ''tiering'' structure was built into certain rules so that firms that only introduce their customer accounts and do not have exposure to the settlement system are provided relief from the higher standards required of firms that carry or clear transactions and accounts. Below is a list of rules in the FINRA Rule 4000 Series where tiering has been employed for carrying or clearing firms and a brief description of the tiered requirements for such firms:

• FINRA Rule 4110 (Capital Compliance) includes requirements for carrying or clearing firms to keep greater net capital, seek permission for withdrawals of capital and seek approval for certain add-backs to net capital.

• FINRA Rule 4120 (Regulatory Notification and Business Curtailment) includes restrictions on expanding, or requirements to reduce business, if sufficient capital levels are not maintained.

• FINRA Rule 4521 (Notifications, Questionnaires and Reports) allows FINRA to collect additional data and require reporting of a material decline in tentative net capital.

• FINRA Rule 4522 (Periodic Security Counts, Verification and Comparison) requires more frequent security counts, verifications and comparisons than would be required under Exchange Act Rule 17a–13.

• Rule 4523 (Assignment of Responsibility for General Ledger Accounts and Identification of Suspense Accounts) requires a record of primary and supervisory named individuals over general ledger bookkeeping accounts.[129]

According to FINRA, the intent of the tiering employed in these rules in the FINRA Rule 4000 Series is to impose higher capital, recordkeeping and operational standards on firms that carry or clear transactions and accounts, and therefore may have financial exposure to customers, other broker-dealers, central counterparties or others.[130] FINRA believes that similar considerations apply for members with exposure to SBS.[131] FINRA states that SBS are complex transactions that will, by their nature, require detailed recordkeeping, margining, legal agreements, collateral management, reconciliation and risk management.[132] FINRA therefore believes it is appropriate to also employ tiering in the FINRA Rule 4000 Series for members that enter into SBS on a principal basis or otherwise have financial exposure to SBS.[133] Specifically, under the proposed rule change, proposed FINRA Rule 0180(h) would provide that, for purposes of the FINRA Rule 4000 Series, all requirements that apply to a member that clears or carries customer accounts shall also apply to any member that acts as a principal counterparty to an SBS, clears or carries an SBS, guarantees an SBS or otherwise has financial exposure to an SBS.[134] FINRA believes that applying these higher

[120] *See* Notice at 26095.

[121] *Id.*

[122] *See supra* note 101.

[123] *See supra* note 105.

[124] *See* Notice at 26095.

[125] *Id.*

[126] *Id.* at 26096.

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] Although this proposed tiering provision relates to the financial responsibility and operational rules, FINRA believes it should be included as a paragraph in proposed FINRA Rule 0180 so that all provisions relating to the treatment of SBS under FINRA rules are found in a single, consolidated rule. *See id.* at 26096, n.95.

standards when a member enters into SBS or otherwise has exposure to SBS is appropriate and consistent with the protection of investors and the public interest.[135]

J. Margin Requirements

As discussed above, in June 2019 the Commission adopted its final Capital, Margin, and Segregation Release.[136] Among other things, the Capital, Margin, and Segregation Release adopted new Exchange Act Rule 18a–3, which prescribes margin requirements for uncleared SBS for SBSDs for which there is not a prudential regulator (''nonbank SBSD'').[137] Generally, Exchange Act Rule 18a–3 requires a nonbank SBSD to calculate, for each account of an SBS counterparty as of the close of business of each day: (i) The amount of current exposure in the account (*i.e.,* variation margin) and (ii) the initial margin amount for the account.[138] Under Exchange Act Rule 18a–3, variation margin is calculated by marking the position to market, while initial margin must generally be calculated using standardized haircuts, which are prescribed in Exchange Act Rule 15c3–1 for nonbank SBSDs that are registered broker-dealers.[139] Nonbank SBSDs may apply to the SEC for authorization to use models to calculate initial margin instead of the standardized haircuts (including the option to use the more risk sensitive methodology in Exchange Act Rule 15c3–1a), but nonbank SBSDs that are registered broker-dealers must use standardized haircuts to calculate initial margin for uncleared equity SBS.[140] Based on these calculations, Exchange Act Rule 18a–3 generally requires a nonbank SBSD to collect and deliver variation margin, and to collect (but not deliver) initial margin.[141] Exchange Act Rule 18a–3 also provides certain exceptions from the margin requirements, establishes thresholds and minimum transfer amounts, specifies collateral requirements (including collateral haircuts), establishes risk monitoring requirements and includes other miscellaneous provisions, such as definitions. All nonbank SBSDs, including nonbank SBSDs that are FINRA members, are subject to the margin requirements set forth in Exchange Act Rule 18a–3.

The FINRA Rule 4200 Series sets forth margin requirements applicable to FINRA members. In particular, FINRA Rule 4210 describes the margin requirements that determine the amount of equity or ''margin'' customers are expected to maintain in their securities accounts, including margin requirements for equity and fixed income securities as well as options, warrants and security futures. Current FINRA Rule 4240 separately establishes an interim pilot program with respect to margin requirements for any transactions in CDS held in an account at a member (the ''Interim Pilot Program''). Under current FINRA Rule 0180, FINRA Rule 4210 does not apply to members' activities and positions with respect to SBS, but current FINRA Rule 4240 does apply to activities and positions within its scope. Therefore, to the extent that a FINRA member enters into SBS that are CDS, the margin requirements under the Interim Pilot Program apply to such SBS.[142] However, the Interim Pilot Program is a temporary rule, and SBS that are not CDS are not currently subject to any margin requirements under FINRA rules.[143]

The Interim Pilot Program was originally proposed by FINRA and approved by the Commission in 2009 specifically to address concerns arising from systemic risk posed by CDS.[144] Pending the SEC's final implementation of the Title VII rulemakings, FINRA has extended the expiration date of the Interim Pilot Program a number of times, most recently in September 2021.[145] The Interim Pilot Program under current FINRA Rule 4240 is currently set to expire on April 6, 2022.[146]

In light of the finalization of the Commission's margin requirements for nonbank SBSDs under Exchange Act Rule 18a–3 and the registration compliance date, FINRA believes it is appropriate and in the public interest for the Interim Pilot Program to expire and for FINRA to adopt a new margin rule specifically applicable to SBS.[147] Accordingly, under the proposed rule change, current FINRA Rule 4240 would be replaced by a new FINRA Rule 4240 that would prescribe margin requirements for SBS. Consistent with Exchange Act Rule 18a–3—and unlike the Interim Pilot Program—proposed new Rule 4240 would apply margin requirements to all SBS, not just CDS. However, proposed new FINRA Rule 4240 would not apply to any member that is registered as an SBSD, as such members are subject to the margin requirements of Exchange Act Rule 18a–3. Additionally, proposed FINRA Rule 4240 would defer to registered clearing agencies to set the margin requirements for cleared SBS, and as such would only specify new variation margin and initial margin requirements for uncleared SBS. Therefore, the specific new margin requirements prescribed under proposed FINRA Rule 4240 would only apply to uncleared SBS transacted by FINRA members that are not registered as SBSDs. FINRA believes that, by applying margin requirements in these circumstances, the proposed rule change would fill an important regulatory gap, protect FINRA members against counterparty credit risk, maintain a level playing field for members and prevent regulatory arbitrage.[148] As described in further detail below, the margin requirements under proposed FINRA Rule 4240 would be structurally aligned with the margin requirements that will apply to nonbank SBSDs under Exchange Act Rule 18a–3, with certain modifications that FINRA believes are necessary given

[135] *See id.* at 26096.

[136] *See* Capital, Margin, and Segregation Release at 43954.

[137] *See* 17 CFR 240.18a–3. Exchange Act Rule 18a–3 also prescribes margin requirements for nonbank MSBSPs with respect to uncleared SBS. As discussed above, Exchange Act Rule 18a–3 generally requires SBSDs to collect or deliver variation margin, and also to collect initial margin, with respect to its SBS counterparties. However, Exchange Act Rule 18a–3 requires that a nonbank MSBSP only collect and deliver variation margin, without prescribing any initial margin requirement. *See* Capital, Margin, and Segregation Release at 43877. As discussed below, FINRA believes it is appropriate to apply variation margin and initial margin requirements to all of its members that transact in uncleared SBS. Therefore, proposed FINRA Rule 4240 would provide an exception for members that are registered as SBSDs (and therefore subject to the variation and initial margin requirements of Exchange Act Rule 18a–3), but not for members that are registered as MSBSPs. *See* Notice at 26096, n.97.

[138] *See* 17 CFR 240.18a–3(c)(1)(i); Capital, Margin, and Segregation Release at 43876.

[139] *See* 17 CFR 240.18a–3(d).

[140] *See* Capital, Margin, and Segregation Release at 43876.

[141] *See* 17 CFR 240.18a–3(c)(1)(ii).

[142] For purposes of current FINRA Rule 4240, the term ''credit default swap'' includes any product that is commonly known to the trade as a ''credit default swap'' and is an SBS as defined pursuant to Section 3(a)(68) of the Exchange Act or the rules and guidance of the SEC and its staff. *See* FINRA Rule 4240(a).

[143] *See* Notice at 26097.

[144] *See* Exchange Act Release No. 59955 (May 22, 2009), 74 FR 25586 (May 28, 2009) (Notice of Filing and Order Approving File No. SR–FINRA–2009–012).

[145] *See* Extension Notice at 50392.

[146] *See supra* note 19.

[147] *See* Notice at 26097. FINRA states that, under the proposed rule change, proposed FINRA Rule 0180 would no longer provide an exception from current FINRA Rule 4210 applying to members' activities and positions with respect to SBS. Absent additional changes, therefore, the general margin requirements under FINRA Rule 4210 would apply to SBS. However, as described above, FINRA proposed to specifically list SBS within the exceptions listed in FINRA Rule 4210, and adopt a separate, new FINRA Rule 4240 applicable to SBS. *See id.,* n.106.

[148] *See id.* at 26097.

that such members will not be subject to the SEC's comprehensive regulatory framework for SBSDs.[149] Thus, subject to certain exceptions described in the proposed rule, proposed FINRA Rule 4240 would require members that are not SBSDs to collect and deliver variation margin on a daily basis to cover the member's current exposure to or from each uncleared SBS counterparty, and also to collect (but not deliver) initial margin from each SBS counterparty.

Proposed FINRA Rule 4240 is divided into a header followed by paragraphs (a) through (d). The header would specify the scope of the margin requirements under proposed FINRA Rule 4240. Paragraph (a) would describe the margin requirements for cleared SBS. Paragraph (b) would describe the margin requirements for uncleared SBS. Specifically, paragraph (b)(1) would set forth how variation margin must be calculated, paragraph (b)(2) would set forth how initial margin must be calculated, paragraph (b)(3) would prescribe the collection and delivery requirements for variation and initial margin, paragraph (b)(4) would specify the manner and time of collection or delivery of variation and initial margin, and paragraph (b)(5) would list certain exceptions from the margin requirements. Paragraph (c) would require members to employ specified risk monitoring procedures and guidelines for uncleared SBS. Finally, paragraph (d) would define certain terms used in proposed FINRA Rule 4240. Each of these aspects of the proposed rule change is described in further detail below.

Proposed FINRA Rule 4240 would be entitled ''Security-Based Swap Margin Requirements.'' [150] The header text to the rule would state that each member that is a party to an SBS with a customer, broker or dealer, or other Counterparty,[151] or who has guaranteed or otherwise become responsible for any other person's SBS obligations, shall comply with the requirements of proposed FINRA Rule 4240, except that a member that is registered as an SBSD shall instead comply with Exchange Act Rule 18a–3. This provision of the proposed rule is intended to clarify that the margin requirements under proposed FINRA Rule 4240 apply in all circumstances where a member is a party to an SBS, regardless of the type of counterparty, and also where a member has financial exposure to an SBS, whether through a guarantee or other arrangements under which the member is responsible for another person's SBS obligations. FINRA believes that this provision is necessary to ensure that the proposed margin requirements adequately protect member firms against counterparty credit risk, regardless of the specific manner through which the member has become exposed to such risk.[152] Additionally, as discussed above, this provision clarifies that members that are registered as SBSDs are not subject to the proposed margin requirements because they must comply with Exchange Act Rule 18a–3. FINRA believes it should defer to the SEC's margin framework for registered SBSDs rather than impose additional or different requirements on such entities.[153] Proposed FINRA Rule 4240(a), entitled ''Cleared SBS Margin Requirements,'' would state that, except as provided in paragraph (b)(5) (*i.e.,* specified exceptions from proposed FINRA Rule 4240, discussed below), the margin to be maintained on any Cleared SBS is the margin on such Cleared SBS required by the Clearing Agency through which such SBS is Cleared. As discussed above, this provision clarifies that proposed FINRA Rule 4240 defers to registered clearing agencies to set the margin requirements for cleared SBS. FINRA believes that it is appropriate to defer to clearing agencies to establish margin requirements for cleared SBS in light of the SEC's comprehensive regulation of clearing agencies, including their required margin levels, under the Exchange Act.[154]

Proposed FINRA Rule 4240(b), entitled ''Uncleared SBS Margin Requirements,'' would set forth the substantive margin requirements applicable to members that are not SBSDs when such members transact in uncleared SBS. Paragraph (b)(1), entitled ''Current Exposure Calculation,'' would require that, as of the close of business of each business day, the member calculate, with respect to each Uncleared SBS Account,[155] the Counterparty's Current Exposure to the member (if positive) or the member's Current Exposure to the Counterparty (if negative). Current Exposure would be calculated as an amount equal to the net Value [156] of all uncleared SBS in the Uncleared SBS Account plus the Value of all Variation Margin collected from the Counterparty minus the Value of all Variation margin delivered to the

[149] *Id.*

[150] In addition to the new provisions under proposed FINRA Rule 4240 discussed above, the implementation of new margin requirements for SBS under proposed FINRA Rule 4240 would also require a conforming change to FINRA Rule 4220 (Daily Record of Required Margin). FINRA Rule 4220 requires each member carrying securities margin accounts for customers to make a record each day of every case in which initial or additional margin must be obtained in a customer's account. To ensure that similar records are maintained for SBS margin required under proposed new FINRA Rule 4240, the proposed rule change would update FINRA Rule 4220 to also require such records for each member subject to proposed FINRA Rule 4240.

In addition, the proposed rule change would add new Supplementary Material .06 to FINRA Rule 4210 to clarify that a Regulation T good faith account, other than a non-securities account, is a margin account for purposes of FINRA Rule 4210. This provision is intended merely to codify FINRA's existing interpretation regarding the scope of FINRA Rule 4210. The proposed rule change would also include a parallel provision in new Supplementary Material .01 to proposed new Rule 4240.

Finally, the proposed rule change would make two other conforming changes to FINRA Rule 4210, including to add proposed new FINRA Rule 4240(e)(9) and to make a technical adjustment to FINRA Rule 4240(g)(2)(H). *See id.* at 26097–98, n.107.

[151] ''Counterparty'' would be defined under proposed FINRA Rule 4240(d)(5) to mean a person with whom a member has entered into an uncleared SBS. An ''SBS'' would be defined in proposed FINRA Rule 4240(d)(16) by reference to the definition of ''security-based swap'' under Section 3(a)(68) of the Exchange Act and ''Uncleared'' would be defined in proposed FINRA Rule 4240(d)(18) as an SBS that is not Cleared. Under proposed FINRA Rule 4240(d)(3), an SBS would be considered Cleared if it is cleared through a Clearing Agency by or on behalf of the member, and Clearing Agency would be defined under proposed FINRA Rule 4240(d)(4) as a clearing agency registered pursuant to Section 17A of the Exchange Act or exempted by the SEC from such registration by a rule or order pursuant to Section 17A of the Exchange Act.

[152] *See id.* at 26098.

[153] *Id.*

[154] *Id.*

[155] Under proposed FINRA Rule 4240(d)(19), an ''Uncleared SBS Account'' would be defined to mean an account with respect to a Counterparty consisting of all Uncleared SBS between the member and the Counterparty, together with long or short positions for Variation Margin in the form of securities collected or delivered, respectively, credit or debit balances for Variation Margin in the form of cash collected or delivered, respectively, and long positions or credit balances for Initial Margin collected in the form of securities or cash, respectively.

[156] ''Value'' would be defined in proposed FINRA Rule 4240(d)(20). Under this definition, the Value of one or more SBS would be the mid-market replacement cost for such SBS. The Value of a security position would be the current market value of such margin securities, as defined in FINRA Rule 4210(a)(2) and determined in accordance with FINRA Rule 4210(f)(1) (*i.e.,* the provisions of FINRA's general margin rule used to determine the current market value of margin securities). Alternatively, a member could elect to determine the Value of margin securities collected as Variation Margin or Initial Margin by applying a haircut to the current market value of such securities equal to the margin requirement that would be applicable to them under FINRA Rule 4210 if they were held in the Counterparty's margin account (in which case, however, such margin securities would not be required to be themselves margined under proposed FINRA Rule 4240(b)(2)(A)(iii)). The Value of cash in U.S. dollars would be the amount of such cash, while the Value of freely convertible foreign currency would be the amount of U.S. dollars into which the currency could be converted, provided the currency is marked-to-market daily. *See id.* at 26098, n.110.

Counterparty.[157] This provision would define a member's Current Exposure for purposes of collecting or delivering Variation Margin under proposed FINRA Rule 4240(b)(3), discussed below, by taking into account the net Value of SBS in the Counterparty's account together with any Variation Margin that has already been collected or delivered. FINRA believes this calculation is consistent with the variation margin requirements under Exchange Act Rule 18a–3.[158]

Proposed FINRA Rule 4240(b)(2), entitled ''Initial Margin Computation,'' would require that, as of the close of business on each business day, the member compute the Initial Margin Requirement for each Uncleared SBS Account equal to the sum of the Initial Margin Requirements on the Uncleared SBS and securities positions in that Uncleared SBS Account. The remainder of proposed FINRA Rule 4240(b)(2) would describe how a member must calculate the Initial Margin Requirement, which is then used for purposes of collecting Initial Margin under proposed FINRA Rule 4240(b)(3), discussed below.[159] Under the proposed rule change, the Initial Margin Requirement would depend on the type of uncleared SBS involved, with different requirements depending on whether the uncleared SBS is (i) a ''plain vanilla'' CDS; (ii) a ''plain vanilla'' SBS other than an CDS (*i.e.,* an SBS that is the economic equivalent of a margin account containing a portfolio of long or short positions in securities or options, such as a ''plain vanilla'' equity total return swap (''TRS'')); or (iii) any other type of SBS (*e.g.,* a complex CDS or equity TRS that would not be considered ''plain vanilla'' under the proposed rule, including for example a CDS swaption, or a dividend swap). FINRA believes that differentiation as to initial margin requirements among these different types of SBS is appropriate and necessary given the unique characteristics and risks posed by different SBS products.[160]

Proposed paragraphs (b)(2)(A)(i) and (ii) would define the Initial Margin Requirements for uncleared plain vanilla CDS (referred to as ''Basic CDS'') [161] and other uncleared ''plain vanilla'' SBS (referred to as ''Basic SBS''),[162] respectively. First, the Initial Margin Requirement for an uncleared Basic CDS would generally be computed based on the term and spread of the uncleared Basic CDS, using the chart and offsets set out in Exchange Act Rule 15c3–1(c)(2)(vi)(P).[163] In FINRA's view, the proposed rule would therefore follow Exchange Act Rule 18a–3(d)(1)(i) by determining the Initial Margin Requirement for uncleared Basic CDS using the haircuts applicable to such SBS under the SEC's net capital rule.[164] FINRA believes that determining initial margin for CDS in this manner would promote regulatory consistency and reduce potential arbitrage.[165] Additionally, in FINRA's view, the haircuts prescribed in Exchange Act Rule 15c3–1(c)(2)(vi)(P) are analogous to existing FINRA Rule 4240 margin requirements, so in effect the proposed requirements have already been used during the Interim Pilot Program.[166] Second, the Initial Margin Requirement for a Basic SBS would generally be computed by applying FINRA Rule 4210 to the Equivalent Margin Account. Since an uncleared Basic SBS would be the economic equivalent of a margin account that would otherwise be governed by the margin provisions of FINRA Rule 4210, FINRA believes it is appropriate to treat such SBS similarly.[167]

In addition, proposed FINRA Rule 4240(b)(2)(A) would permit the Initial Margin Requirements for both uncleared Basic CDS and uncleared Basic SBS to be computed based on a combination of multiple SBS and securities or options positions, as applicable and subject to certain conditions. Specifically, proposed FINRA Rule 4240(b)(2)(A)(i) would provide that, if the member has a netting or collateral agreement that is legally enforceable against the Counterparty and covers any combination of uncleared Basic CDS or securities specified in clause (iii), (iv) or (v) of Exchange Act Rule 15c3–1(c)(2)(vi)(P)(1) (*i.e.,* specified offsetting debt securities), the member may compute the Initial Margin Requirement on such combination of positions equal to the ''haircut'' on that combination under Exchange Act Rule 15c3–1(c)(2)(vi)(P)(1). Proposed FINRA Rule 4240(b)(2)(A)(ii) would similarly provide that, if the member has a netting or collateral agreement that is legally enforceable against the Counterparty and covers any combination of uncleared Basic SBS, securities or options positions, the member may compute the Initial Margin Requirement on the combination of such positions equal to the margin that FINRA Rule 4210 would require to be maintained on the combination of Equivalent Margin Accounts for such uncleared Basic SBS and securities or options positions. Proposed FINRA Rule 4240(b)(2)(B) would impose conditions on computing the Initial Margin Requirement using these combination methods, including that (i) securities positions must be in the Counterparty's uncleared SBS Account or margin account at the member; (ii) securities may not be included if the member has chosen to haircut them for purposes of determining their Value; (iii) options

[157] Under proposed FINRA Rule 4240(d)(21), ''Variation Margin'' would be defined to mean the cash or margin securities collected from, or delivered to, a Counterparty in accordance with proposed FINRA Rule 4240(b)(3)(A), as discussed below. Under proposed FINRA Rule 4240(b)(2)(A)(iii), all securities deposited as Variation Margin for uncleared SBS would themselves be margined in accordance with FINRA Rule 4210, unless the member has chosen to haircut them for purposes of determining their Value.

[158] *See id.* at 26098.

[159] Under proposed FINRA Rule 4240(d)(9), the term ''Initial Margin'' would be defined to mean all cash or marginable securities, excluding Variation Margin, received by the member for a Counterparty's Uncleared SBS Account or transferred to the Counterparty's Uncleared SBS Account from another account at the member, including margin collected from a Counterparty in accordance with proposed FINRA Rule 4240(b)(3)(B), as discussed below, that in each case have not been returned to the Counterparty or applied to an obligation of the Counterparty. Under proposed FINRA Rule 4240(b)(2)(A)(iii), all securities deposited as Initial Margin for uncleared SBS would themselves be margined in accordance with FINRA Rule 4210, unless the member has chosen to haircut them for purposes of determining their Value.

[160] *See id.* at 26099.

[161] Under proposed FINRA Rule 4240(d)(1), a ''Basic CDS'' would be defined to mean a Basic Single Name Credit Default Swap or a Basic Narrow-Based Index Credit Default Swap. A Basic Single-Name Credit Default Swap would mean an SBS in which one party pays either a single fixed amount or periodic fixed amounts or floating amounts determined by reference to a specified notional amount, and the other party pays either a fixed amount or an amount determined by reference to the value of one or more loans, debt securities or other financial instruments issued, guaranteed or otherwise entered into by a third party (*i.e.,* the ''Reference Entity'') upon the occurrence of one or more specified credit events with respect to the Reference Entity (for example, bankruptcy or payment default). The term ''Basic Single-Name Credit Default Swap'' would also include a swap that, upon the occurrence of one or more specified credit events with respect to the Reference Entity, is physically settled by payment of a specified fixed amount by one party against delivery by the other party of eligible obligations of the Reference Entity. A Basic Narrow-Based Index Credit Default Swap would be defined to mean an SBS consisting of multiple component Basic Single-Name Credit Default Swaps. *See id.* at 26099, n.113.

[162] Under proposed FINRA Rule 4240(d)(2), a ''Basic SBS'' would be defined to mean an SBS, other than a CDS, under which each party is contractually obligated to provide the other the economic equivalent of a margin account containing a portfolio of long or short positions in securities or options (*i.e.,* an ''Equivalent Margin Account''). *See id.* at 26099, n.114.

[163] *See* 17 CFR 240.15c3–1(c)(2)(vi)(P). This provision of the SEC's broker-dealer net capital rule prescribes the haircuts applicable to uncleared SBS.

[164] *See* Notice at 26099.

[165] *Id.*

[166] *Id.*

[167] *Id.*

positions must be in the Counterparty's margin account at the member; (iv) no SBS, security or option positions may be included in more than one combination; and (v) no combinations may include securities or options positions for which reduced margin requirements are computed under FINRA Rule 4210(e)(1) (*i.e.,* reduced margin requirements for offsetting long and short positions) or 4210(f)(2)(F)(ii) through (f)(2)(l) (*i.e.,* various reduced margin requirements for certain options, including covered options and offsetting options positions).[168] FINRA believes these conditions would ensure that the Initial Margin Requirement calculated using the combination method is based on securities and options positions that the member actually has in its possession and does not reflect reductions in value that would inappropriately lower the margin requirement.[169] In addition, proposed FINRA Rule 4240(b)(2)(B) would provide that if the Initial Margin Requirement is computed on a combination as described above, the Initial Margin Requirement on the uncleared SBS included in the combination shall be reduced (but not below zero) by the aggregate maintenance margin requirements under FINRA Rule 4210 applicable to such margin account positions. FINRA believes that this provision would appropriately take into account margin already collected under FINRA Rule 4210 with respect to such positions.[170]

The proposed rule change would not specify Initial Margin Requirements for other uncleared SBS that do not qualify as Basic CDS or Basic SBS. Instead, proposed FINRA Rule 4240(b)(2)(A)(iv) would provide that the Initial Margin Requirement for any uncleared SBS other than a Basic CDS or Basic SBS would be determined in a manner approved by FINRA pursuant to proposed FINRA Rule 4240(b)(2)(C), which would permit a member to apply to FINRA for the approval of an Initial Margin Requirement for any other type of SBS. Under the proposed rule change, any such application would be required to:

- Define the specific type of SBS covered by the application;
- describe the purpose(s) that the member and its Counterparties would have for entering that type of SBS;
- identify all variables that influence the value of that type of SBS;
- explain all risks of that type of SBS;
- propose a specific Initial Margin Requirement (not a margin model) for that type of SBS;
- explain how the proposed specific Initial Margin Requirement would adequately protect a member and its capital against each of those risks;
- attach copies of the member's SBS risk management procedures and describe the application of those procedures to that type of SBS; and
- provide the results of backtesting of the proposed specific Initial Margin Requirement over periods of significant volatility in the variables influencing the value of that type of SBS.[171]

Proposed FINRA Rule 4240(b)(2)(C) would further provide that, if FINRA approves any such application, the approval may be unconditional or conditional, including in the form of a time-limited pilot program; may approve the use of the specific Initial Margin Requirement only by the applicant; or may take the form of a *Regulatory Notice* or other communication approving the use of the specific margin requirements by members generally. Under proposed FINRA Rule 4240(b)(2)(C), no member would be permitted to become a party to an SBS other than a Basic CDS or Basic SBS unless FINRA has approved an Initial Margin Requirement for such member's use with respect to that type of SBS. As described above, FINRA states that the Initial Margin Requirements for Basic CDS are based on the Commission's treatment of such SBS under its net capital rule, while the Initial Margin Requirements for Basic SBS are based on the margin that would be required for a margin account that would be the economic equivalent of such SBS.[172] However, in FINRA's view, other types of SBS—including CDS and equity TRS with complex features—may not be easily accommodated under these frameworks, and the specific risks that accompany such SBS may not be readily apparent or quantifiable to FINRA without additional information.[173] Moreover, as noted above, SBS can be complex financial instruments that pose substantial risks to members and margin serves as an important means of protecting member firms, and thereby their customers and investors, from such risks. FINRA therefore believes that members that are not SBSDs (and therefore not subject to the SEC's comprehensive regulatory framework for registrants under Title VII of Dodd-Frank) should not be permitted to enter into other types of SBS unless and until FINRA has evaluated the risks of such SBS and approved margin requirements that adequately address such risks.[174] If FINRA determines that a proposed margin requirement does not adequately address the risks for a particular type of SBS, FINRA would not approve the application under proposed FINRA Rule 4240(b)(2)(C), and members would not be permitted to enter into such SBS. To FINRA's knowledge, this SBS activity by members that do not plan to register as SBSDs is relatively limited.[175]

Proposed FINRA Rule 4240(b)(3), entitled ''Collection or Delivery of Variation and Initial Margin,'' would set forth a member's obligation to collect or deliver margin as calculated pursuant to proposed FINRA Rule 4240(b)(1) and (2), as described above. Paragraph (b)(3)(A) would require each member to deliver or return to each Counterparty cash or margin securities with a Value equal to the Counterparty's Current Exposure (if any) to the member, or collect or retrieve from the Counterparty cash or margin securities with a Value equal to the member's Current Exposure (if any) to the Counterparty. Paragraph (b)(3)(B) would require each member to collect from each Counterparty cash or margin securities with a Value at least equal to any Initial Margin Deficit.[176] Therefore, consistent with Exchange Act Rule 18a–3, proposed FINRA Rule 4240(b)(3) would require members that are not SBSDs to collect and deliver Variation Margin, and also to collect (but not deliver) Initial Margin, in amounts determined pursuant to the

[168] *Id.*

[169] *Id.*

[170] *Id.* In connection with this proposed provision of FINRA Rule 4240(b)(2)(B), the proposed rule change would also add a new paragraph (e)(9) to FINRA Rule 4210, entitled ''Security-Based Swaps; SBS Offsets.'' Specifically, where the Initial Margin Requirement on the combination of SBS and securities or options position in the margin account would be less than the FINRA Rule 4210 maintenance requirement on the margin account positions, proposed FINRA Rule 4210(e)(9) would reduce the FINRA Rule 4210 maintenance requirement on the margin account positions to equal the computed Initial Margin Requirement.

In addition, proposed FINRA Rule 4210(e)(9) would clarify that, except for SBS carried by a member in a portfolio margin account subject to the requirements of FINRA Rule 4210(g), as discussed below, margin requirements on SBS and positions in Uncleared SBS Accounts are determined by proposed FINRA Rule 4240, rather than FINRA Rule 4210. *See id.* at 26099, n.117.

[171] *See* Notice at 26100.

[172] *Id.*

[173] *Id.*

[174] *Id.*

[175] *Id.*

[176] Under proposed FINRA Rule 4240(d)(10), the term ''Initial Margin Deficit'' would be defined as the amount, if any, by which (A) the sum of the Value of the Initial Margin in an Uncleared SBS Account and the Counterparty's Rule 4210 Excess is less than (B) the Initial Margin Requirement for the Uncleared SBS Account. A person's ''Rule 4210 Excess'' would be defined in proposed FINRA Rule 4240(d)(15) to mean the amount, if any, by which the equity (as defined in FINRA Rule 4210(a)(5)) in the Counterparty's margin account at the member exceeds the amount required by FINRA Rule 4210. *See id.* at 26100, n.118.

provisions of FINRA Rule 4240(b)(1) and (2) as described above, for their transactions in uncleared SBS.[177]

Proposed FINRA Rule 4240(b)(4), entitled ''Manner and Time of Collection or Delivery of Variation and Initial Margin; Prohibited Returns and Withdrawals,'' would set forth additional detailed requirements and clarifications regarding the manner and time of collection or delivery of variation and initial margin, as calculated pursuant to proposed FINRA Rules 4240(b)(1) and (2) and collected or delivered in accordance with proposed FINRA Rule 4240(b)(3), as described above. Specifically, proposed FINRA Rule 4240(b)(4) would provide for the following:[178]

- Under proposed FINRA Rule 4240(b)(4)(A), margin would be deemed collected or returned to the member when it is received in the Counterparty's Uncleared SBS Account at the member (or transferred to such account from another account at the member).
- Under proposed FINRA Rule 4240(b)(4)(B), margin would be deemed collected or returned to the Counterparty when it is transferred from the Counterparty's Uncleared SBS Account at the member in accordance with the Counterparty's instructions or agreement with the member, which could potentially include transfer to another account of the Counterparty carried by the member.
- Under proposed FINRA Rule 4240(b)(4)(C), margin would be required to be collected or delivered pursuant to proposed FINRA Rule 4240(b)(3) as promptly as possible, but in any case no later than the close of business on the business day after the date on which the Current Exposure or Initial Margin Requirement was required to be computed in accordance with proposed FINRA Rule 4240(b)(1) or (2) (*i.e.,* margin would generally be required to be delivered or collected on a T+1 basis). Further, unless FINRA has specifically granted the member additional time, a member that has not collected margin as required by the close of business on the third business day (*i.e.,* by T+3) would be required to take prompt steps to liquidate positions in the Counterparty's Uncleared SBS Account to eliminate the margin deficiency.
- Proposed FINRA Rule 4240(b)(4)(D) would require a member to net the delivery or return of Variation Margin against the collection of Initial Margin, if applicable, and would further permit a member to net the return of Initial Margin against the collection or retrieval of Variation Margin, if applicable.
- Proposed FINRA Rule 4240(b)(4)(E) would prohibit a member from returning Initial Margin to a Counterparty, or permitting a Counterparty to make a withdrawal from the Counterparty's margin account, if doing so would create or increase an Initial Margin Deficit.

FINRA believes it is appropriate and consistent with the protection of member firms and investors to require margin for uncleared SBS to be delivered or collected, as applicable, on a T+1 basis, and to further require that uncleared SBS positions be liquidated if margin is not collected within a T+3 timeframe.[179] FINRA also believes the other clarifications described above are necessary to ensure that members and their uncleared SBS counterparties have a clear and consistent understanding of when and how margin must be delivered or collected under the proposed rule change.[180]

Proposed FINRA Rule 4240(b)(5), entitled ''Exceptions,'' would provide eight specific exceptions from a member's general obligation to collect or deliver margin, as applicable, under proposed FINRA Rule 4240(b)(3), as described above. FINRA believes the proposed exceptions would further align the requirements of proposed FINRA Rule 4240 with the margin requirements applicable to SBSDs under Exchange Act Rule 18a–3 and provide members with additional flexibility in managing their risk exposures, while still ensuring that the risks to members with respect to their uncleared SBS exposures are adequately addressed.[181] The proposed exceptions under FINRA Rule 4240(b)(5) would include the following:

- *Clearing Agencies.* A member would not be required to deliver Variation Margin to, or collect Initial Margin or Variation Margin from, any Clearing Agency, and would also not be required to deduct otherwise required Variation Margin or Initial Margin in the computation of its net capital under Exchange Act Rule 15c3–1 or, if applicable, FINRA Rule 4110(a). FINRA believes this exception is consistent with its determination to defer to Clearing Agency margin requirements with respect to Cleared SBS.[182]
- *Legacy SBS.* A member would be permitted to omit all (but not less than all) Legacy SBS with a Counterparty from the Counterparty's Uncleared SBS Account when computing Current Exposure and the Initial Margin Requirement, provided that the member collects and delivers margin on Legacy SBS to the extent of its contractual rights and obligations to do so.[183] However, a member would be required to take a capital deduction under Exchange Act Rule 15c3–1 or, if applicable, FINRA Rule 4110(a), to reflect the amount of any margin that it would have otherwise been required to collect if the Legacy SBS had been included in the Counterparty's Uncleared SBS Account. FINRA believes it is appropriate to provide a general exception for legacy SBS, as members would not be in a position to require their counterparties to legacy SBS to exchange margin under existing SBS agreements as would otherwise be required under proposed FINRA Rule 4240.[184] However, in such cases, FINRA believes it is appropriate to require a member to take a corresponding capital charge to account for the member's ongoing risk exposure under such SBS.[185]
- *Multilateral Organizations.* A member would not be required to deliver Variation Margin to, or collect Initial Margin or Variation Margin from, any Multilateral Organization.[186]

[177] To account for situations where a member is not the actual party to an SBS, but nonetheless has financial exposure for uncleared SBS (*e.g.,* through a guarantee), proposed FINRA Rule 4240(b)(3)(C) would also require a member to collect both Variation Margin and Initial Margin from the party that has obligations under the uncleared SBS for which the member has responsibility, to the extent that such collection would be required if the member were a party to the uncleared SBS, unless the member can establish that such margin has been delivered to the other party. *See id.* at 26100, n.119.

[178] *See id.* at 26100.

[179] *See id.* at 26101.

[180] *Id.*

[181] *Id.*

[182] *Id.*

[183] Under proposed FINRA Rule 4240(d)(12), a ''Legacy SBS'' would be defined as an uncleared SBS entered into before April 6, 2022. *See* Amendment No. 1. Proposed FINRA Rule 4240(b)(2)(A)(iv) would also clarify that for any Legacy SBS for which proposed Rule 4240 does not specify an Initial Margin Requirement (*i.e.,* an SBS other than a Basic CDS, Basic SBS or other SBS for which FINRA has approved specific margin requirements), the Initial Margin Requirement must be calculated using the applicable method specified in Exchange Act Rule 15c3–1(c)(2)(vi)(P). The Initial Margin Requirement for Legacy SBS calculated under this provision would be used for purposes of determining the appropriate corresponding capital charge, as well as to determine the Initial Margin Requirement for a Legacy SBS to the extent that a member elects not to utilize the Legacy SBS exception under proposed FINRA Rule 4240(b)(5). *See id.* at 26101, n.120.

[184] *See id.* at 26101.

[185] *Id.*

[186] Under proposed FINRA Rule 4240(d)(13), a ''Multilateral Organization'' would be defined to mean the Bank for International Settlements, the European Stability Mechanism, the International Bank for Reconstruction and Development, the Multilateral Investment Guarantee Agency, the International Finance Corporation, the Inter-

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However, a member would be required to take a capital deduction to reflect the amount of any margin that it would otherwise have been required to collect from such a Multilateral Organization. FINRA believes it is appropriate to follow Exchange Act Rule 18a–3 by providing an exception for Multilateral Organizations and requiring the risk posed by such SBS to be accounted for in a member's capital computations.[187]

• *Financial Market Intermediaries.* A member would not be required to collect Initial Margin from a Counterparty that is a Financial Market Intermediary (but would still be required to collect or deliver Variation Margin, as applicable).[188] In such case, a member would be required to take a capital deduction to reflect the amount of any Initial Margin that it would have otherwise been required to collect from such Financial Market Intermediary. A Counterparty that is a Financial Market Intermediary generally would be subject to a comprehensive regulatory framework, including capital requirements. FINRA therefore believes it is appropriate to account for the reduced counterparty credit risk posed by such Counterparties by permitting a member to take a capital charge in lieu of requiring such Counterparties to post Initial Margin.[189] However, FINRA continues to believe that Variation Margin should be exchanged with such Counterparties to account for ongoing the market risk posed by such uncleared SBS.[190]

• *Sovereign Counterparties.* A member would generally be required to deliver Variation Margin to, and collect Initial Margin or Variation Margin from, a Sovereign Counterparty.[191] However, under proposed FINRA Rule 4240(b)(5)(E), if the member has determined pursuant to policies and procedures or credit risk models established pursuant to Exchange Act Rule 15c3–1(c)(2)(vi)(l) that the Sovereign Counterparty has only a minimal amount of credit risk, the member would not be required to collect Initial Margin from such Sovereign Counterparty (but would still be required to collect or deliver Variation Margin, as applicable). In such case, a member would be required to take a capital deduction to reflect the amount of any Initial Margin that it would have otherwise been required to collect from such Sovereign Counterparty. As for Financial Market Intermediaries, FINRA believes it is appropriate to account for the reduced counterparty credit risk posted by highly creditworthy Sovereign Counterparties by permitting a member to take a capital charge in lieu of requiring such Counterparties to post Initial Margin.[192] However, FINRA continues to believe that Variation Margin should be exchanged with such Counterparties to account for ongoing the market risk posed by such uncleared SBS.[193]

• *Majority Owners; ANC Firms Transacting with Majority Owners or Registered or Foreign SBS Dealers Under Common Ownership.* FINRA states that it understands that members may enter into uncleared SBS with affiliated entities for a variety of reasons, including for risk management purposes.[194] FINRA does not believe a broad exception from the proposed margin requirements for uncleared SBS with all affiliates would adequately account for the risks posed to its members by uncleared SBS in such circumstances.[195] However, FINRA does believe that two specific, more limited exceptions for SBS entered into with certain affiliates would be appropriate.[196] First, under proposed FINRA Rule 4240(b)(5)(F), a member would not be required to collect Initial Margin from a Counterparty that is a direct or indirect owner of a majority of the equity and voting interests in the member (a ''Majority Owner'') (but would still be required to collect or deliver Variation Margin, as applicable). In such case, a member would be required to take a capital deduction to reflect the amount of any Initial Margin that it would have otherwise been required to collect from such Majority Owner. Second, under proposed FINRA Rule 4240(b)(5)(G), a member that is an ANC Firm would not be required to collect Initial Margin from a Counterparty that is a Majority Owner or a Registered or Foreign SBS Dealer under common ownership (but would still be required to collect or deliver Variation Margin, as applicable).[197] In such case, an ANC Firm member would be required to take a deduction for credit risk on such transactions computed in accordance with Exchange Act Rule 15c3–1e(c).[198] FINRA believes that the proposed exception from the Initial Margin Requirements for uncleared SBS with Majority Owners, provided that the member takes a capital charge in lieu of collecting Initial Margin, would adequately protect members in such circumstances due to the lower risk presented by Majority Owners, which typically must satisfy capital and other requirements applicable to bank holding companies and similar entities.[199] FINRA also believes that the proposed exception for ANC Firms with respect to SBS with Majority Owners and Registered or Foreign SBS Dealer affiliates, provided that the member takes a corresponding credit risk charge, would adequately protect such members while reducing potential competitive disparity as between ANC Firms that are registered as SBSDs (and therefore subject to Exchange Act Rule 18a–3) and ANC Firms that are not registered as SBSDs (and therefore would be subject to proposed FINRA Rule 4240 with respect to their uncleared SBS).[200]

• *Portfolio Margin.* Proposed FINRA Rule 4240(b)(5)(H) would provide that proposed FINRA Rule 4240 would not

American Development Bank, the Asian Development Bank, the African Development Bank, the European Bank for Reconstruction and Development, the European Investment Bank, the European Investment Fund, the Nordic Investment Bank, the Caribbean Development Bank, the Islamic Development Bank, the Council of Europe Development Bank, or any other multilateral development bank that provides financing for national or regional development in which the U.S. government is a shareholder or contributing member. *See id.* at 26101, n.121.

[187] *See id.* at 26101.

[188] Under proposed FINRA Rule 4240(d)(8), a ''Financial Market Intermediary'' would be defined to mean an SBSD, swap dealer, broker or dealer, FCM, bank, foreign bank, or foreign broker or dealer. *See id.* at 26101, n.122.

[189] *See id.* at 26101.

[190] *Id.*

[191] Under proposed FINRA Rule 4240(d)(17), a ''Sovereign Counterparty'' would be defined as a Counterparty that is a central government (including the U.S. government) or an agency, department, ministry or central bank of a central government. *See id.* at 26101, n.122.

[192] *See id.* at 26101–102.

[193] *Id.* at 26102.

[194] *Id.*

[195] *Id.*

[196] *Id.*

[197] Under proposed FINRA Rule 4240(d)(14), a ''Registered or Foreign SBS Dealer'' would be defined to mean (i) any person registered with the SEC as an SBSD or (ii) any foreign person if the SEC has made a substituted compliance determination under Exchange Act Rule 3a71–6(a)(1) that compliance by an SBSD or class thereof with specified requirements of a foreign regulatory system that are applicable to such foreign person may satisfy the capital requirements of Section 15F(e) of the Exchange Act and Exchange Act Rule 18a–1 that would otherwise apply to such SBSD or class thereof. Therefore, the definition would cover registered SBSDs and entities that are subject to equivalent SBSD capital requirements in a foreign jurisdiction. *See id.* at 26102, n.124.

[198] FINRA states that an ANC Firm transacting with a Counterparty that is its Majority Owner would also benefit from the general exception for collecting Initial Margin from Majority Owners, as described above. However, under this additional exception, an ANC Firm would be permitted to take only a deduction for the credit risk on its transactions with Majority Owner counterparties as calculated in accordance with Exchange Act Rule 15c3–1e, rather than the full amount of the Initial Margin Requirement that would otherwise have applied. *See id.* at 26102, n.125.

[199] *See id.* at 26102.

[200] *Id.*

apply to any unlisted derivative, as defined in FINRA Rule 4120(g)(2)(H), carried by the member in a portfolio margin account subject to the requirements of FINRA Rule 4210(g) if such unlisted derivative is of a type addressed in the comprehensive written risk analysis methodology filed by the member with FINRA in accordance with FINRA Rule 4210(g)(1).[201] In addition, proposed FINRA Rule 4240 would not apply to any SBS carried in a commodity account or other account under the jurisdiction of the CFTC in accordance with an SEC rule, order or no-action letter permitting SBS and swaps to be carried and portfolio margined together in such an account. According to FINRA, portfolio margining provides members with the flexibility to manage their risk exposures based on a broader view of their overall relationship with a particular Counterparty.[202] FINRA believes it is appropriate to provide an exception from proposed FINRA Rule 4240 for any SBS in a portfolio margin account if the SBS is of a type whose risk is appropriately addressed by an approved theoretical pricing model (*e.g.,* TIMS) and covered by portfolio risk management procedures filed by the member with FINRA, as well as for SBS permitted by the SEC to be portfolio margined in a commodity account.[203] In these circumstances, in FINRA's view, the risks presented by such SBS would already be subject to a comprehensive risk management framework, and therefore FINRA does not believe it is necessary to apply the proposed new margin requirements to such SBS.[204]

Proposed FINRA Rule 4240(c), entitled ''Risk Monitoring Procedures and Guidelines,'' would require members to monitor the risk of any Uncleared SBS Accounts and maintain a comprehensive risk analysis methodology for assessing the potential risk to the member's capital over a specified range of possible market movements over a specified time period. For purposes of this requirement, members would be required to employ the following risk monitoring procedures and guidelines:[205]

- Obtaining and reviewing the required documentation and financial information necessary for assessing the amount of credit to be extended to SBS Counterparties;
- determining and documenting the legal enforceability of netting or collateral agreements, including enforceability in the event a Counterparty becomes subject to bankruptcy or other insolvency proceedings;
- assessing the determination, review and approval of credit limits to each Counterparty, and across all Counterparties;
- monitoring credit risk exposure to the member from SBS, including the type, scope and frequency of reporting to senior management;
- the use of stress testing of accounts containing SBS contracts in order to monitor market risk exposure from individual accounts and in the aggregate;
- managing the impact of credit extended related to SBS contracts on the member's overall risk exposure;
- determining the need to collect additional margin from a particular customer or broker or dealer, including whether that determination was based upon the creditworthiness of the customer or broker or dealer and/or the risk of the specific contracts;
- determining the need for higher margin requirements than required by proposed FINRA Rule 4240 and formulating the member's own margin requirements, including procedures for identifying unusually volatile positions, concentrated positions (with a particular Counterparty and across all Counterparties and customers), or positions that cannot be liquidated promptly;
- monitoring the credit exposure resulting from concentrated positions with a single Counterparty and across all Counterparties, and during periods of extreme volatility;
- identifying any Uncleared SBS Accounts with intraday risk exposures that are not reflected in their end of day positions (*e.g.,* Uncleared SBS Accounts that frequently establish positions and then trade out of, or hedge, those positions by the end of the day) and collecting appropriate margin to address those intraday risk exposures;
- identifying any Uncleared SBS Account that, in light of current market conditions, could not be promptly liquidated for an amount corresponding to the Current Exposure computed with respect to such account and determining the need for higher margin requirements on such accounts or the positions therein;
- maintaining sufficient Initial Margin in the accounts of each Counterparty to protect against the largest individual potential future exposure of an Uncleared SBS in such Counterparty's Uncleared SBS Account, as measured by computing the largest maximum possible loss that could result from the exposure; and
- increasing the frequency of calculations of Current Exposure and Initial Margin Requirements during periods of extreme volatility and for accounts with concentrated positions.

Proposed FINRA Rule 4240(c) would further require a member to review, in accordance with the member's written procedures, at reasonable periodic intervals, the member's SBS activities for consistency with these risk monitoring procedures and guidelines, and to determine whether the data necessary to apply the risk monitoring procedures and guidelines is accessible on a timely basis and information systems are available to adequately capture, monitor, analyze and report relevant data.

In FINRA's view, the risk monitoring procedures and guidelines under proposed FINRA Rule 4240(c) are analogous to the risk monitoring and procedure requirements applicable to nonbank SBSDs with respect to their uncleared SBS transactions under Exchange Act Rule 18a–3.[206] These requirements are also based in part on aspects of FINRA Rule 4210, including procedures related to the need for additional margin under FINRA Rule 4210(d) and the portfolio margin risk monitoring requirements under FINRA Rule 4210(g)(1). In FINRA's view, SBS are complex financial instruments that may expose a member to significant risks, including, for example, market risk, counterparty credit risk, operational risk and legal risk.[207] FINRA accordingly believes it is appropriate and necessary, and consistent with the protection of investors, for members with exposure to uncleared SBS to maintain a comprehensive risk monitoring program, including the specific elements described above, to address such risks.[208]

K. Effective Date

As discussed above in Section II.A., current FINRA Rule 0180 temporarily excepts the application of most FINRA rules to the SBS activities of its members. Now that the Commission has finalized the majority of its Title VII rulemakings, FINRA believes it is appropriate and in the public interest

[201] FINRA is also proposing a technical adjustment to the definition of ''unlisted derivative'' under FINRA Rule 4210(g)(2)(H) to clarify that, to qualify under the definition, the option, forward contract or SBS must be able to be valued by a theoretical pricing model that is approved by the SEC for valuing that type of options, forward contract or SBS.

[202] *Id.*

[203] *Id.*

[204] *Id.*

[205] *Id.*

[206] *See id.* at 26103; *see also* 17 CFR 240.18a–3(e); Capital, Margin, and Segregation Release at 43930.

[207] *See* Notice at 26103.

[208] *Id.*

for the current temporary FINRA Rule 0180 to expire and for FINRA to clarify the application of FINRA rules to SBS through a permanent FINRA rule.[209] Additionally, since FINRA filed its proposed rule change, as modified by Amendment No. 1, the Commission's regulatory framework governing SBS Entities has gone into effect. FINRA is proposing to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to take into account members' SBS activities.[210] FINRA states that if the proposed rule change, as modified by Amendment No. 1, is approved by the Commission, the effective date for the proposed amendments to FINRA Rules 0180, 4120 and 9610 will be February 6, 2022, and the effective date for the proposed amendments to FINRA Rules 4210, 4220 and 4240 will be April 6, 2022.[211]

The proposed effective dates will also align with the new expiration dates of current FINRA Rules 0180 and 4240, such that the temporary rules will expire on the day the proposed permanent rules become effective.[212]

III. Discussion and Commission Findings

After careful review of the proposed rule change, as modified by Amendment No. 1, the comment letters, and FINRA's responses to the comments, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.[213] Specifically, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 15A(b)(6) of the Exchange Act,[214] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to facilitate transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

A. Proposed Rule 0180(a) (Application of FINRA Rules to Security-Based Swaps)

As discussed above in Section II.B., the proposed rule change would replace current FINRA Rule 0180 with new FINRA Rule 0180 and would apply all FINRA rules to SBS activities and positions with respect to SBS, unless subject to specific exceptions set forth in proposed FINRA Rule 0180. Five commenters were supportive of the proposed rule change generally.[215] One commenter suggested that, as an alternative, FINRA members be permitted to comply with the Commission's SBS rules in lieu of a parallel FINRA rule.[216] The commenter proposed that FINRA could either consider incorporating into the FINRA rules a reference to the analogous Commission rules or permit FINRA-regulated broker-dealers not registered with the Commission as an SBSD to ''opt-in'' to the relevant Commission SBS rules.[217]

In its response, FINRA stated that neither of these alternatives would be appropriate.[218] FINRA believes the limited exceptions in proposed Rules 0180(c) through (g) are appropriate only in the context of registered SBS Entities subject to the SEC's full regulatory framework applicable to such registrants.[219] FINRA does not believe that it would be appropriate to permit members that are not SBS Entities registered with the Commission to ''opt-in'' to the parallel SEC rules, or to incorporate SEC rules by reference for FINRA members not registered with the Commission as SBS Entities.[220] FINRA stated that a FINRA member engaged in SBS activities below the *de minimis* threshold for registration with the Commission may nonetheless elect to register with the Commission on a voluntary basis, and thereby become subject to the Commission's full regulatory framework for SBS.[221]

FINRA's determination to generally apply FINRA rules to members' activities and positions with respect to SBS,[222] other than the specific enumerated exceptions discussed below, is reasonable. Specifically, FINRA reasonably determined that, because SBS are securities under the Exchange Act, FINRA's existing rule framework, which is designed to regulate the securities activity of its members, should apply absent a specific exception. FINRA's determination is consistent with the requirement in the Exchange Act that FINRA, as a registered securities association, have rules designed to, among other things, facilitate transactions in securities and enforce compliance with the Exchange Act by its members.[223] Applying these rules to FINRA members' SBS activities and positions with respect to SBS will help prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and protect investors and the public interest.

The general presumption under Rule 0180(a) that FINRA rules apply to members' SBS activities and positions, except where otherwise specified in the rule, would help ensure that FINRA members that are not also registered as an SBS Entity with the Commission will be subject to a comprehensive set of FINRA rules governing, among other things, conduct and communication by members, with respect to the members' SBS activities and positions. It is appropriate that, with the exception of proposed Rule 0180(b),[224] an exception to this general presumption will apply only where a FINRA member is registered with the Commission as an SBS Entity. This important limitation will provide appropriate regulatory oversight with respect to SBS activity—where the FINRA member is registered with the Commission as an SBS Entity, the comprehensive framework the Commission has adopted for regulation of SBS, including its examination program, will apply. Conversely, where the FINRA member is not registered with the Commission as an SBS Entity, it is appropriate for the member to

[209] *See* Notice at 26086.

[210] *See id.*

[211] A commenter expressed concern as to FINRA's initial proposed effective date for the proposed rule change. *See* SIFMA Letter at 1–3, 11. In response, on August 9, 2021, FINRA filed Amendment No. 1, which: (1) Extended the effective date of the proposed amendments to FINRA Rules 0180, 4120 and 9610 to February 6, 2022; (2) extended the effective date of the proposed amendments to FINRA Rules 4210, 4220 and 4240 to April 6, 2022; and (3) conformed the proposed definition of ''Legacy Swap'' in proposed FINRA Rule 4240(d)(12) to reflect the new effective date of April 6, 2022. *See* FINRA Letter at 14–15.

[212] As discussed above in Section II.A, in September 2021, the existing exceptions for current FINRA Rules 0180 and 4240 were extended to February 6, 2022 and April 6, 2022, respectively, and current Rule 4240 was amended to add Supplementary Material .02, which clarifies that the rule does not apply to a member that is registered with the Commission as an SBSD. *See* Extension Notice, *supra* note 17.

[213] In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[214] 15 U.S.C. 78o–3(b)(6).

[215] *See* Letters at 1 (stating the need for the proposed rule change ''to be enacted, as is, for the protection and operation of free and fair markets.''); *see also* SIFMA Letter at 1 (stating support for many aspects of the proposed rule change).

[216] *See* PML Letter at 4.

[217] *Id.*

[218] *See* FINRA Letter at 3.

[219] *Id.*

[220] *Id.*

[221] *Id.* at 3–4.

[222] *See* Notice at 26086. FINRA believes this determination is consistent with both Congress's intent and FINRA's regulatory responsibility. *Id.*

[223] *See* Exchange Act Section 15A(b)(2); (6).

[224] As discussed below, the proposed exception in FINRA Rule 0180(b) is not conditioned on registration as an SBS Entity but rather the general inapplicability of those rule sets to SBS activity.

comply with a comprehensive set of FINRA rules as set forth in the proposed rule change and be primarily subject to FINRA's examination program. In the event a FINRA member that is not required to be registered with the Commission as an SBS Entity would prefer to instead comply with the Commission's SBS regulatory framework (and avail itself of the exceptions specified in proposed FINRA Rule 0180(b)–(g)), the member may voluntarily elect to register as an SBS Entity with the Commission and thus become subject to the full regulatory framework for registered SBS Entities, which includes Commission examination authority for compliance with such rules. Accordingly, for the foregoing reasons, the Commission finds the proposed rule change is consistent with the protection of investors and in the public interest.

B. Proposed Rule 0180(b) (General Exceptions From Applicability to FINRA Rules)

Proposed FINRA Rule 0180(b) would specify certain exceptions from the general presumption of applicability of FINRA rules to SBS. Specifically, FINRA Rule 0180(b) would except members' SBS activities and positions from the FINRA Rule 6000 Series (Quotation, Order, and Transaction Reporting Facilities); the FINRA Rule 7000 Series (Clearing, Transaction, and Order Data Requirements, and Facility Charges); and the FINRA Rule 11000 Series (Uniform Practice Code). All commenters expressed support for FINRA's proposed rule change to exempt members' SBS activities and positions from these rules.[225] One commenter stated that ''providing exceptions for [FINRA Rules 6000 Series, 7000 Series, and 11000 Series] will promote clarity, considering that these rules are not designed to apply to SBS, and arguably overlap with some of the [Commission's] SBS rules (such as reporting and public dissemination under Regulation SBSR).'' [226]

As discussed above in Section II.C., FINRA believes that the 6000, 7000 and 11000 series rules are not designed to apply to SBS and are not particularly well-adapted to positions in or activities involving SBS.[227] FINRA believes that while some of these rules could potentially be interpreted as applying to SBS activities by their terms, doing so could create operational difficulties and/or create confusion and uncertainty in the SBS market.[228] FINRA believes the proposed rule change would provide legal certainty and clarity for its members by specifically excepting these rules from applying to members' activities and positions with respect to SBS.[229]

The FINRA Rule 6000 and 7000 Series include various rules relating to trading, quoting, clearing and reporting for different types of securities. Many of these rules do not appear to apply to SBS by their terms.[230] As discussed in Section II.C, the FINRA Rule 11000 Series sets forth the UPC, a series of rules, interpretations and explanations created to simplify and facilitate the day-to-day business of investment banking and securities between FINRA members, particularly with respect to operational and settlement issues.[231] Because the UPC generally applies to all OTC secondary market transactions in securities, it could be interpreted as applying to SBS transactions. However, because the UPC applies only to transactions between FINRA members, even if the UPC were to apply, it could be invoked only for those specific transactions.[232] FINRA believes that applying the UPC rules to such a limited subset of SBS in the overall SBS market could create confusion and uncertainty.[233]

The Commission finds that the proposed rule change would avoid unnecessary and potentially duplicative regulation in this area by specifically providing exceptions for SBS from the FINRA Rule 6000, 7000, and 11000 series, and is designed to protect investors and the public interest. These rules were not designed to provide regulatory oversight of SBS activity, and even if certain of these rules were interpreted to apply to SBS activity, they would apply only to a subset of SBS activity, leading to the potential for regulatory inconsistency. Accordingly, the Commission finds that the exceptions for the Rule 6000, 7000, and 11000 series in Rule 0180(b) is designed to protect investors and the public interest.

C. Proposed Rules 0180(c) and (d) (Exceptions for Registered SBS Entities and Associated Persons)

Proposed Rules 0180(c) and (d), as discussed above in Section II.D., would provide that specified FINRA Rules shall not apply to members' activities and positions with respect to SBS, only where the following conditions are met: (1) The member is acting in its capacity as an SBS Entity or the associated person of the member is acting in his or her capacity as an associated person of an SBS Entity, as applicable; and (2) that such activities or positions relate to the business of the SBS Entity within the meaning of the Exchange Act Rule 15Fh–3(h)(1), the Commission's supervision rule for SBS Entities. The exceptions in Rule 0180(c) would apply to both SBSDs and MSBSPs or their associated persons, while the exceptions in Rule 0180(d) would apply only to SBSDs or their associated persons (and not MSBSPs or their associated persons), consistent with whether the Commission rule that FINRA believes is analogous with a corresponding FINRA rule is applicable to all SBS Entities or their associated persons, or only SBSDs (and not MSBSPs or their associated persons).[234] One commenter specifically addressed these exceptions, offering support for their inclusion in the proposed rule, subject to requests for clarifications as to some aspects of the proposed exceptions that are addressed below.[235]

1. Proposed Rule 0180(c)

Proposed Rule 0180(c) would except five FINRA rules from applying to members' SBS activities and positions where the conditions described above are met: (1) Rule 2210(d) (Communications with the Public—Content Standards); (2) Rule 2232 (Customer Confirmations); (3) Rule 3110 (Supervision); (4) Rule 3120 (Supervisory Control System); and (5) Rule 3130 (Certification of Compliance and Supervisory Procedures). As discussed below, FINRA believes that each of these rules is similar to a particular Commission rule or set of rules applicable to SBS Entities.[236] FINRA further believes that these proposed exceptions are appropriate only to the extent that the Commission's parallel SBS Entity rules will apply to the SBS activity, and only where the SBS activity relates to the business of the SBS Entity within the meaning of the Commission's SBS Entity supervision rule.[237]

[225] *See* SIFMA Letter at 3; PML Letter at 2; Letters at 1.

[226] *See* SIFMA Letter at 3.

[227] *See* Notice at 26088.

[228] *See id.*

[229] *See id.*

[230] *See id.; see also* FINRA Rules 6000 and 7000 series.

[231] *See* Notice at 26088.

[232] *See id.*

[233] *See supra* note 23 and related text; *see also* Notice at 26088.

[234] *See* Notice at 26089.

[235] *See* SIFMA Letter at 3 (stating the rules to be excepted under the proposal and noting that ''[a]s FINRA observes, these rules would unnecessarily duplicate certain of the Commission's SBS rules if they applied to SBS Entities or their associated persons'').

[236] *See* Notice at 26089.

[237] *Id.*

Rule 2210(d) (Communications With the Public—Content Standards). FINRA Rule 2210(d) governs the content standards of members' communications with the public and requires communications be based on principles of fair dealing and good faith. Under FINRA's proposed rule change, where Exchange Act Rule 15Fh–3(g) applies to SBS Entities—imposing communication standards on both registered SBS Entities that are modeled after several of the existing requirements in FINRA Rule 2210(d)—those FINRA requirements would not also apply. Exchange Act Rule 15Fh–3(g) requires SBS Entities to communicate with parties in a fair and balanced manner based on principles of fair dealing and good faith. As the Commission has previously noted, this standard is consistent with the similarly worded requirement in FINRA Rule 2210(d).[238] Three additional Exchange Act Rule provisions supplement the required content standards of SBS Entities.[239] Taken together, FINRA believes that these provisions are analogous to FINRA requirements contained in Rule 2210(d) that require, among other things, member communications be based on principles of fair dealing and good faith, be fair and balanced, and not omit any material facts or make false or exaggerated claims.[240]

Rule 2232 (Customer Confirmations). Proposed Rule 0180(c) would except members registered as SBS Entities from the application of FINRA Rule 2232 (Customer Confirmations) with respect to their SBS positions and activities when such activities or positions relate to their business as SBS Entities within the meaning of the SBS supervision rule.[241]

FINRA Rule 2232 (Customer Confirmations) generally requires members to provide customers with written confirmations in conformity with Exchange Act Rule 10b–10,[242] along with specified additional disclosures for certain types of securities. Exchange Act Rule 15Fi–2 requires SBS Entities to provide trade acknowledgments and to establish, maintain and enforce written policies and procedures reasonably designed to obtain prompt verification of the terms of such trade acknowledgments.[243] FINRA states that the SEC's trade acknowledgement and verification rule provides that an SBS Entity that is also a broker or dealer, is purchasing from or selling to any counterparty, and that complies with the relevant requirements of the trade acknowledgment and verification rule, is exempt from the requirements of Exchange Act Rule 10b–10 with respect to the SBS transaction.[244]

In the Trade Acknowledgement and Verification Release, the Commission stated that requiring an SBS Entity that is also a broker or a dealer to comply with both Rule 10b–10 and Rule 15Fi–2 could be duplicative and overly burdensome.[245] In seeking the requested exemption from Rule 2232, FINRA has stated that FINRA similarly believes that applying both the SEC's rules for SBS Entities and FINRA's parallel rules for its members to the same SBS activity would result in unnecessary regulatory duplication.[246]

One commenter requested clarification concerning customer confirmations.[247] The commenter stated that the Commission has adopted an exemption concerning a broker-dealer's requirement to give or send the disclosure required by Exchange Act Rule 10b–10(a) at or before completion of the transaction in connection with such broker-dealer or its associated persons arranging, negotiating or executing an SBS transaction on behalf of an affiliated SBSD, provided that the broker-dealer gives or sends the customer written notification containing such disclosures in accordance with the time and form requirements for an SBSD's trade acknowledgment under Exchange Act Rule 15Fi–2(b) and (c) and, as applicable, Rule 10b–10(c).[248] The commenter requested that FINRA clarify that, to the extent a member would be eligible for this exemption, but not the proposed FINRA Rule 0180(c) exception from FINRA Rule 2232 (Customer Confirmations), it can satisfy Rule 2232 by giving and sending a written notification to its customer in accordance with the timing reflected in the exemption provided by the Commission in Exchange Act Rule 3a71–3(d)(5).[249]

In response, FINRA stated that FINRA Rule 2232(a) requires that a member shall, at or before the completion of any transaction in a security effected for or with an account of a customer, give or send to such customer a confirmation in conformity with the requirements of Exchange Act Rule 10b–10.[250] FINRA further stated that since the Commission has provided an exemption permitting a broker-dealer to provide the disclosures required by Exchange Act Rule 10b–10(a) in accordance with the time and form requirements for an SBSD's trade acknowledgment, a member acting in conformity with the requirements of Exchange Act Rule 10b–10, including where the member is acting in accordance with an applicable SEC exemption, would satisfy the requirements of Rule 2232(a) (provided that the member complies with all other provisions of Rule 2232, as applicable).[251]

Rules 3110 (Supervision), 3120 (Supervisory Control System) and 3130 (Annual Certification of Compliance and Supervisory Processes). Proposed Rule 0180(c) would except FINRA members that are also registered SBS Entities from the application of FINRA Rules 3110 (Supervision), 3120 (Supervisory Control System) and 3130 (Annual Certification of Compliance and Supervisory Processes) with respect to their SBS positions and activities where the conditions described above are met. Taken together, these rules require, among other things, that FINRA members establish and maintain a supervisory system, designate a chief compliance officer, and submit annual certifications to FINRA related to the member's compliance policies and written supervisory procedures.[252]

FINRA believes that the Commission has adopted an analogous framework for

[238] *See* Exchange Act Release No. 64766 (Jun. 29, 2011) at 86–7, 76 FR 42396 at 42418 (Jul. 18, 2011) (Proposed Rule: Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants).

[239] FINRA stated that the SEC's business conduct rules also include requirements for SBS Entities to make certain disclosures to their SBS counterparties, including disclosures of material risks and characteristics and material incentives or conflicts of interest; daily mark disclosures; and disclosures regarding clearing rights. *See* Notice at 26090; *see also* Exchange Act Rules 15Fh–3(b)—(d) (addressing requirements for disclosures of material risks and characteristics and material incentives of conflicts of interest; daily mark disclosures; and disclosures regarding clearing rights).

[240] *See* Notice at 26090; *see also* FINRA Rule 2210(d)(1)(A).

[241] *See* Notice at 26089–90.

[242] *See* Notice at 26090; *see also* 17 CFR 240.10b–10.

[243] *See* Notice at 26090; *see also* 17 CFR 240.15Fi–2; *see generally* Trade Acknowledgment and Verification Release, *supra* note 13.

[244] *See* Notice at 26090; *see also* 17 CFR 240.15Fi–2(g); Trade Acknowledgment and Verification Release at 39824–25.

[245] Trade Acknowledgment and Verification Release at 39821.

[246] *See* Notice at 26106.

[247] *See* SIFMA Letter at 3.

[248] *See* 17 CFR 240.3a71–3(d)(5).

[249] *See* SIFMA Letter at 4; *see also* Exchange Act Release No. 90308 (Nov. 2, 2020), 85 FR 70667 (Nov. 5, 2020) (Order Granting Exemptions from Sections 8 and 15(a)(1) of the Securities Exchange Act of 1934 and Rules 3b–13(b)(2), 8c–1, 10b–10, 15a–1(c), 15a–1(d) and 15c2–1 Thereunder in Connection with the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps and Determining the Expiration Date for a Temporary Exemption from Section 29(b) of the Securities Exchange Act of 1934 in Connection with Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants).

[250] *See* FINRA Letter at 4.

[251] *Id.*

[252] *See* Notice at 26090.

supervision of SBS Entities that applies to all FINRA members that are also registered SBS Entities.[253] Exchange Act Rule 15h–3(h) requires, among other things, that an SBS Entity establish and maintain a system to supervise, and to diligently supervise, its business and the activities of its associated persons; designate at least one person with authority to carry out supervisory responsibilities; and establish, maintain and enforce written policies and procedures addressing supervision of the SBS Entity's SBS business. Exchange Act Rule 15Fk–1 requires each SBS Entity to designate a chief compliance officer and submit annual compliance reports to the Commission.

2. Proposed Rule 0180(d)

Proposed Rule 0180(d) would except three additional FINRA rules from applying to members' SBS activities and positions where the conditions described above are met and the FINRA member is a registered SBSD (but not a MSBSP): (1) Rule 2030 (Engaging in Distribution and Solicitation Activities with Government Entities); (2) Rule 2090 (Know Your Customer); and (3) Rule 2111 (Suitability). As discussed below, FINRA believes that each of these rules is similar to a particular Commission rule or set of rules specifically applicable to SBSDs but not MSBSPs.[254] FINRA further believes that these proposed exceptions are appropriate only to the extent that the Commission's parallel rules applicable to SBSDs (but not MSBSPs) will apply to the SBS activity, and only where the SBS activity relates to the business of the SBSD (but not an MSBSP) within the meaning of the Commission's SBS Entity supervision rule.[255]

Rule 2030 (Engaging in Distribution and Solicitation Activities with Government Entities). FINRA Rule 2030 governs ''pay-to-play'' activities by member firms that engage in distribution or solicitation activities for compensation with government entities on behalf of investment advisers. In particular, FINRA Rule 2030(a) prohibits a member from engaging in distribution or solicitation activities for compensation with a government entity within two years after a contribution to an official of the government entity is made by the covered member or a covered associate (including a person who becomes a covered associate within two years after the contribution is made).[256] Similarly, Exchange Act Rule 15Fh–6 generally prohibits an SBSD from engaging in SBS transactions with a municipal entity within two years after certain political contributions have been made to officials of the municipal entity.[257] Under FINRA's proposed rule change, where Exchange Act Rule 15Fh–6 applies to SBS Entities, the SBS Entity would be excepted from FINRA Rule 2030.

Rule 2090 (Know Your Customer). FINRA Rule 2090 requires members to use due diligence to know the essential facts concerning every customer (including the customer's financial profile and investment objectives or policy). Under FINRA's proposed rule change, where Exchange Act Rules 15Fh–3(a) and (e) applies to SBSDs, the SBSDs would be excepted from FINRA Rule 2090. Rule 15Fh–3(a) generally requires SBS Entities to verify the status of their SBS counterparties.[258] Rule 15Fh–3(e) requires an SBSD to establish, maintain and enforce policies and procedures reasonably designed to obtain and retain a record of the essential facts that are necessary for conducting business with each counterparty that is known to the SBSD. Rule 15Fh–3(e) is a modified version of the ''know your customer'' requirements, such as those in FINRA Rule 2090, to which broker-dealers are subject.[259] Under FINRA's proposal, where SBSDs are subject to Rule 15Fh–3(a) and (e), the analogous FINRA requirements would not also apply.

Rule 2111 (Suitability). FINRA Rule 2111(a) requires members, when making a recommendation, to have a reasonable basis to believe that recommendation is suitable for the customer, based on the information obtained through the reasonable diligence of the member or associated person to ascertain the customer's investment profile. FINRA Rule 2111(b) provides that a member fulfills this suitability obligation for an institutional account if the member has a reasonable basis to believe that the institutional customer is capable of evaluating investment risks independently and the institutional customer exercises independent judgment in evaluating the recommendations. Where the institutional customer has delegated decision-making authority to an agent, such as an investment adviser, these suitability rule factors apply to the agent under FINRA's rule. Exchange Act Rule 15h–3(f) creates a suitability obligation for SBSDs, including an institutional suitability alternative that is modeled after FINRA Rule 2111(b).[260] Under FINRA's proposed rule change, where Exchange Act Rule 15Fh–3(f) applies, the SBS Entity would be excepted from FINRA Rule 2111.[261]

As to each of the FINRA rules proposed to be excepted under Rule 0180(c) and Rule 0180(d), an analogous Commission rule already applies to a registered SBS Entity (under Rule 0180(c)) or SBSD (under Rule 0180(d)). Without these proposed exceptions, a FINRA member that is also registered with the Commission as an SBS entity (under Rule 0180(c)) or as an SBSD (under Rule 0180(d)) would be required to comply with both the Commission's comprehensive framework enacted under Title VII as well as FINRA rules with analogous requirements. The Commission concludes it is generally unnecessary for FINRA rules to apply in circumstances where the SBS activities, and the SBS entities (under Rule 0180(c)) or SBSDs (under Rule 0180(d)), are already regulated directly by the Commission. The Commission further concludes it is reasonable that the exceptions in FINRA Rule 0180(d) do not apply to MSBSPs, because they are not subject to either the FINRA rule referenced in Rule 0180(d) and/or the analogous Commission rule. Therefore, FINRA's proposal to provide the limited exceptions in proposed FINRA Rule 0180(c) and 0180(d), is a reasonable, tailored approach that reduces potentially unnecessary and duplicative regulatory requirements.

D. Proposed Rule 0180(e) (Exceptions in Connection With Arranging, Negotiating, and Executing Activity)

As discussed above in Section II.E., Proposed Rule 0180(e) would provide that the following FINRA rules shall not apply to members' activities with respect to SBS, to the extent that the member or the associated person of the member, as applicable, is arranging, negotiating or executing SBS on behalf of a non-U.S. affiliate pursuant to, and in compliance with the conditions of, the exception from counting certain SBS

[253] *See id.* at 26089.

[254] *See* Notice at 26089.

[255] *Id.*

[256] *See* FINRA Regulatory Notice 16–40 (October 2016).

[257] Business Conduct Standards Release at 29962.

[258] *See* Notice at 26090. Although Rule 15Fh–3(a) is applicable to both SBSDs and MSBSPs, FINRA Rule 2090 applies to requires members to use reasonable diligence ''in regard to the opening or maintenance of'' an account. FINRA Rule 2090. As MSBSPs are by definition not SBSDs, MSBSPs do not have customer accounts; therefore, Rule 2090 is inapplicable as to MSBSPs even if they are FINRA members. *See, e.g.,* 17 CFR 240.3a67–1.

[259] *See* Business Conduct Proposal at 42414.

[260] Business Conduct Standards Release at 29967, n.68.

[261] FINRA also noted that Exchange Act Rule 15Fh–5 applies special, enhanced requirements when SBS Entities act as counterparties to special entities. *See* Notice at 26091.

under Exchange Act Rule 3a71–3(d)(1): (1) FINRA Rule 2111 (Suitability); (2) FINRA Rule 2210(d) (Communications with the Public—Content Standards); and (3) FINRA Rule 2232 (Customer Confirmations). The availability of the exceptions under proposed FINRA Rule 0180(e) would require the member's compliance with the conditions specified in Exchange Act Rule 3a71–3(d)(1)(ii)(B) as if the member were the counterparty to the SBS transactions.[262] Specifically, to satisfy the exception from counting certain SBS under Exchange Act Rule 3a71–3(d)(1), the member must comply with, among other things, Exchange Act Rule 15Fh–3(b) (disclosures of material risks and characteristics and material incentives or conflicts of interest), Exchange Act Rule 15Fh–3(f)(1) (recommendations and suitability), Exchange Act Rule 15Fh–3(g) (fair and balanced communications) and Exchange Act Rule 15Fi–2 (acknowledgement and verification of SBS transactions).[263] If a member fails to comply with these Commission rules, the member's foreign affiliate would be required to count each applicable SBS transaction toward its *de minimis* registration threshold.[264] One commenter specifically addressed this exception, offering support for its inclusion in the proposed rule.[265]

The Commission believes that members whose foreign affiliates are seeking to rely on the exception from counting certain SBS transactions under Exchange Act Rule 3a71–3(d)(1), may have their own obligations to comply with FINRA's rules governing suitability, customer communications, and customer confirmations, apart from any obligation to comply with analogous Commission rules noted above as a condition of Exchange Act Rule 3a71–3(d)(1). Without the exceptions in proposed FINRA Rule 0180(e), this could result in unnecessarily duplicative obligations. Where the member is in fact complying with the specified Commission rules, the proposed rule change is designed to help protect investors and the public interest by avoiding potential confusion surrounding whether FINRA rules apply in addition to analogous Commission rules to regulate the same conduct. It is appropriate to provide exceptions from these FINRA rules to provide clarity and avoid unnecessary regulatory duplication. Accordingly, the Commission finds that the proposed rule change is designed to protect investors and the public interest.

E. Proposed Rule 0180(f) (Exceptions From Rules 2231, Customer Account Statements, and 4512, Customer Account Information)

Proposed Rule 0180(f), as discussed above in Section II.F., would provide that FINRA Rules 2231 (Customer Account Statements) and 4512 (Customer Account Information) shall not apply to members' activities and positions with respect to SBS, to the extent that the member is acting in its capacity as an SBS Entity and the customer's account solely holds SBS and collateral posted as margin in connection with such SBS, provided that the member complies with the portfolio reconciliation requirements of Exchange Act Rule 15Fi–3 with respect to such account and that such portfolio reconciliations include collateral posted as margin in connection with SBS in the account.[266]

A commenter requested that FINRA provide two clarifications with respect to proposed FINRA Rule 0180(f). First, the commenter stated that FINRA should clarify that a member may rely on the Rule 0180(f) exception in circumstances where the member's SBS account for the customer also includes non-securities positions, such as swaps.[267] Second, the commenter stated that FINRA should clarify that a member may rely on the Rule 0180(f) exception when, in addition to a customer's SBS account, the member carries a non-SBS securities account for the customer and there is no portfolio margining or other commingling between the two accounts.[268] In response, FINRA stated that the Commission, jointly with the CFTC, has published a request for comment on the portfolio margining of uncleared swaps and uncleared SBS.[269] As such, FINRA believes it would be premature to provide further guidance in this area at this time, but will consider addressing remaining questions through interpretive guidance when appropriate.[270]

Another commenter expressed support for eliminating the exceptions set forth in FINRA's proposed Rule 0180(f), maintaining that there is potential for confusion and disparate treatment as it pertains to FINRA Rules 2231 (Customer Account Statements) and 4512 (Books and Records/Customer Account Information) relative to Exchange Act Rule 15Fi–3 (the Commission's portfolio reconciliation rule for SBS Entities).[271] While the commenter respected FINRA's attempt to reduce burdens for participants, the commenter believes that with increased SBS activity, the exemption could be burdensome to some SBS Entities, while providing relief to other SBS Entities.[272] The commenter further believes that differences between FINRA Rule 2231 and Exchange Act Rule 15Fi–3 are ''stark.''[273] The commenter strongly supports portfolio reconciliation as a vital component to reducing systemic risk and other issues associated with SBS. However, as a practical matter this commenter believes that the burden of providing account statements based on a pre-defined methodology serves an important purpose for risk control as well.[274] Further, the commenter stated that there is a high likelihood that an existing SBS Entity that solely holds SBS and related collateral also is an affiliate of larger organizations with sufficient infrastructure to comply with FINRA Rule 2231.[275]

FINRA responded that the exception in proposed Rule 0180(f) applies only where a member is acting in its capacity as a registered SBS Entity and a customer's account solely holds SBS and collateral posted as margin in connection with SBS, provided that the member complies with the portfolio reconciliation requirements of Exchange Act Rule 15Fi–3 with respect to such account and that such portfolio reconciliations include collateral posted as margin in connection with SBS in the account.[276] FINRA believes that the SEC's portfolio reconciliation requirements set forth in Exchange Act Rule 15Fi–3[277] and the customer

[262] As discussed above, all other FINRA rules would remain applicable to a member acting as the U.S. Registered Affiliate under Exchange Act Rule 3a71–3(d). *See supra* note 46.

[263] *See* Notice at 26092–93.

[264] *Id.* at 26093.

[265] *See* SIFMA Letter at 1 (stating, ''[w]e support this exception, which appropriately avoids overlaps between FINRA's suitability, communication standards, and confirmation requirements, on the one hand, and SEC Rules 15Fh–3(f)(1), 15Fh–3(g), and 15Fi–2, on the other hand, which the FINRA member would be required to satisfy when acting for its non-U.S. affiliate pursuant to SEC Rule 3a71–3(d)(1)(ii).'').

[266] As a practical matter, the Commission states that most, if not all, requirements pertaining to the amount of collateral posted will be a ''material term'' for purposes of Exchange Act Rule 15Fi–1(i), such that this information would be required to be reconciled pursuant to Exchange Act Rule 15Fi–3.

[267] *See* SIFMA Letter at 4.

[268] *See id.*

[269] *See* FINRA Letter at 5; *see also* Exchange Act Release No. 90246 (Oct. 22, 2020), 85 FR 70536 (Nov. 5, 2020) (Request for Comment: Portfolio Margining of Uncleared Swaps and Non-Cleared Security-Based Swaps).

[270] *See* FINRA Letter at 5.

[271] *See* PML Letter at 5.

[272] *Id.*

[273] *See id.* at 6.

[274] *Id.*

[275] *Id.*

[276] *See* FINRA Letter at 5.

[277] *See supra* note 56.

account statement requirements under FINRA Rule 2231 serve similar purposes such that requiring delivery of customer account statements for SBS-only accounts that are also subject to portfolio reconciliation would be unnecessary duplication.[278] FINRA further believes that it does not anticipate that this exception would create confusion, as SBS customers of an SBS Entity would expect to engage in portfolio reconciliation for their SBS accounts in accordance with the Commission rules, rather than for such SBS to appear on the customer account statement they may receive because the firm is also a FINRA member broker-dealer.[279]

The Commission recognizes that there are differences with respect to the frequency and timing requirements under Exchange Act Rule 15Fi–3 and FINRA Rule 2231. For example, whereas Exchange Act Rule 15Fi–3 requires SBS Entities to reconcile their portfolios with other counterparties more frequently than FINRA Rule 2231 requires its members to deliver an account statement to its customers, in some limited circumstances the Commission's rule would require portfolio reconciliation to occur less frequently than the timing requirements of FINRA's account statement rule.[280] Nevertheless, the Commission finds that under the limited circumstances in which the exception from FINRA Rule 2231 in proposed FINRA Rule 0180(f) applies, Exchange Act Rule 15Fi–3 should sufficiently serve similar purposes to FINRA Rule 2231, as it relates to providing information about an SBS with a customer who is a counterparty to an SBS, such that requiring members that are SBS Entities to also provide customer account statements for accounts holding solely SBS and related collateral would be unnecessarily duplicative. Further, as the exception only applies to accounts holding solely SBS and related collateral, the portfolio reconciliation requirements of Rule 15Fi–3 should provide sufficient risk control. To the extent that a customer's account includes SBS along with other securities positions or activity, or related money balances, then the account statement under FINRA Rule 2231 should include SBS. Thus, it is appropriate and consistent with the protection of investors and the public interest to provide an exception from FINRA Rule 2231 under circumstances when the Commission's risk mitigation requirements for SBS Entities under Exchange Act Rule 15Fi–3 will apply to SBS Entities, subject to the conditions discussed above. The Commission also recognizes, however, that this is an evolving market and a new regulatory framework, and acknowledges FINRA's commitment to consider providing interpretive guidance as appropriate.[281]

Similarly, the Commission's requirements pertaining to written SBS trading relationship documentation pursuant to Exchange Act Rule 15Fi–5, and the books and records requirements for SBS Entities that are also registered broker-dealers Exchange Act Rule 17a–3 will also continue to apply. These rules sufficiently serve similar purposes to FINRA Rule 4512, such that also applying FINRA Rule 4512 to SBS-only accounts would be duplicative. Accordingly, these limited circumstances in Proposed Rule 0180(f) reduce unnecessary and duplicative regulation.

F. Proposed Rule 0180(g) (Exception From FINRA Registration for Certain Associated Persons of Registered SBS Entities)

The FINRA qualification and registration requirements are set forth in the FINRA Rule 1200 series.[282] Proposed Rule 0180(g), as discussed above in Section II.G., would provide that persons associated with a member whose functions are related solely and exclusively to SBS, and undertaken in such person's capacity as an associated person of an SBS Entity, are not required to be registered with FINRA.

One commenter generally supported the exception but requested clarification that an associated person relying on the exception set forth in FINRA's proposed Rule 0810(g) may, in addition to their SBS activities, also engage in non-securities activities on behalf of the member, such as soliciting or accepting swaps in the capacity as an associated person or a swap dealer, and that additional activity would not otherwise trigger FINRA registration or continuing education requirements and would not prevent reliance on the proposed exception.[283] Further, the commenter suggested that FINRA Rule 0180(g) should clarify that the person's ''*securities-related* functions'' must be related solely and exclusively to SBS undertaken in such person's capacity as an associated person of a registered SBS Entity.[284]

A second commenter questioned the exemptions provided in proposed Rule 0180(g) and whether there are likely many, or even any, individuals associated with a FINRA member who would trade in SBS exclusively without also engaging in transactions in the underlying equity.[285] To the extent there are such individuals, the commenter further questioned whether such individuals should be exempt from FINRA's qualifications and registration requirements.[286] The commenter also expressed the belief that the likelihood of such individuals to enter the SBS market has the potential to increase.[287] It is the commenter's belief that, although the qualification examinations and continuing education (''CE'') requirements may not specifically address SBS, the examination and CE requirements do require an associated person to have familiarity with the characteristics of the underlying equity securities and regulatory framework, which the commenter considers important to have for anyone engaged in SBS activities.[288] The commenter further maintained that the exemptions provided in proposed Rule 0180(g) may potentially cause ''confusion for both exempt persons and 'dual-hatted' personnel,'' and that such persons could avoid regulations such as FINRA Rule 2111 (Suitability) to which other registered persons are subject.[289] The

[278] *Id.* at 6.

[279] *Id.* FINRA further explained that it believes that a member that is not an SBS Entity and thus not subject to the SEC's portfolio reconciliation requirements—as well as other Commission rules related to risk mitigation, such as portfolio compression and trading relationship documentation—should include any SBS on a customer's account statements, regardless of whether such SBS are in a separate account from other securities, because SBS are securities. *See id.*

[280] Specifically, FINRA Rule 2231 requires each member to provide its customer with an account statement that satisfies the requirements of the rule on at least a quarterly basis. By contrast, the timing requirements in Exchange Act Rule 15Fi–3 vary, depending on whether the applicable counterparty is also an SBS Entity and the size of the SBS portfolio. The only time that portfolio reconciliation would be required to occur less frequently than quarterly would when an SBS Entity is facing a counterparty that is not also an SBS Entity and the size of the SBS portfolio does not exceed 100 SBS at any time during the calendar year, in which case the SBS Entity would only be required to have policies and procedures reasonably designed to ensure reconciliation on an annual basis. *See* 17 CFR 240.15Fi–3(b)(3)(ii).

[281] *See e.g.,* Exchange Act Release No. 90246 (Oct. 22, 2020), 85 FR 70536 (Nov. 5, 2020) (Request for Comment: Portfolio Margining of Uncleared Swaps and Non-Cleared Security-Based Swaps).

[282] FINRA Rule 1210 requires that each person engaged in the securities business of a member register with FINRA unless an exemption applies. *See* FINRA Rule 1210.

[283] *See* SIFMA Letter at 5.

[284] *Id.*

[285] *See* PML Letter at 4.

[286] *Id.*

[287] *Id.*

[288] *Id.*

[289] *Id.* at 5. With respect to the applicable suitability standard specifically, the commenter

Continued

commenter also stated that it may be unclear if FINRA Rule 4530 (Reporting Requirements) would apply to a member if the potentially reportable conduct involved a person associated with a member whose functions are related solely and exclusively to SBS undertaken in the person's capacity as an associated person of a registered SBS Entity.[290]

In response to the comments, FINRA stated that a member is responsible for monitoring the activities of each of its associated persons to determine whether such person is required to be registered with FINRA and, if so required, to ensure that each associated person is registered in the appropriate category or categories.[291] FINRA cited to FINRA Rule 1210 (Registration Requirements), which requires persons engaged in the investment banking or securities business of a member to be registered ''in each category of registration appropriate to his or her functions and responsibilities as specified'' in FINRA Rule 1220.[292] FINRA Rule 1210 further states that persons ''shall not be qualified to function in any registered capacity other than that for which the person is registered, unless otherwise stated in the rules.'' [293] FINRA also stated that the exception in proposed FINRA Rule 0180(g) would only apply to associated persons in the limited circumstances set forth in Rule 0180(g), and does not otherwise affect FINRA members' responsibilities regarding the registration of their associated persons.[294] Thus, according to FINRA, a member relying on the proposed exception with respect to one or more of its associated persons would still need to monitor the activities of all of its associated persons, including any associated persons relying on the exception, to determine whether any of the person's activities require registration under FINRA rules.[295] Accordingly, with respect to the commenter's request for clarification, FINRA stated that it was not necessary to change to the text of proposed FINRA Rule 0180(g).[296] In so concluding, FINRA stated that the exception is structured similarly to existing exceptions from registration for persons associated with a member whose functions are related solely and exclusively to certain other products—specifically, associated persons transacting solely and exclusively in municipal securities, commodities, and security futures.[297]

FINRA stated that although it understands that the number of associated persons that would be eligible for the exception is likely to be limited, it believes the proposed exception is nonetheless appropriate to avoid unnecessary regulatory burdens with respect to even this limited set of individuals.[298] FINRA further stated that, under Commission rules, associated persons of SBS Entities, while subject to statutory disqualification prohibitions (and related background check requirements), are not independently subject to registration, licensing or continuing education (''CE'') requirements imposed or administered by the Commission.[299] FINRA believes that, at the current time, there would be limited benefit to requiring FINRA registration for the limited group of individuals that would qualify for the proposed exception.[300] FINRA stated that it will monitor developments and continue to consider whether requiring registration for an associated person whose functions are related solely and exclusively to SBS in such person's capacity as an associated person of a registered SBS Entity would be appropriate.[301]

In response to the comments concerning the potential for persons to avoid regulation, FINRA further stated that even in instances where an associated person is exempt from registration under proposed Rule 0180(g), the associated person would remain subject to all FINRA rules applicable to associated persons with respect to their SBS activities, unless another specific exception applied.[302] For example, an associated person excepted under proposed Rule 0180(g) would remain subject to suitability obligations under FINRA Rule 2111 (as well as Exchange Act Rule 15Fh–3(f) and, as applicable Rule 15Fh–5) when recommending SBS, unless the member satisfied the conditions of the exception in proposed FINRA Rule 0180(d) with respect to such activity.[303] In such circumstances, the member and the associated person would be required to comply with the Commission's business conduct obligations, which impose analogous requirements.[304] FINRA also stated that, notwithstanding the proposed rule change, a member and its associated persons would still be subject to FINRA Rule 4530 and related guidance with respect to their SBS activities (regardless of whether a particular individual relies on the exception from registration under proposed Rule 0180(g)).[305]

The Commission finds that the proposed registration exception is reasonable. The exception is limited in scope and applies only to persons associated with a FINRA member that is also a Commission-registered SBS Entity, where the associated person's functions are related solely and exclusively to SBS undertaken in such person's capacity as an associated person of the registered SBS Entity. Additionally, not only is the exception expected to apply to a limited number of persons, those individuals are still subject to other regulatory obligations. In particular: (1) Persons qualifying for the Rule 0180(g) exceptions are still subject to all FINRA rules applicable to associated persons unless another specific exception applies; (2) all Commission rules applicable to associated persons of SBS Entities, including rules designed to prevent a statutorily disqualified person from associating with an SBS Entity, will apply; [306] and (3) FINRA members are obligated to monitor the activities of their associated persons and determine whether those activities give rise to an obligation to register the person under FINRA's rules. For the foregoing reasons, the Commission finds that the proposed exemption in Rule 0180(g) is designed to protect investors and the public interest. The Commission also recognizes, however, that this is an evolving market and a new regulatory

stated that SBSDs are afforded different treatment under the proposed rule change, as the Commission's suitability rules would apply, creating another disparity for a non-SBS Entities participating in SBS to manage competing regulations. *Id.* As explained further below, contrary to the commenter's assertion, proposed Rule 0810(g) provides no exemption to FINRA Rule 2111 for an associated person (unless the FINRA member satisfied the conditions of the exception in proposed FINRA Rule 0180(d)).

[290] *Id.*

[291] FINRA Letter at 6.

[292] *Id.* at 6, n.9. FINRA Rule 1220 sets forth registration categories. *See* FINRA Rule 1220.

[293] *Id.; see also* FINRA Rule 1210.

[294] FINRA Letter at 6.

[295] *Id.* at 6–7.

[296] *Id.* at 7.

[297] *Id.* at 7; *see also* FINRA Rule 1230.

[298] *Id.* at 7–8.

[299] *Id.* at 8.

[300] *Id.*

[301] *Id.* at 8, n.12.

[302] *Id.* at 8.

[303] *Id.* The Commission notes that Exchange Act Rules 15Fh–3(f) and 15Fh–5 contain requirements that extend beyond the requirements found in FINRA Rule 2111—for example, an explicit requirement that an SBSD have a reasonable basis to believe the counterparty have an ability to absorb potential losses associated with the recommendation.

[304] *Id.*

[305] *Id.* at 9.

[306] For example, Exchange Act Rule 15Fh–3(h)(2)(iii)(D) requires an SBS Entity to have procedures to conduct a reasonable investigation regarding, among other things, the qualifications and experience of any potential associated person.

framework, and acknowledges FINRA's commitment to monitor developments and to consider whether it would be appropriate to rescind the exception as the market develops further.[307]

G. Proposed Rule 0180(i) (Authority To Grant Exemptions From the Application of Rule 0180 Upon Member Application) and 9610 (Application for Exemptive Relief)

Proposed FINRA Rule 0180(i), as discussed above in Section II.H., would provide FINRA with authority to consider exemptive relief from the application of specific FINRA rules to SBS on a rule-by-rule, member-by-member basis, other than the general presumption of applicability contained in proposed Rule 0180(a), which is not subject to exemption.[308] FINRA's proposed rule change would also make a conforming change to FINRA Rule 9610 to add FINRA Rule 0180 to the list of rules pursuant to which FINRA has exemptive authority.[309] A member's application for an exemption under proposed FINRA Rule 0180(i) would be subject to FINRA's existing procedures for all exemptive applications set forth in its Rule 9600 Series and described in more detail in Section II.G.[310] Pursuant to its procedures in FINRA Rule 9620, FINRA would be required to issue a written decision setting forth its findings and conclusions in response to the request for an exemption, which may be made publicly available.[311]

FINRA states that it needs the exemptive authority to respond to the evolving SBS market and to particular circumstances that may arise in which applying specific FINRA rules to SBS activities or positions, not otherwise excepted by the proposed rule change, may not be appropriate or feasible.[312]

Proposed Rule 0180(i) would allow FINRA to exempt a person unconditionally or on specified terms from the application of individual FINRA rules beyond what is already proposed to be permitted under proposed Rule 0180.[313] Notably, the proposed rule change would not permit any exemption from proposed Rule 0180(a), which would provide that FINRA Rules shall apply to members' activities and positions unless specifically excepted elsewhere in the rule.[314] Thus, as proposed, FINRA could not use its authority under FINRA Rule 0180(i) to grant an exemption from the general application of FINRA rules to SBS activities.[315] Rather, FINRA would only be permitted to grant exemptions only on a rule-by-rule, member-by-member basis, consistent with the existing framework for granting exemptions for other FINRA rules as provided by Rule 9610.[316] Furthermore, any exemption must consider ''all relevant factors,'' and FINRA may grant exemptions only if FINRA deems the exemption consistent with the protection of investors and the public interest.[317]

One commenter supported this proposed exemptive authority, noting that the exceptions described in the proposed rule change are tailored to the existing SBS market, and that this market may evolve in a manner that would justify further exceptions to FINRA rules.[318] As an example, the commenter noted that FINRA rules applicable to quoting and trading ''may become more relevant to SBS in the future if trading or execution of SBS on exchanges or SBS execution facilities becomes prevalent,'' and that it may then be appropriate for FINRA to adopt additional exemptions ''or otherwise clarify or tailor the application of those rules to SBS.''[319]

The Commission finds that the proposed exemptive authority under Rule 0180(i) is designed to protect investors and the public interest. The rule change will allow FINRA members to avail themselves of an existing procedural vehicle—FINRA's Rule 9600 Series—to apply for exemptive relief from specific FINRA rules, on a case-by-case basis, to address unanticipated factual circumstances as market participants navigate the newly-regulated SBS market. As stated above, the Commission agrees with FINRA that, in light of Title VII's amendment of the Exchange Act to specifically encompass SBS as securities, FINRA rules should generally apply to SBS in the same manner that such rules apply to securities generally, subject to the exceptions set forth elsewhere in proposed FINRA Rule 0180.[320] However, the Commission also recognizes the evolving nature of the SBS market, and that unanticipated factual circumstances may give rise to a need for FINRA to consider member applications for additional exceptions to specific FINRA rules on a case-by-case basis. The Commission expects that FINRA will, as it previously stated, apply heightened scrutiny to such applications for exemptive relief from its members not otherwise registered as SBS Entities with the Commission.[321]

To the extent that FINRA grants a number of exemptions pursuant to the process in its Rule 9600 Series for similar factual circumstances and/or identical FINRA rules, FINRA should consider filing a proposed rule change with the Commission to address those circumstances on a member-wide basis. Proposed Rule 0180(i) provides an appropriate vehicle that relies on an existing process for FINRA to consider providing limited exceptions on a member-by-member, case-by-case basis as warranted by specific facts, and only where FINRA deems appropriate consistent with the protection of investors and the public interest. The proposed exemptive authority is reasonably designed to allow FINRA to consider unanticipated and novel factual scenarios that may warrant additional exceptions from its rules, but only where FINRA finds that such relief is in the public interest and would protect investors. Thus, the Commission finds that the proposed FINRA Rule 0180(i) is designed to protect investors and the public interest.

H. Financial Responsibility and Operational Requirements

As discussed above in Section II.I., FINRA Rule 4120 (Regulatory Notification and Business Curtailment) sets forth certain early warning notification and business curtailment requirements if a member's capital falls below certain thresholds. These thresholds are based on the minimum capital requirements applicable to a member broker-dealer under Exchange Act Rule 15c3–1. As discussed above in Section II.I., the proposed amendments to FINRA Rule 4120 would conform the rule to the new and increased minimum capital requirements for Non-ANC Firms that are also registered as SBSDs and for ANC Firms, adopted in the Capital, Margin, and Segregation Release.

The proposed amendments to FINRA Rule 4120 will align FINRA's historical early warning notification and business curtailment thresholds with the Commission's amended capital requirements for Non-ANC Firms that

[307] *See* FINRA Letter at 9, n.11–12; *see also* Notice at 26092.

[308] *See* Notice at 26093.

[309] *Id.*

[310] *Id.*

[311] *Id.* A FINRA member seeking a non-public exemption under Rule 9600 must include in its application a detailed statement, including supporting facts, showing good cause for treating the application or decision as confidential in whole or in part. *See* FINRA Rule 9610(b).

[312] *See* Notice at 26093.

[313] *Id.*

[314] *Id.*

[315] *Id.*

[316] *Id.*

[317] *Id.*

[318] *See* SIFMA Letter at 6.

[319] *Id.*

[320] *See* Notice at 26086.

[321] *See* Notice at 26093, n.66.

are also registered as SBSDs and for ANC Firms, adopted in the Capital, Margin, and Segregation Release. The modified early warning thresholds are appropriately calibrated to provide FINRA with sufficient early warning that a FINRA member's capital levels may be deteriorating. The modified business curtailment thresholds also are appropriately calibrated to provide FINRA with the ability to require a FINRA member to reduce its business activities when its capital levels have deteriorated to a level that may jeopardize its ability to comply with regulatory capital requirements.

In addition, as discussed above in Section II.I., proposed FINRA Rule 0180(h) would provide that, for purposes of the FINRA Rule 4000 Series, all requirements that apply to a member that clears or carries customer accounts must also apply to any member that acts as a principal counterparty to an SBS, clears or carries an SBS, guarantees an SBS or otherwise has financial exposure to an SBS. Applying these higher standards when a member enters into SBS transactions, or otherwise has exposure to SBS is appropriate given that SBS are complex transactions that will require detailed recordkeeping, margining, legal agreements, collateral management, reconciliation and risk management.

I. Margin Requirements

As discussed above in Section II.J., FINRA is proposing to adopt a new margin rule specifically applicable to SBS. Current FINRA Rule 4240 would be replaced by new FINRA Rule 4240 that would prescribe margin requirements for SBS, including CDS. However, proposed FINRA Rule 4240 would not apply to any FINRA member that is registered as an SBSD. FINRA members that are SBSDs are subject to the margin requirements of Exchange Act Rule 18a–3 discussed above in Section II.J. FINRA stated that by applying margin requirements in these circumstances, the proposed rule change would fill an important regulatory gap, protect FINRA members against counterparty credit risk, maintain a level playing field for members, and prevent regulatory arbitrage. As discussed above in Section II.J., the margin requirements under proposed FINRA Rule 4240 would be structurally aligned with the margin requirements that apply to SBSDs under Exchange Act Rule 18a–3, with certain modifications that FINRA believes are necessary because FINRA members that are not SBSDS will not be subject to the Commission's comprehensive regulatory framework for SBSDs.[322] Thus, subject to certain exceptions in the proposed rule discussed above in Section II.J., proposed FINRA Rule 4240 would require members that are not SBSDs to collect and deliver variation margin on a daily basis to cover the member's current exposure to or from each SBS counterparty, and also to collect (but not deliver) initial margin from each SBS counterparty. FINRA members that are not SBSDs would also be required to monitor the risk of any Uncleared SBS Account and maintain a comprehensive risk analysis methodology for assessing the potential risk to the member's capital. Finally, FINRA is also proposing to amend FINRA Rules 4210 and 4220 to take into account members' SBS activities.[323]

Applying the proposed margin requirements to FINRA members that are not registered as SBSDs will fill an important regulatory gap because it will prescribe margin requirements for uncleared SBS for FINRA members that are not SBSDs and not subject to Exchange Act Rule 18a–3. The margin requirements in the proposed rule change will protect FINRA members against counterparty credit risk with respect to transactions in uncleared SBS.[324] In particular, the proposed margin requirements will address the risk of uncollateralized exposures in uncleared SBS for FINRA members that are not registered as SBSDs by prescribing variation and initial margin requirements, subject to certain exceptions, as well as requiring these firms to maintain a comprehensive written risk analysis methodology. In addition, adopting a stand-alone rule that applies margin requirements to uncleared SBS under proposed new FINRA Rule 4240 will reduce unnecessary and duplicative regulation for FINRA members regarding which FINRA margin requirements apply to uncleared SBS.

A commenter stated that proposed FINRA Rule 4240 would differ in several material respects from Exchange Act Rule 18a–3.[325] More specifically, the commenter stated that FINRA Rule 4240 would (1) not permit a member to use an approved model to calculate initial margin, (2) require a member to collect initial margin from affiliates that are not financial market intermediaries or majority owners, (3) not permit a member to apply an initial margin threshold, (4) not permit a member to apply a minimum transfer amount, and (5) not permit an ANC Firm to apply credit risk charges under paragraph (c) to Exchange Act Rule 15c3–1e in lieu of collecting margin, except for SBS with a majority owner, or a registered or foreign SBS Dealer affiliate.[326] The commenter stated that these differences would present material issues for members subject to proposed FINRA Rule 4240, particularly in connection with certain inter-affiliate SBS designed to promote centralized, group-wide risk management, as well as SBS entered into with unaffiliated financial market intermediaries for hedging purposes. The commenter provided examples where it believed that the differences between Exchange Act Rule 18a–3 and proposed FINRA Rule 4240 would present material issues, including: (1) When a foreign dealer affiliate of a U.S. broker-dealer hedges risks of SBS based on U.S. securities with their foreign customers via offsetting SBS with the U.S. broker-dealer, (2) when a broker-dealer forms an affiliated special purpose vehicle to issue a structured note that references a security, and (3) when a broker-dealer, in order to hedge the risk of its securities inventory, enters into one or more SBS with unaffiliated financial market intermediaries.[327]

The commenter recommended that FINRA permit a broker-dealer to comply with Exchange Act Rule 18a–3 rather than proposed FINRA Rule 4240 to address these issues.[328] However, the commenter also stated that it appreciates FINRA's concerns regarding a smaller broker-dealer entering into uncleared SBS with margin requirements that differ from the requirements that would apply under FINRA Rule 4210 to equivalent securities positions.[329] To address this consideration, the commenter proposed that, in order for a FINRA member to apply Exchange Act Rule 18a–3 in lieu of proposed FINRA Rule 4240, the member must satisfy the higher capital requirements applicable to an SBSD in Exchange Act Rule 15c3–1(a)(10) (or the higher capital requirements applicable to an ANC Firm in Exchange Act Rule 15c3–1(a)(7)). The commenter further proposed that for such a member to use a model to calculate initial margin, the Commission would need to approve the model for use by an affiliate of the member that is registered as an SBSD.[330] The commenter also stated that if

[322] *See* Notice at 26097.

[323] *See supra* note 147.

[324] *See* Notice at 26097.

[325] *See* SIFMA Letter at 7–11.

[326] *Id.; see also supra* note 197 (defining ''Registered or Foreign SBS Dealer'').

[327] *See* SIFMA Letter at 8.

[328] *Id.*

[329] *Id.*

[330] *Id.*

FINRA does not adopt these recommendations, then it should further modify proposed FINRA Rule 4240 to align more closely with Exchange Act Rule 18a–3.[331] The commenter stated that FINRA previously declined to incorporate this suggested modification because broker-dealers subject to the proposed margin requirements for uncleared SBS would not be subject to the regulatory framework applicable to SBSDs, in particular higher capital requirements applicable to registered SBSDs.[332]

FINRA responded to the comments stating that FINRA acknowledges that proposed FINRA Rule 4240 would differ from Exchange Act Rule 18a–3 in some respects.[333] While such differences may in some cases result in increased costs for members that are not registered SBSDs when entering into uncleared SBS transactions with certain counterparties, FINRA responded that the requirements of proposed FINRA Rule 4240 as set forth in the Notice are important to protect the financial condition of its members, given that members subject to the rule would not be subject to the comprehensive regulatory framework applicable to SBSDs.[334] FINRA also stated that a member can ''opt-in'' to Exchange Act Rule 18a–3 by registering as an SBSD.[335] FINRA further stated that SBSD registration is an important precondition to margining pursuant to Exchange Act Rule 18a-3, because SBSD registration assures that the entity is fully regulated as an SBSD, including the higher minimum capital requirements applicable to SBSDs.[336] Therefore, FINRA believes it would not be appropriate to incorporate Commission margin rules by reference or allow non-SBSD members to ''opt-in'' to the Commission margin rules as an alternative to FINRA margin rules.[337] Further, FINRA stated the specific requirements of proposed FINRA Rule 4240 are appropriately calibrated to provide parity with both FINRA Rule 4210 and Exchange Act Rule 18a–3, where possible, but also to provide greater protection to the financial condition of members not subject to the Commission's comprehensive requirements for registered SBSDs.[338]

The Commission concludes that it would not be appropriate for a FINRA member that is not registered as an SBSD to ''opt in'' to compliance with Exchange Act Rule 18a–3 in lieu of complying with proposed FINRA Rule 4240, including in cases where a member would comply with higher capital requirements. While the proposed margin requirements differ from Exchange Act Rule 18a–3 in some respects, FINRA proposed the amendments in part to reduce regulatory arbitrage between existing margin requirements under FINRA Rule 4210 and the proposed requirements for uncleared SBS under FINRA Rule 4240. For example, the margin requirements in proposed FINRA Rule 4240 do not contain any thresholds that are prescribed in Exchange Act Rule 18a–3 (such as the $50 million threshold below which initial margin need not be collected by an SBSD). Therefore, the proposed margin requirements should reduce the risk that a broker-dealer would be incentivized to restructure existing securities margin accounts as uncleared SBS, since existing FINRA Rule 4210 does not contain any margin thresholds for securities. In addition, while broker-dealers and SBSDs are subject to comprehensive financial responsibility requirements, FINRA member firms that are not SBSDs are not subject to the Commission's specific regulatory framework for registered SBSDs under Title VII of the Dodd-Frank Act, and Exchange Act Rule 18a–3, in particular, only applies to SBSDs and MSBSPs.

For those same reasons, FINRA declined to adopt a number of specific modifications suggested by a commenter to align proposed Rule 4240 more closely with Exchange Act Rule 18a–3 in lieu of allowing members to comply with Exchange Act Rule 18a–3.[339] FINRA stated that the commenter made a number of similar recommendations in its comments responding to the Concept Proposal.[340] FINRA stated that it had responded previously to these recommendations, which included several modifications from the margin rule described in the Concept Proposal that were intended to address the comments and enhance competitive parity, while still providing appropriate protection for the financial condition of non-SBSD members entering into uncleared SBS.[341] FINRA further stated that, as a general matter, proposed FINRA Rule 4240 is not intended to level the playing field between SBSDs and non-SBSD members entering into SBS, such as *de minimis* dealers.[342] Rather, FINRA stated that the proposed rule is intended to adequately protect members from counterparty credit risk and prevent regulatory arbitrage, in particular by removing incentives for members to restructure their traditional extensions of credit (*e.g.,* margin lending) subject to FINRA Rule 4210 as uncleared SBS.[343]

Further, with respect to a commenter's request for FINRA to align proposed new FINRA Rule 4240's collateral haircuts with Exchange Act Rule 18a–3, FINRA stated that it does not believe permitting the use of the haircuts applicable to SBS collateral under Exchange Act Rule 18a–3 would be appropriate.[344] As FINRA previously stated, the proposed rule change is not intended to level the playing field between SBSDs and non-SBSD members entering into SBS, such as *de minimis* dealers, but rather to prevent regulatory arbitrage between members extending credit through SBS and members extending credit through traditional means.[345]

With respect to the request for FINRA to extend the deadline for posting or collecting margin for counterparties in distant time zones, FINRA stated that Exchange Act Rule 18a–3 requires that a member take an applicable capital charge on positions that do not meet the margin requirements generally within T+1, but extends that deadline to T+2 if the counterparty is located in another country and four time zones away.[346] While proposed FINRA Rule 4240 would similarly require a capital charge if required margin is not collected on T+1, FINRA stated that FINRA Rule 4240 would not require liquidation of the position until T+3. FINRA stated that this timing follows the portfolio margin requirements under FINRA Rule 4210, and stated it is appropriate to require a capital charge on T+1 because the location of the counterparty does not affect the counterparty credit risk to the

[331] *Id.*

[332] *Id.*

[333] *See* FINRA Letter at 10.

[334] *Id.*

[335] *Id.*

[336] *Id.*

[337] *Id.*

[338] *Id.*

[339] *Id.* Specifically, the commenter proposed that FINRA: (1) Adopt an initial margin exception for all majority-owned affiliates; (2) permit an ANC Firm to calculate credit risk charges in accordance with Exchange Act Rule 15c3–1e(c) for exposures to all counterparty types; (3) permit use of SEC-approved initial margin models for non-equity SBS; (4) adopt a $50 million initial margin threshold, applicable on a group-wide basis; (5) adopt a $500,000 minimum transfer amount; (6) align FINRA Rule 4240's collateral haircuts with Exchange Act Rule 18a–3; and (7) extend the deadline for posting or collecting margin for counterparties in distant time zones. *See* SIFMA Letter at 9–11.

[340] *See* Notice at 26107–09; *see also* FINRA Letter at 10.

[341] FINRA Letter at 10.

[342] *Id.*

[343] *Id.* at 10–11.

[344] *Id.* at 11.

[345] *Id.*

[346] In this context, ''T+1'' and similar terms refer to the number of business days after the date on which the person was required to compute the margin requirement. *Id.*

member.[347] However, FINRA believes that, generally, the additional time before liquidation is required should be sufficient to accommodate counterparties in distant time zones.[348]

The Commission concludes that it is appropriate for FINRA to decline to adopt commenters suggestions to modify proposed new FINRA Rule 4240 to more closely align with the requirements of Exchange Act Rule 18a–3, including the rule's collateral haircuts. Proposed FINRA Rule 4240 will promote consistent margin requirements, including haircut requirements, between FINRA members extending credit through traditional means under FINRA Rule 4240 and FINRA members extending credit through SBS under FINRA Rule 4240. The requirements under new FINRA Rule 4240 will protect FINRA members from counterparty credit risk and prevent regulatory arbitrage by reducing incentives for members to restructure their traditional extensions of credit (*e.g.,* margin lending) subject to FINRA Rule 4210 as uncleared SBS. Further, the proposed time period (T+3) with respect to required liquidations above should provide FINRA members that are not SBSDs the flexibility to accommodate counterparties in additional time zones.

Another commenter raised concerns regarding the disparate treatment for SBSDs with respect to uncleared SBS. The commenter stated that proposed FINRA Rule 4240 and Exchange Act Rule 18a–3 impose different margin and collateral requirements, depending on whether an entity is designated as an SBSD or a FINRA broker-dealer.[349] This commenter raised concerns that this difference could hinder the ability of a FINRA broker-dealer to compete with SBSDs or other SBS market participants on a level playing field. In particular, the commenter raised concerns that counterparties would potentially choose to transact with an SBSD rather than a similarly capitalized FINRA broker-dealer, in order to avoid the need for the daily collection of initial margin and variation margin, which could lead to reduced firm participation impacting overall costs and liquidity.[350]

In response, as discussed above in Section II.J., while proposed FINRA Rule 4240 would diverge from Exchange Act Rule 18a–3 in some respects, FINRA believes that proposed FINRA Rule 4240 appropriately protects members from counterparty credit risk and prevents regulatory arbitrage between different methods of extending credit.[351] FINRA does not believe that the potential for increased market liquidity if more members functioned as *de minimis* dealers justifies replacing the specific margin requirements set forth in proposed FINRA Rule 4240.[352] Moreover, FINRA stated that a FINRA member seeking to establish parity with other SBSDs with respect to margin requirements may elect to register as an SBSD and become subject to the Commission's comprehensive SBSD regulatory framework. FINRA stated that the intent of proposed Rule 4240 is not to level the playing field between SBSDs and members engaged in *de minimis* SBS activity, but rather to prevent regulatory arbitrage as between members extending credit through SBS and members extending credit in the traditional fashion.[353]

The proposed rule change will serve to promote consistent and transparent margin requirements for the uncleared SBS market and traditional securities markets for FINRA members that are not SBSDs. Further, proposed Rule 4240 will require a FINRA member to collect initial margin, and collect or post variation margin, unless an exception applies.[354] In structuring the proposed rule, FINRA has reasonably balanced the goal of reducing firm exposure to counterparty credit risk stemming from unsecured credit exposures in uncleared SBS transactions, with the potential costs and competitive impacts that may result from the proposed rule change. For example, FINRA has proposed a number of exceptions to the proposed margin requirements,[355] which may lessen the competitive impacts and costs of the proposed margin requirements.

A commenter further sought clarification regarding Non-Basic SBS, and more specifically uncleared TRS structures.[356] The commenter stated that the SBS market is dynamic and that market developments, such as its proposed alternative trading system platform, may make commonplace transactions that today are limited. The commenter also stated that a key blocker to growth of this activity is potential ambiguity around timing and the open-ended nature of the approval process for margin requirements for Non-Basic SBS.[357] Finally, this commenter stated that SBSDs would be placed at a significant advantage under the proposed margin framework, and supported a more clearly defined process for FINRA members that are not SBSDs to evaluate new products within existing or potentially expanded lines of business.[358]

In response, FINRA stated that under proposed FINRA Rule 4240(b)(2)(C), a member may apply to FINRA for the approval of an Initial Margin Requirement for a type of SBS other than Basic CDS and Basic SBS. FINRA further stated that the proposed rule change sets forth the requirements for any such application, and provides that no member shall become a party to an SBS other than a Basic CDS or Basic SBS unless FINRA has approved an Initial Margin Requirement for such member's use with respect to that type of SBS.[359] In addition, FINRA believes other types of SBS—including CDS and equity TRS with complex features—may not be easily accommodated under the frameworks applicable to Basic CDS and Basic SBS, and that the specific risks of such SBS may not be readily apparent or quantifiable to FINRA without additional information. Further, FINRA stated that SBS can be complex financial instruments that pose substantial risks to the financial condition of members, and margin serves as an important means of protecting member firms, and thereby their customers and investors, from such risks.[360] FINRA also believes that the application process under proposed FINRA Rule 4240(b)(2)(C) permits appropriate flexibility so that FINRA and its member firms may analyze all relevant risks that may be associated with a new type of SBS product. FINRA also stated that proposed FINRA Rule 4240 defers to registered clearing agencies with respect to the margin requirements for Cleared SBS. Therefore, FINRA believes that FINRA members that are not SBSDs may enter into Cleared SBS without seeking approval under Rule 4240(b)(2)(C); the application process would only be required before entering into new types of uncleared SBS.[361]

The proposed application process for margin requirements for SBS that are not Basic SBS or CDS provides specific detail with respect to the application's requirements, while providing FINRA with the flexibility to determine if a proposed margin requirement adequately addresses the risks for a

[347] *Id.*

[348] *Id.*

[349] *See* PML Letter at 7.

[350] *Id.*

[351] *See* FINRA Letter at 11.

[352] *Id.* at 11–12.

[353] *Id.* at 12.

[354] *See* Notice at 26097.

[355] *Id.* at 26101.

[356] *See* PML Letter at 6.

[357] *Id.* at 7.

[358] *Id.*

[359] *See* FINRA Letter at 12.

[360] *Id.*

[361] *Id.*

particular type of SBS, including through the ability to request additional information. These requirements will protect FINRA member firms from the risks associated with uncleared SBS with complex features by ensuring FINRA member firms that are not SBSDs set prudent margin levels for these instruments.

In conclusion, the proposed changes to FINRA Rules 4210, 4420, and 4240 will help to ensure that the risks to FINRA members that are not SBSDs with respect to their uncleared SBS exposures are adequately addressed through the collection of margin. In addition, the proposed rule changes will enhance risk management practices at FINRA members that are not SBSDs and that participate in the SBS markets. They also will prevent unnecessary regulatory duplication by applying the proposed margin requirements in proposed FINRA Rule 4240 to FINRA members that are not SBSDs, and will not be subject to the margin requirements of Rule 18a–3.

IV. Conclusion

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act [362] that the proposed rule change (SR–FINRA–2021–008), as modified by Amendment No. 1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[363]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00376 Filed 1–11–22; 8:45 am]

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[362] 15 U.S.C. 78s(b)(2).

[363] 17 CFR 200.30–3(a)(12).

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Part IV

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys of the Guerrero Gap in the Eastern Tropical Pacific; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB628]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys of the Guerrero Gap in the Eastern Tropical Pacific

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible Renewal.

SUMMARY: NMFS has received a request from the Lamont-Doherty Earth Observatory (L–DEO) for authorization to take marine mammals incidental to geophysical surveys of the Guerrero Gap off the coast of Mexico in the Eastern Tropical Pacific. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than February 11, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service submitted via email to *ITP.Fowler@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

Accordingly, NMFS plans to adopt the National Science Foundation's (NSF's) Environmental Assessment (EA), provided our independent evaluation of the document finds that it includes adequate information analyzing the effects on the human environment of issuing the IHA. The NSF's EA is available at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On August 21, 2021, NMFS received a request from L–DEO for an IHA to take marine mammals incidental to geophysical surveys of the Guerrero Gap off the coast of Mexico in the Eastern Tropical Pacific (ETP). The application was deemed adequate and complete on December 14, 2021. L–DEO's request is for take of a small number of 30 species of marine mammals by Level B harassment and, for two of those species, by Level A harassment. Neither L–DEO nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

Researchers from L–DEO, University of Texas Institute of Geophysics (UTIG), and Northern Arizona University (NAU), with funding from the NSF, and in collaboration with researchers from the National Autonomous University of Mexico (Universidad Nacional Autonoma de Mexico or UNAM) and Kyoto University, propose to conduct high-energy seismic surveys from the research vessel (R/V) *Marcus G. Langseth* (*Langseth*) in and around the Guerrero Gap off western Mexico, in the ETP. The proposed study would use two-dimensional (2–D) seismic surveying to quantify incoming plate hydration and examine the role of fluids on megathrust slip behavior in and around the Guerrero Gap of the Middle America Trench. This is one of the best-known examples in the world of along-strike variations in slip behavior of the plate boundary. L–DEO proposes to conduct two different methods of seismic acquisition, multi-channel seismic (MCS) using a hydrophone streamer and refraction surveys using ocean bottom seismometers (OBSs). The

surveys would use a 36-airgun towed array with a total discharge volume of ~6600 cubic inches (in^3) as an acoustic source, acquiring return signals using both a towed streamer as well as OBSs. The majority of the proposed 2–D seismic surveys would occur within the Exclusive Economic Zone (EEZ) of Mexico, including territorial seas, and a small portion would occur in International Waters.

Dates and Duration

The proposed research cruise would be expected to last for 48 days, including approximately 20 days of seismic survey operations, 3 days of transit to and from the survey area, 19 days for equipment deployment/recovery, and 6 days of contingency time for poor weather, etc. The R/V *Langseth* would likely leave out of and return to port in Manzanillo, Mexico, during spring 2022. The proposed IHA would be valid from March 1, 2022 through February 28, 2023.

Specific Geographic Region

The proposed surveys would occur within the area of approximately 14–18.5°N and approximately 99–105°W. Representative survey tracklines are shown in Figure 1. Some deviation in actual track lines, including the order of survey operations, could be necessary for reasons such as science drivers, poor data quality, inclement weather, or mechanical issues with the research vessel and/or equipment. The majority of the proposed surveys would occur within the EEZ of Mexico, including territorial seas, and a small portion would occur in International Waters. The surveys would occur in waters up to 5,560 meters (m) deep. Most of the survey effort (94 percent) would occur in deep water (≤1000 m), and 6 percent would occur in intermediate water (100–1000 m deep); no effort would occur in shallow water (<100 m deep). A total of 3,600 kilometers (km) of transect lines would be surveyed (2,230 km of 2–D MCS reflection data and 1,370 km of OBS refraction data).

Approximately 6 percent of the total survey effort would occur in Mexican territorial waters. Note that the MMPA does not apply in Mexican territorial waters. L–DEO is subject only to Mexican law in conducting that portion of the survey. However, NMFS has calculated the expected level of incidental take in the entire activity area (including Mexican territorial waters) as part of the analysis supporting our determination under the MMPA that the activity will have a negligible impact on the affected species (see Estimated Take and Negligible Impact Analysis and Determination).

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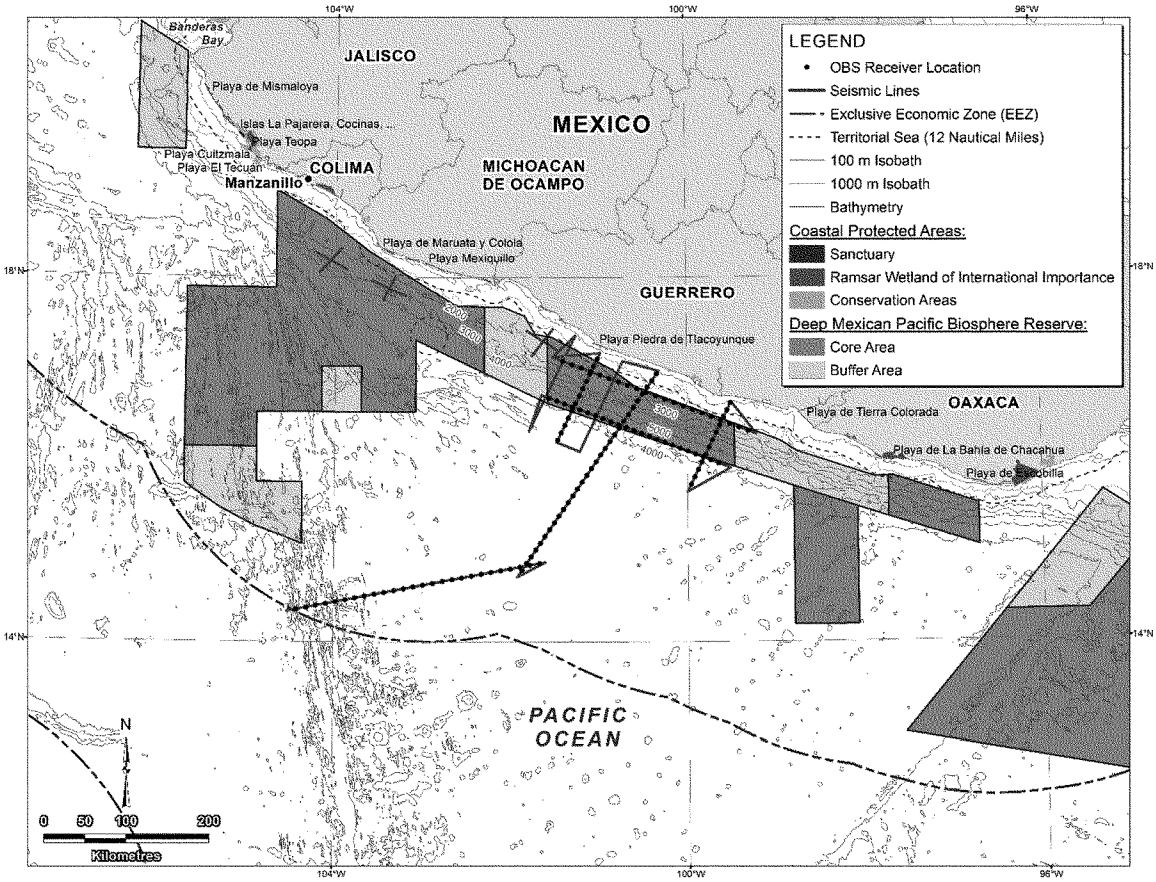

Figure 1. Location of the Proposed Seismic Surveys and OBS Deployments in the Eastern Tropical Pacific Ocean

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Detailed Description of Specific Activity

The procedures to be used for the proposed marine geophysical surveys would be similar to those used during previous surveys by L–DEO that received incidental take authorizations from NMFS (*e.g.,* 85 FR 55645; September 9, 2020, 84 FR 35073; July 22, 2019) and would use conventional seismic methodology. The survey would involve one source vessel, R/V *Langseth,* which would tow a 36-airgun array with a discharge volume of ~6600 in^3 at a depth of 12 m. The array consists of 36 elements, including 20 Bolt 1500LL airguns with volumes of 180 to 360 in^3 and 16 Bolt 1900LLX airguns with volumes of 40 to 120 in^3. The airgun array configuration is illustrated in Figure 2–11 of NSF and the U.S. Geological Survey's (USGS's) Programmatic Environmental Impact Statement (PEIS; NSF–USGS, 2011). (The PEIS is available online at: *www.nsf.gov/geo/oce/envcomp/usgs-nsf-marine-seismic-research/nsf-usgs-final-eis-oeis-with-appendices.pdf*).

The proposed surveys consist of eight MCS lines, of which six are coincident OBS refraction lines that are located perpendicular to the margin; these six lines would therefore be acquired twice. Approximately 62 percent of the total survey effort would be MCS surveys, with the remaining 38 percent using OBSs. There could be additional seismic survey operations associated with turns, airgun testing, and repeat coverage of any areas where initial data quality is sub-standard, and 25 percent has been added to the assumed survey line-kms to account for this potential. NMFS considers this a conservative approach to estimating potential acoustic exposures.

The vessel speed during seismic survey operations would be ~4.1 knots (~7.6 km/hour) during MCS reflection surveys and 5 knots (~9.3 km/hour) during OBS refraction surveys. The airguns would fire at a shot interval of 50 m (approximately 24 seconds) during MCS surveys with the hydrophone streamer and at a 400-m (155 seconds) interval during refraction surveys to OBSs. The receiving system would consist of a 15-km long hydrophone streamer and short-period OBSs. As the airgun arrays are towed along the survey lines, the OBSs would receive and store the returning acoustic signals internally for later analysis, and the hydrophone streamer would transfer the data to the on-board processing system.

The seismometers would consist of 33 OBSs, which would be deployed at a total of 124 sites. The instruments would be deployed by R/V *Langseth* and spaced 10 or 12 km apart. Following refraction shooting of one line, short-period instruments on that line would be recovered, serviced, and redeployed on a subsequent refraction line while MCS data are acquired. The OBSs have a height and diameter of approximately 1 m and an anchor weighing roughly 80 kilograms (kg). OBS sample rate would be set at 200 hertz (Hz). All OBSs would be recovered by the end of the survey.

To retrieve OBSs, an acoustic release transponder (pinger) is used to interrogate the instrument at a frequency of 8–11 kilohertz (kHz), and a response is received at a frequency of 11.5–13 kHz. The burn-wire release assembly is then activated, and the instrument is released to float to the surface from the anchor which is not retrieved. Take of marine mammals is not expected to occur incidental to L–DEO's use of OBSs.

In addition to the operations of the airgun array, a multibeam echosounder (MBES), a sub-bottom profiler (SBP), and an Acoustic Doppler Current Profiler (ADCP) would be operated from R/V *Langseth* continuously during the seismic surveys, but not during transit to and from the survey area. Take of marine mammals is not expected to occur incidental to use of the MBES, SBP, or ADCP as, due to these sources' characteristics (*e.g.,* narrow downward-directed beam), marine mammals would experience no more than one or two brief ping exposures from them, if any exposure were to occur. Accordingly, the use of MBES, SBP, and ADCP are not analyzed further in this document.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Brief discussions of some species and stocks is presented below. For all other species, we refer the reader to the descriptions in L–DEO's IHA application, incorporated here by reference, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

Table 1 lists all species or stocks for which take is expected and proposed to be authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2021). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no serious injury or mortality is anticipated or proposed for authorization here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Pacific SARs. All values presented in Table 1 are the most recent available at the time of publication and are available in the 2020 SARs (Carretta *et al.,* 2021) and draft 2021 SARs (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*). Where available, abundance and status information is also presented for marine mammals in the Pacific waters of Mexico and/or the greater ETP region. Table 1 denotes the status of species and stocks under the U.S. MMPA and ESA. We note also that the Guadalupe fur seal is classified as ''En peligro de extinción'' (in danger of extinction) under the Norma Oficial Mexicana NOM–059–SEMARNAT–2010 and all other marine mammal species listed in Table 1, with the exception of Longman's beaked whales and Deraniyagala's beaked whales, are listed as ''Sujetas a protección especial'' (subject to special protection).

TABLE 1—MARINE MAMMALS THAT COULD OCCUR IN THE SURVEY AREA

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]	ETP abundance [4]	Mexico Pacific abundance [5]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales) Family Balaenopteridae (rorquals)								
Humpback Whale	*Megaptera novaeangliae.*	Central N Pacific	-, -, Y	10,103 (0.3, 7,890, 2006).	83	26	2,566	
Minke whale	*Balaenoptera acutorostrata.*	N/A	-, -, N	N/A	N/A	N/A	115	
Bryde's whale	*Balaenoptera edeni.*	Eastern Tropical Pacific	-, -, N	Unknown (Unknown, Unknown, N/A).	Undetermined	Unknown	10,411	649
Sei whale	*Balaenoptera borealis.*	Eastern N Pacific	E, D, Y	519 (0.4, 374, 2014).	0.75	≥0.2	0	
Fin whale	*Balaenoptera physalus.*	N/A	E, D, Y	N/A	N/A	N/A	574	145
Blue whale	*Balaenoptera musculus.*	Eastern N Pacific	E, D, Y	1,898 (0.085, 1,767, 2018).	4.1	≥19.4	1,415	773
Superfamily Odontoceti (toothed whales, dolphins, and porpoises) Family Physeteridae								
Sperm whale	*Physeter macrocephalus.*	N/A	E, D, Y	N/A	N/A	N/A	4,145	2810
Family Kogiidae								
Dwarf Sperm Whale.	*Kogia sima*	N/A	N/A	N/A	N/A	N/A	[6] 11,200	
Family Ziphiidae (beaked whales)								
Cuvier's Beaked Whale.	*Ziphius cavirostris*	N/A	-, -, N	N/A	N/A	N/A	[7] 20,000	[8] 68,828
Longman's beaked whale.	*Indopacetus pacificus.*	N/A	-, -, N	N/A	N/A	N/A	1,007	
Blainville's beaked whale.	*Mesoplodon densirostris.*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Ginkgo-toothed beaked whale.	*M. ginkgodens*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Deraniyagala's beaked whale.	*M. hotaula*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Pygmy beaked whale.	*M. peruvianus*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Family Delphinidae								
Risso's dolphin	*Grampus griseus*	N/A	-, -, N	N/A	N/A	N/A	110,457	24,084
Rough-toothed dolphin.	*Steno bredanensis.*	N/A	-, -, N	N/A	N/A	N/A	107,663	37,511
Common bottlenose dolphin.	*Tursiops truncatus.*	N/A	-, -, N	N/A	N/A	N/A	335,834	61,536
Pantropical spotted dolphin.	*Stenella attenuata*	N/A [10]	-, D, N	N/A	N/A	N/A	[11] 1,297,091	146,296
Spinner dolphin	*Stenella longirostris.*	N/A [10]	-, D, N	N/A	N/A	N/A	[11] 2,075,871	186,906
Striped dolphin	*Stenella coeruleoalba.*	N/A	-, -, N	N/A	N/A	N/A	964,362	128,867
Short-beaked common dolphin.	*Delphinus delphis*	N/A	-, -, N	N/A	N/A	N/A	3,127,203	283196
Fraser's dolphin	*Lagenodelphis hosei.*	N/A	-, -, N	N/A	N/A	N/A	[7] 289,300	
Short-finned pilot whale.	*Globicephala macrorhynchus.*	N/A	-, -, N	N/A	N/A	N/A	[12] 589,315	3,348
Killer whale	*Orcinus orca*	N/A	-, -, N	N/A	N/A	N/A	[7] 8,500	852
False killer whale	*Pseudorca crassidens.*	N/A	-, -, N	N/A	N/A	N/A	[7] 39,800	
Pygmy killer whale	*Feresa attenuata*	N/A	-, -, N	N/A	N/A	N/A	[7] 38,900	
Melon-headed whale.	*Peponocephala electra.*	N/A	-, -, N	N/A	N/A	N/A	[7] 45,400	
Order Carnivora—Superfamily Pinnipedia Family Otariidae (eared seals and sea lions)								
Guadalupe fur seal	*Arctocephalus townsendi.*	Mexico	T, D, Y	34,187 (N/A, 31,019, 2013).	1062	≥3.8		

TABLE 1—MARINE MAMMALS THAT COULD OCCUR IN THE SURVEY AREA—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI[3]	ETP abundance [4]	Mexico Pacific abundance [5]
California sea lion	*Zalophus californianus.*	U.S.	-, -, N	257,606 (N/A,233,515, 2014).	14011	>320	105,000	.....

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports* . CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] From NMFS (2015b) unless otherwise noted.

[5] Pacific Mexico excluding the Gulf of California (from Gerrodette and Palacios (1996) unless otherwise noted).

[6] Estimate for ETP is mostly for *K. sima* but may also include some *K. breviceps* (Wade and Gerrodette 1993).

[7] Wade and Gerrodette 1993.

[8] Abundance for all ziphiids.

[9] This estimate for the ETP includes all species of the genus *Mesoplodon.*

[10] Several stocks of these species, while not classified as such in the U.S. SARs, are considered depleted due to historical interactions with tuna fisheries in the area. Please see below for a discussion of these stocks.

[11] Includes abundance of several stocks added together.

[12] Based on surveys in 2000 (Gerrodette and Forcada 2002).

As indicated above, all 30 species (with six managed stocks) in Table 1 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing it. As the planned survey lines are outside of the U.S. EEZ, they do not directly overlap with the defined ranges for most U.S. managed stocks (Carretta *et al.,* 2021). For some species (*e.g.,* Bryde's whale, Guadalupe fur seal; see Table 1), animals encountered during the surveys could be from a defined stock under the MMPA but most marine mammals in the survey area do not belong to any defined stock. Species that could potentially occur in the proposed research area but are not likely to be encountered due to the rarity of their occurrence (*i.e.,* are considered extralimital or rare visitors to the coastal waters of Mexico in the Eastern Tropical Pacific) are described briefly but omitted from further analysis. These generally include species that do not normally occur in the area but for which there are one or more occurrence records that are considered beyond the normal range of the species. These species include the gray whale (*Eschrichtius robustus*), Hubbs' beaked whale (*Mesoplodon carlhubbsi*), Stejneger's beaked whale (*M. stejnegeri*), Perrin's beaked whale (*M. perrini*), Baird's beaked whale (*Berardius bairdii*), pygmy sperm whale (*Kogia breviceps*), long-finned pilot whale (*Globicephala melas*), Dall's porpoise (*Phocoenoides dalli*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), and northern right whale dolphin (*Lissodelphis borealis*), which all generally occur well north of the proposed survey area (*e.g,* north of the Baja peninsula). Five additional pinniped species are known to occur in the ETP but are considered extralimital in the proposed survey area: The Galápagos sea lion (*Zalophus wollebaeki*), Galápagos fur seal (*Arctocephalus galapagoensis*), South American fur seal (*A. australis*), and the South American sea lion (*Otaria flavescens*), which all occur south of the survey area, and the northern elephant seal (*Mirounga angustirostris*) which is found north of the survey area.

Prior to 2016, humpback whales were listed under the ESA as an endangered species worldwide. Following a 2015 global status review (Bettridge *et al.,* 2015), NMFS delineated 14 distinct population segments (DPSs) with different listing statuses (81 FR 62259; September 8, 2016) pursuant to the ESA. The DPSs that occur in U.S. waters do not necessarily equate to the existing stocks designated under the MMPA and shown in Table 1. The threatened Mexico DPS and endangered Central America DPS may occur within the proposed survey area. However, due to the expected timing of the proposed survey (spring), most humpbacks from the Mexico DPS will have begun their migration north toward the feeding grounds off of the U.S. west coast and are likely to be outside of the survey area. Humpbacks from the Central America DPS will likely be migrating northward through the survey area at the time of the proposed survey. Therefore, we assume that most humpback whales taken by the proposed survey activities will be from the Central America DPS.

The pantropical spotted dolphin is one of the most abundant cetaceans and is distributed worldwide in tropical and some subtropical waters, between ~40°N and 40°S (Jefferson *et al.,* 2015). In the ETP, this species ranges from 25° N off the Baja California Peninsula to 17° S, off southern Peru (Perrin and Hohn, 1994). There are two forms of pantropical spotted dolphin (Perrin 2018a): Coastal (*Stenella attenuata graffmani*) and offshore (*S. a. attenuata*), both of which could occur within the proposed survey area. Along the coast of Latin America, the coastal form typically occurs within 20 km from shore (Urbán 2008 *in* Heckel *et al.,* 2020). There are currently three recognized stocks of spotted dolphins in the ETP: The coastal stock and two offshore stocks—the northeast and the west/south stocks (Wade and Gerrodette 1993; Leslie *et al.,* 2019). Much of what is known about the pantropical spotted dolphin in the ETP is related to the historical tuna purse-seine fishery in that area (Perrin and Hohn 1994). There was an overall stock decline of spotted dolphins from 1960–1980 because of the fishery (Allen 1985). In 1979, the population size of spotted dolphins in the ETP was estimated at 2.9–3.3 million (Allen 1985). For 1986–1990, Wade and Gerrodette (1993) reported an estimate of 2.1 million. Gerrodette and Forcada (2005) noted that the population of offshore northeastern spotted dolphins had not yet recovered from the earlier population declines; possible reasons for the lack of growth were attributed to unreported bycatch, effects of fishing activity on survival and reproduction, and long-term changes in the ecosystem. The abundance estimate for 2006 was ~857,884 northeastern offshore spotted

dolphins, and 439,208 western-southern offshore spotted dolphins; the coastal subspecies was estimated at 278,155 and was less affected by fishing activities (Gerrodette *et al.,* 2008). In 2004, the mortality rate in the tuna fishery was estimated at 0.03 percent (Bayliff 2004). Perrin (2018a) noted that for the last few years, hundreds of spotted dolphins have been taken in the fishery. Currently, there are ~640,000 northeastern offshore spotted dolphins inhabiting the ETP (Perrin 2018a). This stock is still considered depleted and may be slow to recover due to continued chase and encirclement by the tuna fishery, which may in turn affect reproductive rates (Cramer *et al.,* 2008; Kellar *et al.,* 2013). The northeastern offshore and coastal stocks of pantropical spotted dolphins are likely to be encountered during the proposed surveys.

The spinner dolphin is pantropical in distribution, including oceanic tropical and sub-tropical waters between 40° N and 40° S (Jefferson *et al.,* 2015). It is generally considered a pelagic species, but it can also be found in coastal waters (Perrin 2018b). In the ETP, three types of spinner dolphins have been identified and two of those are recognized as subspecies: The eastern spinner dolphin (*Stenella longirostris orientalis*), considered an offshore species, the Central American spinner (*S.l. centroamericana;* also known as the Costa Rican spinner), considered a coastal species occurring from southern Mexico to Costa Rica (Perrin 1990; Dizon *et al.,* 1991), and the 'whitebelly' spinner which is thought to be a hybrid of the eastern spinner and Gray's spinner (*S.l. longirostris*). Gray's spinner dolphin is not expected to occur within the proposed study area. Although there is a great deal of overlap between the ranges of eastern and whitebelly spinner dolphins, the eastern form generally occurs in the northeastern portion of the ETP, whereas the whitebelly spinner occurs in the southern portion of the ETP, ranging farther offshore (Wade and Gerrodette 1993; Reilly and Fiedler 1994). Reilly and Fiedler (1994) noted that eastern spinners are associated with waters that have high surface temperatures and chlorophyll and shallow thermoclines, whereas whitebelly spinners are associated with cooler surface temperatures, lower chlorophyll levels, and deeper thermoclines. The eastern spinner dolphins are the most likely to occur in the proposed survey area (see Ferguson and Barlow 2001; Heckel *et al.,* 2020), as this subspecies occurs in the ETP, east of 145° W, between 24° N off the Baja California Peninsula and 10° S off Peru (Perrin 1990). Wade and Gerrodette (1993) reported an abundance estimate of 1.7 million, and Gerrodette *et al.* (2005) estimated the abundance at 1.1 million for 2003. Gerrodette and Forcada (2005) noted that the population of eastern spinner dolphins had not yet recovered from the earlier population declines due to the tuna fishery. The population estimate for eastern spinner dolphins in 2003 was 612,662 (Gerrodette *et al.,* 2005). In 2000, the whitebelly dolphin was estimated to number 801,000 in the ETP (Gerrodette *et al.,* 2005). Bayliff (2004) noted a spinner dolphin mortality rate in the tuna fishery of 0.03 percent for 2004. Possible reasons why the population has not recovered include under-reported bycatch, effects of fishing activity on survival and reproduction, and long-term changes in the ecosystem (Gerrodette and Forcada, 2005). The continued chase and encirclement by the tuna fishery may be affecting the reproductive rates of the eastern spinner dolphin (Cramer *et al.,* 2008).

The common dolphin is found in oceanic and nearshore waters of tropical and warm temperate oceans around the world, ranging from ~60° N to ~50° S (Jefferson *et al.,* 2015). There are two subspecies of common dolphins that occur in the eastern Pacific Ocean, the short-beaked form (*Delphinus delphis delphis*) and the long-beaked form (*D. delphis bairdii*). The long-beaked form generally prefers shallower water (Perrin 2018c), typically occurring within 180 km from shore (Jefferson *et al.,* 2015). The short-beaked form occurs along the entire coast of Mexico and has been sighted near the proposed survey area off Nayarit, Michoacán, and Guerrero; the long-beaked form occurs off the Baja California Peninsula and the Gulf of California (Heckel *et al.,* 2020). The southern limit of the long-beaked form appears to be 22° N (Urbán 2008), and no sightings in Mexican waters have been made to the south of that. Thus, only the short-beaked form is expected to occur within the study area.

Unusual Mortality Events (UME)

A UME is defined under the MMPA as ''a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response.'' For more information on UMEs, please visit: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-unusual-mortality-events.*

Increased strandings of Guadalupe fur seals have occurred along the entire coast of California. Guadalupe fur seal strandings began in January 2015 and were eight times higher than the historical average. Strandings have continued since 2015 and have remained well above average through 2019. Strandings are seasonal and generally peak in April through June of each year. Strandings in Oregon and Washington became elevated starting in 2019 and have continued to present. Strandings in these two states in 2019 are five times higher than the historical average. As of December 2021, a total of 724 Guadalupe fur seals have stranded and are considered part of the UME (542 in California and 182 in Oregon and Washington). Stranded Guadalupe fur seals are mostly weaned pups and juveniles (1–2 years old). The majority of stranded animals showed signs of malnutrition with secondary bacterial and parasitic infections. For more information, please visit *https://www.fisheries.noaa.gov/national/marine-life-distress/2015-2021-guadalupe-fur-seal-unusual-mortality-event-california.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. 30 marine mammal species (28 cetacean and two pinniped (both otariid) species) have the reasonable potential to co-occur with the proposed survey activities. Please refer to Table 1. Of the cetacean species that may be present, six are classified as low-frequency cetaceans (*i.e.,* all mysticete species), 20 are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale), and two are classified as high-frequency cetaceans (*i.e.,* harbor porpoise and *Kogia* spp.).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Description of Active Acoustic Sound Sources

This section contains a brief technical background on sound, the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document.

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ''loudness'' of a sound and is typically described using the relative unit of the dB. A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)) and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of 1 m from the source (referenced to 1 μPa) while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 $\mu Pa^2 - s$) represents the total energy contained within a pulse and considers both intensity and duration of exposure. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-p) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source and is represented in the same units as the rms sound pressure. Another common metric is peak-to-peak sound pressure (pk-pk), which is the algebraic difference between the peak positive and peak negative sound pressures. Peak-to-peak pressure is typically approximately 6 dB higher than peak pressure (Southall *et al.,* 2007).

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam or beams or may radiate in all directions (omnidirectional sources), as is the case for pulses produced by the airgun arrays considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound. Ambient sound is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995), and the sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,*

sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including the following (Richardson *et al.,* 1995):

- *Wind and waves:* The complex interactions between wind and water surface, including processes such as breaking waves and wave-induced bubble oscillations and cavitation, are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kHz (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Surf sound becomes important near shore, with measurements collected at a distance of 8.5 km from shore showing an increase of 10 dB in the 100 to 700 Hz band during heavy surf conditions;
- *Precipitation:* Sound from rain and hail impacting the water surface can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times;
- *Biological:* Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz; and
- *Anthropogenic:* Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, seismic surveys, sonar, explosions, and ocean acoustic studies. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly. Sound from identifiable anthropogenic sources other than the activity of interest (*e.g.,* a passing vessel) is sometimes termed background sound, as opposed to ambient sound.

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from a given activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals. Details of source types are described in the following text.

Sounds are often considered to fall into one of two general types: Pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts.

Pulsed sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems (such as those used by the U.S. Navy). The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Airgun arrays produce pulsed signals with energy in a frequency range from about 10–2,000 Hz, with most energy radiated at frequencies below 200 Hz. The amplitude of the acoustic wave emitted from the source is equal in all directions (*i.e.,* omnidirectional), but airgun arrays do possess some directionality due to different phase delays between guns in different directions. Airgun arrays are typically tuned to maximize functionality for data acquisition purposes, meaning that sound transmitted in horizontal directions and at higher frequencies is minimized to the extent possible.

Acoustic Effects

Here, we discuss the effects of active acoustic sources on marine mammals.

Potential Effects of Underwater Sound—Please refer to the information given previously (''*Description of Active Acoustic Sound Sources*'') regarding sound, characteristics of sound types, and metrics used in this document. Note that, in the following discussion, we refer in many cases to a review article concerning studies of noise-induced hearing loss conducted from 1996–2015 (*i.e.,* Finneran, 2015). For study-specific citations, please see that work. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can potentially result in one or more of the following: Temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We first describe specific manifestations of acoustic effects before providing discussion specific to the use of airgun arrays.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the animal, but not strong enough to elicit any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity

to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

We describe the more severe effects of certain non-auditory physical or physiological effects only briefly as we do not expect that use of airgun arrays are reasonably likely to result in such effects (see below for further discussion). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.,* 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Tal *et al.,* 2015). The survey activities considered here do not involve the use of devices such as explosives or mid-frequency tactical sonar that are associated with these types of effects.

Threshold Shift—Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several dBs above (a 40-dB threshold shift approximates PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; *e.g.,* Southall *et al.* 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as airgun pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

For mid-frequency cetaceans in particular, potential protective mechanisms may help limit onset of TTS or prevent onset of PTS. Such mechanisms include dampening of hearing, auditory adaptation, or behavioral amelioration (*e.g.,* Nachtigall and Supin, 2013; Miller *et al.,* 2012; Finneran *et al.,* 2015; Popov *et al.,* 2016).

TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts.

Finneran *et al.* (2015) measured hearing thresholds in three captive bottlenose dolphins before and after exposure to ten pulses produced by a seismic airgun in order to study TTS induced after exposure to multiple pulses. Exposures began at relatively low levels and gradually increased over a period of several months, with the highest exposures at peak SPLs from 196 to 210 dB and cumulative (unweighted) SELs from 193–195 dB. No substantial TTS was observed. In addition, behavioral reactions were observed that indicated that animals can learn behaviors that effectively mitigate noise exposures (although exposure patterns must be learned, which is less likely in wild animals than for the captive animals considered in this study). The authors note that the failure to induce more significant auditory effects likely due to the intermittent nature of exposure, the relatively low peak pressure produced by the acoustic source, and the low-frequency energy in airgun pulses as compared with the frequency range of best sensitivity for dolphins and other mid-frequency cetaceans.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale (*Delphinapterus leucas*), harbor porpoise (*Phocoena phocoena*), and Yangtze finless porpoise (*Neophocaena asiaeorientalis*)) exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). In general, harbor porpoises have a lower TTS onset than other measured cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes.

Critical questions remain regarding the rate of TTS growth and recovery after exposure to intermittent noise and the effects of single and multiple pulses. Data at present are also insufficient to construct generalized models for recovery and determine the time necessary to treat subsequent exposures as independent events. More

information is needed on the relationship between auditory evoked potential and behavioral measures of TTS for various stimuli. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007, 2019), Finneran and Jenkins (2012), Finneran (2015), and NMFS (2018).

Behavioral Effects—Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007, 2019; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). Please see Appendices B–C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC, 2003; Wartzok *et al.,* 2003). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997). Observed responses of wild marine mammals to loud pulsed sound sources (typically seismic airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson *et al.,* 1995; Nowacek *et al.,* 2007). However, many delphinids approach acoustic source vessels with no apparent discomfort or obvious behavioral change (*e.g.,* Barkaszi *et al.,* 2012; Barkaszi and Kelly, 2018).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely, and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Ng and Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013a, b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.;* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Of note for one of the species that occur in the survey area, visual tracking, passive acoustic monitoring, and movement recording tags were used to quantify sperm whale behavior prior to, during, and following exposure to airgun arrays at received levels in the range 140–160 dB at distances of 7–13 km, following a phase-in of sound intensity and full array exposures at 1–13 km (Madsen *et al.,* 2006; Miller *et al.,* 2009). Sperm whales did not exhibit horizontal avoidance behavior at the surface. However, foraging behavior may have been affected. The sperm whales exhibited 19 percent less vocal (buzz) rate during full exposure relative to post exposure, and the whale that was approached most closely had an extended resting period and did not resume foraging until the airguns had ceased firing. The remaining whales continued to execute foraging dives throughout exposure; however, swimming movements during foraging dives were 6 percent lower during exposure than control periods (Miller *et al.,* 2009). These data raise concerns that seismic surveys may impact foraging behavior in sperm whales, although more data are required to understand whether the differences were due to exposure or natural variation in sperm whale behavior (Miller *et al.,* 2009).

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in

understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2001, 2005, 2006; Gailey *et al.,* 2007, 2016).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs or amplitude of calls (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004; Holt *et al.,* 2012), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.,* 1994).

Cerchio *et al.* (2014) used passive acoustic monitoring to document the presence of singing humpback whales off the coast of northern Angola and to opportunistically test for the effect of seismic survey activity on the number of singing whales. Two recording units were deployed between March and December 2008 in the offshore environment; numbers of singers were counted every hour. Generalized Additive Mixed Models were used to assess the effect of survey day (seasonality), hour (diel variation), moon phase, and received levels of noise (measured from a single pulse during each 10 minute sampled period) on singer number. The number of singers significantly decreased with increasing received level of noise, suggesting that humpback whale breeding activity was disrupted to some extent by the survey activity.

Castellote *et al.* (2012) reported acoustic and behavioral changes by fin whales in response to shipping and airgun noise. Acoustic features of fin whale song notes recorded in the Mediterranean Sea and northeast Atlantic Ocean were compared for areas with different shipping noise levels and traffic intensities and during a seismic airgun survey. During the first 72 hours of the survey, a steady decrease in song received levels and bearings to singers indicated that whales moved away from the acoustic source and out of the study area. This displacement persisted for a time period well beyond the 10-day duration of seismic airgun activity, providing evidence that fin whales may avoid an area for an extended period in the presence of increased noise. The authors hypothesize that fin whale acoustic communication is modified to compensate for increased background noise and that a sensitization process may play a role in the observed temporary displacement.

Seismic pulses at average received levels of 131 dB re 1 μPa^2-s caused blue whales to increase call production (Di Iorio and Clark, 2010). In contrast, McDonald *et al.* (1995) tracked a blue whale with seafloor seismometers and reported that it stopped vocalizing and changed its travel direction at a range of 10 km from the acoustic source vessel (estimated received level 143 dB pk-pk). Blackwell *et al.* (2013) found that bowhead whale call rates dropped significantly at onset of airgun use at sites with a median distance of 41–45 km from the survey. Blackwell *et al.* (2015) expanded this analysis to show that whales actually increased calling rates as soon as airgun signals were detectable before ultimately decreasing calling rates at higher received levels (*i.e.,* 10-minute SELcum of ~127 dB). Overall, these results suggest that bowhead whales may adjust their vocal output in an effort to compensate for noise before ceasing vocalization effort and ultimately deflecting from the acoustic source (Blackwell *et al.,* 2013, 2015). These studies demonstrate that even low levels of noise received far from the source can induce changes in vocalization and/or behavior for mysticetes.

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.,* 1984). Humpback whales showed avoidance behavior in the presence of an active seismic array during observational studies and controlled exposure experiments in western Australia (McCauley *et al.,* 2000). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

Forney *et al.* (2017) detail the potential effects of noise on marine mammal populations with high site fidelity, including displacement and auditory masking, noting that a lack of observed response does not imply absence of fitness costs and that apparent tolerance of disturbance may have population-level impacts that are less obvious and difficult to document. Forney *et al.* (2017) state that, for these animals, remaining in a disturbed area may reflect a lack of alternatives rather than a lack of effects. The authors discuss several case studies, including western Pacific gray whales, which are a small population of mysticetes believed to be adversely affected by oil and gas development off Sakhalin Island, Russia (Weller *et al.,* 2002; Reeves *et al.,* 2005). Western gray whales display a high degree of interannual site fidelity to the area for foraging purposes, and observations in the area during airgun surveys has shown the potential for harm caused by displacement from such an important area (Weller *et al.,* 2006; Johnson *et al.,* 2007). Forney *et al.* (2017) also discuss beaked whales, noting that anthropogenic effects in areas where they are resident could cause severe biological consequences, in part because displacement may adversely affect foraging rates, reproduction, or health, while an overriding instinct to remain could lead to more severe acute effects.

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans and England, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in

costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Stone (2015) reported data from at-sea observations during 1,196 seismic surveys from 1994 to 2010. When large arrays of airguns (considered to be 500 in^3 or more) were firing, lateral displacement, more localized avoidance, or other changes in behavior were evident for most odontocetes. However, significant responses to large arrays were found only for the minke whale and fin whale. Behavioral responses observed included changes in swimming or surfacing behavior, with indications that cetaceans remained near the water surface at these times. Cetaceans were recorded as feeding less often when large arrays were active. Behavioral observations of gray whales during a seismic survey monitored whale movements and respirations pre-, during, and post-seismic survey (Gailey *et al.,* 2016). Behavioral state and water depth were the best 'natural' predictors of whale movements and respiration and, after considering natural variation, none of the response variables were significantly associated with seismic survey or vessel sounds.

Stress Responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficiently to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

Auditory Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995; Erbe *et al.,* 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with

abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

Masking effects of pulsed sounds (even from large arrays of airguns) on marine mammal calls and other natural sounds are expected to be limited, although there are few specific data on this. Because of the intermittent nature and low duty cycle of seismic pulses, animals can emit and receive sounds in the relatively quiet intervals between pulses. However, in exceptional situations, reverberation occurs for much or all of the interval between pulses (*e.g.,* Simard *et al.* 2005; Clark and Gagnon 2006), which could mask calls. Situations with prolonged strong reverberation are infrequent. However, it is common for reverberation to cause some lesser degree of elevation of the background level between airgun pulses (*e.g.,* Gedamke 2011; Guerra *et al.* 2011, 2016; Klinck *et al.* 2012; Guan *et al.* 2015), and this weaker reverberation presumably reduces the detection range of calls and other natural sounds to some degree. Guerra *et al.* (2016) reported that ambient noise levels between seismic pulses were elevated as a result of reverberation at ranges of 50 km from the seismic source. Based on measurements in deep water of the Southern Ocean, Gedamke (2011) estimated that the slight elevation of background levels during intervals between pulses reduced blue and fin whale communication space by as much as 36–51 percent when a seismic survey was operating 450–2,800 km away. Based on preliminary modeling, Wittekind *et al.* (2016) reported that airgun sounds could reduce the communication range of blue and fin whales 2000 km from the seismic source. Nieukirk *et al.* (2012) and Blackwell *et al.* (2013) noted the potential for masking effects from seismic surveys on large whales.

Some baleen and toothed whales are known to continue calling in the presence of seismic pulses, and their calls usually can be heard between the pulses (*e.g.,* Nieukirk *et al.* 2012; Thode *et al.* 2012; Bröker *et al.* 2013; Sciacca *et al.* 2016). As noted above, Cerchio *et al.* (2014) suggested that the breeding display of humpback whales off Angola could be disrupted by seismic sounds, as singing activity declined with increasing received levels. In addition, some cetaceans are known to change their calling rates, shift their peak frequencies, or otherwise modify their vocal behavior in response to airgun sounds (*e.g.,* Di Iorio and Clark 2010; Castellote *et al.* 2012; Blackwell *et al.* 2013, 2015). The hearing systems of baleen whales are undoubtedly more sensitive to low-frequency sounds than are the ears of the small odontocetes that have been studied directly (*e.g.,* MacGillivray *et al.* 2014). The sounds important to small odontocetes are predominantly at much higher frequencies than are the dominant components of airgun sounds, thus limiting the potential for masking. In general, masking effects of seismic pulses are expected to be minor, given the normally intermittent nature of seismic pulses.

Vessel Noise

Vessel noise from the *Langseth* could affect marine animals in the proposed survey areas. Houghton *et al.* (2015) proposed that vessel speed is the most important predictor of received noise levels, and Putland *et al.* (2017) also reported reduced sound levels with decreased vessel speed. Sounds produced by large vessels generally dominate ambient noise at frequencies from 20 to 300 Hz (Richardson *et al.* 1995). However, some energy is also produced at higher frequencies (Hermannsen *et al.* 2014); low levels of high-frequency sound from vessels has been shown to elicit responses in harbor porpoise (Dyndo *et al.* 2015). Increased levels of ship noise have been shown to affect foraging by porpoise (Teilmann *et al.* 2015; Wisniewska *et al.* 2018); Wisniewska *et al.* (2018) suggest that a decrease in foraging success could have long-term fitness consequences.

Ship noise, through masking, can reduce the effective communication distance of a marine mammal if the frequency of the sound source is close to that used by the animal, and if the sound is present for a significant fraction of time (*e.g.,* Richardson *et al.* 1995; Clark *et al.* 2009; Jensen *et al.* 2009; Gervaise *et al.* 2012; Hatch *et al.* 2012; Rice *et al.* 2014; Dunlop 2015; Erbe *et al.* 2015; Jones *et al.* 2017; Putland *et al.* 2017). In addition to the frequency and duration of the masking sound, the strength, temporal pattern, and location of the introduced sound also play a role in the extent of the masking (Branstetter *et al.* 2013, 2016; Finneran and Branstetter 2013; Sills *et al.* 2017). Branstetter *et al.* (2013) reported that time-domain metrics are also important in describing and predicting masking. In order to compensate for increased ambient noise, some cetaceans are known to increase the source levels of their calls in the presence of elevated noise levels from shipping, shift their peak frequencies, or otherwise change their vocal behavior (*e.g.,* Parks *et al.* 2016a,b; Bittencourt *et al.* 2016; Dahlheim and Castellote 2016; Gospić and Picciulin 2016; Gridley *et al.* 2016; Heiler *et al.* 2016; Martins *et al.* 2016; O'Brien *et al.* 2016; Tenessen and Parks 2016). Holt *et al.* (2015) reported that changes in vocal modifications can have increased energetic costs for individual marine mammals. A negative correlation between the presence of some cetacean species and the number of vessels in an area has been demonstrated by several studies (*e.g.,* Campana *et al.* 2015; Culloch *et al.* 2016).

Baleen whales are thought to be more sensitive to sound at these low frequencies than are toothed whales (*e.g.,* MacGillivray *et al.* 2014), possibly causing localized avoidance of the proposed survey area during seismic operations. Reactions of gray and humpback whales to vessels have been studied, and there is limited information available about the reactions of right whales and rorquals (*e.g.,* fin, blue, minke, humpback, sei, and Bryde's whales). Reactions of humpback whales to boats are variable, ranging from approach to avoidance (Payne 1978; Salden 1993). Baker *et al.* (1982, 1983) and Baker and Herman (1989) found humpbacks often move away when vessels are within several kilometers. Humpbacks seem less likely to react overtly when actively feeding than when resting or engaged in other activities (Krieger and Wing 1984, 1986). Increased levels of ship noise have been shown to affect foraging by humpback whales (Blair *et al.* 2016). Fin whale sightings in the western Mediterranean were negatively correlated with the number of vessels in the area (Campana *et al.* 2015). Minke whales have shown slight displacement in response to construction-related vessel traffic (Anderwald *et al.* 2013).

Many odontocetes show considerable tolerance of vessel traffic, although they sometimes react at long distances if confined by ice or shallow water, if previously harassed by vessels, or have had little or no recent exposure to ships (Richardson *et al.* 1995). Dolphins of many species tolerate and sometimes approach vessels (*e.g.,* Anderwald *et al.* 2013). Some dolphin species approach moving vessels to ride the bow or stern waves (Williams *et al.* 1992). Pirotta *et al.* (2015) noted that the physical presence of vessels, not just ship noise, disturbed the foraging activity of bottlenose dolphins. Sightings of striped dolphin, Risso's dolphin, sperm whale, and Cuvier's beaked whale in the western Mediterranean were negatively correlated with the number of vessels in the area (Campana *et al.* 2015).

There are few data on the behavioral reactions of beaked whales to vessel noise, though they seem to avoid approaching vessels (*e.g.,* Würsig *et al.* 1998) or dive for an extended period when approached by a vessel (*e.g.,* Kasuya 1986). Based on a single observation, Aguilar Soto *et al.* (2006) suggest foraging efficiency of Cuvier's beaked whales may be reduced by close approach of vessels.

Sounds emitted by the *Langseth* are low frequency and continuous, but would be widely dispersed in both space and time. Vessel traffic associated with the proposed survey is of low density compared to traffic associated with commercial shipping, industry support vessels, or commercial fishing vessels, and would therefore be expected to represent an insignificant incremental increase in the total amount of anthropogenic sound input to the marine environment, and the effects of vessel noise described above are not expected to occur as a result of this survey. In summary, project vessel sounds would not be at levels expected to cause anything more than possible localized and temporary behavioral changes in marine mammals, and would not be expected to result in significant negative effects on individuals or at the population level. In addition, in all oceans of the world, large vessel traffic is currently so prevalent that it is commonly considered a usual source of ambient sound (NSF–USGS 2011).

Ship Strike

Vessel collisions with marine mammals, or ship strikes, can result in death or serious injury of the animal. Wounds resulting from ship strike may include massive trauma, hemorrhaging, broken bones, or propeller lacerations (Knowlton and Kraus, 2001). An animal at the surface may be struck directly by a vessel, a surfacing animal may hit the bottom of a vessel, or an animal just below the surface may be cut by a vessel's propeller. Superficial strikes may not kill or result in the death of the animal. These interactions are typically associated with large whales (*e.g.,* fin whales), which are occasionally found draped across the bulbous bow of large commercial ships upon arrival in port. Although smaller cetaceans are more maneuverable in relation to large vessels than are large whales, they may also be susceptible to strike. The severity of injuries typically depends on the size and speed of the vessel, with the probability of death or serious injury increasing as vessel speed increases (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Vanderlaan and Taggart, 2007; Conn and Silber, 2013). Impact forces increase with speed, as does the probability of a strike at a given distance (Silber *et al.,* 2010; Gende *et al.,* 2011).

Pace and Silber (2005) also found that the probability of death or serious injury increased rapidly with increasing vessel speed. Specifically, the predicted probability of serious injury or death resulting from a strike increased from 45 to 75 percent as vessel speed increased from 10 to 14 knots, and exceeded 90 percent at 17 knots. Higher speeds during collisions result in greater force of impact, but higher speeds also appear to increase the chance of severe injuries or death through increased likelihood of collision by pulling whales toward the vessel (Clyne, 1999; Knowlton *et al.,* 1995). In a separate study, Vanderlaan and Taggart (2007) analyzed the probability of lethal mortality of large whales at a given speed, showing that the greatest rate of change in the probability of a lethal injury to a large whale as a function of vessel speed occurs between 8.6 and 15 knots. The chances of a lethal injury decline from approximately 80 percent at 15 knots to approximately 20 percent at 8.6 knots. At speeds below 11.8 knots, the chances of lethal injury drop below 50 percent, while the probability asymptotically increases toward 100 percent above 15 knots.

The vessel speed during seismic survey operations would be approximately 4.1 knots (7.6 km/h) during MCS reflection surveys and 5 knots (9.3 km/h) during OBS refraction surveys. At this speed, both the possibility of striking a marine mammal and the possibility of a strike resulting in serious injury or mortality are so low as to be discountable. At average transit speed, the probability of serious injury or mortality resulting from a strike is less than 50 percent. However, the likelihood of a strike actually happening is again low. Ship strikes, as analyzed in the studies cited above, generally involve commercial shipping, which is much more common in both space and time than is geophysical survey activity. Commercial shipping vessels are also generally much larger than typical geophysical survey vessels (*e.g.,* up to 360 m long cargo vessels compared to the 71-m R/V *Langseth*). Jensen and Silber (2004) summarized ship strikes of large whales worldwide from 1975–2003 and found that most collisions occurred in the open ocean and involved large vessels (*e.g.,* commercial shipping vessels). No such incidents were reported for geophysical survey vessels during that time period.

It is possible for ship strikes to occur while traveling at slow speeds. For example, a hydrographic survey vessel traveling at low speed (5.5 knots) while conducting mapping surveys off the central California coast struck and killed a blue whale in 2009. The State of California determined that the whale had suddenly and unexpectedly surfaced beneath the hull, with the result that the propeller severed the whale's vertebrae, and that this was an unavoidable event. This strike represents the only such incident in approximately 540,000 hours of similar coastal mapping activity ($p = 1.9 \times 10^{-6}$; 95 percent CI = $0–5.5 \times 10^{-6}$; NMFS, 2013b). In addition, a research vessel

reported a fatal strike in 2011 of a dolphin in the Atlantic, demonstrating that it is possible for strikes involving smaller cetaceans to occur. In that case, the incident report indicated that an animal apparently was struck by the vessel's propeller as it was intentionally swimming near the vessel. While indicative of the type of unusual events that cannot be ruled out, neither of these instances represents a circumstance that would be considered reasonably foreseeable or that would be considered preventable.

Although the likelihood of the vessel striking a marine mammal is low, we require a robust ship strike avoidance protocol (see Proposed Mitigation), which we believe eliminates any foreseeable risk of ship strike during transit. We anticipate that vessel collisions involving a seismic data acquisition vessel towing gear, while not impossible, represent unlikely, unpredictable events for which there are no preventive measures. Given the required mitigation measures, the relatively slow speed of the vessel towing gear, the presence of bridge crew watching for obstacles at all times (including marine mammals), and the presence of marine mammal observers, we believe that the possibility of ship strike is discountable and, further, that were a strike of a large whale to occur, it would be unlikely to result in serious injury or mortality. No incidental take resulting from ship strike is anticipated, and this potential effect of the specified activity will not be discussed further in the following analysis.

Stranding—When a living or dead marine mammal swims or floats onto shore and becomes ''beached'' or incapable of returning to sea, the event is a ''stranding'' (Geraci *et al.,* 1999; Perrin and Geraci, 2002; Geraci and Lounsbury, 2005; NMFS, 2007). The legal definition for a stranding under the MMPA is that ''(A) a marine mammal is dead and is (i) on a beach or shore of the United States; or (ii) in waters under the jurisdiction of the United States (including any navigable waters); or (B) a marine mammal is alive and is (i) on a beach or shore of the United States and is unable to return to the water; (ii) on a beach or shore of the United States and, although able to return to the water, is in need of apparent medical attention; or (iii) in the waters under the jurisdiction of the United States (including any navigable waters), but is unable to return to its natural habitat under its own power or without assistance.''

Marine mammals strand for a variety of reasons, such as infectious agents, biotoxicosis, starvation, fishery interaction, ship strike, unusual oceanographic or weather events, sound exposure, or combinations of these stressors sustained concurrently or in series. However, the cause or causes of most strandings are unknown (Geraci *et al.,* 1976; Eaton, 1979; Odell *et al.,* 1980; Best, 1982). Numerous studies suggest that the physiology, behavior, habitat relationships, age, or condition of cetaceans may cause them to strand or might pre-dispose them to strand when exposed to another phenomenon. These suggestions are consistent with the conclusions of numerous other studies that have demonstrated that combinations of dissimilar stressors commonly combine to kill an animal or dramatically reduce its fitness, even though one exposure without the other does not produce the same result (Chroussos, 2000; Creel, 2005; DeVries *et al.,* 2003; Fair and Becker, 2000; Foley *et al.,* 2001; Moberg, 2000; Relyea, 2005a; 2005b, Romero, 2004; Sih *et al.,* 2004).

There is no conclusive evidence that exposure to airgun noise results in behaviorally-mediated forms of injury. Behaviorally-mediated injury (*i.e.,* mass stranding events) has been primarily associated with beaked whales exposed to mid-frequency active (MFA) naval sonar. Tactical sonar and the alerting stimulus used in Nowacek *et al.* (2004) are very different from the noise produced by airguns. One should therefore not expect the same reaction to airgun noise as to these other sources. As explained below, military MFA sonar is very different from airguns, and one should not assume that airguns will cause the same effects as MFA sonar (including strandings).

To understand why Navy MFA sonar affects beaked whales differently than airguns do, it is important to note the distinction between behavioral sensitivity and susceptibility to auditory injury. To understand the potential for auditory injury in a particular marine mammal species in relation to a given acoustic signal, the frequency range the species is able to hear is critical, as well as the species' auditory sensitivity to frequencies within that range. Current data indicate that not all marine mammal species have equal hearing capabilities across all frequencies and, therefore, species are grouped into hearing groups with generalized hearing ranges assigned on the basis of available data (Southall *et al.,* 2007, 2019). Hearing ranges as well as auditory sensitivity/susceptibility to frequencies within those ranges vary across the different groups. For example, in terms of hearing range, the high-frequency cetaceans (*e.g., Kogia* spp.) have a generalized hearing range of frequencies between 275 Hz and 160 kHz, while mid-frequency cetaceans—such as dolphins and beaked whales—have a generalized hearing range between 150 Hz to 160 kHz. Regarding auditory susceptibility within the hearing range, while mid-frequency cetaceans and high-frequency cetaceans have roughly similar hearing ranges, the high-frequency group is much more susceptible to noise-induced hearing loss during sound exposure, *i.e.,* these species have lower thresholds for these effects than other hearing groups (NMFS, 2018). Referring to a species as behaviorally sensitive to noise simply means that an animal of that species is more likely to respond to lower received levels of sound than an animal of another species that is considered less behaviorally sensitive. So, while dolphin species and beaked whale species—both in the mid-frequency cetacean hearing group—are assumed to (generally) hear the same sounds equally well and be equally susceptible to noise-induced hearing loss (auditory injury), the best available information indicates that a beaked whale is more likely to behaviorally respond to that sound at a lower received level compared to an animal from other mid-frequency cetacean species that are less behaviorally sensitive. This distinction is important because, while beaked whales are more likely to respond behaviorally to sounds than are many other species (even at lower levels), they cannot hear the predominant, lower frequency sounds from seismic airguns as well as sounds that have more energy at frequencies that beaked whales can hear better (such as military MFA sonar).

Navy MFA sonar affects beaked whales differently than airguns do because it produces energy at different frequencies than airguns. Mid-frequency cetacean hearing is generically thought to be best between 8.8 to 110 kHz, *i.e.,* these cutoff values define the range above and below which a species in the group is assumed to have declining auditory sensitivity, until reaching frequencies that cannot be heard (NMFS, 2018). However, beaked whale hearing is likely best within a higher, narrower range (20–80 kHz, with best sensitivity around 40 kHz), based on a few measurements of hearing in stranded beaked whales (Cook *et al.,* 2006; Finneran *et al.,* 2009; Pacini *et al.,* 2011) and several studies of acoustic signals produced by beaked whales (*e.g.,* Frantzis *et al.,* 2002; Johnson *et al.,* 2004, 2006; Zimmer *et al.,* 2005). While precaution requires that the full range of

audibility be considered when assessing risks associated with noise exposure (Southall *et al.,* 2007, 2019), animals typically produce sound at frequencies where they hear best. More recently, Southall *et al.* (2019) suggested that certain species amongst the historical mid-frequency hearing group (beaked whales, sperm whales, and killer whales) are likely more sensitive to lower frequencies within the group's generalized hearing range than are other species within the group and state that the data for beaked whales suggest sensitivity to approximately 5 kHz. However, this information is consistent with the general conclusion that beaked whales (and other mid-frequency cetaceans) are relatively insensitive to the frequencies where most energy of an airgun signal is found. Military MFA sonar is typically considered to operate in the frequency range of approximately 3–14 kHz (D'Amico *et al.,* 2009), *i.e.,* outside the range of likely best hearing for beaked whales but within or close to the lower bounds, whereas most energy in an airgun signal is radiated at much lower frequencies, below 500 Hz (Dragoset, 1990).

It is important to distinguish between energy (loudness, measured in dB) and frequency (pitch, measured in Hz). In considering the potential impacts of mid-frequency components of airgun noise (1–10 kHz, where beaked whales can be expected to hear) on marine mammal hearing, one needs to account for the energy associated with these higher frequencies and determine what energy is truly ''significant.'' Although there is mid-frequency energy associated with airgun noise (as expected from a broadband source), airgun sound is predominantly below 1 kHz (Breitzke *et al.,* 2008; Tashmukhambetov *et al.,* 2008; Tolstoy *et al.,* 2009). As stated by Richardson *et al.* (1995), ''[. . .] most emitted [seismic airgun] energy is at 10–120 Hz, but the pulses contain some energy up to 500–1,000 Hz.'' Tolstoy *et al.* (2009) conducted empirical measurements, demonstrating that sound energy levels associated with airguns were at least 20 dB lower at 1 kHz (considered ''mid-frequency'') compared to higher energy levels associated with lower frequencies (below 300 Hz) (''all but a small fraction of the total energy being concentrated in the 10–300 Hz range'' [Tolstoy *et al.,* 2009]), and at higher frequencies (*e.g.,* 2.6–4 kHz), power might be less than 10 percent of the peak power at 10 Hz (Yoder, 2002). Energy levels measured by Tolstoy *et al.* (2009) were even lower at frequencies above 1 kHz. In addition, as sound propagates away from the source, it tends to lose higher-frequency components faster than low-frequency components (*i.e.,* low-frequency sounds typically propagate longer distances than high-frequency sounds) (Diebold *et al.,* 2010). Although higher-frequency components of airgun signals have been recorded, it is typically in surface-ducting conditions (*e.g.,* DeRuiter *et al.,* 2006; Madsen *et al.,* 2006) or in shallow water, where there are advantageous propagation conditions for the higher frequency (but low-energy) components of the airgun signal (Hermannsen *et al.,* 2015). This should not be of concern because the likely behavioral reactions of beaked whales that can result in acute physical injury would result from noise exposure at depth (because of the potentially greater consequences of severe behavioral reactions). In summary, the frequency content of airgun signals is such that beaked whales will not be able to hear the signals well (compared to MFA sonar), especially at depth where we expect the consequences of noise exposure could be more severe.

Aside from frequency content, there are other significant differences between MFA sonar signals and the sounds produced by airguns that minimize the risk of severe behavioral reactions that could lead to strandings or deaths at sea, *e.g.,* significantly longer signal duration, horizontal sound direction, typical fast and unpredictable source movement. All of these characteristics of MFA sonar tend towards greater potential to cause severe behavioral or physiological reactions in exposed beaked whales that may contribute to stranding. Although both sources are powerful, MFA sonar contains significantly greater energy in the mid-frequency range, where beaked whales hear better. Short-duration, high energy pulses—such as those produced by airguns—have greater potential to cause damage to auditory structures (though this is unlikely for mid-frequency cetaceans, as explained later in this document), but it is longer duration signals that have been implicated in the vast majority of beaked whale strandings. Faster, less predictable movements in combination with multiple source vessels are more likely to elicit a severe, potentially anti-predator response. Of additional interest in assessing the divergent characteristics of MFA sonar and airgun signals and their relative potential to cause stranding events or deaths at sea is the similarity between the MFA sonar signals and stereotyped calls of beaked whales' primary predator: The killer whale (Zimmer and Tyack, 2007). Although generic disturbance stimuli—as airgun noise may be considered in this case for beaked whales—may also trigger antipredator responses, stronger responses should generally be expected when perceived risk is greater, as when the stimulus is confused for a known predator (Frid and Dill, 2002). In addition, because the source of the perceived predator (*i.e.,* what is actually a MFA sonar signal) will likely be closer to the whales (because attenuation limits the range of detection of mid-frequencies) and moving faster (because it will be on faster-moving vessels), any antipredator response would be more likely to be severe (with greater perceived predation risk, an animal is more likely to disregard the cost of the response; Frid and Dill, 2002). Indeed, when analyzing movements of a beaked whale exposed to playback of killer whale predation calls, Allen *et al.* (2014) found that the whale engaged in a prolonged, directed avoidance response, suggesting a behavioral reaction that could pose a risk factor for stranding. Overall, these significant differences between sound from MFA sonar and the mid-frequency sound component from airguns and the likelihood that MFA sonar signals will be interpreted in error as a predator are critical to understanding the likely risk of behaviorally-mediated injury due to seismic surveys.

The available scientific literature also provides a useful contrast between airgun noise and MFA sonar regarding the likely risk of behaviorally-mediated injury. There is strong evidence for the association of beaked whale stranding events with MFA sonar use, and particularly detailed accounting of several events is available (*e.g.,* a 2000 Bahamas stranding event for which investigators concluded that MFA sonar use was responsible; Evans and England, 2001). D'Amico *et al.* (2009) reviewed 126 beaked whale mass stranding events over the period from 1950 (*i.e.,* from the development of modern MFA sonar systems) through 2004. Of these, there were two events where detailed information was available on both the timing and location of the stranding and the concurrent nearby naval activity, including verification of active MFA sonar usage, with no evidence for an alternative cause of stranding. An additional ten events were at minimum spatially and temporally coincident with naval activity likely to have included MFA sonar use and, despite incomplete knowledge of timing and location of the stranding or the naval activity in some cases, there was no evidence for an alternative cause of

stranding. The U.S. Navy has publicly stated agreement that five such events since 1996 were associated in time and space with MFA sonar use, either by the U.S. Navy alone or in joint training exercises with the North Atlantic Treaty Organization. The U.S. Navy additionally noted that, as of 2017, a 2014 beaked whale stranding event in Crete coincident with naval exercises was under review and had not yet been determined to be linked to sonar activities (U.S. Navy, 2017). Separately, the International Council for the Exploration of the Sea reported in 2005 that, worldwide, there have been about 50 known strandings, consisting mostly of beaked whales, with a potential causal link to MFA sonar (ICES, 2005). In contrast, very few such associations have been made to seismic surveys, despite widespread use of airguns as a geophysical sound source in numerous locations around the world.

A more recent review of possible stranding associations with seismic surveys (Castellote and Llorens, 2016) states plainly that, ''[s]peculation concerning possible links between seismic survey noise and cetacean strandings is available for a dozen events but without convincing causal evidence.'' The authors' ''exhaustive'' search of available information found 10 events worth further investigation via a ranking system representing a rough metric of the relative level of confidence offered by the data for inferences about the possible role of the seismic survey in a given stranding event. Only three of these events involved beaked whales. Whereas D'Amico *et al.* (2009) used a 1–5 ranking system, in which ''1'' represented the most robust evidence connecting the event to MFA sonar use, Castellote and Llorens (2016) used a 1–6 ranking system, in which ''6'' represented the most robust evidence connecting the event to the seismic survey. As described above, D'Amico *et al.* (2009) found that two events were ranked ''1'' and ten events were ranked ''2'' (*i.e.,* 12 beaked whale stranding events were found to be associated with MFA sonar use). In contrast, Castellote and Llorens (2016) found that none of the three beaked whale stranding events achieved their highest ranks of 5 or 6. Of the 10 total events, none achieved the highest rank of 6. Two events were ranked as 5: One stranding in Peru involving dolphins and porpoises and a 2008 stranding in Madagascar. This latter ranking can only broadly be associated with the survey itself, as opposed to use of seismic airguns. An exhaustive investigation of this stranding event, which did not involve beaked whales, concluded that use of a high-frequency mapping system (12-kHz multibeam echosounder) was the most plausible and likely initial behavioral trigger of the event, which was likely exacerbated by several site- and situation-specific secondary factors. The review panel found that seismic airguns were used after the initial strandings and animals entering a lagoon system, that airgun use clearly had no role as an initial trigger, and that there was no evidence that airgun use dissuaded animals from leaving (Southall et al., 2013).

However, one of these stranding events, involving two Cuvier's beaked whales, was contemporaneous with and reasonably associated spatially with a 2002 seismic survey in the Gulf of California conducted by L–DEO, as was the case for the 2007 Gulf of Cadiz seismic survey discussed by Castellote and Llorens (also involving two Cuvier's beaked whales). However, neither event was considered a ''true atypical mass stranding'' (according to Frantzis [1998]) as used in the analysis of Castellote and Llorens (2016). While we agree with the authors that this lack of evidence should not be considered conclusive, it is clear that there is very little evidence that seismic surveys should be considered as posing a significant risk of acute harm to beaked whales or other mid-frequency cetaceans. We have considered the potential for the proposed surveys to result in marine mammal stranding and have concluded that, based on the best available information, stranding is not expected to occur.

Entanglement—Entanglements occur when marine mammals become wrapped around cables, lines, nets, or other objects suspended in the water column. During seismic survey operations, numerous cables, lines, and other objects primarily associated with the airgun array and hydrophone streamers will be towed behind the *Langseth* near the water's surface. However, we are not aware of any cases of entanglement of mysticetes in seismic survey equipment. No incidents of entanglement of marine mammals with seismic survey gear have been documented in over 54,000 nmi (100,000 km) of previous NSF-funded seismic surveys when observers were aboard (*e.g.,* Smultea and Holst 2003; Haley and Koski 2004; Holst 2004; Smultea *et al.,* 2004; Holst *et al.,* 2005; Haley and Ireland 2006; SIO and NSF 2006; Hauser *et al.,* 2008; Holst and Smultea 2008). Although entanglement with the streamer is theoretically possible, it has not been documented during tens of thousands of miles of NSF-sponsored seismic cruises or, to our knowledge, during hundreds of thousands of miles of industrial seismic cruises. Entanglement in OBSs and ocean bottom nodes (OBNs) is also not expected to occur. There are a relative few deployed devices, and no interaction between marine mammals and any such device has been recorded during prior NSF surveys using the devices. There are no meaningful entanglement risks posed by the proposed survey, and entanglement risks are not discussed further in this document.

Anticipated Effects on Marine Mammal Habitat

Physical Disturbance—Sources of seafloor disturbance related to geophysical surveys that may impact marine mammal habitat include placement of anchors, nodes, cables, sensors, or other equipment on or in the seafloor for various activities. Equipment deployed on the seafloor has the potential to cause direct physical damage and could affect bottom-associated fish resources.

Placement of OBSs on the seafloor could damage areas of hard bottom where direct contact with the seafloor occurs and could crush epifauna (organisms that live on the seafloor or surface of other organisms). Damage to unknown or unseen hard bottom could occur, but because of the small area covered by most bottom-founded equipment and the patchy distribution of hard bottom habitat, contact with unknown hard bottom is expected to be rare and impacts minor. Seafloor disturbance in areas of soft bottom can cause loss of small patches of epifauna and infauna due to burial or crushing, and bottom-feeding fishes could be temporarily displaced from feeding areas. Overall, any effects of physical damage to habitat are expected to be minor and temporary.

Effects to Prey—Marine mammal prey varies by species, season, and location and, for some, is not well documented. Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. However, the reaction of fish to airguns depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Several studies have demonstrated that airgun sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,*

1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017), though the bulk of studies indicate no or slight reaction to noise (*e.g.,* Miller and Cripps, 2013; Dalen and Knutsen, 1987; Pena *et al.,* 2013; Chapman and Hawkins, 1969; Wardle *et al.,* 2001; Sara *et al.,* 2007; Jorgenson and Gyselman, 2009; Blaxter *et al.,* 1981; Cott *et al.,* 2012; Boeger *et al.,* 2006), and that, most commonly, while there are likely to be impacts to fish as a result of noise from nearby airguns, such effects will be temporary. For example, investigators reported significant, short-term declines in commercial fishing catch rate of gadid fishes during and for up to 5 days after seismic survey operations, but the catch rate subsequently returned to normal (Engas *et al.,* 1996; Engas and Lokkeborg, 2002). Other studies have reported similar findings (Hassel *et al.,* 2004). Skalski *et al.* (1992) also found a reduction in catch rates—for rockfish (*Sebastes* spp.) in response to controlled airgun exposure—but suggested that the mechanism underlying the decline was not dispersal but rather decreased responsiveness to baited hooks associated with an alarm behavioral response. A companion study showed that alarm and startle responses were not sustained following the removal of the sound source (Pearson *et al.,* 1992). Therefore, Skalski *et al.* (1992) suggested that the effects on fish abundance may be transitory, primarily occurring during the sound exposure itself. In some cases, effects on catch rates are variable within a study, which may be more broadly representative of temporary displacement of fish in response to airgun noise (*i.e.,* catch rates may increase in some locations and decrease in others) than any long-term damage to the fish themselves (Streever *et al.,* 2016).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality and, in some studies, fish auditory systems have been damaged by airgun noise (McCauley *et al.,* 2003; Popper *et al.,* 2005; Song *et al.,* 2008). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b. (2012) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long—both of which are conditions unlikely to occur for this survey that is necessarily transient in any given location and likely result in brief, infrequent noise exposure to prey species in any given area. For this survey, the sound source is constantly moving, and most fish would likely avoid the sound source prior to receiving sound of sufficient intensity to cause physiological or anatomical damage. In addition, ramp-up may allow certain fish species the opportunity to move further away from the sound source.

A recent comprehensive review (Carroll *et al.,* 2017) found that results are mixed as to the effects of airgun noise on the prey of marine mammals. While some studies suggest a change in prey distribution and/or a reduction in prey abundance following the use of seismic airguns, others suggest no effects or even positive effects in prey abundance. As one specific example, Paxton *et al.* (2017), which describes findings related to the effects of a 2014 seismic survey on a reef off of North Carolina, showed a 78 percent decrease in observed nighttime abundance for certain species. It is important to note that the evening hours during which the decline in fish habitat use was recorded (via video recording) occurred on the same day that the seismic survey passed, and no subsequent data is presented to support an inference that the response was long-lasting. Additionally, given that the finding is based on video images, the lack of recorded fish presence does not support a conclusion that the fish actually moved away from the site or suffered any serious impairment. In summary, this particular study corroborates prior studies indicating that a startle response or short-term displacement should be expected.

Available data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect airgun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Similar to fish, however, the transient nature of the survey leads to an expectation that effects will be largely limited to behavioral reactions and would occur as a result of brief, infrequent exposures.

With regard to potential impacts on zooplankton, McCauley *et al.* (2017) found that exposure to airgun noise resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa, within 1 km of the airguns. However, the authors also stated that in order to have significant impacts on r-selected species (*i.e.,* those with high growth rates and that produce many offspring) such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned, and it is possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). In addition, the results of this study are inconsistent with a large body of research that generally finds limited spatial and temporal impacts to zooplankton as a result of exposure to airgun noise (*e.g.,* Dalen and Knutsen, 1987; Payne, 2004; Stanley *et al.,* 2011). Most prior research on this topic, which has focused on relatively small spatial scales, has showed minimal effects (*e.g.,* Kostyuchenko, 1973; Booman *et al.,* 1996; Sætre and Ona, 1996; Pearson *et al.,* 1994; Bolle *et al.,* 2012).

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study (as recommended by McCauley *et al.*), in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that for copepods with a short life cycle in a high-energy environment, a full-scale airgun survey would impact copepod abundance up to three days following the end of the survey, suggesting that effects such as those found by McCauley *et al.* (2017) would not be expected to be detectable downstream of the survey areas, either spatially or temporally.

Notably, a more recent study produced results inconsistent with those of McCauley *et al.* (2017). Researchers conducted a field and laboratory study to assess if exposure to airgun noise affects mortality, predator escape response, or gene expression of the copepod *Calanus finmarchicus* (Fields *et al.,* 2019). Immediate mortality of copepods was significantly higher, relative to controls, at distances of 5 m or less from the airguns. Mortality one week after the airgun blast was significantly higher in the copepods placed 10 m from the airgun but was not significantly different from the controls at a distance of 20 m from the airgun. The increase in mortality, relative to controls, did not exceed 30 percent at any distance from the airgun. Moreover,

the authors caution that even this higher mortality in the immediate vicinity of the airguns may be more pronounced than what would be observed in free-swimming animals due to increased flow speed of fluid inside bags containing the experimental animals. There were no sublethal effects on the escape performance or the sensory threshold needed to initiate an escape response at any of the distances from the airgun that were tested. Whereas McCauley *et al.* (2017) reported an SEL of 156 dB at a range of 509–658 m, with zooplankton mortality observed at that range, Fields *et al.* (2019) reported an SEL of 186 dB at a range of 25 m, with no reported mortality at that distance. Regardless, if we assume a worst-case likelihood of severe impacts to zooplankton within approximately 1 km of the acoustic source, the brief time to regeneration of the potentially affected zooplankton populations does not lead us to expect any meaningful follow-on effects to the prey base for marine mammals.

A 2017 review article concluded that, while laboratory results provide scientific evidence for high-intensity and low-frequency sound-induced physical trauma and other negative effects on some fish and invertebrates, the sound exposure scenarios in some cases are not realistic to those encountered by marine organisms during routine seismic survey operations (Carroll *et al.,* 2017). The review finds that there has been no evidence of reduced catch or abundance following seismic activities for invertebrates, and that there is conflicting evidence for fish with catch observed to increase, decrease, or remain the same. Further, where there is evidence for decreased catch rates in response to airgun noise, these findings provide no information about the underlying biological cause of catch rate reduction (Carroll *et al.,* 2017).

In summary, impacts of the specified activity on marine mammal prey species will likely be limited to behavioral responses, the majority of prey species will be capable of moving out of the area during the survey, a rapid return to normal recruitment, distribution, and behavior for prey species is anticipated, and, overall, impacts to prey species will be minor and temporary. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to airgun noise exposure are available (Hawkins *et al.,* 2014). The most likely impacts for most prey species in the survey area would be temporary avoidance of the area. The proposed survey would move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once the survey moves out of the area or ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of this survey and the likelihood of temporary avoidance behavior suggest that impacts would be minor.

Acoustic Habitat—Acoustic habitat is the soundscape—which encompasses all of the sound present in a particular location and time, as a whole—when considered from the perspective of the animals experiencing it. Animals produce sound for, or listen for sounds produced by, conspecifics (communication during feeding, mating, and other social activities), other animals (finding prey or avoiding predators), and the physical environment (finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain, waves) make up the natural contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

Soundscapes are also defined by, and acoustic habitat influenced by, the total contribution of anthropogenic sound. This may include incidental emissions from sources such as vessel traffic, or may be intentionally introduced to the marine environment for data acquisition purposes (as in the use of airgun arrays). Anthropogenic noise varies widely in its frequency content, duration, and loudness and these characteristics greatly influence the potential habitat-mediated effects to marine mammals (please see also the previous discussion on masking under ''Acoustic Effects''), which may range from local effects for brief periods of time to chronic effects over large areas and for long durations. Depending on the extent of effects to habitat, animals may alter their communications signals (thereby potentially expending additional energy) or miss acoustic cues (either conspecific or adventitious). For more detail on these concepts see, *e.g.,* Barber *et al.,* 2010; Pijanowski *et al.,* 2011; Francis and Barber, 2013; Lillis *et al.,* 2014.

Problems arising from a failure to detect cues are more likely to occur when noise stimuli are chronic and overlap with biologically relevant cues used for communication, orientation, and predator/prey detection (Francis and Barber, 2013). Although the signals emitted by seismic airgun arrays are generally low frequency, they would also likely be of short duration and transient in any given area due to the nature of these surveys. As described previously, exploratory surveys such as these cover a large area but would be transient rather than focused in a given location over time and therefore would not be considered chronic in any given location.

Based on the information discussed herein, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact analysis and determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of seismic airguns has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) for mysticetes and high frequency cetaceans (*i.e.,*

porpoises, *Kogia* spp.). The proposed mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable.

As noted previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μPa (rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. L–DEO's proposed activity includes the use of impulsive seismic sources. Therefore, the 160 dB re 1 μPa (rms) threshold is applicable for analysis of Level B harassment.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). L–DEO's proposed seismic survey includes the use of impulsive (seismic airguns) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat:}$ 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1μPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The proposed 2–D survey would acquire data using the 36-airgun array with a total discharge of 6,600 in^3 at a maximum tow depth of 12 m. L–DEO model results are used to determine the 160-dBrms radius for the 36-airgun array in deep water (>1,000 m) down to a maximum water depth of 2,000 m. Received sound levels were predicted by L–DEO's model (Diebold *et al.,* 2010) which uses ray tracing for the direct wave traveling from the array to the receiver and its associated source ghost (reflection at the air-water interface in the vicinity of the array), in a constant-velocity half-space (infinite homogeneous ocean layer, unbounded by a seafloor). In addition, propagation measurements of pulses from the 36-airgun array at a tow depth of 6 m have been reported in deep water (approximately 1,600 m), intermediate water depth on the slope (approximately 600–1,100 m), and shallow water (approximately 50 m) in the Gulf of Mexico in 2007–2008 (Tolstoy *et al.* 2009; Diebold *et al.* 2010).

For deep and intermediate-water cases, the field measurements cannot be used readily to derive Level A and Level B harassment isopleths, as at those sites the calibration hydrophone was located at a roughly constant depth of 350–500 m, which may not intersect all the SPL isopleths at their widest point from the sea surface down to the maximum relevant water depth for marine mammals of ~2,000 m. At short ranges, where the direct arrivals dominate and the effects of seafloor interactions are minimal, the data recorded at the deep and slope sites are suitable for comparison with modeled levels at the depth of the calibration hydrophone. At longer ranges, the comparison with the model—constructed from the maximum SPL through the entire water column at varying distances from the airgun array—is the most relevant.

In deep and intermediate-water depths, comparisons at short ranges between sound levels for direct arrivals recorded by the calibration hydrophone and model results for the same array tow depth are in good agreement (Fig. 12 and 14 in Appendix H of NSF–USGS, 2011). Consequently, isopleths falling within this domain can be predicted reliably by the L–DEO model, although they may be imperfectly sampled by measurements recorded at a single depth. At greater distances, the calibration data show that seafloor-reflected and sub-seafloor-refracted arrivals dominate, whereas the direct arrivals become weak and/or incoherent. Aside from local topography effects, the region around the critical distance is where the observed levels rise closest to the model curve. However, the observed sound levels are found to fall almost entirely below the model curve. Thus, analysis of the Gulf of Mexico calibration measurements demonstrates that although simple, the L–DEO model is a robust tool for conservatively estimating isopleths.

For deep water (>1,000 m), L–DEO used the deep-water radii obtained from model results down to a maximum water depth of 2,000 m. The radii for intermediate water depths (100–1,000 m) were derived from the deep-water ones by applying a correction factor (multiplication) of 1.5, such that observed levels at very near offsets fall below the corrected mitigation curve (See Fig. 16 in Appendix H of NSF–USGS, 2011).

L–DEO's modeling methodology is described in greater detail in their IHA application. The estimated distances to the Level B harassment isopleths for the array are shown in Table 4. Please note that no survey effort will occur in waters <100 m deep. The estimated isopleth distance specific to shallow water depths are provided for reference only.

TABLE 4—PREDICTED RADIAL DISTANCES TO ISOPLETHS CORRESPONDING TO LEVEL B HARASSMENT THRESHOLD

Source and volume	Tow depth (m)	Water depth (m)	Level B harassment zone (m)
36 airgun array; 6,600 in^3	12	>1,000	[1] 6,733
		100–1,000	[2] 10,100
		[3] <100	[4] 25,494

[1] Distance based on L–DEO model results.
[2] Distance is based on L–DEO model results with a 1.5 × correction factor between deep and intermediate water depths.
[3] No survey effort will occur in waters <100 m deep.
[4] Distance is based on empirically derived measurements in the Gulf of Mexico (GoM) with scaling applied to account for differences in tow depth.

Predicted distances to Level A harassment isopleths, which vary based on marine mammal hearing groups, were calculated based on modeling performed by L–DEO using the NUCLEUS source modeling software program and the NMFS User Spreadsheet, described below. The acoustic thresholds for impulsive sounds (*e.g.,* airguns) contained in the Technical Guidance were presented as dual metric acoustic thresholds using both SEL_{cum} and peak sound pressure metrics (NMFS 2018). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group. In recognition of the fact that the requirement to calculate Level A harassment ensonified areas could be more technically challenging to predict due to the duration component and the use of weighting functions in the new SEL_{cum} thresholds, NMFS developed an optional User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to facilitate the estimation of take numbers.

The values for SEL_{cum} and peak SPL for the *Langseth* airgun arrays were derived from calculating the modified far-field signature. The far-field signature is often used as a theoretical representation of the source level. To compute the far-field signature, the source level is estimated at a large distance below the array (*e.g.,* 9 km), and this level is back projected mathematically to a notional distance of 1 m from the array's geometrical center. However, when the source is an array of multiple airguns separated in space, the source level from the theoretical far-field signature is not necessarily the best measurement of the source level that is physically achieved at the source (Tolstoy *et al.,* 2009). Near the source (at short ranges, distances <1 km), the pulses of sound pressure from each individual airgun in the source array do not stack constructively, as they do for the theoretical far-field signature. The pulses from the different airguns spread out in time such that the source levels observed or modeled are the result of the summation of pulses from a few airguns, not the full array (Tolstoy *et al.,* 2009). At larger distances, away from the source array center, sound pressure of all the airguns in the array stack coherently, but not within one time sample, resulting in smaller source levels (a few dB) than the source level derived from the far-field signature. Because the far-field signature does not take into account the large array effect near the source and is calculated as a point source, the modified far-field signature is a more appropriate measure of the sound source level for distributed sound sources, such as airgun arrays. L–DEO used the acoustic modeling methodology as used for estimating Level B harassment distances with a small grid step of 1 m in both the inline and depth directions. The propagation modeling takes into account all airgun

interactions at short distances from the source, including interactions between subarrays, which are modeled using the NUCLEUS software to estimate the notional signature and MATLAB software to calculate the pressure signal at each mesh point of a grid.

In order to more realistically incorporate the Technical Guidance's weighting functions over the seismic array's full acoustic band, unweighted spectrum data for the *Langseth's* airgun array (modeled in 1 Hz bands) was used to make adjustments (dB) to the unweighted spectrum levels, by frequency, according to the weighting functions for each relevant marine mammal hearing group. These adjusted/weighted spectrum levels were then converted to pressures (μPa) in order to integrate them over the entire broadband spectrum, resulting in broadband weighted source levels by hearing group that could be directly incorporated within the User Spreadsheet (*i.e.,* to override the Spreadsheet's more simple weighting factor adjustment). Using the User Spreadsheet's ''safe distance'' methodology for mobile sources (described by Sivle *et al.,* 2014) with the hearing group-specific weighted source levels, and inputs assuming spherical spreading propagation and information specific to the planned survey (*i.e.,* the 2.2 m/s source velocity and (worst-case) 50-m shot interval, equivalent to a repetition rate of 23.1 seconds), potential radial distances to auditory injury zones were then calculated for SEL_{cum} thresholds.

Inputs to the User Spreadsheets in the form of estimated source levels are shown in Appendix A of L–DEO's application. User Spreadsheets used by L–DEO to estimate distances to Level A harassment isopleths for the airgun arrays are also provided in Appendix A of the application. Outputs from the User Spreadsheets in the form of estimated distances to Level A harassment isopleths for the survey are shown in Table 5. As described above, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the dual metrics (SEL_{cum} and Peak SPL_{flat}) is exceeded (*i.e.,* metric resulting in the largest isopleth). L–DEO proposes to conduct two different methods of seismic acquisition, MCS using a hydrophone streamer (approximately 62 percent of the total survey effort) and refraction surveys using OBSs (approximately 38 percent of the total survey effort). The airguns would fire at a shot interval of 50 m (repetition rate of 23 seconds) during MCS surveys and at a 400-m interval (repetition rate of 155 seconds) during refraction surveys to OBSs. The distances presented in Table 5 were calculated using the MCS survey inputs as using the 50-m shot interval provides more conservative distances than the 400-m shot interval.

TABLE 5—MODELED RADIAL DISTANCES (m) TO ISOPLETHS CORRESPONDING TO LEVEL A HARASSMENT THRESHOLDS

Source (volume)	Threshold	Level A harassment zone (m)			
		LF cetaceans	MF cetaceans	HF cetaceans	Otariids
36-airgun array (6,600 in³)	SEL_{cum}	320.2	0	1.0	0
	Peak	8.9	13.9	268.3	10.6

Note that because of some of the assumptions included in the methods used (*e.g.,* stationary receiver with no vertical or horizontal movement in response to the acoustic source), isopleths produced may be overestimates to some degree, which will ultimately result in some degree of overestimation of Level A harassment. However, these tools offer the best way to predict appropriate isopleths when more sophisticated modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools and will qualitatively address the output where appropriate. For mobile sources, such as the proposed seismic survey, the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed.

Auditory injury is unlikely to occur for mid-frequency cetaceans and otariid pinnipeds, given very small modeled zones of injury for those species (all estimated zones less than 15 m for mid-frequency cetaceans and otariid pinnipeds), in context of distributed source dynamics. The source level of the array is a theoretical definition assuming a point source and measurement in the far-field of the source (MacGillivray, 2006). As described by Caldwell and Dragoset (2000), an array is not a point source, but one that spans a small area. In the far-field, individual elements in arrays will effectively work as one source because individual pressure peaks will have coalesced into one relatively broad pulse. The array can then be considered a ''point source.'' For distances within the near-field, *i.e.,* approximately 2–3 times the array dimensions, pressure peaks from individual elements do not arrive simultaneously because the observation point is not equidistant from each element. The effect is destructive interference of the outputs of each element, so that peak pressures in the near-field will be significantly lower than the output of the largest individual element. Here, the relevant peak isopleth distances would in all cases be expected to be within the near-field of the array where the definition of source level breaks down. Therefore, actual locations within this distance of the array center where the sound level exceeds the relevant peak SPL thresholds would not necessarily exist. In general, Caldwell and Dragoset (2000) suggest that the near-field for airgun arrays is considered to extend out to approximately 250 m.

In order to provide quantitative support for this theoretical argument, we calculated expected maximum distances at which the near-field would transition to the far-field (Table 5). For a specific array one can estimate the distance at which the near-field transitions to the far-field by:

$$D = \frac{L^2}{4\lambda}$$

with the condition that $D >> \lambda$, and where D is the distance, L is the longest dimension of the array, and λ is the wavelength of the signal (Lurton, 2002).

Given that λ can be defined by:

$$\lambda = \frac{v}{f}$$

where f is the frequency of the sound signal and v is the speed of the sound in the medium of interest, one can rewrite the equation for D as:

$$D = \frac{fL^2}{4v}$$

and calculate D directly given a particular frequency and known speed

of sound (here assumed to be 1,500 meters per second in water, although this varies with environmental conditions).

To determine the closest distance to the arrays at which the source level predictions in Table 5 are valid (*i.e.,* maximum extent of the near-field), we calculated *D* based on an assumed frequency of 1 kHz. A frequency of 1 kHz is commonly used in near-field/far-field calculations for airgun arrays (Zykov and Carr, 2014; MacGillivray, 2006; NSF and USGS, 2011), and based on representative airgun spectrum data and field measurements of an airgun array used on the *Langseth,* nearly all (greater than 95 percent) of the energy from airgun arrays is below 1 kHz (Tolstoy *et al.,* 2009). Thus, using 1 kHz as the upper cut-off for calculating the maximum extent of the near-field should reasonably represent the near-field extent in field conditions.

If the largest distance to the peak sound pressure level threshold was equal to or less than the longest dimension of the array (*i.e.,* under the array), or within the near-field, then received levels that meet or exceed the threshold in most cases are not expected to occur. This is because within the near-field and within the dimensions of the array, the source levels specified in Appendix A of L–DEO's application are overestimated and not applicable. In fact, until one reaches a distance of approximately three or four times the near-field distance the average intensity of sound at any given distance from the array is still less than that based on calculations that assume a directional point source (Lurton, 2002). The 6,600-in^3 airgun array planned for use during the proposed survey has an approximate diagonal of 28.8 m, resulting in a near-field distance of 138.7 m at 1 kHz (NSF and USGS, 2011). Field measurements of this array indicate that the source behaves like multiple discrete sources, rather than a directional point source, beginning at approximately 400 m (deep site) to 1 km (shallow site) from the center of the array (Tolstoy *et al.,* 2009), distances that are actually greater than four times the calculated 140-m near-field distance. Within these distances, the recorded received levels were always lower than would be predicted based on calculations that assume a directional point source, and increasingly so as one moves closer towards the array (Tolstoy *et al.,* 2009). Given this, relying on the calculated distance (138.7 m) as the distance at which we expect to be in the near-field is a conservative approach since even beyond this distance the acoustic modeling still overestimates the actual received level. Within the near-field, in order to explicitly evaluate the likelihood of exceeding any particular acoustic threshold, one would need to consider the exact position of the animal, its relationship to individual array elements, and how the individual acoustic sources propagate and their acoustic fields interact. Given that within the near-field and dimensions of the array source levels would be below those assumed here, we believe exceedance of the peak pressure threshold would only be possible under highly unlikely circumstances.

In consideration of the received sound levels in the near-field as described above, we expect the potential for Level A harassment of mid-frequency cetaceans, otariid pinnipeds, and phocid pinnipeds to be de minimis, even before the likely moderating effects of aversion and/or other compensatory behaviors (*e.g.,* Nachtigall *et al.,* 2018) are considered. We do not believe that Level A harassment is a likely outcome for any mid-frequency cetacean, otariid pinniped, or phocid pinniped and do not propose to authorize any Level A harassment for these species.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

L–DEO used habitat-based stratified marine mammal densities for summer for the ETP when available (Barlow *et al.,* 2009), and densities for the ETP from NMFS (2015b) for all other species (Table 6). Barlow *et al.* (2009) used data from 16 NMFS Southwest Fisheries Science Center (SWFSC) ship-based cetacean and ecosystem assessment surveys between 1986 and 2006 to develop habitat models to predict density for 15 cetacean species in the ETP. Model predictions were then used in standard line-transect formulae to estimate density for each transect segment for each survey year. Predicted densities for each year were smoothed with geospatial methods to obtain a continuous grid of density estimates for the surveyed area in the ETP. These annual grids were then averaged to obtain a composite grid that represents our best estimates of cetacean density over the past 20 years in the ETP. The models developed by Barlow *et al.* (2009) have been incorporated into a web-based GIS software system developed by Duke University's Strategic Environmental Research and Development Program. The habitat-based density models consist of 100 km × 100 km grid cells. Densities in the grid cells that overlapped the survey area were averaged for each of the three water depth categories (shallow, intermediate, deep).

The NMFS SWFSC also developed density estimates for species in the ETP that may be affected by their own fisheries research activities (NMFS 2015b). These estimates were derived from abundance estimates using ship-based surveys of marine mammals in the ETP, as reported by Gerrodette *et al.* (2008). While the SWFSC developed volumetric density estimates (animals/km^3) to account for typical dive depth of each species (0–200 m and >200 m), L–DEO used the area density (animals/km^2) to represent expected density across all water depth strata.

For the sei whale, for which NMFS (2015b) reported a density of zero, L–DEO used the spring density for Baja from U.S. Navy (2017b). No regional density estimates are available for Guadalupe fur seals in the ETP; therefore, NMFS (2015b) used the density of Guadalupe fur seals in the California Current Ecosystem (CCE) as a proxy. However, as the survey area is south of the typical range of Guadalupe fur seals (Ortiz *et al.,* 2019), the density from the CCE is likely an overestimate. In the survey area, Guadalupe fur seals are extremely unlikely to occur in waters over the continental shelf under 2,000 m (T. Norris, pers. comm.). NMFS has therefore assumed that the density of Guadalupe fur seals in water depths under 2,000 m is zero animals per square km, and have retained the CCE density estimate for waters over 2,000 m deep (Table 6).

TABLE 6—ESTIMATED DENSITIES OF MARINE MAMMALS IN THE PROPOSED SURVEY AREA

Species	Density (#/km²) in survey area		
	Shallow water (<100 m)	Intermediate water (100–1,000 m)	Deep water (>1,000 m)
Humpback whale	[1] 0.00013	[1] 0.00013	[1] 0.00013
Minke whale	[1] 0.00001	[1] 0.00001	[1] 0.00001
Bryde's whale	[2] 0.000486	[2] 0.000489	[2] 0.000451
Fin whale	[1] 0.00003	[1] 0.00003	[1] 0.00003
Sei whale	[3] 0.00005	[3] 0.00005	[3] 0.00005
Blue whale	[2] 0.00010	[2] 0.00009	[2] 0.00008
Sperm whale	[1] 0.00019	[1] 0.00019	[1] 0.00019
Cuvier's beaked whale	[2] 0.00105	[2] 0.00106	[2] 0.00107
Longman's beaked whale	[1] 0.00004	[1] 0.00004	[1] 0.00004
Mesoplodon spp [4]	[2] 0.00032	[2] 0.00033	[2] 0.00036
Risso's dolphin	[1] 0.00517	[1] 0.00517	[1] 0.00517
Rough-toothed dolphin	[2] 0.00880	[2] 0.00891	[2] 0.00945
Common bottlenose dolphin	[2] 0.04809	[2] 0.04502	[2] 0.03557
Pantropical spotted dolphin	[1] 0.12263	[1] 0.12263	[1] 0.12263
Spinner dolphin (whitebelly)	[2] 0.00148	[2] 0.00155	[2] 0.00193
Spinner dolphin (eastern)	[2] 0.13182	[2] 0.12989	[2] 0.12791
Striped dolphin	[2] 0.02800	[2] 0.02890	[2] 0.03516
Short-beaked common dolphin	[2] 0.04934	[2] 0.04881	[2] 0.04435
Fraser's dolphin	[1] 0.01355	[1] 0.01355	[1] 0.01355
Short-finned pilot whale [5]	[2] 0.00346	[2] 0.00344	[2] 0.00382
Killer whale	[1] 0.0004	[1] 0.0004	[1] 0.0004
False killer whale	[1] 0.00186	[1] 0.00186	[1] 0.00186
Pygmy killer whale	[1] 0.00183	[1] 0.00183	[1] 0.00183
Melon-headed whale	[1] 0.00213	[1] 0.00213	[1] 0.00213
Kogia spp	[1] 0.00053	[1] 0.00053	[1] 0.00053
Guadalupe fur seal	0	[1] [6] 0.00741	[1] 0.00741
California sea lion	[1] 0.16262	[1] 0.16262	[7] 0

[1] Density in greater ETP (NMFS 2015b).
[2] Density in proposed survey area (Barlow *et al.,* 2009).
[3] Density for Baja (U.S. Navy 2017b).
[4] Density for Mesoplodon species guild (Blainville's beaked whale, Gingko-toothed beaked whale, Deraniyagala's beaked whale, and pygmy beaked whale).
[5] Density for *Globicephala* species guild.
[6] Density is assumed to be zero in waters <2,000 m.
[7] Density is assumed to be zero in deep water (>1,000 m).

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in Level A or Level B harassment, radial distances from the airgun array to predicted isopleths corresponding to the Level A harassment and Level B harassment thresholds are calculated, as described above. Those radial distances are then used to calculate the area(s) around the airgun array predicted to be ensonified to sound levels that exceed the Level A and Level B harassment thresholds. L–DEO identified specific seismic survey trackline(s) that could be surveyed on one day of research; in this case, a representative 182-km MCS line and a 222-km long OBS line were chosen. The distances to the 160-dB Level B harassment threshold and PTS (Level A harassment) thresholds (based on L–DEO model results) were used to draw a buffer around every transect line in GIS to determine the daily ensonified area in each depth category. The ensonified areas were then multiplied by the number of survey days (7 days for OBS survey effort; 13 days for MCS survey effort) increased by 25 percent. As noted previously, L–DEO has added 25 percent in the form of operational days, which is equivalent to adding 25 percent to the proposed line kilometers to be surveyed. This accounts for the possibility that additional operational days are required, but likely results in an overestimate of actual exposures. For additional details regarding calculations of ensonified area, please see Appendix D of L–DEO's application. L–DEO's estimated incidents of exposure above Level A and Level B harassment criteria are presented in Table 7.

As previously noted, NMFS does not have authority under the MMPA within the territorial seas of foreign nations (from 0–12 nmi (22.2 km) from shore), as the MMPA does not apply in those waters, and therefore does not authorize incidental take that may occur as a result of activities occurring within territorial waters. However, NMFS has still calculated the estimated level of incidental take in the entire activity area (including Mexican territorial waters) as part of the analysis supporting our determination under the MMPA that the activity will have a negligible impact on the affected species. The total estimated take in U.S. and Mexican waters is presented in Table 8 (see Negligible Impact Analysis and Determination).

L–DEO generally assumed that their estimates of marine mammal exposures above harassment thresholds to equate to take and requested authorization of those takes. Those estimates in turn form the basis for our proposed take authorization numbers. For the species for which NMFS does not expect there to be a reasonable potential for take by Level A harassment to occur, *i.e.,* mid-frequency cetaceans and all pinnipeds, we have added L–DEO's estimated exposures above Level A harassment thresholds (and requests for take by Level A harassment) to their estimated exposures above the Level B harassment threshold to produce a total number of incidents of take by Level B harassment

that is proposed for authorization. Estimated exposures and proposed take numbers for authorization are shown in Table 7.

TABLE 7—ESTIMATED AND PROPOSED TAKE BY LEVEL A AND LEVEL B HARASSMENT, AND PERCENTAGE OF POPULATION

Species	Estimated takes by Level B harassment	Estimated takes by Level A harassment	Proposed takes by Level B harassment	Proposed takes by Level A harassment	Total proposed take	Regional population size	Percent of population
Humpback whale	8	0	8	0	8	[a] 2,566	0.31
Minke whale	1	0	[b] 2	0	[b] 2	115	1.74
Bryde's whale	27	1	27	1	28	[a] 649	4.31
Fin whale	2	0	2	0	2	[a] 145	1.38
Sei whale	3	0	3	0	3	[c] 29,600	0.01
Blue whale	5	0	5	0	5	773	0.65
Sperm whale	12	0	12	0	12	2,810	0.43
Cuvier's beaked whale	69	0	69	0	69	[c] 20,000	0.35
Longman's beaked whale	3	0	3	0	3	[c] 1,007	0.30
Mesoplodon spp	23	0	23	0	23	[c] 25,300	0.09
Risso's dolphin	327	1	328	0	328	[a] 24,084	1.36
Rough-toothed dolphin	596	1	597	0	597	[a] 37,511	1.59
Common bottlenose dolphin	2,268	6	2274	0	2274	[a] 61,536	3.70
Pantropical spotted dolphin	7,973	15	7988	0	7988	[a] 146,296	5.46
Spinner dolphin (whitebelly)	121	0	121	0	121	[a] 186,906	0.06
Spinner dolphin (eastern)	8,173	16	8,189	0	8189	[a] 186,906	4.38
Striped dolphin	2,209	3	2212	0	2212	[a] 128,867	1.72
Short-beaked common dolphin	2,812	6	2818	0	2818	[a] 283,196	1.00
Fraser's dolphin	856	2	858	0	858	[c] 289,300	0.30
Short-finned pilot whale	244	0	244	0	244	[a] 3,348	7.29
Killer whale	25	0	25	0	25	[a] 852	2.93
False killer whale	118	0	118	0	118	[c] 39,600	0.30
Pygmy killer whale	116	0	116	0	116	[c] 38,900	0.30
Melon-headed whale	135	0	135	0	135	[c] 45,400	0.30
Kogia spp	33	1	33	1	34	[c d] 11,200	0.30
Guadalupe fur seal	415	1	416	0	416	[c] 34,187	1.22
California sea lion	349	16	365	0	365	[c] 105,000	0.35

[a] Estimated population in Pacific waters of Mexico (Gerrodette and Palacios (1996)).
[b] Proposed take increased to maximum group size.
[c] Population in ETP or wider Pacific (NMFS 2015b).
[d] Population of *Kogia* species guild.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) and the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

In order to satisfy the MMPA's least practicable adverse impact standard, NMFS has evaluated a suite of basic mitigation protocols for seismic surveys that are required regardless of the status of a stock. Additional or enhanced protections may be required for species whose stocks are in particularly poor health and/or are subject to some significant additional stressor that lessens that stock's ability to weather the effects of the specified activities without worsening its status. We reviewed seismic mitigation protocols required or recommended elsewhere

(*e.g.,* HESS, 1999; DOC, 2013; IBAMA, 2018; Kyhn *et al.,* 2011; JNCC, 2017; DEWHA, 2008; BOEM, 2016; DFO, 2008; GHFS, 2015; MMOA, 2016; Nowacek *et al.,* 2013; Nowacek and Southall, 2016), recommendations received during public comment periods for previous actions, and the available scientific literature. We also considered recommendations given in a number of review articles (*e.g.,* Weir and Dolman, 2007; Compton *et al.,* 2008; Parsons *et al.,* 2009; Wright and Cosentino, 2015; Stone, 2015b). This exhaustive review and consideration of public comments regarding previous, similar activities has led to development of the protocols included here.

Vessel-Based Visual Mitigation Monitoring

Visual monitoring requires the use of trained observers (herein referred to as visual protected species observers (PSOs)) to scan the ocean surface for the presence of marine mammals. The area to be scanned visually includes primarily the exclusion zone (EZ), within which observation of certain marine mammals requires shutdown of the acoustic source, but also a buffer zone and, to the extent possible depending on conditions, the surrounding waters. The buffer zone means an area beyond the EZ to be monitored for the presence of marine mammals that may enter the EZ. During pre-start clearance monitoring (*i.e.,* before ramp-up begins), the buffer zone also acts as an extension of the EZ in that observations of marine mammals within the buffer zone would also prevent airgun operations from beginning (*i.e.,* ramp-up). The buffer zone encompasses the area at and below the sea surface from the edge of the 0–500 m EZ, out to a radius of 1,000 m from the edges of the airgun array (500–1,000 m). This 1,000-m zone (EZ plus buffer) represents the pre-start clearance zone. Visual monitoring of the EZ and adjacent waters is intended to establish and, when visual conditions allow, maintain zones around the sound source that are clear of marine mammals, thereby reducing or eliminating the potential for injury and minimizing the potential for more severe behavioral reactions for animals occurring closer to the vessel. Visual monitoring of the buffer zone is intended to (1) provide additional protection to marine mammals that may be in the vicinity of the vessel during pre-start clearance, and (2) during airgun use, aid in establishing and maintaining the EZ by alerting the visual observer and crew of marine mammals that are outside of, but may approach and enter, the EZ.

L–DEO must use dedicated, trained, NMFS-approved PSOs. The PSOs must have no tasks other than to conduct observational effort, record observational data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements. PSO resumes shall be provided to NMFS for approval.

At least one of the visual and two of the acoustic PSOs (discussed below) aboard the vessel must have a minimum of 90 days at-sea experience working in those roles, respectively, with no more than 18 months elapsed since the conclusion of the at-sea experience. One visual PSO with such experience shall be designated as the lead for the entire protected species observation team. The lead PSO shall serve as primary point of contact for the vessel operator and ensure all PSO requirements per the IHA are met. To the maximum extent practicable, the experienced PSOs should be scheduled to be on duty with those PSOs with appropriate training but who have not yet gained relevant experience.

During survey operations (*e.g.,* any day on which use of the acoustic source is planned to occur, and whenever the acoustic source is in the water, whether activated or not), a minimum of two visual PSOs must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). Visual monitoring of the pre-start clearance zone must begin no less than 30 minutes prior to ramp-up, and monitoring must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset. Visual PSOs shall coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts, and shall conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner.

PSOs shall establish and monitor the exclusion and buffer zones. These zones shall be based upon the radial distance from the edges of the acoustic source (rather than being based on the center of the array or around the vessel itself). During use of the acoustic source (*i.e.,* anytime airguns are active, including ramp-up), detections of marine mammals within the buffer zone (but outside the EZ) shall be communicated to the operator to prepare for the potential shutdown of the acoustic source. Visual PSOs will immediately communicate all observations to the on duty acoustic PSO(s), including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination. Any observations of marine mammals by crew members shall be relayed to the PSO team. During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), visual PSOs shall conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the acoustic source and between acquisition periods, to the maximum extent practicable.

Visual PSOs may be on watch for a maximum of 4 consecutive hours followed by a break of at least one hour between watches and may conduct a maximum of 12 hours of observation per 24-hour period. Combined observational duties (visual and acoustic but not at same time) may not exceed 12 hours per 24-hour period for any individual PSO.

Passive Acoustic Monitoring

Acoustic monitoring means the use of trained personnel (sometimes referred to as passive acoustic monitoring (PAM) operators, herein referred to as acoustic PSOs) to operate PAM equipment to acoustically detect the presence of marine mammals. Acoustic monitoring involves acoustically detecting marine mammals regardless of distance from the source, as localization of animals may not always be possible. Acoustic monitoring is intended to further support visual monitoring (during daylight hours) in maintaining an EZ around the sound source that is clear of marine mammals. In cases where visual monitoring is not effective (*e.g.,* due to weather, nighttime), acoustic monitoring may be used to allow certain activities to occur, as further detailed below.

PAM would take place in addition to the visual monitoring program. Visual monitoring typically is not effective during periods of poor visibility or at night, and even with good visibility, is unable to detect marine mammals when they are below the surface or beyond visual range. Acoustic monitoring can be used in addition to visual observations to improve detection, identification, and localization of cetaceans. The acoustic monitoring would serve to alert visual PSOs (if on duty) when vocalizing cetaceans are detected. It is only useful when marine mammals vocalize, but it can be effective either by day or by night, and does not depend on good visibility. It would be monitored in real time so that the visual observers can be advised when cetaceans are detected.

The R/V *Langseth* will use a towed PAM system, which must be monitored

by at a minimum one on duty acoustic PSO beginning at least 30 minutes prior to ramp-up and at all times during use of the acoustic source. Acoustic PSOs may be on watch for a maximum of 4 consecutive hours followed by a break of at least one hour between watches and may conduct a maximum of 12 hours of observation per 24-hour period. Combined observational duties (acoustic and visual but not at same time) may not exceed 12 hours per 24-hour period for any individual PSO.

Survey activity may continue for 30 minutes when the PAM system malfunctions or is damaged, while the PAM operator diagnoses the issue. If the diagnosis indicates that the PAM system must be repaired to solve the problem, operations may continue for an additional 5 hours without acoustic monitoring during daylight hours only under the following conditions:

- Sea state is less than or equal to BSS 4;
- No marine mammals (excluding delphinids) detected solely by PAM in the applicable EZ in the previous 2 hours;
- NMFS is notified via email as soon as practicable with the time and location in which operations began occurring without an active PAM system; and
- Operations with an active acoustic source, but without an operating PAM system, do not exceed a cumulative total of 5 hours in any 24-hour period.

Establishment of Exclusion and Pre-Start Clearance Zones

An EZ is a defined area within which occurrence of a marine mammal triggers mitigation action intended to reduce the potential for certain outcomes, *e.g.,* auditory injury, disruption of critical behaviors. The PSOs would establish a minimum EZ with a 500-m radius. The 500-m EZ would be based on radial distance from the edge of the airgun array (rather than being based on the center of the array or around the vessel itself). With certain exceptions (described below), if a marine mammal appears within or enters this zone, the acoustic source would be shut down.

The pre-start clearance zone is defined as the area that must be clear of marine mammals prior to beginning ramp-up of the acoustic source, and includes the EZ plus the buffer zone. Detections of marine mammals within the pre-start clearance zone would prevent airgun operations from beginning (*i.e.,* ramp-up).

The 500-m EZ is intended to be precautionary in the sense that it would be expected to contain sound exceeding the injury criteria for all cetacean hearing groups, (based on the dual criteria of SEL_{cum} and peak SPL), while also providing a consistent, reasonably observable zone within which PSOs would typically be able to conduct effective observational effort. Additionally, a 500-m EZ is expected to minimize the likelihood that marine mammals will be exposed to levels likely to result in more severe behavioral responses. Although significantly greater distances may be observed from an elevated platform under good conditions, we believe that 500 m is likely regularly attainable for PSOs using the naked eye during typical conditions. The pre-start clearance zone simply represents the addition of a buffer to the EZ, doubling the EZ size during pre-clearance.

An extended EZ of 1,500 m must be enforced for all beaked whales and *Kogia* species. No buffer of this extended EZ is required.

Pre-Start Clearance and Ramp-Up

Ramp-up (sometimes referred to as ''soft start'') means the gradual and systematic increase of emitted sound levels from an airgun array. Ramp-up begins by first activating a single airgun of the smallest volume, followed by doubling the number of active elements in stages until the full complement of an array's airguns are active. Each stage should be approximately the same duration, and the total duration should not be less than approximately 20 minutes. The intent of pre-start clearance observation (30 minutes) is to ensure no protected species are observed within the pre-clearance zone (or extended EZ, for beaked whales and *Kogia* spp.) prior to the beginning of ramp-up. During pre-start clearance period is the only time observations of marine mammals in the buffer zone would prevent operations (*i.e.,* the beginning of ramp-up). The intent of ramp-up is to warn marine mammals of pending seismic survey operations and to allow sufficient time for those animals to leave the immediate vicinity. A ramp-up procedure, involving a step-wise increase in the number of airguns firing and total array volume until all operational airguns are activated and the full volume is achieved, is required at all times as part of the activation of the acoustic source. All operators must adhere to the following pre-start clearance and ramp-up requirements:

- The operator must notify a designated PSO of the planned start of ramp-up as agreed upon with the lead PSO; the notification time should not be less than 60 minutes prior to the planned ramp-up in order to allow the PSOs time to monitor the pre-start clearance zone (and extended EZ) for 30 minutes prior to the initiation of ramp-up (pre-start clearance);
- Ramp-ups shall be scheduled so as to minimize the time spent with the source activated prior to reaching the designated run-in;
- One of the PSOs conducting pre-start clearance observations must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed;
- Ramp-up may not be initiated if any marine mammal is within the applicable exclusion or buffer zone. If a marine mammal is observed within the pre-start clearance zone (or extended EZ, for beaked whales and *Kogia* species) during the 30 minute pre-start clearance period, ramp-up may not begin until the animal(s) has been observed exiting the zones or until an additional time period has elapsed with no further sightings (15 minutes for small odontocetes and pinnipeds, and 30 minutes for all mysticetes and all other odontocetes, including sperm whales, beaked whales, and large delphinids, such as killer whales);
- Ramp-up shall begin by activating a single airgun of the smallest volume in the array and shall continue in stages by doubling the number of active elements at the commencement of each stage, with each stage of approximately the same duration. Duration shall not be less than 20 minutes. The operator must provide information to the PSO documenting that appropriate procedures were followed;
- PSOs must monitor the pre-start clearance zone (and extended EZ) during ramp-up, and ramp-up must cease and the source must be shut down upon detection of a marine mammal within the applicable zone. Once ramp-up has begun, detections of marine mammals within the buffer zone do not require shutdown, but such observation shall be communicated to the operator to prepare for the potential shutdown;
- Ramp-up may occur at times of poor visibility, including nighttime, if appropriate acoustic monitoring has occurred with no detections in the 30 minutes prior to beginning ramp-up. Acoustic source activation may only occur at times of poor visibility where operational planning cannot reasonably avoid such circumstances;
- If the acoustic source is shut down for brief periods (*i.e.,* less than 30 minutes) for reasons other than that described for shutdown (*e.g.,* mechanical difficulty), it may be activated again without ramp-up if PSOs have maintained constant visual and/or acoustic observation and no visual or

acoustic detections of marine mammals have occurred within the applicable EZ. For any longer shutdown, pre-start clearance observation and ramp-up are required. For any shutdown at night or in periods of poor visibility (*e.g.,* BSS 4 or greater), ramp-up is required, but if the shutdown period was brief and constant observation was maintained, pre-start clearance watch of 30 minutes is not required; and

- Testing of the acoustic source involving all elements requires ramp-up. Testing limited to individual source elements or strings does not require ramp-up but does require pre-start clearance of 30 min.

Shutdown

The shutdown of an airgun array requires the immediate de-activation of all individual airgun elements of the array. Any PSO on duty will have the authority to delay the start of survey operations or to call for shutdown of the acoustic source if a marine mammal is detected within the applicable EZ. The operator must also establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. When both visual and acoustic PSOs are on duty, all detections will be immediately communicated to the remainder of the on-duty PSO team for potential verification of visual observations by the acoustic PSO or of acoustic detections by visual PSOs. When the airgun array is active (*i.e.,* anytime one or more airguns is active, including during ramp-up) and (1) a marine mammal appears within or enters the applicable EZ and/or (2) a marine mammal (other than delphinids, see below) is detected acoustically and localized within the applicable EZ, the acoustic source will be shut down. When shutdown is called for by a PSO, the acoustic source will be immediately deactivated and any dispute resolved only following deactivation. Additionally, shutdown will occur whenever PAM alone (without visual sighting), confirms presence of marine mammal(s) in the EZ. If the acoustic PSO cannot confirm presence within the EZ, visual PSOs will be notified but shutdown is not required.

Following a shutdown, airgun activity would not resume until the marine mammal has cleared the EZ. The animal would be considered to have cleared the EZ if it is visually observed to have departed the EZ (*i.e.,* animal is not required to fully exit the buffer zone where applicable), or it has not been seen within the EZ for 15 minutes for small odontocetes and pinnipeds, or 30 minutes for all mysticetes and all other odontocetes, including sperm whales, beaked whales, *Kogia* species, and large delphinids, such as killer whales.

The shutdown requirement is waived for small dolphins if an individual is detected within the EZ. As defined here, the small dolphin group is intended to encompass those members of the Family Delphinidae most likely to voluntarily approach the source vessel for purposes of interacting with the vessel and/or airgun array (*e.g.,* bow riding). This exception to the shutdown requirement applies solely to specific genera of small dolphins (*Delphinus, Lagenodelphis, Lissodelphis, Stenella, Steno, and Tursiops*).

We include this small dolphin exception because shutdown requirements for small dolphins under all circumstances represent practicability concerns without likely commensurate benefits for the animals in question. Small dolphins are generally the most commonly observed marine mammals in the specific geographic region and would typically be the only marine mammals likely to intentionally approach the vessel. As described above, auditory injury is extremely unlikely to occur for mid-frequency cetaceans (*e.g.,* delphinids), as this group is relatively insensitive to sound produced at the predominant frequencies in an airgun pulse while also having a relatively high threshold for the onset of auditory injury (*i.e.,* permanent threshold shift).

A large body of anecdotal evidence indicates that small dolphins commonly approach vessels and/or towed arrays during active sound production for purposes of bow riding, with no apparent effect observed in those delphinoids (*e.g.,* Barkaszi *et al.,* 2012, Barkaszi and Kelly, 2018). The potential for increased shutdowns resulting from such a measure would require the *Langseth* to revisit the missed track line to reacquire data, resulting in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area. Although other mid-frequency hearing specialists (*e.g.,* large delphinids) are no more likely to incur auditory injury than are small dolphins, they are much less likely to approach vessels. Therefore, retaining a shutdown requirement for large delphinids would not have similar impacts in terms of either practicability for the applicant or corollary increase in sound energy output and time on the water. We do anticipate some benefit for a shutdown requirement for large delphinids in that it simplifies somewhat the total range of decision-making for PSOs and may preclude any potential for physiological effects other than to the auditory system as well as some more severe behavioral reactions for any such animals in close proximity to the *Langseth.*

Visual PSOs shall use best professional judgment in making the decision to call for a shutdown if there is uncertainty regarding identification (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived or one of the species with a larger EZ).

L–DEO must implement shutdown if a marine mammal species for which take was not authorized, or a species for which authorization was granted but the takes have been met, approaches the Level A or Level B harassment zones. L–DEO must also implement shutdown if any large whale (defined as a sperm whale or any mysticete species) with a calf (defined as an animal less than two-thirds the body size of an adult observed to be in close association with an adult) and/or an aggregation of six or more large whales are observed at any distance.

Vessel Strike Avoidance

Vessel operators and crews must maintain a vigilant watch for all protected species and slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel (distances stated below). Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.,* PSOs) or crew members, but crew members responsible for these duties must be provided sufficient training to (1) distinguish marine mammals from other phenomena and (2) broadly to identify a marine mammal as a whale or other marine mammal.

Vessel speeds must be reduced to 10 knots or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel.

All vessels must maintain a minimum separation distance of 100 m from sperm whales and all other baleen whales.

All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an understanding that at times this may not be possible (*e.g.,* for animals that approach the vessel).

When marine mammals are sighted while a vessel is underway, the vessel shall take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area). If marine mammals are sighted within the relevant separation distance, the vessel must reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

These requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

We have carefully evaluated the suite of mitigation measures described here and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of the proposed measures, as well as other measures considered by NMFS described above, NMFS has preliminarily determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Mitigation Measures in Mexican Waters

As stated previously, NMFS cannot authorize the incidental take of marine mammals in the territorial seas of foreign nations, as the MMPA does not apply in those waters. L–DEO is required to adhere to the mitigation measures described above while operating within the Mexican EEZ and International Waters. The requirements do not apply within Mexican territorial waters. Mexico may prescribe mitigation measures that would apply to survey operations within the Mexican EEZ and territorial waters but NMFS is currently unaware of any specific potential requirements. While operating within the Mexican EEZ but outside Mexican territorial waters, if mitigation requirements prescribed by NMFS differ from the requirements established under Mexican law, L–DEO would adhere to the most protective measure. For operations in Mexican territorial waters, L–DEO would implement measures required under Mexican law (if any). If information regarding measures required under Mexican law becomes available prior to NMFS' final decision on this request for IHA, NMFS will consider it as appropriate in making its negligible impact determination.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Vessel-Based Visual Monitoring

As described above, PSO observations would take place during daytime airgun operations. During seismic survey operations, at least five visual PSOs would be based aboard the *Langseth.* Two visual PSOs would be on duty at all time during daytime hours. Monitoring shall be conducted in accordance with the following requirements:

- The operator shall provide PSOs with bigeye binoculars (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) of appropriate quality (*i.e.,* Fujinon or equivalent) solely for PSO use. These shall be pedestal-mounted on the deck at the most appropriate vantage point that provides for optimal sea surface observation, PSO safety, and safe operation of the vessel; and
- The operator will work with the selected third-party observer provider to ensure PSOs have all equipment (including backup equipment) needed to adequately perform necessary tasks, including accurate determination of distance and bearing to observed marine mammals.

PSOs must have the following requirements and qualifications:

- PSOs shall be independent, dedicated, trained visual and acoustic PSOs and must be employed by a third-party observer provider;
- PSOs shall have no tasks other than to conduct observational effort (visual or acoustic), collect data, and communicate with and instruct relevant vessel crew with regard to the presence of protected species and mitigation requirements (including brief alerts regarding maritime hazards);
- PSOs shall have successfully completed an approved PSO training course appropriate for their designated task (visual or acoustic). Acoustic PSOs are required to complete specialized training for operating PAM systems and are encouraged to have familiarity with the vessel with which they will be working;
- PSOs can act as acoustic or visual observers (but not at the same time) as long as they demonstrate that their training and experience are sufficient to perform the task at hand;
- NMFS must review and approve PSO resumes accompanied by a relevant training course information packet that includes the name and qualifications (*i.e.,* experience, training completed, or educational background) of the instructor(s), the course outline or syllabus, and course reference material as well as a document stating successful completion of the course;

• PSOs must successfully complete relevant training, including completion of all required coursework and passing (80 percent or greater) a written and/or oral examination developed for the training program;

• PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics; and

• The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Requests shall be granted or denied (with justification) by NMFS within 1 week of receipt of submitted information. Alternate experience that may be considered includes, but is not limited to (1) secondary education and/or experience comparable to PSO duties; (2) previous work experience conducting academic, commercial, or government-sponsored protected species surveys; or (3) previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties.

For data collection purposes, PSOs shall use standardized data collection forms, whether hard copy or electronic. PSOs shall record detailed information about any implementation of mitigation requirements, including the distance of animals to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up of the acoustic source. If required mitigation was not implemented, PSOs should record a description of the circumstances. At a minimum, the following information must be recorded:

• Vessel names (source vessel and other vessels associated with survey) and call signs;

• PSO names and affiliations;

• Dates of departures and returns to port with port name;

• Date and participants of PSO briefings;

• Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;

• Vessel location (latitude/longitude) when survey effort began and ended and vessel location at beginning and end of visual PSO duty shifts;

• Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;

• Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions changed significantly), including BSS and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon;

• Factors that may have contributed to impaired observations during each PSO shift change or as needed as environmental conditions changed (*e.g.,* vessel traffic, equipment malfunctions); and

• Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in the array, tow depth of the array, and any other notes of significance (*i.e.,* pre-start clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.).

The following information should be recorded upon visual observation of any protected species:

• Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);

• PSO who sighted the animal;

• Time of sighting;

• Vessel location at time of sighting;

• Water depth;

• Direction of vessel's travel (compass direction);

• Direction of animal's travel relative to the vessel;

• Pace of the animal;

• Estimated distance to the animal and its heading relative to vessel at initial sighting;

• Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified) and the composition of the group if there is a mix of species;

• Estimated number of animals (high/low/best);

• Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);

• Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);

• Detailed behavior observations (*e.g.,* number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);

• Animal's closest point of approach (CPA) and/or closest distance from any element of the acoustic source;

• Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and

• Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up) and time and location of the action.

If a marine mammal is detected while using the PAM system, the following information should be recorded:

• An acoustic encounter identification number, and whether the detection was linked with a visual sighting;

• Date and time when first and last heard;

• Types and nature of sounds heard (*e.g.,* clicks, whistles, creaks, burst pulses, continuous, sporadic, strength of signal); and

• Any additional information recorded such as water depth of the hydrophone array, bearing of the animal to the vessel (if determinable), species or taxonomic group (if determinable), spectrogram screenshot, and any other notable information.

Reporting

A report would be submitted to NMFS within 90 days after the end of the cruise. The report would summarize the dates and locations of seismic survey operations, and all marine mammal sightings (dates, times, locations, activities, associated seismic survey activities), and provide full documentation of methods, results, and interpretation pertaining to all monitoring.

The draft report shall also include geo-referenced time-stamped vessel tracklines for all time periods during which airguns were operating. Tracklines should include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off, or when they changed from full array to single gun or vice versa). GIS files shall be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates shall be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data shall be made available to NMFS. The report must summarize the data collected as described above and in the IHA. A final report must be submitted within 30 days following resolution of any comments on the draft report.

Reporting Injured or Dead Marine Mammals

Discovery of injured or dead marine mammals—In the event that personnel involved in survey activities covered by

the authorization discover an injured or dead marine mammal, the L–DEO shall report the incident to the Office of Protected Resources (OPR), NMFS and to the NMFS West Coast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Vessel strike—In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, L–DEO shall report the incident to OPR, NMFS and to the NMFS West Coast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measure were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Species identification (if known) or description of the animal(s) involved;
- Estimated size and length of the animal that was struck;
- Description of the behavior of the animal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals present immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Actions To Minimize Additional Harm to Live-Stranded (or Milling) Marine Mammals

In the event of a live stranding (or near-shore atypical milling) event within 50 km of the survey operations, where the NMFS stranding network is engaged in herding or other interventions to return animals to the water, the Director of OPR, NMFS (or designee) will advise L–DEO of the need to implement shutdown for all active acoustic sources operating within 50 km of the stranding. Procedures related to shutdowns for live stranding or milling marine mammals include the following:

- If at any time, the marine mammal(s) die or are euthanized, or if herding/intervention efforts are stopped, the Director of OPR, NMFS (or designee) will advise L–DEO that the shutdown around the animals' location is no longer needed.
- Otherwise, shutdown procedures will remain in effect until the Director of OPR, NMFS (or designee) determines and advises L–DEO that all live animals involved have left the area (either of their own volition or following an intervention).
- If further observations of the marine mammals indicate the potential for re-stranding, additional coordination with L–DEO will be required to determine what measures are necessary to minimize that likelihood (*e.g.,* extending the shutdown or moving operations farther away) and to implement those measures as appropriate.

Additional Information Requests—If NMFS determines that the circumstances of any marine mammal stranding found in the vicinity of the activity suggest investigation of the association with survey activities is warranted, and an investigation into the stranding is being pursued, NMFS will submit a written request to L–DEO indicating that the following initial available information must be provided as soon as possible, but no later than 7 business days after the request for information:

- Status of all sound source use in the 48 hours preceding the estimated time of stranding and within 50 km of the discovery/notification of the stranding by NMFS; and
- If available, description of the behavior of any marine mammal(s) observed preceding (*i.e.,* within 48 hours and 50 km) and immediately after the discovery of the stranding.

In the event that the investigation is still inconclusive, the investigation of the association of the survey activities is still warranted, and the investigation is still being pursued, NMFS may provide additional information requests, in writing, regarding the nature and location of survey operations prior to the time period above.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, our analysis applies to all species listed in Table 1, given that NMFS expects the anticipated effects of the planned geophysical survey to be similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, NMFS has identified species-specific factors to inform the analysis.

As described above, we propose to authorize only the takes estimated to occur outside of Mexican territorial waters (Table 7); however, for the purposes of our negligible impact analysis and determination, we consider the total number of takes that are

anticipated to occur as a result of the entire survey (including the portion of the survey that would occur within the Mexican territorial waters (approximately 6 percent of the survey) (Table 8).

TABLE 8—TOTAL ESTIMATED TAKE INCLUDING MEXICAN TERRITORIAL WATERS

Species	Level B harassment (excluding Mexican territorial waters)	Level A harassment (excluding Mexican territorial waters)	Level B harassment (Mexican territorial waters)	Level A harassment (Mexican territorial waters)	Total Level B harassment	Total Level A harassment
Humpback whale	8	0	1	0	9	0
Minke whale	2	0	0	0	2	0
Bryde's whale	27	1	2	0	29	1
Fin whale	2	0	0	0	2	0
Sei whale	3	0	0	0	3	0
Blue whale	5	0	0	0	5	0
Sperm whale	12	0	1	0	13	0
Cuvier's beaked whale	69	0	69	0	138	0
Longman's beaked whale	3	0	0	0	3	0
Mesoplodon spp	23	0	1	0	24	0
Risso's dolphin	328	0	22	0	350	0
Rough-toothed dolphin	597	0	38	0	635	0
Common bottlenose dolphin	2,274	0	196	0	2,470	0
Pantropical spotted dolphin	7,988	0	519	0	8,507	0
Spinner dolphin (whitebelly)	121	0	7	0	128	0
Spinner dolphin (eastern)	8,189	0	557	0	8,746	0
Striped dolphin	2,212	0	122	0	2,334	0
Short-beaked common dolphin	2,818	0	209	0	3,027	0
Fraser's dolphin	858	0	58	0	916	0
Short-finned pilot whale	244	0	15	0	259	0
Killer whale	25	0	2	0	27	0
False killer whale	118	0	8	0	126	0
Pygmy killer whale	116	0	8	0	124	0
Melon-headed whale	135	0	9	0	144	0
Kogia spp	33	1	2	0	35	1
Guadalupe fur seal	416	0	1	0	417	0
California sea lion	365	0	693	0	1,058	0

NMFS does not anticipate that serious injury or mortality would occur as a result of L–DEO's planned survey, even in the absence of mitigation, and none are proposed for authorization. Non-auditory physical effects, stranding, and vessel strike are also not expected to occur.

We are proposing to authorize a limited number of instances of Level A harassment of two species (Bryde's whale and dwarf sperm whales, which are members of the low- and high-frequency cetacean hearing groups, respectively) in the form of PTS, and Level B harassment only of the remaining marine mammal species. We believe that any PTS incurred in marine mammals as a result of the planned activity would be in the form of only a small degree of PTS, not total deafness, because of the constant movement of both the R/V *Langseth* and of the marine mammals in the project areas, as well as the fact that the vessel is not expected to remain in any one area in which individual marine mammals would be expected to concentrate for an extended period of time. Additionally, L–DEO would shut down the airgun array if marine mammals approach within 500 m (with the exception of specific genera of dolphins, see Proposed Mitigation), further reducing the expected duration and intensity of sound, and therefore the likelihood of marine mammals incurring PTS. Since the duration of exposure to loud sounds will be relatively short it would be unlikely to affect the fitness of any individuals. Also, as described above, we expect that marine mammals would likely move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice of the R/V *Langseth's* approach due to the vessel's relatively low speed when conducting seismic surveys. Accordingly, we expect that the majority of takes would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007, Ellison *et al.,* 2012).

Marine mammal habitat may be impacted by elevated sound levels, but these impacts would be temporary. Prey species are mobile and are broadly distributed throughout the project areas; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the relatively short duration (up to 24 days) and temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Yazvenko *et al.* (2007) reported no apparent changes in the frequency of feeding activity in Western gray whales exposed to airgun sounds in their feeding grounds near Sakhalin Island. Goldbogen *et al.* (2013) found blue whales feeding on highly concentrated prey in shallow depths were less likely to respond and cease foraging than whales feeding on deep, dispersed prey when exposed to simulated sonar sources, suggesting that the benefits of feeding for humpbacks foraging on high-density prey may outweigh perceived

harm from the acoustic stimulus, such as the seismic survey (Southall *et al.,* 2016). Additionally, L–DEO will shut down the airgun array upon observation of an aggregation of six or more large whales, which would reduce impacts to cooperatively foraging animals. For all habitats, no physical impacts to habitat are anticipated from seismic activities. While SPLs of sufficient strength have been known to cause injury to fish and fish and invertebrate mortality, in feeding habitats, the most likely impact to prey species from survey activities would be temporary avoidance of the affected area and any injury or mortality of prey species would be localized around the survey and not of a degree that would adversely impact marine mammal foraging. The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution and behavior is expected. Given the short operational seismic time near or traversing specific habitat areas, as well as the ability of cetaceans and prey species to move away from acoustic sources, NMFS expects that there would be, at worst, minimal impacts to animals and habitat within these areas. The proposed survey tracklines do not overlap with any designated critical habitat for ESA-listed species or areas of known importance for any species.

Negligible Impact Conclusions

The proposed survey would be of short duration (up to 25 days of seismic operations), and the acoustic ''footprint'' of the proposed survey would be small relative to the ranges of the marine mammals that would potentially be affected. Sound levels would increase in the marine environment in a relatively small area surrounding the vessel compared to the range of the marine mammals within the proposed survey area. Short term exposures to survey operations are not likely to significantly disrupt marine mammal behavior, and the potential for longer-term avoidance of important areas is limited.

The proposed mitigation measures are expected to reduce the number of takes by Level A harassment (in the form of PTS) by allowing for detection of marine mammals in the vicinity of the vessel by visual and acoustic observers. The proposed mitigation measures are also expected to minimize the severity of any potential behavioral disturbance (Level B harassment) via shutdowns of the airgun array. Based on previous monitoring reports for substantially similar activities that have been previously authorized by NMFS (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities*), we expect that the proposed mitigation will be effective in preventing, at least to some extent, potential PTS in marine mammals that may otherwise occur in the absence of the proposed mitigation (although all authorized PTS has been accounted for in this analysis).

NMFS concludes that exposures to marine mammal species and stocks due to L–DEO's proposed seismic survey activities would result in only short-term (temporary and short in duration) effects to individuals exposed, over relatively small areas of the affected animals' ranges. Animals may temporarily avoid the immediate area, but are not expected to permanently abandon the area. Major shifts in habitat use, distribution, or foraging success are not expected. NMFS does not anticipate the proposed take estimates to impact annual rates of recruitment or survival.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or proposed to be authorized, even absent mitigation;
- The proposed activity is temporary and of relatively short duration (up to 25 days);
- The anticipated impacts of the proposed activity on marine mammals would primarily be temporary behavioral changes due to avoidance of the area around the survey vessel;
- The number of instances of potential PTS that may occur are expected to be very small in number. Instances of potential PTS that are incurred in marine mammals are expected to be of a low level, due to constant movement of the vessel and of the marine mammals in the area, and the nature of the survey design (not concentrated in areas of high marine mammal concentration);
- The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the proposed survey to avoid exposure to sounds from the activity;
- The potential adverse effects on fish or invertebrate species that serve as prey species for marine mammals from the proposed survey would be temporary and spatially limited, and impacts to marine mammal foraging would be minimal; and
- The proposed mitigation measures, including visual and acoustic monitoring and shutdowns are expected to minimize potential impacts to marine mammals (both amount and severity).

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed mitigation and monitoring measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS proposes to authorize is below one third of the estimated population abundance of all species (Gerrodette and Palacios 1996); NMFS 2015b). In fact, take of individuals is less than 8 percent of the abundance of any affected population.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

NMFS is proposing to authorize take of blue whales, fin whales, sei whales, sperm whales, Mexico DPS humpback whales, Central America DPS humpback whales, and Guadalupe fur seals, which are listed under the ESA. The NMFS OPR Permits and Conservation Division has requested initiation of Section 7 consultation with the NMFS OPR ESA Interagency Cooperation Division for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to L–DEO for conducting marine geophysical surveys in the ETP, beginning in spring 2022, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed geophysical surveys. We also request at this time comment on the potential Renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activities section of this notice is planned or (2) the activities as described in the Description of Proposed Activities section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

(1) A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA);

(2) The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and
- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

(3) Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: January 7, 2022.

Catherine Marzin,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

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